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CHAMBER ACTION

Senate

House

Floor: 1/AD/3R
4/28/2008 4:08 PM

Floor: C
5/1/2008 9:29 PM

1 Senator Peaden moved the following **amendment**:

2
3 **Senate Amendment (with title amendment)**

4 Delete everything after the enacting clause
5 and insert:

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

16 499.002 Purpose, administration, and enforcement of and
17 exemption from this part ss. 499.001-499.081.--



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

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

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

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

31 (2) ~~499.004 Administration and enforcement by~~
32 ~~department.~~ The department of Health shall administer and
33 enforce this part ss. 499.001-499.081 to prevent fraud,
34 adulteration, misbranding, or false advertising in the
35 preparation, manufacture, repackaging, or distribution of drugs,
36 devices, and cosmetics.

37 (3) ~~499.0053 Power to administer oaths, take depositions,~~
38 ~~and issue and serve subpoenas.~~ For the purpose of any
39 investigation or proceeding conducted by the department under
40 this part ss. 499.001-499.081, the department may administer
41 oaths, take depositions, issue and serve subpoenas, and compel
42 the attendance of witnesses and the production of books, papers,
43 documents, or other evidence. The department shall exercise this
44 power on its own initiative. Challenges to, and enforcement of,
45 the subpoenas and orders shall be handled as provided in s.
46 120.569.



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47 (4) ~~499.07 Duty of prosecuting officer.~~ Each state
48 attorney, county attorney, or municipal attorney to whom the
49 department or its designated agent reports any violation of this
50 part ss. ~~499.001-499.081~~ shall cause appropriate proceedings to
51 be instituted in the proper courts without delay and to be
52 prosecuted in the manner required by law.

53 (5) ~~499.071 Issuance of warnings for minor~~
54 ~~violations.~~ This part does Sections ~~499.001-499.081~~ do not
55 require the department to report, for the institution of
56 proceedings under this part ss. ~~499.001-499.081~~, minor violations
57 of this part ss. ~~499.001-499.081~~ when it believes that the public
58 interest will be adequately served in the circumstances by a
59 suitable written notice or warning.

60 (6) ~~499.081 Carriers in interstate commerce exempted from~~
61 ~~ss. ~~499.001-499.081~~.~~ Common carriers engaged in interstate
62 commerce are not subject to this part ss. ~~499.001-499.081~~ if they
63 are engaged in the usual course of business as common carriers.

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

75 499.003 Definitions of terms used in this part ss. ~~499.001-~~
76 ~~499.081~~.--As used in this part ss. ~~499.001-499.081~~, the term:



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

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

87 ~~(3)-(2)~~ "Affiliated party" means:

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

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

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

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

103 ~~(4)-(3)~~ "Applicant" means a person applying for a permit or
104 certification under this part ~~ss. 499.001-499.081~~.

105 ~~(5)-(4)~~ "Authenticate" means to affirmatively verify upon
106 receipt ~~before any distribution~~ of a prescription ~~legend~~ drug



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107 | ~~occurs~~ that each transaction listed on the pedigree paper has
108 | occurred.

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

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

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

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

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

128 | ~~(9)~~~~(7)~~ "Color" includes black, white, and intermediate
129 | grays.

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

133 | (a) Is a dye pigment, or other substance, made by a process
134 | of synthesis or similar artifice, or extracted, isolated, or
135 | otherwise derived, with or without intermediate or final change



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136 of identity from a vegetable, animal, mineral, or other source;
137 or

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

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

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

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

154 ~~(13)-(11)~~ "Cosmetic" means an article, with the exception of
155 soap, that is:

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

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

161
162 ~~except that the term does not include soap.~~

163 ~~(14)-(12)~~ "Counterfeit drug," "counterfeit device," or
164 "counterfeit drug, counterfeit device, or counterfeit cosmetic"
165 means a drug, device, or cosmetic which, or the container, seal,



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

175 ~~(15)-(13)~~ "Department" means the Department of Health.

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

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

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

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

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

193 ~~(17)-(15)~~ "Distribute ~~or distribution~~" or "distribution"
194 means to sell; offer to sell; give away; transfer, whether by



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

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

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

208 (19)~~(17)~~ "Drug" means an article that is:

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

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

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

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

222 (20)~~(18)~~ "Establishment" means a place of business at one
223 general physical location.



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224 ~~(21)-(19)~~ "Federal act" means the Federal Food, Drug, and
225 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

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

230 ~~(23)-(21)~~ "Health care entity" means a closed pharmacy or
231 any person, organization, or business entity that provides
232 diagnostic, medical, surgical, or dental treatment or care, or
233 chronic or rehabilitative care, but does not include any
234 wholesale distributor or retail pharmacy licensed under state law
235 to deal in prescription drugs.

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

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

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

242 ~~(27)-(22)~~ "Immediate container" does not include package
243 liners.

244 ~~(28)-(23)~~ "Label" means a display of written, printed, or
245 graphic matter upon the immediate container of any drug, device,
246 or cosmetic. A requirement made by or under authority of this
247 part ~~ss. 499.001-499.081~~ or rules adopted under this part ~~these~~
248 ~~sections~~ that any word, statement, or other information appear on
249 the label is not complied with unless such word, statement, or
250 other information also appears on the outside container or
251 wrapper, if any, of the retail package of such drug, device, or
252 cosmetic or is easily legible through the outside container or
253 wrapper.



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254 ~~(29)-(24)~~ "Labeling" means all labels and other written,
255 printed, or graphic matters:

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

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

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

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

271 ~~(30)-(27)~~ "Manufacture" means the preparation, deriving,
272 compounding, propagation, processing, producing, or fabrication
273 of any drug, device, or cosmetic.

274 ~~(31)-(28)~~ "Manufacturer" means:

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

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



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

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

292 (32)-(29) "New drug" means:

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

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

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



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

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

319 ~~(35)(30)~~ "Official compendium" means the current edition of
320 the official United States Pharmacopoeia and National Formulary,
321 or any supplement thereto.

322 ~~(36)(31)~~ "Pedigree paper" means:

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



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

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

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

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

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

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

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

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



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

378
379 ~~The department may adopt rules and forms relating to the~~
380 ~~requirements of this subsection.~~

381 ~~(37)(1) DEFINITION. As used in this section, the term~~
382 ~~"Permittee" means any person holding a permit issued pursuant to~~
383 ~~s. 499.012.~~

384 ~~(38)(32)~~ "Person" means any individual, child, joint
385 venture, syndicate, fiduciary, partnership, corporation, division
386 of a corporation, firm, trust, business trust, company, estate,
387 public or private institution, association, organization, group,
388 city, county, city and county, political subdivision of this
389 state, other governmental agency within this state, and any
390 representative, agent, or agency of any of the foregoing, or any
391 other group or combination of the foregoing.

392 ~~(39)(1)~~ "Pharmacist" means a person licensed under chapter
393 465.

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

396 ~~(41)(33)~~ "Prepackaged drug product" means a drug that
397 originally was in finished packaged form sealed by a manufacturer
398 and that is placed in a properly labeled container by a pharmacy
399 or practitioner authorized to dispense pursuant to chapter 465
400 for the purpose of dispensing in the establishment in which the
401 prepackaging occurred.

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



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

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

413 (44)-(34) "Prescription label" means any display of written,
414 printed, or graphic matter upon the immediate container of any
415 prescription legend drug dispensed pursuant to a prescription of
416 a practitioner authorized by law to prescribe.

417 (45)-(35) "Prescription medical oxygen" means oxygen USP
418 which is a drug that can only be sold on the order or
419 prescription of a practitioner authorized by law to prescribe.
420 The label of prescription medical oxygen must comply with current
421 labeling requirements for oxygen under the Federal Food, Drug,
422 and Cosmetic Act.

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

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

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

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



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

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

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

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

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

451 (47)(36) "Proprietary drug," or "OTC drug," means a patent
452 or over-the-counter drug in its unbroken, original package, which
453 drug is sold to the public by, or under the authority of, the
454 manufacturer or primary distributor thereof, is not misbranded
455 under the provisions of this part ~~ss. 499.001-499.081~~, and can be
456 purchased without a prescription.

457 (48)(37) "Repackage" includes repacking or otherwise
458 changing the container, wrapper, or labeling to further the
459 distribution of the drug, device, or cosmetic.

460 (49)(38) "Repackager" means a person who repackages. The
461 term excludes pharmacies that are operating in compliance with
462 pharmacy practice standards as defined in chapter 465 and rules
463 adopted under that chapter.



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

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

471 ~~(53)(39)~~ "Veterinary prescription drug" means a
472 prescription ~~legend~~ drug intended solely for veterinary use. The
473 label of the drug must bear the statement, "Caution: Federal law
474 restricts this drug to sale by or on the order of a licensed
475 veterinarian."

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

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

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

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

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



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

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

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

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

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

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

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

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



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

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

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



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

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

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

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

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

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

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



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

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

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

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

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

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



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

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

624 499.005 Prohibited acts.--It is unlawful for a person to
625 perform or cause the performance of any of the following acts in
626 this state:

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

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

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

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



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

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

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

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

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

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

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

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

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



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

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

685 499.0051 Criminal acts ~~involving contraband or adulterated~~
686 ~~drugs.--~~

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

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

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



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

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

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

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

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

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



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

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

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

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

757 (7) ~~499.0052~~ KNOWING TRAFFICKING IN CONTRABAND PRESCRIPTION
758 LEGEND DRUGS.--A person who knowingly sells, purchases,
759 manufactures, delivers, or brings into this state, or who is
760 knowingly in actual or constructive possession of any amount of
761 contraband prescription ~~legend~~ drugs valued at \$25,000 or more



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

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

766 1.(1) If the value of contraband prescription ~~legend~~ drugs
767 involved is \$25,000 or more, but less than \$100,000, the
768 defendant shall pay a mandatory fine of \$25,000. If the defendant
769 is a corporation or other person that is not a natural person, it
770 shall pay a mandatory fine of \$75,000.

771 2.(2) If the value of contraband prescription ~~legend~~ drugs
772 involved is \$100,000 or more, but less than \$250,000, the
773 defendant shall pay a mandatory fine of \$100,000. If the
774 defendant is a corporation or other person that is not a natural
775 person, it shall pay a mandatory fine of \$300,000.

776 3.(3) If the value of contraband prescription ~~legend~~ drugs
777 involved is \$250,000 or more, the defendant shall pay a mandatory
778 fine of \$200,000. If the defendant is a corporation or other
779 person that is not a natural person, it shall pay a mandatory
780 fine of \$600,000.

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



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791 (8)(7) KNOWING FORGERY OF PRESCRIPTION OR PRESCRIPTION
792 ~~LEGEND~~ DRUG LABELS.--A person who knowingly forges, counterfeits,
793 or falsely creates any prescription label or prescription legend
794 drug label, or who falsely represents any factual matter
795 contained on any prescription label or prescription legend drug
796 label, commits a felony of the first degree, punishable as
797 provided in s. 775.082, s. 775.083, or s. 775.084.

798 (9) ~~499.00535~~ KNOWING Sale or purchase of contraband
799 prescription legend drugs resulting in great bodily harm.--A
800 person who knowingly sells, purchases, manufactures, delivers, or
801 brings into this state, or who is knowingly in actual or
802 constructive possession of any amount of contraband prescription
803 ~~legend~~ drugs, and whose acts in violation of this subsection
804 ~~section~~ result in great bodily harm to a person, commits a felony
805 of the first degree, as provided in s. 775.082, s. 775.083, or s.
806 775.084.

807 (10) ~~499.00545~~ Knowing Sale or purchase of contraband
808 prescription legend drugs resulting in death.--A person who
809 knowingly manufactures, sells, purchases, delivers, or brings
810 into this state, or who is knowingly in actual or constructive
811 possession of any amount of contraband prescription legend drugs,
812 and whose acts in violation of this subsection ~~section~~ result in
813 the death of a person, commits a felony of the first degree,
814 punishable by a term of years not exceeding life, as provided in
815 s. 775.082, s. 775.083, or s. 775.084.

816 (11) ~~499.069~~ ~~Criminal punishment for~~ violations of s.
817 499.005 related to devices and cosmetics; dissemination of false
818 advertisement.--

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



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

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

842 | **(12)499.0691** ADULTERATED AND MISBRANDED DRUGS; FALSE
843 | ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS
844 | ~~Criminal punishment for violations related to drugs;~~
845 | ~~dissemination of false advertisement.--(1)~~ Any person who
846 | violates any of the following provisions commits a misdemeanor of
847 | the second degree, punishable as provided in s. 775.082 or s.
848 | 775.083; but, if the violation is committed after a conviction of
849 | such person under this subsection ~~section~~ has become final, such
850 | person commits a misdemeanor of the first degree, punishable as



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

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

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

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

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

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

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

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

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

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



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



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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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



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

973 499.0054 Advertising and labeling of drugs, devices, and
974 cosmetics; exemptions.--

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

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

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

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

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

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

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



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1000 with this requirement, the department may consider the following
1001 factors:

1002 1.~~(a)~~ The packaging of the product.
1003 2.~~(b)~~ The name and labeling of the product.
1004 3.~~(c)~~ The manner of distribution, advertising, and
1005 promotion of the product, including verbal representations at the
1006 point of sale.

1007 4.~~(d)~~ The duration, scope, and significance of abuse of the
1008 particular product.

1009 (g)~~(7)~~ The advertising of any drug or device represented to
1010 have any effect in any of the following conditions, disorders,
1011 diseases, or processes:

- 1012 1.~~(a)~~ Blood disorders.
1013 2.~~(b)~~ Bone or joint diseases.
1014 3.~~(c)~~ Kidney diseases or disorders.
1015 4.~~(d)~~ Cancer.
1016 5.~~(e)~~ Diabetes.
1017 6.~~(f)~~ Gall bladder diseases or disorders.
1018 7.~~(g)~~ Heart and vascular diseases.
1019 8.~~(h)~~ High blood pressure.
1020 9.~~(i)~~ Diseases or disorders of the ear or auditory
1021 apparatus, including hearing loss or deafness.
1022 10.~~(j)~~ Mental disease or mental retardation.
1023 11.~~(k)~~ Paralysis.
1024 12.~~(l)~~ Prostate gland disorders.
1025 13.~~(m)~~ Conditions of the scalp affecting hair loss.
1026 14.~~(n)~~ Baldness.
1027 15.~~(o)~~ Endocrine disorders.
1028 16.~~(p)~~ Sexual impotence.
1029 17.~~(q)~~ Tumors.



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- 1030 | 18.~~(r)~~ Venereal diseases.
- 1031 | 19.~~(s)~~ Varicose ulcers.
- 1032 | 20.~~(t)~~ Breast enlargement.
- 1033 | 21.~~(u)~~ Purifying blood.
- 1034 | 22.~~(v)~~ Metabolic disorders.
- 1035 | 23.~~(w)~~ Immune system disorders or conditions affecting the
1036 | immune system.
- 1037 | 24.~~(x)~~ Extension of life expectancy.
- 1038 | 25.~~(y)~~ Stress and tension.
- 1039 | 26.~~(z)~~ Brain stimulation or performance.
- 1040 | 27.~~(aa)~~ The body's natural defense mechanisms.
- 1041 | 28.~~(bb)~~ Blood flow.
- 1042 | 29.~~(cc)~~ Depression.
- 1043 | 30.~~(dd)~~ Human immunodeficiency virus or acquired immune
1044 | deficiency syndrome or related disorders or conditions.
- 1045 | (h)~~(8)~~ The representation or suggestion in labeling or
1046 | advertising that an article is approved under this part ss.
1047 | ~~499.001-499.081~~, when such is not the case.
- 1048 | (2)~~499.0055 False or misleading advertisement.~~ In
1049 | determining whether an advertisement is false or misleading, the
1050 | department shall review the representations made or suggested by
1051 | statement, word, design, device, sound, or any combination
1052 | thereof within the advertisement and the extent to which the
1053 | advertisement fails to reveal material facts with respect to
1054 | consequences that can result from the use of the drug, device, or
1055 | cosmetic to which the advertisement relates under the conditions
1056 | of use prescribed in the labeling or advertisement.
- 1057 | (3)~~499.0057 Advertisement exemptions.~~



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1058 ~~(a)(1)~~ An advertisement that is not prohibited under
1059 paragraph (1)(a) ~~s. 499.0054(1)~~ is not prohibited under paragraph
1060 (1)(g) ~~s. 499.0054(7)~~ if it is disseminated:

1061 1. To the public solely to advertise the product for those
1062 indications that are safe and effective indications and the
1063 product is safe and effective for self-medication, as established
1064 by the United States Food and Drug Administration; or

1065 2. ~~if it is disseminated~~ Only to members of the medical,
1066 dental, pharmaceutical, or veterinary professions or appears only
1067 in the scientific periodicals of these professions.

1068 ~~(b)(2)~~ Compliance with this part ~~ss. 499.001-499.081~~ and
1069 the rules adopted under this part ~~those sections~~ creates no legal
1070 presumption that a drug or device is safe or effective.

1071 Section 6. Subsections (3), (10), and (11) of section
1072 499.006, Florida Statutes, are amended to read:

1073 499.006 Adulterated drug or device.--A drug or device is
1074 adulterated:

1075 (3) If it is a drug and the methods used in, or the
1076 facilities or controls used for, its manufacture, processing,
1077 packing, or holding do not conform to, or are not operated or
1078 administered in conformity with, current good manufacturing
1079 practices to assure that the drug meets the requirements of this
1080 part ~~ss. 499.001-499.081~~ and that the drug has the identity and
1081 strength, and meets the standard of quality and purity, which it
1082 purports or is represented to possess;

1083 (10) If it is a prescription ~~legend~~ drug for which the
1084 required pedigree paper is nonexistent, fraudulent, or incomplete
1085 under the requirements of this part ~~ss. 499.001-499.081~~ or
1086 applicable rules, or that has been purchased, held, sold, or



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1087 distributed at any time by a person not authorized under federal
1088 or state law to do so; or

1089 (11) If it is a prescription drug subject to, defined by,
1090 or described by s. 503(b) of the Federal Food, Drug, and Cosmetic
1091 Act which has been returned by a veterinarian to a limited
1092 prescription drug veterinary wholesale distributor ~~wholesaler~~.

1093 Section 7. Section 499.007, Florida Statutes, is amended to
1094 read:

1095 499.007 Misbranded drug or device.--A drug or device is
1096 misbranded:

1097 (1) If its labeling is in any way false or misleading.

1098 (2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a
1099 label containing:

1100 (a) The name and place of business of the manufacturer,
1101 repackager, or distributor of the finished dosage form of the
1102 drug. For the purpose of this paragraph, the finished dosage form
1103 of a prescription medicinal drug is that form of the drug which
1104 is, or is intended to be, dispensed or administered to the
1105 patient and requires no further manufacturing or processing other
1106 than packaging, reconstitution, and labeling; and

1107 (b) An accurate statement of the quantity of the contents
1108 in terms of weight, measure, or numerical count. ~~;~~ However, under
1109 this section, reasonable variations are permitted, and the
1110 department shall establish by rule exemptions for small packages.

1111 (3) If it is an active pharmaceutical ingredient in bulk
1112 form and does not bear a label containing:

1113 (a) The name and place of business of the manufacturer,
1114 repackager, or distributor; and

1115 (b) An accurate statement of the quantity of the contents
1116 in terms of weight, measure, or numerical count.



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1117 ~~(4)(3)~~ If any word, statement, or other information
1118 required by or under this part ~~ss. 499.001-499.081~~ to appear on
1119 the label or labeling is not prominently placed thereon with such
1120 conspicuousness as compared with other words, statements,
1121 designs, or devices in the labeling, and in such terms, as to
1122 render the word, statement, or other information likely to be
1123 read and understood under customary conditions of purchase and
1124 use.

1125 ~~(5)(4)~~ If it is a drug and is not designated solely by a
1126 name recognized in an official compendium and, ~~unless~~ its label
1127 does not bear ~~bears~~:

- 1128 (a) The common or usual name of the drug, if any; and
1129 (b) In case it is fabricated from two or more ingredients,
1130 the common or usual name and quantity of each active ingredient.

1131 ~~(6)(5)~~ If ~~Unless~~ its labeling does not bear ~~bears~~:

- 1132 (a) Adequate directions for use; and
1133 (b) Adequate warnings against use in those pathological
1134 conditions in which its use may be dangerous to health or against
1135 use by children if its use may be dangerous to health, or against
1136 unsafe dosage or methods or duration of administration or
1137 application, in such manner and form as are necessary for the
1138 protection of users.

1139 ~~(7)(6)~~ If it purports to be a drug the name of which is
1140 recognized in the official compendium and, ~~unless~~ it is not
1141 packaged and labeled as prescribed therein. ~~‡~~ However, the method
1142 of packaging may be modified with the consent of the department.

1143 ~~(8)(7)~~ If it has been found by the department to be a drug
1144 liable to deterioration and, ~~unless~~ it is not packaged in such
1145 form and manner, and its label bears a statement of such
1146 precautions, as the department by rule requires as necessary to



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1147 | protect the public health. Such rule may not be established for
1148 | any drug recognized in an official compendium until the
1149 | department has informed the appropriate body charged with the
1150 | revision of such compendium of the need for such packaging or
1151 | labeling requirements and that body has failed within a
1152 | reasonable time to prescribe such requirements.

1153 | ~~(9)~~~~(8)~~ If it is:

1154 | (a) A drug and its container or finished dosage form is so
1155 | made, formed, or filled as to be misleading;

1156 | (b) An imitation of another drug; or

1157 | (c) Offered for sale under the name of another drug.

1158 | ~~(10)~~~~(9)~~ If it is dangerous to health when used in the
1159 | dosage or with the frequency or duration prescribed, recommended,
1160 | or suggested in the labeling of the drug.

1161 | ~~(11)~~~~(10)~~ If it is, purports to be, or is represented as a
1162 | drug composed wholly or partly of insulin and, ~~unless:~~

1163 | ~~(a)~~ it is not from a batch with respect to which a
1164 | certificate has been issued pursuant to s. 506 of the federal
1165 | act, which; ~~and~~

1166 | ~~(b)~~ ~~The~~ certificate is in effect with respect to the drug.

1167 | ~~(12)~~~~(11)~~ If it is, purports to be, or is represented as a
1168 | drug composed wholly or partly of any kind of antibiotic
1169 | requiring certification under the federal act and ~~unless:~~

1170 | ~~(a)~~ it is not from a batch with respect to which a
1171 | certificate has been issued pursuant to s. 507 of the federal
1172 | act, which; ~~and~~

1173 | ~~(b)~~ the certificate is in effect with respect to the drug. ~~+~~

1174 |



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1175 | However, this subsection does not apply to any drug or class of
1176 | drugs exempted by regulations adopted under s. 507(c) or (d) of
1177 | the federal act.

1178 | ~~(13)-(12)~~ If it is a drug intended for use by humans which
1179 | is a habit-forming drug or which, because of its toxicity or
1180 | other potentiality for harmful effect, or the method of its use,
1181 | or the collateral measures necessary to its use, is not safe for
1182 | use except under the supervision of a practitioner licensed by
1183 | law to administer such drugs,~~+~~ or which is limited by an
1184 | effective application under s. 505 of the federal act to use
1185 | under the professional supervision of a practitioner licensed by
1186 | law to prescribe such drug, if ~~unless~~ it is not dispensed only:

1187 | (a) Upon the written prescription of a practitioner
1188 | licensed by law to prescribe such drug;

1189 | (b) Upon an oral prescription of such practitioner, which
1190 | is reduced promptly to writing and filled by the pharmacist; or

1191 | (c) By refilling any such written or oral prescription, if
1192 | such refilling is authorized by the prescriber ~~either~~ in the
1193 | original prescription or by oral order which is reduced promptly
1194 | to writing and filled by the pharmacist.

1195 |
1196 | This subsection does not relieve any person from any requirement
1197 | prescribed by law with respect to controlled substances as
1198 | defined in the applicable federal and state laws.

1199 | ~~(14)-(13)~~ If it is a drug that is subject to paragraph
1200 | ~~(13)-(12)~~(a), and if, at any time before it is dispensed, its
1201 | label does not ~~fails to~~ bear the statement:

1202 | (a) "Caution: Federal Law Prohibits Dispensing Without
1203 | Prescription";

1204 | (b) "Rx Only";



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1205 (c) The prescription symbol followed by the word "Only"; or
1206 (d) "Caution: State Law Prohibits Dispensing Without
1207 Prescription."
1208 ~~(15)-(14)~~ If it is a drug that is not subject to paragraph
1209 ~~(13)-(12)~~(a), if at any time before it is dispensed its label
1210 bears the statement of caution required in subsection ~~(14)~~ ~~(13)~~.
1211 ~~(16)-(15)~~ If it is a color additive, the intended use of
1212 which in or on drugs is for the purpose of coloring only ~~and~~
1213 ~~unless~~ its packaging and labeling are not in conformity with the
1214 packaging and labeling requirements that apply to such color
1215 additive and are prescribed under the federal act.
1216 (17) A drug dispensed by filling or refilling a written or
1217 oral prescription of a practitioner licensed by law to prescribe
1218 such drug is exempt from the requirements of this section, except
1219 subsections (1), (9) ~~(8)~~, (11) ~~(10)~~, and (12) ~~(11)~~ and the
1220 packaging requirements of subsections (7) ~~(6)~~ and (8) ~~(7)~~, if the
1221 drug bears a label that contains the name and address of the
1222 dispenser or seller, the prescription number and the date the
1223 prescription was written or filled, the name of the prescriber
1224 and the name of the patient, and the directions for use and
1225 cautionary statements. This exemption does not apply to any drug
1226 dispensed in the course of the conduct of a business of
1227 dispensing drugs pursuant to diagnosis by mail or to any drug
1228 dispensed in violation of subsection (13) ~~(12)~~. The department
1229 may, by rule, exempt drugs subject to s. 499.062 ~~ss. 499.062-~~
1230 ~~499.064~~ from subsection (13) ~~(12)~~ if compliance with that
1231 subsection is not necessary to protect the public health, safety,
1232 and welfare.



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1233 Section 8. Subsection (1) of section 499.008, Florida
1234 Statutes, is amended and subsection (5) is added to that section
1235 to read:

1236 499.008 Adulterated cosmetics.--A cosmetic is adulterated:

1237 (1) If it bears or contains any poisonous or deleterious
1238 substance that is injurious to users under the conditions of use
1239 prescribed in the labeling or advertisement thereof or under such
1240 conditions of use as are customary or usual; however, this
1241 subsection does not apply to coal-tar hair dye:

1242 (a) The label of which bears the following legend
1243 conspicuously displayed thereon: "Caution: This product contains
1244 ingredients which may cause skin irritation on certain
1245 individuals, and a preliminary test according to accompanying
1246 directions should first be made. This product must not be used
1247 for dyeing the eyelashes or eyebrows; to do so may cause
1248 blindness"; and

1249 (b) The labeling of which bears adequate directions for
1250 such preliminary testing.

1251

1252 ~~For the purposes of this subsection and subsection (4), the term~~
1253 ~~"hair dye" does not include eyelash dyes or eyebrow dyes.~~

1254 (5) For the purposes of subsections (1) and (4), the term
1255 "hair dye" does not include eyelash dyes or eyebrow dyes.

1256 Section 9. Subsections (2), (3), and (5) of section
1257 499.009, Florida Statutes, are amended to read:

1258 499.009 Misbranded cosmetics.--A cosmetic is misbranded:

1259 (2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a
1260 label containing:

1261 (a) The name and place of business of the manufacturer,
1262 packer, or distributor;



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1263 (b) An accurate statement of the quantity of the contents
1264 in terms of weight, measure, or numerical count; however, under
1265 this paragraph reasonable variations are permitted, and the
1266 department shall establish by rule exemptions for small packages;
1267 and

1268 (c) A declaration of ingredients in descending order of
1269 predominance, or as otherwise required by federal law.

1270 (3) If any word, statement, or other information required
1271 by or under authority of this part ~~ss. 499.001-499.081~~ to appear
1272 on the label or labeling is not prominently placed thereon with
1273 such conspicuousness as compared with other words, statements,
1274 designs, or devices in the labeling, and in such terms, as to
1275 render the word, statement, or other information likely to be
1276 read and understood by an individual under customary conditions
1277 of purchase and use.

1278 (5) ~~Unless,~~ If it is a color additive, its packaging and
1279 labeling are not in conformity with the packaging and labeling
1280 requirements applicable to that color additive prescribed under
1281 the federal act. This subsection does not apply to packages of
1282 color additives that, with respect to their use for cosmetics,
1283 are marketed and intended for use only in or on hair dyes.

1284 Section 10. Section 499.01, Florida Statutes, is amended;
1285 the introductory paragraph and paragraphs (a) through (h) of
1286 subsection (2) of section 499.012, Florida Statutes, are
1287 redesignated as the introductory paragraph and paragraphs (d),
1288 (n), (e), (f), (c), (i), (k), and (l), respectively, of
1289 subsection (2) of that section and amended; paragraphs (b)
1290 through (e) of subsection (2) of section 499.013, Florida
1291 Statutes, are redesignated as paragraphs (p), (o), (q), and (r),
1292 respectively, of subsection (2) of that section and amended; and



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1293 section 499.014, Florida Statutes, is redesignated as paragraph
1294 (g) of subsection (2) of that section and amended, to read:

1295 499.01 Permits; ~~applications; renewal; general~~
1296 ~~requirements.~~--

1297 (1) Prior to operating, a permit is required for each
1298 person and establishment that intends to operate as:

1299 (a) A prescription drug manufacturer;

1300 (b) A prescription drug repackager;

1301 (c) A nonresident prescription drug manufacturer;

1302 (d) A prescription drug wholesale distributor;

1303 (e) An out-of-state prescription drug wholesale
1304 distributor;

1305 (f) A retail pharmacy drug wholesale distributor;

1306 (g) A restricted prescription drug distributor;

1307 (h) A complimentary drug distributor;

1308 (i) A freight forwarder;

1309 (j) A veterinary prescription drug retail establishment;

1310 (k) A veterinary prescription drug wholesale distributor;

1311 (l) A limited prescription drug veterinary wholesale
1312 distributor;

1313 (m) A medical oxygen retail establishment;

1314 (n) A compressed medical gas wholesale distributor;

1315 (o) A compressed medical gas manufacturer;

1316 (p) ~~(e)~~ An over-the-counter drug manufacturer;

1317 ~~(d)~~ ~~A compressed medical gas manufacturer;~~

1318 (q) ~~(e)~~ A device manufacturer;

1319 (r) ~~(f)~~ A cosmetic manufacturer;

1320 (s) A third party logistic provider; or

1321 (t) A health care clinic establishment.

1322 ~~(g) A prescription drug wholesaler;~~



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- 1323 ~~(h) A veterinary prescription drug wholesaler;~~
- 1324 ~~(i) A compressed medical gas wholesaler;~~
- 1325 ~~(j) An out-of-state prescription drug wholesaler;~~
- 1326 ~~(k) A nonresident prescription drug manufacturer;~~
- 1327 ~~(l) A freight forwarder;~~
- 1328 ~~(m) A retail pharmacy drug wholesaler;~~
- 1329 ~~(n) A veterinary legend drug retail establishment;~~
- 1330 ~~(o) A medical oxygen retail establishment;~~
- 1331 ~~(p) A complimentary drug distributor;~~
- 1332 ~~(q) A restricted prescription drug distributor; or~~
- 1333 ~~(r) A limited prescription drug veterinary wholesaler.~~

1334 (2) The following ~~types of wholesaler~~ permits are
1335 established:

1336 (a) Prescription drug manufacturer permit.--A prescription
1337 drug manufacturer permit is required for any person that
1338 manufactures a prescription drug in this state.

1339 1. A person that operates an establishment permitted as a
1340 prescription drug manufacturer may engage in wholesale
1341 distribution of prescription drugs manufactured at that
1342 establishment and must comply with all the provisions of this
1343 part and the rules adopted under this part that apply to a
1344 wholesale distributor.

1345 2. A prescription drug manufacturer must comply with all
1346 appropriate state and federal good manufacturing practices.

1347 (b) Prescription drug repackager permit.--A prescription
1348 drug repackager permit is required for any person that repackages
1349 a prescription drug in this state.

1350 1. A person that operates an establishment permitted as a
1351 prescription drug repackager may engage in wholesale distribution
1352 of prescription drugs repackaged at that establishment and must



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1353 comply with all the provisions of this part and the rules adopted
1354 under this part that apply to a wholesale distributor.

1355 2. A prescription drug repackager must comply with all
1356 appropriate state and federal good manufacturing practices.

1357 (c)(e) Nonresident prescription drug manufacturer
1358 permit.--A nonresident prescription drug manufacturer permit is
1359 required for any person that is a manufacturer of prescription
1360 drugs, or the distribution point for a manufacturer of
1361 prescription drugs unless permitted as a third party logistics
1362 provider, and located outside of this state, or that is an entity
1363 to whom an approved new drug application has been issued by the
1364 United States Food and Drug Administration, or the contracted
1365 manufacturer of the approved new drug application holder, and
1366 located outside the United States, which engages in the wholesale
1367 distribution in this state of the prescription drugs it
1368 manufactures or is responsible for manufacturing. Each such
1369 manufacturer or entity must be permitted by the department and
1370 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



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1383 wholesaled into this state must comply with this part ss.
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), but not the requirements of s. 499.01212. The
1402 prescription drug manufacturer purchasing and receiving the
1403 active pharmaceutical ingredient shall maintain on file a record
1404 of the FDA registration number; the out-of-state license, permit,
1405 or registration number; and, if available, a copy of the most
1406 current FDA inspection report, for all manufacturers from whom
1407 they purchase active pharmaceutical ingredients under this
1408 section. The department shall specify by rule the allowable
1409 number of transactions within a given period of time and the
1410 amount of active pharmaceutical ingredients that qualify as
1411 limited quantities for purposes of this exemption. The failure to
1412 comply with the requirements of this subparagraph, or rules



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1413 adopted by the department to administer this subparagraph, for
1414 the purchase of prescription drug active pharmaceutical
1415 ingredients is a violation of s. 499.005(14).

1416 (d) (a) A Prescription drug wholesale distributor
1417 ~~wholesaler's~~ permit.--A prescription drug wholesale distributor
1418 ~~wholesaler~~ is a wholesale distributor that may engage in the
1419 wholesale distribution of prescription drugs. A prescription drug
1420 wholesale distributor ~~wholesaler~~ that applies to the department
1421 for a new permit or the renewal of a permit must submit a bond of
1422 \$100,000, or other equivalent means of security acceptable to the
1423 department, such as an irrevocable letter of credit or a deposit
1424 in a trust account or financial institution, payable to the
1425 Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the
1426 bond is to secure payment of any administrative penalties imposed
1427 by the department and any fees and costs incurred by the
1428 department regarding that permit which are authorized under state
1429 law and which the permittee fails to pay 30 days after the fine
1430 or costs become final. The department may make a claim against
1431 such bond or security until 1 year after the permittee's license
1432 ceases to be valid or until 60 days after any administrative or
1433 legal proceeding authorized in this part ~~ss. 499.001-499.081~~
1434 which involves the permittee is concluded, including any appeal,
1435 whichever occurs later. The department may adopt rules for
1436 issuing a prescription drug wholesale distributor-broker
1437 ~~wholesaler-broker~~ permit to a person who engages in the wholesale
1438 distribution of prescription drugs and does not take physical
1439 possession of any prescription drugs.

1440 (e) (e) An Out-of-state prescription drug wholesale
1441 distributor ~~wholesaler's~~ permit.--An out-of-state prescription
1442 drug wholesale distributor ~~wholesaler~~ is a wholesale distributor



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1443 | located outside this state which engages in the wholesale
1444 | distribution of prescription drugs into this state and which must
1445 | be permitted by the department and comply with all the provisions
1446 | required of a wholesale distributor under this part ~~ss. 499.001-~~
1447 | ~~499.081~~. An out-of-state prescription drug wholesale distributor
1448 | ~~wholesaler~~ that applies to the department for a new permit or the
1449 | renewal of a permit must submit a bond of \$100,000, or other
1450 | equivalent means of security acceptable to the department, such
1451 | as an irrevocable letter of credit or a deposit in a trust
1452 | account or financial institution, payable to the Florida Drug,
1453 | Device, and Cosmetic Trust Fund. The purpose of the bond is to
1454 | secure payment of any administrative penalties imposed by the
1455 | department and any fees and costs incurred by the department
1456 | regarding that permit which are authorized under state law and
1457 | which the permittee fails to pay 30 days after the fine or costs
1458 | become final. The department may make a claim against such bond
1459 | or security until 1 year after the permittee's license ceases to
1460 | be valid or until 60 days after any administrative or legal
1461 | proceeding authorized in this part ~~ss. 499.001-499.081~~ which
1462 | involves the permittee is concluded, including any appeal,
1463 | whichever occurs later.

1464 | 1. The out-of-state prescription drug wholesale distributor
1465 | ~~wholesaler~~ must maintain at all times a license or permit to
1466 | engage in the wholesale distribution of prescription drugs in
1467 | compliance with laws of the state in which it is a resident.

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



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1473 licensed prescription drug wholesale distributor ~~wholesaler~~ in
1474 this state, if both wholesale distributors ~~wholesalers~~ conduct
1475 wholesale distributions of prescription drugs under the same
1476 business name. The recordkeeping requirements of ss. ~~s.~~
1477 499.0121(6) and 499.01212 must be followed for this transaction.

1478 (f)(d) A Retail pharmacy drug wholesale distributor
1479 ~~wholesaler's~~ permit.--A retail pharmacy drug wholesale
1480 distributor ~~wholesaler~~ is a retail pharmacy engaged in wholesale
1481 distribution of prescription drugs within this state under the
1482 following conditions:

1483 1. The pharmacy must obtain a retail pharmacy drug
1484 wholesale distributor ~~wholesaler's~~ permit pursuant to this part
1485 ~~ss. 499.001-499.081~~ and the rules adopted under this part ~~these~~
1486 ~~sections~~.

1487 2. The wholesale distribution activity does not exceed 30
1488 percent of the total annual purchases of prescription drugs. If
1489 the wholesale distribution activity exceeds the 30-percent
1490 maximum, the pharmacy must obtain a prescription drug wholesale
1491 distributor ~~wholesaler's~~ permit.

1492 3. The transfer of prescription drugs that appear in any
1493 schedule contained in chapter 893 is subject to chapter 893 and
1494 the federal Comprehensive Drug Abuse Prevention and Control Act
1495 of 1970.

1496 4. The transfer is between a retail pharmacy and another
1497 retail pharmacy, or a Modified Class II institutional pharmacy,
1498 or a health care practitioner licensed in this state and
1499 authorized by law to dispense or prescribe prescription drugs.

1500 5. All records of sales of prescription drugs subject to
1501 this section must be maintained separate and distinct from other



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1502 records and comply with the recordkeeping requirements of this
1503 part ss. ~~499.001-499.081~~.

1504 (g) ~~499.014~~ Restricted prescription drug distributor permit
1505 ~~Distribution of legend drugs by hospitals, health care entities,~~
1506 ~~charitable organizations, and return or destruction companies;~~
1507 ~~permits, general requirements.--~~

1508 ~~(1)~~ A restricted prescription drug distributor permit is
1509 required for any person that engages in the distribution of a
1510 prescription ~~legend~~ drug, which distribution is not considered
1511 "wholesale distribution" under s. 499.003(53)(a) ~~s.~~
1512 ~~499.012(1)(a)1.~~

1513 1.~~(2)~~ A person who engages in the receipt or distribution
1514 of a prescription ~~legend~~ drug in this state for the purpose of
1515 processing its return or its destruction must obtain a permit as
1516 a restricted prescription drug distributor if such person is not
1517 the person initiating the return, the prescription drug wholesale
1518 supplier of the person initiating the return, or the manufacturer
1519 of the drug.

1520 2.~~(3)~~ Storage, handling, and recordkeeping of these
1521 distributions must comply with the requirements for wholesale
1522 distributors under s. 499.0121, but not ~~except~~ those set forth in
1523 s. 499.01212 ~~s. 499.0121(6)(d).~~

1524 3.~~(4)~~ A person who applies for a permit as a restricted
1525 prescription drug distributor, or for the renewal of such a
1526 permit, must provide to the department the information required
1527 under s. 499.012 ~~s. 499.01~~.

1528 4.~~(5)~~ The department may ~~issue permits to restricted~~
1529 ~~prescription drug distributors and may~~ adopt rules regarding the
1530 distribution of prescription drugs by hospitals, health care
1531 entities, charitable organizations, or other persons not involved



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1532 in wholesale distribution, which rules are necessary for the
1533 protection of the public health, safety, and welfare.

1534 (h) Complimentary drug distributor permit.--A complimentary
1535 drug distributor permit is required for any person that engages
1536 in the distribution of a complimentary drug, subject to the
1537 requirements of s. 499.028.

1538 (i) ~~(f)~~ Freight forwarder permit.--A freight forwarder
1539 permit is required for any person that engages in the
1540 distribution of a prescription ~~legend~~ drug as a freight forwarder
1541 unless the person is a common carrier. The storage, handling, and
1542 recordkeeping of such distributions must comply with the
1543 requirements for wholesale distributors under s. 499.0121, but
1544 ~~not except~~ those set forth in s. 499.01212 ~~s. 499.0121(6)(d)~~. A
1545 freight forwarder must provide the source of the prescription
1546 ~~legend~~ drugs with a validated airway bill, bill of lading, or
1547 other appropriate documentation to evidence the exportation of
1548 the product.

1549 (j) Veterinary prescription drug retail establishment
1550 permit.--A veterinary prescription drug retail establishment
1551 permit is required for any person that sells veterinary
1552 prescription drugs to the public but does not include a pharmacy
1553 licensed under chapter 465.

1554 1. The sale to the public must be based on a valid written
1555 order from a veterinarian licensed in this state who has a valid
1556 client-veterinarian relationship with the purchaser's animal.

1557 2. Veterinary prescription drugs may not be sold in excess
1558 of the amount clearly indicated on the order or beyond the date
1559 indicated on the order.

1560 3. An order may not be valid for more than 1 year.



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1561 4. A veterinary prescription drug retail establishment may
1562 not purchase, sell, trade, or possess human prescription drugs or
1563 any controlled substance as defined in chapter 893.

1564 5. A veterinary prescription drug retail establishment must
1565 sell a veterinary prescription drug in the original, sealed
1566 manufacturer's container with all labeling intact and legible.
1567 The department may adopt by rule additional labeling requirements
1568 for the sale of a veterinary prescription drug.

1569 6. A veterinary prescription drug retail establishment must
1570 comply with all of the wholesale distribution requirements of s.
1571 499.0121.

1572 7. Prescription drugs sold by a veterinary prescription
1573 drug retail establishment pursuant to a practitioner's order may
1574 not be returned into the retail establishment's inventory.

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



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1590 under s. 499.0121, but not except those set forth in s. 499.01212
1591 ~~s. 499.0121(6)(d)~~.

1592 ~~(1)(h)~~ Limited prescription drug veterinary wholesale
1593 distributor wholesaler permit.--Unless engaging in the activities
1594 of and permitted as a prescription drug manufacturer, nonresident
1595 prescription drug manufacturer, prescription drug wholesale
1596 distributor wholesaler, or out-of-state prescription drug
1597 wholesale distributor wholesaler, a limited prescription drug
1598 veterinary wholesale distributor wholesaler permit is required
1599 for any person that engages in the distribution in or into this
1600 state of veterinary prescription drugs and prescription drugs
1601 subject to, defined by, or described by s. 503(b) of the Federal
1602 Food, Drug, and Cosmetic Act under the following conditions:

1603 1. The person is engaged in the business of wholesaling
1604 prescription and veterinary prescription legend drugs to persons:

1605 a. Licensed as veterinarians practicing on a full-time
1606 basis;

1607 b. Regularly and lawfully engaged in instruction in
1608 veterinary medicine;

1609 c. Regularly and lawfully engaged in law enforcement
1610 activities;

1611 d. For use in research not involving clinical use; or

1612 e. For use in chemical analysis or physical testing or for
1613 purposes of instruction in law enforcement activities, research,
1614 or testing.

1615 2. No more than 30 percent of total annual prescription
1616 drug sales may be prescription drugs approved for human use which
1617 are subject to, defined by, or described by s. 503(b) of the
1618 Federal Food, Drug, and Cosmetic Act.



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1619 3. The person does not distribute ~~is not permitted,~~
1620 ~~licensed, or otherwise authorized~~ in any jurisdiction state to
1621 ~~wholesale~~ prescription drugs subject to, defined by, or described
1622 by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any
1623 person who is authorized to sell, distribute, purchase, trade, or
1624 use these drugs on or for humans.

1625 4. A limited prescription drug veterinary wholesale
1626 distributor ~~wholesaler~~ that applies to the department for a new
1627 permit or the renewal of a permit must submit a bond of \$20,000,
1628 or other equivalent means of security acceptable to the
1629 department, such as an irrevocable letter of credit or a deposit
1630 in a trust account or financial institution, payable to the
1631 Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the
1632 bond is to secure payment of any administrative penalties imposed
1633 by the department and any fees and costs incurred by the
1634 department regarding that permit which are authorized under state
1635 law and which the permittee fails to pay 30 days after the fine
1636 or costs become final. The department may make a claim against
1637 such bond or security until 1 year after the permittee's license
1638 ceases to be valid or until 60 days after any administrative or
1639 legal proceeding authorized in this part ~~ss. 499.001-499.081~~
1640 which involves the permittee is concluded, including any appeal,
1641 whichever occurs later.

1642 5. A limited prescription drug veterinary wholesale
1643 distributor ~~wholesaler~~ must maintain at all times a license or
1644 permit to engage in the wholesale distribution of prescription
1645 drugs in compliance with laws of the state in which it is a
1646 resident.

1647 6. A limited prescription drug veterinary wholesale
1648 distributor ~~wholesaler~~ must comply with the requirements for



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1649 wholesale distributors under ss. ~~s.~~ 499.0121 and 499.01212,
1650 except that a limited prescription drug veterinary wholesale
1651 distributor ~~wholesaler~~ is not required to provide a pedigree
1652 paper as required by s. 499.01212 ~~s. 499.0121(6)(d)~~ upon the
1653 wholesale distribution of a prescription drug to a veterinarian.

1654 7. A limited prescription drug veterinary wholesale
1655 distributor ~~wholesaler~~ may not return to inventory for subsequent
1656 wholesale distribution any prescription drug subject to, defined
1657 by, or described by s. 503(b) of the Federal Food, Drug, and
1658 Cosmetic Act which has been returned by a veterinarian.

1659 8. ~~An out-of-state prescription drug wholesaler's permit or~~
1660 A limited prescription drug veterinary wholesale distributor
1661 ~~wholesaler~~ permit is not required for an intracompany sale or
1662 transfer of a prescription drug from an out-of-state
1663 establishment that is duly licensed to engage in the wholesale
1664 distribution of prescription drugs in its state of residence to a
1665 licensed limited prescription drug veterinary wholesale
1666 distributor ~~wholesaler~~ in this state if both wholesale
1667 distributors ~~wholesalers~~ conduct wholesale distributions of
1668 prescription drugs under the same business name. The
1669 recordkeeping requirements of ss. ~~s.~~ 499.0121(6) and 499.01212
1670 must be followed for this transaction.

1671 (m) Medical oxygen retail establishment permit.--A medical
1672 oxygen retail establishment permit is required for any person
1673 that sells medical oxygen to patients only. The sale must be
1674 based on an order from a practitioner authorized by law to
1675 prescribe. The term does not include a pharmacy licensed under
1676 chapter 465.



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1677 1. A medical oxygen retail establishment may not possess,
1678 purchase, sell, or trade any prescription drug other than medical
1679 oxygen.

1680 2. A medical oxygen retail establishment may refill medical
1681 oxygen for an individual patient based on an order from a
1682 practitioner authorized by law to prescribe. A medical oxygen
1683 retail establishment that refills medical oxygen must comply with
1684 all appropriate state and federal good manufacturing practices.

1685 3. A medical oxygen retail establishment must comply with
1686 all of the wholesale distribution requirements of s. 499.0121.

1687 4. Prescription medical oxygen sold by a medical oxygen
1688 retail establishment pursuant to a practitioner's order may not
1689 be returned into the retail establishment's inventory.

1690 (n) ~~(b)~~ A compressed medical gas wholesale distributor
1691 ~~wholesaler's~~ permit.--A compressed medical gas wholesale
1692 distributor ~~wholesaler~~ is a wholesale distributor that is limited
1693 to the wholesale distribution of compressed medical gases to
1694 other than the consumer or patient. The compressed medical gas
1695 must be in the original sealed container that was purchased by
1696 that ~~wholesale distributor wholesaler~~. A compressed medical gas
1697 wholesale distributor ~~wholesaler~~ may not possess or engage in the
1698 wholesale distribution of any prescription drug other than
1699 compressed medical gases. The department shall adopt rules that
1700 govern the wholesale distribution of prescription medical oxygen
1701 for emergency use. With respect to the emergency use of
1702 prescription medical oxygen, those rules may not be inconsistent
1703 with rules and regulations of federal agencies unless the
1704 Legislature specifically directs otherwise.

1705 (o) ~~(e)~~ Compressed medical gas manufacturer permit.--A
1706 compressed medical gas ~~manufacturer~~ ~~manufacturer's~~ permit is



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1707 required for any person that engages in the manufacture of
1708 compressed medical gases or repackages compressed medical gases
1709 from one container to another.

1710 1. A compressed medical gas manufacturer ~~permittee~~ may not
1711 manufacture or possess any prescription drug other than
1712 compressed medical gases.

1713 2. A compressed medical gas manufacturer ~~permittee~~ may
1714 engage in wholesale distribution of compressed medical gases
1715 manufactured at that establishment and must comply with all the
1716 provisions of this part ss. 499.001-499.081 and the rules adopted
1717 under this part ~~those sections~~ that apply to a wholesale
1718 distributor.

1719 3. A compressed medical gas manufacturer ~~permittee~~ must
1720 comply with all appropriate state and federal good manufacturing
1721 practices.

1722 ~~(p)-(b)~~ Over-the-counter drug manufacturer permit.--An over-
1723 the-counter drug manufacturer ~~manufacturer's~~ permit is required
1724 for any person that engages in the manufacture or repackaging of
1725 an over-the-counter drug.

1726 1. An over-the-counter drug manufacturer ~~permittee~~ may not
1727 possess or purchase prescription drugs.

1728 2. A pharmacy is exempt from obtaining an over-the-counter
1729 drug manufacturer ~~manufacturer's~~ permit if it is operating in
1730 compliance with pharmacy practice standards as defined in chapter
1731 465 and the rules adopted under that chapter.

1732 3. An over-the-counter drug manufacturer ~~permittee~~ must
1733 comply with all appropriate state and federal good manufacturing
1734 practices.

1735 ~~(q)-(d)~~ Device manufacturer permit.--A device manufacturer
1736 ~~manufacturer's~~ permit is required for any person that engages in



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1737 the manufacture, repackaging, or assembly of medical devices for
1738 human use in this state, except that a permit is not required if
1739 the person is engaged only in manufacturing, repackaging, or
1740 assembling a medical device pursuant to a practitioner's order
1741 for a specific patient.

1742 1. A manufacturer or repackager of medical devices in this
1743 state must comply with all appropriate state and federal good
1744 manufacturing practices and quality system rules.

1745 2. The department shall adopt rules related to storage,
1746 handling, and recordkeeping requirements for manufacturers of
1747 medical devices for human use.

1748 (r) (e) Cosmetic manufacturer permit.--A cosmetic
1749 manufacturer manufacturer's permit is required for any person
1750 that manufactures or repackages cosmetics in this state. A person
1751 that only labels or changes the labeling of a cosmetic but does
1752 not open the container sealed by the manufacturer of the product
1753 is exempt from obtaining a permit under this paragraph.

1754 (s) Third party logistics provider permit.--A third party
1755 logistics provider permit is required for any person that
1756 contracts with a prescription drug wholesale distributor or
1757 prescription drug manufacturer to provide warehousing,
1758 distribution, or other logistics services on behalf of a
1759 manufacturer or wholesale distributor, but who does not take
1760 title to the prescription drug or have responsibility to direct
1761 the sale or disposition of the prescription drug. Each third
1762 party logistics provider permittee shall comply with the
1763 requirements for wholesale distributors under ss. 499.0121 and
1764 499.01212, with the exception of those wholesale distributions
1765 described in s. 499.01212(3) (a), and other rules that the
1766 department requires.



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1767 (t) Health care clinic establishment permit.--Effective
1768 January 1, 2009, a health care clinic establishment permit is
1769 required for the purchase of a prescription drug by a place of
1770 business at one general physical location owned and operated by a
1771 professional corporation or professional limited liability
1772 company described in chapter 621, or a corporation that employs a
1773 veterinarian as a qualifying practitioner. For the purpose of
1774 this paragraph, the term "qualifying practitioner" means a
1775 licensed health care practitioner defined in s. 456.001 or a
1776 veterinarian licensed under chapter 474, who is authorized under
1777 the appropriate practice act to prescribe and administer a
1778 prescription drug.

1779 1. An establishment must provide, as part of the
1780 application required under s. 499.012, designation of a
1781 qualifying practitioner who will be responsible for complying
1782 with all legal and regulatory requirements related to the
1783 purchase, recordkeeping, storage, and handling of the
1784 prescription drugs. In addition, the designated qualifying
1785 practitioner shall be the practitioner whose name, establishment
1786 address, and license number is used on all distribution documents
1787 for prescription drugs purchased or returned by the health care
1788 clinic establishment. Upon initial appointment of a qualifying
1789 practitioner, the qualifying practitioner and the health care
1790 clinic establishment shall notify the department on a form
1791 furnished by the department within 10 days after such employment.
1792 In addition, the qualifying practitioner and health care clinic
1793 establishment shall notify the department within 10 days after
1794 any subsequent change.

1795 2. The health care clinic establishment must employ a
1796 qualifying practitioner at each establishment.



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1797 3. In addition to the remedies and penalties provided in
1798 this part, a violation of this chapter by the health care clinic
1799 establishment or qualifying practitioner constitutes grounds for
1800 discipline of the qualifying practitioner by the appropriate
1801 regulatory board.

1802 4. The purchase of prescription drugs by the health care
1803 clinic establishment is prohibited during any period of time when
1804 the establishment does not comply with this paragraph.

1805 5. A health care clinic establishment permit is not a
1806 pharmacy permit or otherwise subject to chapter 465. A health
1807 care clinic establishment that meets the criteria of a modified
1808 Class II institutional pharmacy under s. 465.019 is not eligible
1809 to be permitted under this paragraph.

1810 6. This paragraph does not prohibit a qualifying
1811 practitioner from purchasing prescription drugs.

1812 Section 11. Section 499.012, Florida Statutes, is amended
1813 and subsections (2) through (8) of section 499.01, Florida
1814 States, are redesignated as subsections (1) through (7) of that
1815 section and amended, to read:

1816 499.012 Permit application ~~Wholesale distribution;~~
1817 ~~definitions; permits; applications; general requirements.--~~

1818 (1) ~~As used in this section, the term:~~

1819 ~~(2)~~(a) A permit issued pursuant to this part ~~ss. 499.001-~~
1820 ~~499.081~~ may be issued only to a natural person who is at least 18
1821 years of age or to an applicant that is not a natural person if
1822 each person who, directly or indirectly, manages, controls, or
1823 oversees the operation of that applicant is at least 18 years of
1824 age.



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1825 (b) An establishment that is a place of residence may not
1826 receive a permit and may not operate under this part ~~ss. 499.001-~~
1827 ~~499.081~~.

1828 (c) A person that applies for or renews a permit to
1829 manufacture or distribute prescription ~~legend~~ drugs may not use a
1830 name identical to the name used by any other establishment or
1831 licensed person authorized to purchase prescription drugs in this
1832 state, except that a restricted drug distributor permit issued to
1833 a health care entity will be issued in the name in which the
1834 institutional pharmacy permit is issued and a retail pharmacy
1835 drug wholesale distributor ~~wholesaler~~ will be issued a permit in
1836 the name of its retail pharmacy permit.

1837 (d) A permit for a prescription drug manufacturer,
1838 prescription drug repackager, prescription drug wholesale
1839 distributor ~~wholesaler~~, limited prescription drug veterinary
1840 wholesale distributor ~~wholesaler~~, or retail pharmacy drug
1841 wholesale distributor ~~wholesaler~~ may not be issued to the address
1842 of a health care entity or to a pharmacy licensed under chapter
1843 465, except as provided in this paragraph. The department may
1844 issue a prescription drug manufacturer permit to an applicant at
1845 the same address as a licensed nuclear pharmacy, which is a
1846 health care entity, for the purpose of manufacturing prescription
1847 drugs used in positron emission tomography or other
1848 radiopharmaceuticals, as listed in a rule adopted by the
1849 department pursuant to this paragraph. The purpose of this
1850 exemption is to assure availability of state-of-the-art
1851 pharmaceuticals that would pose a significant danger to the
1852 public health if manufactured at a separate establishment address
1853 from the nuclear pharmacy from which the prescription drugs are
1854 dispensed. The department may also issue a retail pharmacy drug



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1855 wholesale distributor ~~wholesaler~~ permit to the address of a
1856 community pharmacy licensed under chapter 465 which does not meet
1857 the definition of a closed pharmacy in s. 499.003.

1858 (e) A county or municipality may not issue an occupational
1859 license for any licensing period beginning on or after October 1,
1860 2003, for any establishment that requires a permit pursuant to
1861 this part ~~ss. 499.001-499.081~~, unless the establishment exhibits
1862 a current permit issued by the department for the establishment.
1863 Upon presentation of the requisite permit issued by the
1864 department, an occupational license may be issued by the
1865 municipality or county in which application is made. The
1866 department shall furnish to local agencies responsible for
1867 issuing occupational licenses a current list of all
1868 establishments licensed pursuant to this part ~~ss. 499.001-~~
1869 ~~499.081~~.

1870 ~~(2)(3)~~ Notwithstanding subsection ~~(6)~~ ~~(7)~~, a permitted
1871 person in good standing may change the type of permit issued to
1872 that person by completing a new application for the requested
1873 permit, paying the amount of the difference in the permit fees if
1874 the fee for the new permit is more than the fee for the original
1875 permit, and meeting the applicable permitting conditions for the
1876 new permit type. The new permit expires on the expiration date of
1877 the original permit being changed; however, a new permit for a
1878 prescription drug wholesale distributor ~~wholesaler~~, an out-of-
1879 state prescription drug wholesale distributor ~~wholesaler~~, or a
1880 retail pharmacy drug wholesale distributor ~~wholesaler~~ shall
1881 expire on the expiration date of the original permit or 1 year
1882 after the date of issuance of the new permit, whichever is
1883 earlier. A refund may not be issued if the fee for the new permit
1884 is less than the fee that was paid for the original permit.



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1885 (3)~~(4)~~ A written application for a permit or to renew a
1886 permit must be filed with the department on forms furnished by
1887 the department. The department shall establish, by rule, the form
1888 and content of the application to obtain or renew a permit. The
1889 applicant must submit to the department with the application a
1890 statement that swears or affirms that the information is true and
1891 correct.

1892 (4)~~(5)~~(a) Except for a permit for a prescription drug
1893 wholesale distributor ~~wholesaler~~ or an out-of-state prescription
1894 drug wholesale distributor ~~wholesaler~~, an application for a
1895 permit must include:

1896 1. The name, full business address, and telephone number of
1897 the applicant;

1898 2. All trade or business names used by the applicant;

1899 3. The address, telephone numbers, and the names of contact
1900 persons for each facility used by the applicant for the storage,
1901 handling, and distribution of prescription drugs;

1902 4. The type of ownership or operation, such as a
1903 partnership, corporation, or sole proprietorship; and

1904 5. The names of the owner and the operator of the
1905 establishment, including:

1906 a. If an individual, the name of the individual;

1907 b. If a partnership, the name of each partner and the name
1908 of the partnership;

1909 c. If a corporation, the name and title of each corporate
1910 officer and director, the corporate names, and the name of the
1911 state of incorporation;

1912 d. If a sole proprietorship, the full name of the sole
1913 proprietor and the name of the business entity;



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1914 e. If a limited liability company, the name of each member,
1915 the name of each manager, the name of the limited liability
1916 company, and the name of the state in which the limited liability
1917 company was organized; and

1918 f. Any other relevant information that the department
1919 requires.

1920 (b) Upon approval of the application by the department and
1921 payment of the required fee, the department shall issue a permit
1922 to the applicant, if the applicant meets the requirements of this
1923 part ss. 499.001-499.081 and rules adopted under this part ~~those~~
1924 ~~sections.~~

1925 (c) Any change in information required under paragraph (a)
1926 must be submitted to the department before the change occurs.

1927 (d) The department shall consider, at a minimum, the
1928 following factors in reviewing the qualifications of persons to
1929 be permitted under this part ss. 499.001-499.081:

1930 1. The applicant's having been found guilty, regardless of
1931 adjudication, in a court of this state or other jurisdiction, of
1932 a violation of a law that directly relates to a drug, device, or
1933 cosmetic. A plea of nolo contendere constitutes a finding of
1934 guilt for purposes of this subparagraph.

1935 2. The applicant's having been disciplined by a regulatory
1936 agency in any state for any offense that would constitute a
1937 violation of this part ss. 499.001-499.081.

1938 3. Any felony conviction of the applicant under a federal,
1939 state, or local law;

1940 4. The applicant's past experience in manufacturing or
1941 distributing drugs, devices, or cosmetics;



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1942 5. The furnishing by the applicant of false or fraudulent
1943 material in any application made in connection with manufacturing
1944 or distributing drugs, devices, or cosmetics;

1945 6. Suspension or revocation by a federal, state, or local
1946 government of any permit currently or previously held by the
1947 applicant for the manufacture or distribution of any drugs,
1948 devices, or cosmetics;

1949 7. Compliance with permitting requirements under any
1950 previously granted permits;

1951 8. Compliance with requirements to maintain or make
1952 available to the state permitting authority or to federal, state,
1953 or local law enforcement officials those records required under
1954 this section; and

1955 9. Any other factors or qualifications the department
1956 considers relevant to and consistent with the public health and
1957 safety.

1958 ~~(5)-(6)~~ Except for a permit ~~permits~~ for a prescription drug
1959 wholesale distributor ~~wholesalers~~ or an out-of-state prescription
1960 drug wholesale distributor ~~wholesalers~~:

1961 (a) The department shall adopt rules for the biennial
1962 renewal of permits.

1963 (b) The department shall renew a permit upon receipt of the
1964 renewal application and renewal fee if the applicant meets the
1965 requirements established under this part ~~ss. 499.001-499.081~~ and
1966 the rules adopted under this part ~~those sections~~.

1967 (c) A permit, unless sooner suspended or revoked,
1968 automatically expires 2 years after the last day of the
1969 anniversary month in which the permit was originally issued. A
1970 permit issued under this part ~~ss. 499.001-499.081~~ may be renewed
1971 by making application for renewal on forms furnished by the



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1972 department and paying the appropriate fees. If a renewal
1973 application and fee are submitted and postmarked after the
1974 expiration date of the permit, the permit may be renewed only
1975 upon payment of a late renewal delinquent fee of \$100, plus the
1976 required renewal fee, not later than 60 days after the expiration
1977 date.

1978 (d) Failure to renew a permit in accordance with this
1979 section precludes any future renewal of that permit. If a permit
1980 issued pursuant to this part ~~section~~ has expired and cannot be
1981 renewed, before an establishment may engage in activities that
1982 require a permit under this part ~~ss. 499.001-499.081~~, the
1983 establishment must submit an application for a new permit, pay
1984 the applicable application fee, the initial permit fee, and all
1985 applicable penalties, and be issued a new permit by the
1986 department.

1987 (6) ~~(7)~~ A permit issued by the department is
1988 nontransferable. Each permit is valid only for the person or
1989 governmental unit to which it is issued and is not subject to
1990 sale, assignment, or other transfer, voluntarily or
1991 involuntarily; nor is a permit valid for any establishment other
1992 than the establishment for which it was originally issued.

1993 (a) A person permitted under this part ~~ss. 499.001-499.081~~
1994 must notify the department before making a change of address. The
1995 department shall set a change of location fee not to exceed \$100.

1996 (b)1. An application for a new permit is required when a
1997 majority of the ownership or controlling interest of a permitted
1998 establishment is transferred or assigned or when a lessee agrees
1999 to undertake or provide services to the extent that legal
2000 liability for operation of the establishment will rest with the



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2001 lessee. The application for the new permit must be made before
2002 the date of the sale, transfer, assignment, or lease.

2003 2. A permittee that is authorized to distribute
2004 prescription legend drugs may transfer such drugs to the new
2005 owner or lessee under subparagraph 1. only after the new owner or
2006 lessee has been approved for a permit to distribute prescription
2007 legend drugs.

2008 (c) If an establishment permitted under this part ss.
2009 ~~499.001-499.081~~ closes, the owner must notify the department in
2010 writing before the effective date of closure and must:

2011 1. Return the permit to the department;

2012 2. If the permittee is authorized to distribute
2013 prescription legend drugs, indicate the disposition of such
2014 drugs, including the name, address, and inventory, and provide
2015 the name and address of a person to contact regarding access to
2016 records that are required to be maintained under this part ss.
2017 ~~499.001-499.081~~. Transfer of ownership of prescription legend
2018 drugs may be made only to persons authorized to possess
2019 prescription legend drugs under this part ss. ~~499.001-499.081~~.

2020
2021 The department may revoke the permit of any person that fails to
2022 comply with the requirements of this subsection.

2023 ~~(7)(8)~~ A permit must be posted in a conspicuous place on
2024 the licensed premises.

2025 ~~(8)(3)~~ An application for a permit or to renew a permit for
2026 a prescription drug wholesale distributor ~~wholesaler~~ or an out-
2027 of-state prescription drug wholesale distributor ~~wholesaler~~
2028 submitted to the department must include:

2029 (a) The name, full business address, and telephone number
2030 of the applicant.



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- 2031 (b) All trade or business names used by the applicant.
- 2032 (c) The address, telephone numbers, and the names of
2033 contact persons for each facility used by the applicant for the
2034 storage, handling, and distribution of prescription drugs.
- 2035 (d) The type of ownership or operation, such as a
2036 partnership, corporation, or sole proprietorship.
- 2037 (e) The names of the owner and the operator of the
2038 establishment, including:
- 2039 1. If an individual, the name of the individual.
- 2040 2. If a partnership, the name of each partner and the name
2041 of the partnership.
- 2042 3. If a corporation:
- 2043 a. The name, address, and title of each corporate officer
2044 and director.
- 2045 b. The name and address of the corporation, resident agent
2046 of the corporation, the resident agent's address, and the
2047 corporation's state of incorporation.
- 2048 c. The name and address of each shareholder of the
2049 corporation that owns 5 percent or more of the outstanding stock
2050 of the corporation.
- 2051 4. If a sole proprietorship, the full name of the sole
2052 proprietor and the name of the business entity.
- 2053 5. If a limited liability company:
- 2054 a. The name and address of each member.
- 2055 b. The name and address of each manager.
- 2056 c. The name and address of the limited liability company,
2057 the resident agent of the limited liability company, and the name
2058 of the state in which the limited liability company was
2059 organized.



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2060 (f) If applicable, the name and address of each member of
2061 the affiliated group of which the applicant is a member.

2062 (g)1. For an application for a new permit, the estimated
2063 annual dollar volume of prescription drug sales of the applicant,
2064 the estimated annual percentage of the applicant's total company
2065 sales that are prescription drugs, the applicant's estimated
2066 annual total dollar volume of purchases of prescription drugs,
2067 and the applicant's estimated annual total dollar volume of
2068 prescription drug purchases directly from manufacturers.

2069 2. For an application to renew a permit, the total dollar
2070 volume of prescription drug sales in the previous year, the total
2071 dollar volume of prescription drug sales made in the previous 6
2072 months, the percentage of total company sales that were
2073 prescription drugs in the previous year, the total dollar volume
2074 of purchases of prescription drugs in the previous year, and the
2075 total dollar volume of prescription drug purchases directly from
2076 manufacturers in the previous year.

2077
2078 Such portions of the information required pursuant to this
2079 paragraph which are a trade secret, as defined in s. 812.081,
2080 shall be maintained by the department as trade secret information
2081 is required to be maintained under s. 499.051.

2082 (h) The tax year of the applicant.

2083 (i) A copy of the deed for the property on which
2084 applicant's establishment is located, if the establishment is
2085 owned by the applicant, or a copy of the applicant's lease for
2086 the property on which applicant's establishment is located that
2087 has an original term of not less than 1 calendar year, if the
2088 establishment is not owned by the applicant.



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2089 (j) A list of all licenses and permits issued to the
2090 applicant by any other state which authorize the applicant to
2091 purchase or possess prescription drugs.

2092 (k) The name of the manager of the establishment that is
2093 applying for the permit or to renew the permit, the next four
2094 highest ranking employees responsible for prescription drug
2095 wholesale operations for the establishment, and the name of all
2096 affiliated parties for the establishment, together with the
2097 personal information statement and fingerprints required pursuant
2098 to subsection (9) ~~(4)~~ for each of such persons.

2099 (l) The name of each of the applicant's designated
2100 representatives as required by subsection (16) ~~(11)~~, together
2101 with the personal information statement and fingerprints required
2102 pursuant to subsection (9) ~~(4)~~ for each such person.

2103 (m) For an applicant that is a secondary wholesale
2104 distributor ~~wholesaler~~, each of the following:

2105 1. A personal background information statement containing
2106 the background information and fingerprints required pursuant to
2107 subsection (9) ~~(4)~~ for each person named in the applicant's
2108 response to paragraphs (k) and (l) and for each affiliated party
2109 of the applicant.

2110 2. If any of the five largest shareholders of the
2111 corporation seeking the permit is a corporation, the name,
2112 address, and title of each corporate officer and director of each
2113 such corporation; the name and address of such corporation; the
2114 name of such corporation's resident agent, such corporation's
2115 resident agent's address, and such corporation's state of its
2116 incorporation; and the name and address of each shareholder of
2117 such corporation that owns 5 percent or more of the stock of such
2118 corporation.



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2119 | 3. The name and address of all financial institutions in
2120 | which the applicant has an account which is used to pay for the
2121 | operation of the establishment or to pay for drugs purchased for
2122 | the establishment, together with the names of all persons that
2123 | are authorized signatories on such accounts. The portions of the
2124 | information required pursuant to this subparagraph which are a
2125 | trade secret, as defined in s. 812.081, shall be maintained by
2126 | the department as trade secret information is required to be
2127 | maintained under s. 499.051.

2128 | 4. The sources of all funds and the amounts of such funds
2129 | used to purchase or finance purchases of prescription drugs or to
2130 | finance the premises on which the establishment is to be located.

2131 | 5. If any of the funds identified in subparagraph 4. were
2132 | borrowed, copies of all promissory notes or loans used to obtain
2133 | such funds.

2134 | (n) Any other relevant information that the department
2135 | requires, including, but not limited to, any information related
2136 | to whether the applicant satisfies the definition of a primary
2137 | wholesale distributor ~~wholesaler~~ or a secondary wholesale
2138 | distributor ~~wholesaler~~.

2139 | (9) ~~(4)~~ (a) Each person required by subsection (8) ~~(3)~~ to
2140 | provide a personal information statement and fingerprints shall
2141 | provide the following information to the department on forms
2142 | prescribed by the department:

2143 | 1. The person's places of residence for the past 7 years.

2144 | 2. The person's date and place of birth.

2145 | 3. The person's occupations, positions of employment, and
2146 | offices held during the past 7 years.

2147 | 4. The principal business and address of any business,
2148 | corporation, or other organization in which each such office of



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2149 | the person was held or in which each such occupation or position
2150 | of employment was carried on.

2151 | 5. Whether the person has been, during the past 7 years,
2152 | the subject of any proceeding for the revocation of any license
2153 | and, if so, the nature of the proceeding and the disposition of
2154 | the proceeding.

2155 | 6. Whether, during the past 7 years, the person has been
2156 | enjoined, ~~either~~ temporarily or permanently, by a court of
2157 | competent jurisdiction from violating any federal or state law
2158 | regulating the possession, control, or distribution of
2159 | prescription drugs, together with details concerning any such
2160 | event.

2161 | 7. A description of any involvement by the person with any
2162 | business, including any investments, other than the ownership of
2163 | stock in a publicly traded company or mutual fund, during the
2164 | past 7 years, which manufactured, administered, prescribed,
2165 | distributed, or stored pharmaceutical products and any lawsuits
2166 | in which such businesses were named as a party.

2167 | 8. A description of any felony criminal offense of which
2168 | the person, as an adult, was found guilty, regardless of whether
2169 | adjudication of guilt was withheld or whether the person pled
2170 | guilty or nolo contendere. A criminal offense committed in
2171 | another jurisdiction which would have been a felony in this state
2172 | must be reported. If the person indicates that a criminal
2173 | conviction is under appeal and submits a copy of the notice of
2174 | appeal of that criminal offense, the applicant must, within 15
2175 | days after the disposition of the appeal, submit to the
2176 | department a copy of the final written order of disposition.

2177 | 9. A photograph of the person taken in the previous 30
2178 | days.



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2179 | 10. A set of fingerprints for the person on a form and
2180 | under procedures specified by the department, together with
2181 | payment of an amount equal to the costs incurred by the
2182 | department for the criminal record check of the person.

2183 | 11. The name, address, occupation, and date and place of
2184 | birth for each member of the person's immediate family who is 18
2185 | years of age or older. As used in this subparagraph, the term
2186 | "member of the person's immediate family" includes the person's
2187 | spouse, children, parents, siblings, the spouses of the person's
2188 | children, and the spouses of the person's siblings.

2189 | 12. Any other relevant information that the department
2190 | requires.

2191 | (b) The information required pursuant to paragraph (a)
2192 | shall be provided under oath.

2193 | (c) The department shall submit the fingerprints provided
2194 | by a person for initial licensure to the Department of Law
2195 | Enforcement for a statewide criminal record check and for
2196 | forwarding to the Federal Bureau of Investigation for a national
2197 | criminal record check of the person. The department shall submit
2198 | the fingerprints provided by a person as a part of a renewal
2199 | application to the Department of Law Enforcement for a statewide
2200 | criminal record check, and for forwarding to the Federal Bureau
2201 | of Investigation for a national criminal record check, for the
2202 | initial renewal of a permit after January 1, 2004; for any
2203 | subsequent renewal of a permit, the department shall submit the
2204 | required information for a statewide and national criminal record
2205 | check of the person. Any person who as a part of an initial
2206 | permit application or initial permit renewal after January 1,
2207 | 2004, submits to the department a set of fingerprints required
2208 | for the criminal record check required in this paragraph shall



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2209 | not be required to provide a subsequent set of fingerprints for a
2210 | criminal record check to the department, if the person has
2211 | undergone a criminal record check as a condition of the issuance
2212 | of an initial permit or the initial renewal of a permit of an
2213 | applicant after January 1, 2004.

2214 | (10)-(5) The department may deny an application for a permit
2215 | or refuse to renew a permit for a prescription drug wholesale
2216 | distributor ~~wholesaler~~ or an out-of-state prescription drug
2217 | wholesale distributor ~~wholesaler~~ if:

2218 | (a) The applicant has not met the requirements for the
2219 | permit.

2220 | (b) The management, officers, or directors of the applicant
2221 | or any affiliated party are found by the department to be
2222 | incompetent or untrustworthy.

2223 | (c) The applicant is so lacking in experience in managing a
2224 | wholesale distributor as to make the issuance of the proposed
2225 | permit hazardous to the public health.

2226 | (d) The applicant is so lacking in experience in managing a
2227 | wholesale distributor as to jeopardize the reasonable promise of
2228 | successful operation of the wholesale distributor.

2229 | (e) The applicant is lacking in experience in the
2230 | distribution of prescription drugs.

2231 | (f) The applicant's past experience in manufacturing or
2232 | distributing prescription drugs indicates that the applicant
2233 | poses a public health risk.

2234 | (g) The applicant is affiliated directly or indirectly
2235 | through ownership, control, or other business relations, with any
2236 | person or persons whose business operations are or have been
2237 | detrimental to the public health.



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2238 (h) The applicant, or any affiliated party, has been found
2239 guilty of or has pleaded guilty or nolo contendere to any felony
2240 or crime punishable by imprisonment for 1 year or more under the
2241 laws of the United States, any state, or any other country,
2242 regardless of whether adjudication of guilt was withheld.

2243 (i) The applicant or any affiliated party has been charged
2244 with a felony in a state or federal court and the disposition of
2245 that charge is pending during the application review or renewal
2246 review period.

2247 (j) The applicant has furnished false or fraudulent
2248 information or material in any application made in this state or
2249 any other state in connection with obtaining a permit or license
2250 to manufacture or distribute drugs, devices, or cosmetics.

2251 (k) That a federal, state, or local government permit
2252 currently or previously held by the applicant, or any affiliated
2253 party, for the manufacture or distribution of any drugs, devices,
2254 or cosmetics has been disciplined, suspended, or revoked and has
2255 not been reinstated.

2256 (l) The applicant does not possess the financial or
2257 physical resources to operate in compliance with the permit being
2258 sought, this chapter, and the rules adopted under this chapter.

2259 (m) The applicant or any affiliated party receives,
2260 directly or indirectly, financial support and assistance from a
2261 person who was an affiliated party of a permittee whose permit
2262 was subject to discipline or was suspended or revoked, other than
2263 through the ownership of stock in a publicly traded company or a
2264 mutual fund.

2265 (n) The applicant or any affiliated party receives,
2266 directly or indirectly, financial support and assistance from a
2267 person who has been found guilty of any violation of this part



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2268 ~~ss. 499.001-499.081~~ or chapter 465, chapter 501, or chapter 893,
2269 any rules adopted under any of this part ~~those sections~~ or those
2270 chapters, any federal or state drug law, or any felony where the
2271 underlying facts related to drugs, regardless of whether the
2272 person has been pardoned, had her or his civil rights restored,
2273 or had adjudication withheld, other than through the ownership of
2274 stock in a publicly traded company or a mutual fund.

2275 (o) The applicant for renewal of a permit under s.
2276 499.01(2)(d) ~~paragraph (2)(a)~~ or s. 499.01(2)(e) ~~paragraph (2)(c)~~
2277 has not actively engaged in the wholesale distribution of
2278 prescription drugs, as demonstrated by the regular and systematic
2279 distribution of prescription drugs throughout the year as
2280 evidenced by not fewer than 12 wholesale distributions in the
2281 previous year and not fewer than three wholesale distributions in
2282 the previous 6 months.

2283 (p) Information obtained in response to s. 499.01(2)(d)
2284 ~~paragraph (2)(a)~~ or s. 499.01(2)(e) ~~paragraph (2)(c)~~ demonstrates
2285 it would not be in the best interest of the public health,
2286 safety, and welfare to issue a permit.

2287 (q) The applicant does not possess the financial standing
2288 and business experience for the successful operation of the
2289 applicant.

2290 (r) The applicant or any affiliated party has failed to
2291 comply with the requirements for manufacturing or distributing
2292 prescription drugs under this part ~~ss. 499.001-499.081~~, similar
2293 federal laws, similar laws in other states, or the rules adopted
2294 under such laws.

2295 ~~(11)(6)~~ Upon approval of the application by the department
2296 and payment of the required fee, the department shall issue or
2297 renew a prescription drug wholesale distributor ~~wholesaler~~ or an



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2298 out-of-state prescription drug wholesale distributor ~~wholesaler~~
2299 permit to the applicant.

2300 (12)(7) For a permit ~~permits~~ for a prescription drug
2301 wholesale distributor ~~wholesalers~~ or an out-of-state prescription
2302 drug wholesale distributor ~~wholesalers~~:

2303 (a) The department shall adopt rules for the annual renewal
2304 of permits. At least 90 days before the expiration of a permit,
2305 the department shall forward a permit renewal notification and
2306 renewal application to the prescription drug wholesale
2307 distributor ~~wholesaler~~ or out-of-state prescription drug
2308 wholesale distributor ~~wholesaler~~ at the mailing address of the
2309 permitted establishment on file with the department. The permit
2310 renewal notification must state conspicuously the date on which
2311 the permit for the establishment will expire and that the
2312 establishment may not operate unless the permit for the
2313 establishment is renewed timely.

2314 (b) A permit, unless sooner suspended or revoked,
2315 automatically expires 1 year after the last day of the
2316 anniversary month in which the permit was originally issued. A
2317 permit may be renewed by making application for renewal on forms
2318 furnished by the department and paying the appropriate fees. If a
2319 renewal application and fee are submitted and postmarked after 45
2320 days prior to the expiration date of the permit, the permit may
2321 be renewed only upon payment of a late renewal fee of \$100, plus
2322 the required renewal fee. A permittee that has submitted a
2323 renewal application in accordance with this paragraph may
2324 continue to operate under its permit, unless the permit is
2325 suspended or revoked, until final disposition of the renewal
2326 application.



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2327 (c) Failure to renew a permit in accordance with this
2328 section precludes any future renewal of that permit. If a permit
2329 issued pursuant to this section has expired and cannot be
2330 renewed, before an establishment may engage in activities that
2331 require a permit under this part ~~ss. 499.001-499.081~~, the
2332 establishment must submit an application for a new permit; pay
2333 the applicable application fee, initial permit fee, and all
2334 applicable penalties; and be issued a new permit by the
2335 department.

2336 ~~(13)-(8)~~ A person that engages in wholesale distribution of
2337 prescription drugs in this state must have a wholesale
2338 distributor's permit issued by the department, except as noted in
2339 this section. Each establishment must be separately permitted
2340 except as noted in this subsection.

2341 (a) A separate establishment permit is not required when a
2342 permitted prescription drug wholesale distributor ~~wholesaler~~
2343 consigns a prescription drug to a pharmacy that is permitted
2344 under chapter 465 and located in this state, provided that:

2345 1. The consignor wholesale distributor ~~wholesaler~~ notifies
2346 the department in writing of the contract to consign prescription
2347 drugs to a pharmacy along with the identity and location of each
2348 consignee pharmacy;

2349 2. The pharmacy maintains its permit under chapter 465;

2350 3. The consignor wholesale distributor ~~wholesaler~~, which
2351 has no legal authority to dispense prescription drugs, complies
2352 with all wholesale distribution requirements of ss. ~~s.~~ 499.0121
2353 and 499.01212 with respect to the consigned drugs and maintains
2354 records documenting the transfer of title or other completion of
2355 the wholesale distribution of the consigned prescription drugs;



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2356 4. The distribution of the prescription drug is otherwise
2357 lawful under this chapter and other applicable law;

2358 5. Open packages containing prescription drugs within a
2359 pharmacy are the responsibility of the pharmacy, regardless of
2360 how the drugs are titled; and

2361 6. The pharmacy dispenses the consigned prescription drug
2362 in accordance with the limitations of its permit under chapter
2363 465 or returns the consigned prescription drug to the consignor
2364 wholesale distributor ~~wholesaler~~. In addition, a person who holds
2365 title to prescription drugs may transfer the drugs to a person
2366 permitted or licensed to handle the reverse distribution or
2367 destruction of drugs. Any other distribution by and means of the
2368 consigned prescription drug by any person, not limited to the
2369 consignor wholesale distributor ~~wholesaler~~ or consignee pharmacy,
2370 to any other person is prohibited.

2371 (b) A wholesale distributor's permit is not required for
2372 the one-time transfer of title of a pharmacy's lawfully acquired
2373 prescription drug inventory by a pharmacy with a valid permit
2374 issued under chapter 465 to a consignor prescription drug
2375 wholesale distributor ~~wholesaler~~, permitted under this chapter,
2376 in accordance with a written consignment agreement between the
2377 pharmacy and that wholesale distributor ~~wholesaler~~ if: the
2378 permitted pharmacy and the permitted prescription drug wholesale
2379 distributor ~~wholesaler~~ comply with all of the provisions of
2380 paragraph (a) and the prescription drugs continue to be within
2381 the permitted pharmacy's inventory for dispensing in accordance
2382 with the limitations of the pharmacy permit under chapter 465. A
2383 consignor drug wholesale distributor ~~wholesaler~~ may not use the
2384 pharmacy as a wholesale distributor through which it distributes
2385 the prescription ~~legend~~ drugs to other pharmacies. Nothing in



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2386 | this section is intended to prevent a wholesale ~~drug~~ distributor
2387 | from obtaining this inventory in the event of nonpayment by the
2388 | pharmacy.

2389 | (c) A separate establishment permit is not required when a
2390 | permitted prescription drug wholesale distributor operates
2391 | temporary transit storage facilities for the sole purpose of
2392 | storage, for up to 16 hours, of a delivery of prescription drugs
2393 | when the wholesale distributor was temporarily unable to complete
2394 | the delivery to the recipient.

2395 | (d)(e) The department shall require information from each
2396 | wholesale distributor as part of the permit and renewal of such
2397 | permit, as required under ~~s. 499.01~~ or this section.

2398 | (14)(9) Personnel employed in wholesale distribution must
2399 | have appropriate education and experience to enable them to
2400 | perform their duties in compliance with state permitting
2401 | requirements.

2402 | (15)(10) The name of a permittee or establishment on a
2403 | prescription drug wholesale distributor ~~wholesaler~~ permit or an
2404 | out-of-state prescription drug wholesale distributor ~~wholesaler~~
2405 | permit may not include any indicia of attainment of any
2406 | educational degree, any indicia that the permittee or
2407 | establishment possesses a professional license, or any name or
2408 | abbreviation that the department determines is likely to cause
2409 | confusion or mistake or that the department determines is
2410 | deceptive, including that of any other entity authorized to
2411 | purchase prescription drugs.

2412 | (16)(11)(a) Each establishment that is issued an initial or
2413 | renewal permit as a prescription drug wholesale distributor
2414 | ~~wholesaler~~ or an out-of-state prescription drug wholesale
2415 | distributor ~~wholesaler~~ must designate in writing to the



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2416 department at least one natural person to serve as the designated
2417 representative of the wholesale distributor ~~wholesaler~~. Such
2418 person must have an active certification as a designated
2419 representative from the department.

2420 (b) To be certified as a designated representative, a
2421 natural person must:

2422 1. Submit an application on a form furnished by the
2423 department and pay the appropriate fees;

2424 2. Be at least 18 years of age;

2425 3. Have not less than 2 years of verifiable full-time work
2426 experience in a pharmacy licensed in this state or another state,
2427 where the person's responsibilities included, but were not
2428 limited to, recordkeeping for prescription drugs, or have not
2429 less than 2 years of verifiable full-time managerial experience
2430 with a prescription drug wholesale distributor ~~wholesaler~~
2431 licensed in this state or in another state;

2432 4. Receive a passing score of at least 75 percent on an
2433 examination given by the department regarding federal laws
2434 governing distribution of prescription drugs and this part ~~ss.~~
2435 ~~499.001-499.081~~ and the rules adopted by the department governing
2436 the wholesale distribution of prescription drugs. This
2437 requirement shall be effective 1 year after the results of the
2438 initial examination are mailed to the persons that took the
2439 examination. The department shall offer such examinations at
2440 least four times each calendar year; and

2441 5. Provide the department with a personal information
2442 statement and fingerprints pursuant to subsection (9) ~~(4)~~.

2443 (c) The department may deny an application for
2444 certification as a designated representative or may suspend or



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2445 | revoke a certification of a designated representative pursuant to
2446 | s. 499.067.

2447 | (d) A designated representative:

2448 | 1. Must be actively involved in and aware of the actual
2449 | daily operation of the wholesale distributor.

2450 | 2. Must be employed full time in a managerial position by
2451 | the wholesale distributor.

2452 | 3. Must be physically present at the establishment during
2453 | normal business hours, except for time periods when absent due to
2454 | illness, family illness or death, scheduled vacation, or other
2455 | authorized absence.

2456 | 4. May serve as a designated representative for only one
2457 | wholesale distributor at any one time.

2458 | (e) A wholesale distributor must notify the department when
2459 | a designated representative leaves the employ of the wholesale
2460 | distributor. Such notice must be provided to the department
2461 | within 10 business days after the last day of designated
2462 | representative's employment with the wholesale distributor.

2463 | (f) A wholesale distributor may not operate under a
2464 | prescription drug wholesale distributor ~~wholesaler~~ permit or an
2465 | out-of-state prescription drug wholesale distributor ~~wholesaler~~
2466 | permit for more than 10 business days after the designated
2467 | representative leaves the employ of the wholesale distributor,
2468 | unless the wholesale distributor employs another designated
2469 | representative and notifies the department within 10 business
2470 | days of the identity of the new designated representative.

2471 | Section 12. Section 499.01201, Florida Statutes, is amended
2472 | to read:

2473 | 499.01201 Agency for Health Care Administration review and
2474 | use of statute and rule violation or compliance



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2475 data.--Notwithstanding any other provisions of law to the
2476 contrary, the Agency for Health Care Administration may not:
2477 (1) Review or use any violation or alleged violation of s.
2478 499.0121(6) or s. 499.01212, or any rules adopted under those
2479 sections ~~that section~~, as a ground for denying or withholding any
2480 payment of a Medicaid reimbursement to a pharmacy licensed under
2481 chapter 465; or

2482 (2) Review or use compliance with s. 499.0121(6) or s.
2483 499.01212, or any rules adopted under those sections ~~that~~
2484 ~~section~~, as the subject of any audit of Medicaid-related records
2485 held by a pharmacy licensed under chapter 465.

2486 Section 13. Section 499.0121, Florida Statutes, is amended,
2487 and subsection (4) of section 499.013, Florida Statutes, is
2488 redesignated as paragraph (d) of subsection (6) of that section
2489 and amended, to read:

2490 499.0121 Storage and handling of prescription drugs;
2491 recordkeeping.--The department shall adopt rules to implement
2492 this section as necessary to protect the public health, safety,
2493 and welfare. Such rules shall include, but not be limited to,
2494 requirements for the storage and handling of prescription drugs
2495 and for the establishment and maintenance of prescription drug
2496 distribution records.

2497 (1) ESTABLISHMENTS.--An establishment at which prescription
2498 drugs are stored, warehoused, handled, held, offered, marketed,
2499 or displayed must:

2500 (a) Be of suitable size and construction to facilitate
2501 cleaning, maintenance, and proper operations;

2502 (b) Have storage areas designed to provide adequate
2503 lighting, ventilation, temperature, sanitation, humidity, space,
2504 equipment, and security conditions;



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2505 (c) Have a quarantine area for storage of prescription
2506 drugs that are outdated, damaged, deteriorated, misbranded, or
2507 adulterated, or that are in immediate or sealed, secondary
2508 containers that have been opened;

2509 (d) Be maintained in a clean and orderly condition; and

2510 (e) Be free from infestation by insects, rodents, birds, or
2511 vermin of any kind.

2512 (2) SECURITY.--

2513 (a) An establishment that is used for wholesale drug
2514 distribution must be secure from unauthorized entry.

2515 1. Access from outside the premises must be kept to a
2516 minimum and be well-controlled.

2517 2. The outside perimeter of the premises must be well-
2518 lighted.

2519 3. Entry into areas where prescription drugs are held must
2520 be limited to authorized personnel.

2521 (b) An establishment that is used for wholesale drug
2522 distribution must be equipped with:

2523 1. An alarm system to detect entry after hours; however,
2524 the department may exempt by rule establishments that only hold a
2525 permit as prescription drug wholesale distributor-brokers
2526 ~~wholesaler-brokers~~ and establishments that only handle medical
2527 oxygen; and

2528 2. A security system that will provide suitable protection
2529 against theft and diversion. When appropriate, the security
2530 system must provide protection against theft or diversion that is
2531 facilitated or hidden by tampering with computers or electronic
2532 records.



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2533 (c) Any vehicle that contains prescription drugs must be
2534 secure from unauthorized access to the prescription drugs in the
2535 vehicle.

2536 (3) STORAGE.--All prescription drugs shall be stored at
2537 appropriate temperatures and under appropriate conditions in
2538 accordance with requirements, if any, in the labeling of such
2539 drugs, or with requirements in the official compendium.

2540 (a) If no storage requirements are established for a
2541 prescription drug, the drug may be held at "controlled" room
2542 temperature, as defined in the official compendium, to help
2543 ensure that its identity, strength, quality, and purity are not
2544 adversely affected.

2545 (b) Appropriate manual, electromechanical, or electronic
2546 temperature and humidity recording equipment, devices, or logs
2547 must be used to document proper storage of prescription drugs.

2548 (c) The recordkeeping requirements in subsection (6) must
2549 be followed for all stored prescription drugs.

2550 (4) EXAMINATION OF MATERIALS AND RECORDS.--

2551 (a) Upon receipt, each outside shipping container must be
2552 visually examined for identity and to prevent the acceptance of
2553 contaminated prescription drugs that are otherwise unfit for
2554 distribution. This examination must be adequate to reveal
2555 container damage that would suggest possible contamination or
2556 other damage to the contents.

2557 (b) Each outgoing shipment must be carefully inspected for
2558 identity of the prescription drug products and to ensure that
2559 there is no delivery of prescription drugs that have expired or
2560 been damaged in storage or held under improper conditions.

2561 (c) The recordkeeping requirements in subsection (6) must
2562 be followed for all incoming and outgoing prescription drugs.



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2563 (d) Upon receipt, a wholesale distributor ~~wholesaler~~ must
2564 review records required under this section for the acquisition of
2565 prescription drugs for accuracy and completeness, considering the
2566 total facts and circumstances surrounding the transactions and
2567 the wholesale distributors involved. This includes authenticating
2568 each transaction listed on a pedigree paper, as defined in s.
2569 499.003(35) ~~s. 499.001(31)~~.

2570 (5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.--

2571 (a)1. Prescription drugs that are outdated, damaged,
2572 deteriorated, misbranded, or adulterated must be quarantined and
2573 physically separated from other prescription drugs until they are
2574 destroyed or returned to their supplier. A quarantine section
2575 must be separate and apart from other sections where prescription
2576 drugs are stored so that prescription drugs in this section are
2577 not confused with usable prescription drugs.

2578 2. Prescription drugs must be examined at least every 12
2579 months, and drugs for which the expiration date has passed must
2580 be removed and quarantined.

2581 (b) Any prescription drugs of which the immediate or sealed
2582 outer containers or sealed secondary containers have been opened
2583 or used must be identified as such and must be quarantined and
2584 physically separated from other prescription drugs until they are
2585 ~~either~~ destroyed or returned to the supplier.

2586 (c) If the conditions under which a prescription drug has
2587 been returned cast doubt on the drug's safety, identity,
2588 strength, quality, or purity, the drug must be destroyed or
2589 returned to the supplier, unless examination, testing, or other
2590 investigation proves that the drug meets appropriate standards of
2591 safety, identity, strength, quality, and purity. In determining
2592 whether the conditions under which a drug has been returned cast



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2593 | doubt on the drug's safety, identity, strength, quality, or
2594 | purity, the wholesale ~~drug~~ distributor must consider, among other
2595 | things, the conditions under which the drug has been held,
2596 | stored, or shipped before or during its return and the conditions
2597 | of the drug and its container, carton, or labeling, as a result
2598 | of storage or shipping.

2599 | (d) The recordkeeping requirements in subsection (6) must
2600 | be followed for all outdated, damaged, deteriorated, misbranded,
2601 | or adulterated prescription drugs.

2602 | (6) RECORDKEEPING.--The department shall adopt rules that
2603 | require keeping such records of prescription drugs as are
2604 | necessary for the protection of the public health.

2605 | (a) Wholesale ~~drug~~ distributors must establish and maintain
2606 | inventories and records of all transactions regarding the receipt
2607 | and distribution or other disposition of prescription drugs.
2608 | These records must provide a complete audit trail from receipt to
2609 | sale or other disposition, be readily retrievable for inspection,
2610 | and include, at a minimum, the following information:

2611 | 1. The source of the drugs, including the name and
2612 | principal address of the seller or transferor, and the address of
2613 | the location from which the drugs were shipped;

2614 | 2. The name, principal address, and state license permit or
2615 | registration number of the person authorized to purchase
2616 | prescription drugs;

2617 | 3. The name, strength, dosage form, and quantity of the
2618 | drugs received and distributed or disposed of;

2619 | 4. The dates of receipt and distribution or other
2620 | disposition of the drugs; and

2621 | 5. Any financial documentation supporting the transaction.



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2622 (b) Inventories and records must be made available for
2623 inspection and photocopying by authorized federal, state, or
2624 local officials for a period of 2 years following disposition of
2625 the drugs or 3 years after the creation of the records, whichever
2626 period is longer.

2627 (c) Records described in this section that are kept at the
2628 inspection site or that can be immediately retrieved by computer
2629 or other electronic means must be readily available for
2630 authorized inspection during the retention period. Records that
2631 are kept at a central location outside of this state and that are
2632 not electronically retrievable must be made available for
2633 inspection within 2 working days after a request by an authorized
2634 official of a federal, state, or local law enforcement agency.
2635 Records that are maintained at a central location within this
2636 state must be maintained at an establishment that is permitted
2637 pursuant to this part ~~ss. 499.001-499.081~~ and must be readily
2638 available.

2639 ~~(d) (4)~~ Each manufacturer or repackager of medical devices,
2640 over-the-counter drugs, or cosmetics must maintain records that
2641 include the name and principal address of the seller or
2642 transferor of the product, the address of the location from which
2643 the product was shipped, the date of the transaction, the name
2644 and quantity of the product involved, and the name and principal
2645 address of the person who purchased the product.

2646 (e) A wholesale distributor must maintain pedigree papers
2647 separate and distinct from other records required under this
2648 chapter.

2649 ~~(d)1. Effective July 1, 2006, each person who is engaged in~~
2650 ~~the wholesale distribution of a prescription drug and who is not~~
2651 ~~the manufacturer of that drug must, before each wholesale~~



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2652 ~~distribution of such drug, provide to the person who receives the~~
2653 ~~drug a pedigree paper as defined in s. 499.003(31).~~
2654 ~~2. A repackager must comply with this paragraph.~~
2655 ~~3. The pedigree paper requirements in this paragraph do not~~
2656 ~~apply to compressed medical gases or veterinary legend drugs.~~
2657 ~~4. Each wholesale distributor of prescription drugs must~~
2658 ~~maintain separate and distinct from other required records all~~
2659 ~~statements that are required under subparagraph 1.~~
2660 ~~5. Subparagraph 1. is satisfied when a wholesale~~
2661 ~~distributor takes title to, but not possession of, a prescription~~
2662 ~~drug and the prescription drug's manufacturer ships the~~
2663 ~~prescription drug directly to a person authorized by law to~~
2664 ~~purchase prescription drugs for the purpose of administering or~~
2665 ~~dispensing the drug, as defined in s. 465.003, or a member of an~~
2666 ~~affiliated group, as described in paragraph (f), with the~~
2667 ~~exception of a repackager.~~
2668 ~~a. The wholesale distributor must deliver to the recipient~~
2669 ~~of the prescription drug, within 14 days after the shipment~~
2670 ~~notification from the manufacturer, an invoice and the following~~
2671 ~~sworn statement: "This wholesale distributor purchased the~~
2672 ~~specific unit of the prescription drug listed on the invoice~~
2673 ~~directly from the manufacturer, and the specific unit of~~
2674 ~~prescription drug was shipped by the manufacturer directly to a~~
2675 ~~person authorized by law to administer or dispense the legend~~
2676 ~~drug, as defined in s. 465.003, Florida Statutes, or a member of~~
2677 ~~an affiliated group, as described in s. 499.0121(6) (f), Florida~~
2678 ~~Statutes, with the exception of a repackager." The invoice must~~
2679 ~~contain a unique cross-reference to the shipping document sent by~~
2680 ~~the manufacturer to the recipient of the prescription drug.~~



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2681 ~~b. The manufacturer of the prescription drug shipped~~
2682 ~~directly to the recipient under this section must provide and the~~
2683 ~~recipient of the prescription drug must acquire, within 14 days~~
2684 ~~after receipt of the prescription drug, a shipping document from~~
2685 ~~the manufacturer that contains, at a minimum:~~

2686 ~~(I) The name and address of the manufacturer, including the~~
2687 ~~point of origin of the shipment, and the names and addresses of~~
2688 ~~the wholesaler and the purchaser.~~

2689 ~~(II) The name of the prescription drug as it appears on the~~
2690 ~~label.~~

2691 ~~(III) The quantity, dosage form, and strength of the~~
2692 ~~prescription drug.~~

2693 ~~(IV) The date of the shipment from the manufacturer.~~

2694 ~~e. The wholesale distributor must also maintain and make~~
2695 ~~available to the department, upon request, the lot number of such~~
2696 ~~drug if not contained in the shipping document acquired by the~~
2697 ~~recipient.~~

2698 ~~6. Failure of the manufacturer to provide, the recipient to~~
2699 ~~acquire, or the wholesale distributor to deliver, the~~
2700 ~~documentation required under subparagraph 5. shall constitute~~
2701 ~~failure to acquire or deliver a pedigree paper under s. 499.0051.~~
2702 ~~Forgery by the manufacturer, the recipient, or the wholesale~~
2703 ~~distributor of the documentation required to be acquired or~~
2704 ~~delivered under subparagraph 5. shall constitute forgery of a~~
2705 ~~pedigree paper under s. 499.0051.~~

2706 ~~7. The department may, by rule, specify alternatives to~~
2707 ~~compliance with subparagraph 1. for a prescription drug in the~~
2708 ~~inventory of a permitted prescription drug wholesaler as of June~~
2709 ~~30, 2006, and the return of a prescription drug purchased prior~~



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2710 ~~to July 1, 2006. The department may specify time limits for such~~
2711 ~~alternatives.~~

2712 (7)(e) PRESCRIPTION DRUG PURCHASE LIST.--Each wholesale
2713 distributor, except for a manufacturer, shall annually provide
2714 the department with a written list of all wholesale distributors
2715 and manufacturers from whom the wholesale distributor purchases
2716 prescription drugs. A wholesale distributor, except a
2717 manufacturer, shall notify the department not later than 10 days
2718 after any change to either list. Such portions of the information
2719 required pursuant to this subsection ~~paragraph~~ which are a trade
2720 secret, as defined in s. 812.081, shall be maintained by the
2721 department as trade secret information is required to be
2722 maintained under s. 499.051.

2723 ~~(f)1. This paragraph applies only to an affiliated group,~~
2724 ~~as defined by s. 1504 of the Internal Revenue Code of 1986, as~~
2725 ~~amended, which is composed of chain drug entities, including at~~
2726 ~~least 50 retail pharmacies, warehouses, or repackagers, which are~~
2727 ~~members of the same affiliated group, if the affiliated group:~~

2728 ~~a. Discloses to the department the names of all its~~
2729 ~~members; and~~

2730 ~~b. Agrees in writing to provide records on prescription~~
2731 ~~drug purchases by members of the affiliated group not later than~~
2732 ~~48 hours after the department requests such records, regardless~~
2733 ~~of the location where the records are stored.~~

2734 ~~2. Each warehouse within the affiliated group must comply~~
2735 ~~with all applicable federal and state drug wholesale permit~~
2736 ~~requirements and must purchase, receive, hold, and distribute~~
2737 ~~prescription drugs only to a retail pharmacy or warehouse within~~
2738 ~~the affiliated group. Such a warehouse is exempt from providing a~~



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2739 ~~pedigree paper in accordance with paragraph (d) to its affiliated~~
2740 ~~group member warehouse or retail pharmacy, provided that:~~

2741 ~~a. Any affiliated group member that purchases or receives a~~
2742 ~~prescription drug from outside the affiliated group must receive~~
2743 ~~a pedigree paper if the prescription drug is distributed in or~~
2744 ~~into this state and a pedigree paper is required under this~~
2745 ~~section and must authenticate the documentation as required in~~
2746 ~~subsection (4), regardless of whether the affiliated group member~~
2747 ~~is directly subject to regulation under this chapter; and~~

2748 ~~b. The affiliated group makes available to the department~~
2749 ~~on request all records related to the purchase or acquisition of~~
2750 ~~prescription drugs by members of the affiliated group, regardless~~
2751 ~~of the location where the records are stored, if the prescription~~
2752 ~~drugs were distributed in or into this state.~~

2753 ~~3. If a repackager repackages prescription drugs solely for~~
2754 ~~distribution to its affiliated group members for the exclusive~~
2755 ~~distribution to and among retail pharmacies that are members of~~
2756 ~~the affiliated group to which the repackager is a member:~~

2757 ~~a. The repackager must:~~

2758 ~~(I) In lieu of the written statement required by paragraph~~
2759 ~~(d), for all repackaged prescription drugs distributed in or into~~
2760 ~~this state, state in writing under oath with each distribution of~~
2761 ~~a repackaged prescription drug to an affiliated group member~~
2762 ~~warehouse or repackager: "All repackaged prescription drugs are~~
2763 ~~purchased by the affiliated group directly from the manufacturer~~
2764 ~~or from a prescription drug wholesaler that purchased the~~
2765 ~~prescription drugs directly from the manufacturer.";~~

2766 ~~(II) Purchase all prescription drugs it repackages:~~

2767 ~~(A) Directly from the manufacturer; or~~



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2768 ~~(B) From a prescription drug wholesaler that purchased the~~
2769 ~~prescription drugs directly from the manufacturer; and~~

2770 ~~(III) Maintain records in accordance with this section to~~
2771 ~~document that it purchased the prescription drugs directly from~~
2772 ~~the manufacturer or that its prescription drug wholesale supplier~~
2773 ~~purchased the prescription drugs directly from the manufacturer.~~

2774 ~~b. All members of the affiliated group must provide to~~
2775 ~~agents of the department on request records of purchases by all~~
2776 ~~members of the affiliated group of prescription drugs that have~~
2777 ~~been repackaged, regardless of the location where the records are~~
2778 ~~stored or where the repackager is located.~~

2779 ~~(8) (7)~~ WRITTEN POLICIES AND PROCEDURES.--Wholesale ~~drug~~
2780 distributors must establish, maintain, and adhere to written
2781 policies and procedures, which must be followed for the receipt,
2782 security, storage, inventory, and distribution of prescription
2783 drugs, including policies and procedures for identifying,
2784 recording, and reporting losses or thefts, and for correcting all
2785 errors and inaccuracies in inventories. Wholesale ~~drug~~
2786 distributors must include in their written policies and
2787 procedures:

2788 (a) A procedure whereby the oldest approved stock of a
2789 prescription drug product is distributed first. The procedure may
2790 permit deviation from this requirement, if the deviation is
2791 temporary and appropriate.

2792 (b) A procedure to be followed for handling recalls and
2793 withdrawals of prescription drugs. Such procedure must be
2794 adequate to deal with recalls and withdrawals due to:

2795 1. Any action initiated at the request of the Food and Drug
2796 Administration or any other federal, state, or local law
2797 enforcement or other government agency, including the department.



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2798 2. Any voluntary action by the manufacturer or repackager
2799 to remove defective or potentially defective drugs from the
2800 market; or

2801 3. Any action undertaken to promote public health and
2802 safety by replacing existing merchandise with an improved product
2803 or new package design.

2804 (c) A procedure to ensure that wholesale ~~drug~~ distributors
2805 prepare for, protect against, and handle any crisis that affects
2806 security or operation of any facility if a strike, fire, flood,
2807 or other natural disaster, or a local, state, or national
2808 emergency, occurs.

2809 (d) A procedure to ensure that any outdated prescription
2810 drugs are segregated from other drugs and ~~either~~ returned to the
2811 manufacturer or repackager or destroyed. This procedure must
2812 provide for written documentation of the disposition of outdated
2813 prescription drugs. This documentation must be maintained for 2
2814 years after disposition of the outdated drugs.

2815 (9)~~(8)~~ RESPONSIBLE PERSONS.--Wholesale ~~drug~~ distributors
2816 must establish and maintain lists of officers, directors,
2817 managers, designated representatives, and other persons in charge
2818 of wholesale drug distribution, storage, and handling, including
2819 a description of their duties and a summary of their
2820 qualifications.

2821 (10)~~(9)~~ COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.--A
2822 wholesale ~~drug~~ distributor must operate in compliance with
2823 applicable federal, state, and local laws and regulations.

2824 (a) A wholesale ~~drug~~ distributor must allow the department
2825 and authorized federal, state, and local officials to enter and
2826 inspect its premises and delivery vehicles, and to audit its



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2827 records and written operating procedures, at reasonable times and
2828 in a reasonable manner, to the extent authorized by law.

2829 (b) A wholesale ~~drug~~ distributor that deals in controlled
2830 substances must register with the Drug Enforcement Administration
2831 and must comply with all applicable state, local, and federal
2832 laws. A wholesale ~~drug~~ distributor that distributes any substance
2833 controlled under chapter 893 must notify the department when
2834 registering with the Drug Enforcement Administration pursuant to
2835 that chapter and must provide the department with its DEA number.

2836 (11)~~(10)~~ SALVAGING AND REPROCESSING.--A wholesale ~~drug~~
2837 distributor is subject to any applicable federal, state, or local
2838 laws or regulations that relate to prescription drug product
2839 salvaging or reprocessing.

2840 (12)~~(11)~~ SHIPPING AND TRANSPORTATION.--The person
2841 responsible for shipment and transportation of a prescription
2842 drug in a wholesale distribution may use a common carrier; its
2843 own vehicle or employee acting within the scope of employment if
2844 authorized under s. 499.03 for the possession of prescription
2845 drugs in this state; or, in the case of a prescription drug
2846 intended for domestic distribution, an independent contractor who
2847 must be the agent of the authorized seller or recipient
2848 responsible for shipping and transportation as set forth in a
2849 written contract between the parties. A person selling a
2850 prescription drug for export must obtain documentation, such as a
2851 validated airway bill, bill of lading, or other appropriate
2852 documentation that the prescription drug was exported. A person
2853 responsible for shipping or transporting prescription drugs is
2854 not required to maintain documentation from a common carrier that
2855 the designated recipient received the prescription drugs;
2856 however, the person must obtain such documentation from the



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2857 common carrier and make it available to the department upon
2858 request of the department.

2859 (13)~~(12)~~ DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing
2860 any prescription drugs from another wholesale ~~drug~~ distributor, a
2861 prescription drug wholesale distributor ~~wholesaler~~, an out-of-
2862 state prescription drug wholesale distributor ~~wholesaler~~, or a
2863 prescription drug repackager must:

2864 (a) Enter an agreement with the selling wholesale ~~drug~~
2865 distributor by which the selling wholesale ~~drug~~ distributor will
2866 indemnify the purchasing wholesale ~~drug~~ distributor for any loss
2867 caused to the purchasing wholesale ~~drug~~ distributor related to
2868 the purchase of drugs from the selling wholesale ~~drug~~ distributor
2869 which are determined to be counterfeit or to have been
2870 distributed in violation of any federal or state law governing
2871 the distribution of drugs.

2872 (b) Determine that the selling wholesale ~~drug~~ distributor
2873 has insurance coverage of not less than the greater of 1 percent
2874 of the amount of total dollar volume of the prescription drug
2875 sales reported to the department under s. 499.012(8)(g) ~~s.~~
2876 ~~499.012(3)(g)~~ or \$500,000; however the coverage need not exceed
2877 \$2 million.

2878 (c) Obtain information from the selling wholesale ~~drug~~
2879 distributor, including the length of time the selling wholesale
2880 ~~drug~~ distributor has been licensed in this state, a copy of the
2881 selling wholesale ~~drug~~ distributor's licenses or permits, and
2882 background information concerning the ownership of the selling
2883 wholesale ~~drug~~ distributor, including the experience of the
2884 wholesale distributor in the wholesale distribution of
2885 prescription drugs.



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2886 (d) Verify that the selling wholesale ~~drug~~ distributor's
2887 Florida permit is valid.

2888 (e) Inspect the selling wholesale ~~drug~~ distributor's
2889 licensed establishment to document that it has a policies and
2890 procedures manual relating to the distribution of drugs, the
2891 appropriate temperature controlled environment for drugs
2892 requiring temperature control, an alarm system, appropriate
2893 access restrictions, and procedures to ensure that records
2894 related to the wholesale distribution of prescription drugs are
2895 maintained as required by law:

2896 1. Before purchasing any drug from the wholesale ~~drug~~
2897 distributor, and at least once each subsequent year; or

2898 2. Before purchasing any drug from the wholesale ~~drug~~
2899 distributor, and each subsequent year obtain a complete copy of
2900 the most recent inspection report for the establishment which was
2901 prepared by the department or the regulatory authority
2902 responsible for wholesale ~~drug~~ distributors in the state in which
2903 the establishment is located.

2904 Section 14. Section 499.01211, Florida Statutes, is amended
2905 to read:

2906 499.01211 Drug Wholesale Distributor ~~Wholesaler~~ Advisory
2907 Council.--

2908 (1) There is created the Drug Wholesale Distributor
2909 ~~Wholesaler~~ Advisory Council within the department. The council
2910 shall meet at least once each calendar quarter. Staff for the
2911 council shall be provided by the department. The council shall
2912 consist of 11 members who shall serve without compensation. The
2913 council shall elect a chairperson and a vice chairperson
2914 annually.



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2915 (2) The State Surgeon General, or his or her designee, and
2916 the Secretary of Health Care Administration, or her or his
2917 designee, shall be members of the council. The State Surgeon
2918 General shall appoint nine additional members to the council who
2919 shall be appointed to a term of 4 years each, as follows:

2920 (a) Three different persons each of whom is employed by a
2921 different prescription drug wholesale distributor ~~wholesaler~~
2922 licensed under this part ~~chapter~~ which operates nationally and is
2923 a primary wholesale distributor ~~wholesaler~~, as defined in s.
2924 499.003(46) ~~s. 499.012(1)(d)~~.

2925 (b) One person employed by a prescription drug wholesale
2926 distributor ~~wholesaler~~ licensed under this part ~~chapter~~ which is
2927 a secondary wholesale distributor ~~wholesaler~~, as defined in s.
2928 499.003(51) ~~s. 499.012(1)(f)~~.

2929 (c) One person employed by a retail pharmacy chain located
2930 in this state.

2931 (d) One person who is a member of the Board of Pharmacy and
2932 is a pharmacist licensed under chapter 465.

2933 (e) One person who is a physician licensed pursuant to
2934 chapter 458 or chapter 459.

2935 (f) One person who is an employee of a hospital licensed
2936 pursuant to chapter 395 and is a pharmacist licensed pursuant to
2937 chapter 465.

2938 (g) One person who is an employee of a pharmaceutical
2939 manufacturer.

2940 (3) The council shall review this part ~~ss. 499.001-499.081~~
2941 and the rules adopted to administer this part ~~ss. 499.001-499.081~~
2942 annually, provide input to the department regarding all proposed
2943 rules to administer this part ~~ss. 499.001-499.081~~, make
2944 recommendations to the department to improve the protection of



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2945 the prescription drugs and public health, make recommendations to
2946 improve coordination with other states' regulatory agencies and
2947 the federal government concerning the wholesale distribution of
2948 drugs, and make recommendations to minimize the impact of
2949 regulation of the wholesale distribution industry while ensuring
2950 protection of the public health.

2951 Section 15. Section 499.01212, Florida Statutes, is created
2952 to read:

2953 499.01212 Pedigree paper.--

2954 (1) APPLICATION.--Each person who is engaged in the
2955 wholesale distribution of a prescription drug must, prior to or
2956 simultaneous with each wholesale distribution, provide a pedigree
2957 paper to the person who receives the drug.

2958 (2) FORMAT.--A pedigree paper must contain the following
2959 information:

2960 (a) For the wholesale distribution of a prescription drug
2961 within the normal distribution chain:

2962 1. The following statement: "This wholesale distributor
2963 purchased the specific unit of the prescription drug directly
2964 from the manufacturer."

2965 2. The manufacturer's national drug code identifier and the
2966 name and address of the wholesale distributor and the purchaser
2967 of the prescription drug.

2968 3. The name of the prescription drug as it appears on the
2969 label.

2970 4. The quantity, dosage form, and strength of the
2971 prescription drug.

2972
2973 The wholesale distributor must also maintain and make available
2974 to the department, upon request, the point of origin of the



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2975 prescription drugs, including intracompany transfers, the date of
2976 the shipment from the manufacturer to the wholesale distributor,
2977 the lot numbers of such drugs, and the invoice numbers from the
2978 manufacturer.

2979 (b) For all other wholesale distributions of prescription
2980 drugs:

2981 1. The quantity, dosage form, and strength of the
2982 prescription drugs.

2983 2. The lot numbers of the prescription drugs.

2984 3. The name and address of each owner of the prescription
2985 drug and his or her signature.

2986 4. Shipping information, including the name and address of
2987 each person certifying delivery or receipt of the prescription
2988 drug.

2989 5. An invoice number, a shipping document number, or
2990 another number uniquely identifying the transaction.

2991 6. A certification that the recipient wholesale distributor
2992 has authenticated the pedigree papers.

2993 7. The unique serialization of the prescription drug, if
2994 the manufacturer or repackager has uniquely serialized the
2995 individual prescription drug unit.

2996 8. The name, address, telephone number, and, if available,
2997 e-mail contact information of each wholesale distributor involved
2998 in the chain of the prescription drug's custody.

2999 (3) EXCEPTIONS.--A pedigree paper is not required for:

3000 (a) The wholesale distribution of a prescription drug by
3001 the manufacturer or by a third party logistics provider
3002 performing a wholesale distribution of a prescription drug for a
3003 manufacturer.



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3004 (b) The wholesale distribution of a prescription drug by a
3005 freight forwarder within the authority of a freight forwarder
3006 permit.

3007 (c) The wholesale distribution of a prescription drug by a
3008 limited prescription drug veterinary wholesale distributor to a
3009 veterinarian.

3010 (d) The wholesale distribution of a compressed medical gas.

3011 (e) The wholesale distribution of a veterinary prescription
3012 drug.

3013 (f) A drop shipment, provided:

3014 1. The wholesale distributor delivers to the recipient of
3015 the prescription drug, within 14 days after the shipment
3016 notification from the manufacturer, an invoice and the following
3017 sworn statement: "This wholesale distributor purchased the
3018 specific unit of the prescription drug listed on the invoice
3019 directly from the manufacturer, and the specific unit of
3020 prescription drug was shipped by the manufacturer directly to a
3021 person authorized by law to administer or dispense the legend
3022 drug, as defined in s. 465.003, Florida Statutes, or a member of
3023 an affiliated group, with the exception of a repackager." The
3024 invoice must contain a unique cross-reference to the shipping
3025 document sent by the manufacturer to the recipient of the
3026 prescription drug.

3027 2. The manufacturer of the prescription drug shipped
3028 directly to the recipient provides and the recipient of the
3029 prescription drug acquires, within 14 days after receipt of the
3030 prescription drug, a shipping document from the manufacturer that
3031 contains, at a minimum:



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3032 a. The name and address of the manufacturer, including the
3033 point of origin of the shipment, and the names and addresses of
3034 the wholesale distributor and the purchaser.

3035 b. The name of the prescription drug as it appears on the
3036 label.

3037 c. The quantity, dosage form, and strength of the
3038 prescription drug.

3039 d. The date of the shipment from the manufacturer.

3040 3. The wholesale distributor maintains and makes available
3041 to the department, upon request, the lot number of such drug if
3042 not contained in the shipping document acquired by the recipient.

3043
3044 Failure of the manufacturer to provide, the recipient to acquire,
3045 or the wholesale distributor to deliver the documentation
3046 required under this paragraph shall constitute failure to acquire
3047 or deliver a pedigree paper under ss. 499.005(28) and 499.0051.
3048 Forgery by the manufacturer, the recipient, or the wholesale
3049 distributor of the documentation required to be acquired or
3050 delivered under this paragraph shall constitute forgery of a
3051 pedigree paper under s. 499.0051.

3052 4. The wholesale distributor that takes title to, but not
3053 possession of, the prescription drug is not a member of the
3054 affiliated group that receives the prescription drug directly
3055 from the manufacturer.

3056 (g) The wholesale distribution of a prescription drug by a
3057 warehouse within an affiliated group to a warehouse or retail
3058 pharmacy within its affiliated group, provided:

3059 1. Any affiliated group member that purchases or receives a
3060 prescription drug from outside the affiliated group must receive
3061 a pedigree paper if the prescription drug is distributed in or



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3062 into this state and a pedigree paper is required under this
3063 section and must authenticate the documentation as required in s.
3064 499.0121(4), regardless of whether the affiliated group member is
3065 directly subject to regulation under this part; and

3066 2. The affiliated group makes available, within 48 hours,
3067 to the department on request to one or more of its members all
3068 records related to the purchase or acquisition of prescription
3069 drugs by members of the affiliated group, regardless of the
3070 location where the records are stored, if the prescription drugs
3071 were distributed in or into this state.

3072 (h) The repackaging of prescription drugs by a repackager
3073 solely for distribution to its affiliated group members for the
3074 exclusive distribution to and among retail pharmacies that are
3075 members of the affiliated group to which the repackager is a
3076 member.

3077 1. The repackager must:

3078 a. For all repackaged prescription drugs distributed in or
3079 into this state, state in writing under oath with each
3080 distribution of a repackaged prescription drug to an affiliated
3081 group member warehouse or repackager: "All repackaged
3082 prescription drugs are purchased by the affiliated group directly
3083 from the manufacturer or from a prescription drug wholesale
3084 distributor that purchased the prescription drugs directly from
3085 the manufacturer."

3086 b. Purchase all prescription drugs it repackages:

3087 (I) Directly from the manufacturer; or

3088 (II) From a prescription drug wholesale distributor that
3089 purchased the prescription drugs directly from the manufacturer.

3090 c. Maintain records in accordance with this section to
3091 document that it purchased the prescription drugs directly from



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3092 the manufacturer or that its prescription drug wholesale supplier
3093 purchased the prescription drugs directly from the manufacturer.

3094 2. All members of the affiliated group must provide, within
3095 48 hours, to agents of the department on request to one or more
3096 of its members records of purchases by all members of the
3097 affiliated group of prescription drugs that have been repackaged,
3098 regardless of the location at which the records are stored or at
3099 which the repackager is located.

3100 Section 16. Section 499.0122, Florida Statutes, is
3101 repealed.

3102 Section 17. Section 499.013, Florida Statutes, is repealed.

3103 Section 18. Subsections (1), (3), (4), (6), (8), and (9) of
3104 section 499.015, Florida Statutes, are amended to read:

3105 499.015 Registration of drugs, devices, and cosmetics;
3106 issuance of certificates of free sale.--

3107 (1) (a) Except for those persons exempted from the
3108 definition of manufacturer in s. 499.003(32) ~~s. 499.003(28)~~, any
3109 person who manufactures, packages, repackages, labels, or
3110 relabels a drug, device, or cosmetic in this state must register
3111 such drug, device, or cosmetic biennially with the department;
3112 pay a fee in accordance with the fee schedule provided by s.
3113 499.041; and comply with this section. The registrant must list
3114 each separate and distinct drug, device, or cosmetic at the time
3115 of registration.

3116 (b) The department may not register any product that does
3117 not comply with the Federal Food, Drug, and Cosmetic Act, as
3118 amended, or Title 21 C.F.R. Registration of a product by the
3119 department does not mean that the product does in fact comply
3120 with all provisions of the Federal Food, Drug, and Cosmetic Act,
3121 as amended.



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3122 (3) Except for those persons exempted from the definition
3123 of manufacturer in s. 499.003(31) ~~s. 499.003(28)~~, a person may
3124 not sell any product that he or she has failed to register in
3125 conformity with this section. Such failure to register subjects
3126 such drug, device, or cosmetic product to seizure and
3127 condemnation as provided in s. 499.062 ~~ss. 499.062-499.064~~, and
3128 subjects such person to the penalties and remedies provided in
3129 this part ~~ss. 499.001-499.081~~.

3130 (4) Unless a registration is renewed, it expires 2 years
3131 after the last day of the month in which it was issued. The
3132 department may issue a stop-sale notice or order against a person
3133 that is subject to the requirements of this section and that
3134 fails to comply with this section within 31 days after the date
3135 the registration expires. The notice or order shall prohibit such
3136 person from selling or causing to be sold any drugs, devices, or
3137 cosmetics covered by this part ~~ss. 499.001-499.081~~ until he or
3138 she complies with the requirements of this section.

3139 (6) The department may issue a certificate of free sale for
3140 any product that is required to be registered under this part ~~ss.~~
3141 ~~499.001-499.081~~.

3142 (8) Notwithstanding any requirements set forth in this part
3143 ~~ss. 499.001-499.081~~, a manufacturer of medical devices that is
3144 registered with the federal Food and Drug Administration is
3145 exempt from this section and s. 499.041(6) if:

3146 (a) The manufacturer's medical devices are approved for
3147 marketing by, or listed with the federal Food and Drug
3148 Administration in accordance with federal law for commercial
3149 distribution; or

3150 (b) The manufacturer subcontracts with a manufacturer of
3151 medical devices to manufacture components of such devices.



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3152 (9) However, the manufacturer must submit evidence of such
3153 registration, listing, or approval with its initial application
3154 for a permit to do business in this state, as required in s.
3155 499.01 ~~s. 499.013~~ and any changes to such information previously
3156 submitted at the time of renewal of the permit. Evidence of
3157 approval, listing, and registration by the federal Food and Drug
3158 Administration must include:

3159 (a) For Class II devices, a copy of the pre-market
3160 notification letter (510K);

3161 (b) For Class III devices, a Federal Drug Administration
3162 pre-market approval number;

3163 (c) For a manufacturer who subcontracts with a manufacturer
3164 of medical devices to manufacture components of such devices, a
3165 Federal Drug Administration registration number; or

3166 (d) For a manufacturer of medical devices whose devices are
3167 exempt from pre-market approval by the Federal Drug
3168 Administration, a Federal Drug Administration registration
3169 number.

3170 Section 19. Subsections (3), (5), and (6) of section
3171 499.024, Florida Statutes, are amended to read:

3172 499.024 Drug product classification.--The State Surgeon
3173 General shall adopt rules to classify drug products intended for
3174 use by humans which the United States Food and Drug
3175 Administration has not classified in the federal act or the Code
3176 of Federal Regulations.

3177 (3) Any product that falls under the definition of drug in
3178 s. 499.003(19) definition, s. 499.003(17), may be classified
3179 under the authority of this section. This section does not
3180 subject portable emergency oxygen inhalators to classification;



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3181 | however, this section does not exempt any person from ss. 499.01
3182 | and 499.015.

3183 | (5) The department may by rule reclassify drugs subject to
3184 | this part ~~ss. 499.001-499.081~~ when such classification action is
3185 | necessary to protect the public health.

3186 | (6) The department may adopt rules that exempt from any
3187 | labeling or packaging requirements of this part ~~ss. 499.001-~~
3188 | ~~499.081~~ drugs classified under this section if those requirements
3189 | are not necessary to protect the public health.

3190 | Section 20. Subsections (7), (12), and (15) of section
3191 | 499.028, Florida Statutes, are amended to read:

3192 | 499.028 Drug samples or complimentary drugs; starter packs;
3193 | permits to distribute.--

3194 | (7) A drug manufacturer or distributor must report to the
3195 | department any conviction of itself or of its assigns, agents,
3196 | employees, or representatives for a violation of s. 503(c)(1) of
3197 | the federal act or of this part ~~ss. 499.001-499.081~~ because of
3198 | the sale, purchase, or trade of a drug sample or the offer to
3199 | sell, purchase, or trade a drug sample.

3200 | (12) The department may suspend or revoke a permit issued
3201 | under this section, after giving notice and an opportunity to be
3202 | heard pursuant to chapter 120, when:

3203 | (a) Such permit was obtained by misrepresentation or fraud
3204 | or through a mistake of the department.

3205 | (b) The holder of the permit has distributed or disposed of
3206 | any prescription ~~legend~~ drug, directly or through its agents,
3207 | employees, or independent contractors, to any person not
3208 | authorized to possess such drug.

3209 | (c) The holder of the permit, or its agents, employees, or
3210 | independent contractors, has distributed or possessed any



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3211 prescription ~~legend~~ drug except in the usual course of its
3212 business.

3213 (d) The holder of the permit, or its agents, employees, or
3214 independent contractors, has distributed any prescription ~~legend~~
3215 drug that is misbranded or adulterated under this part ~~ss.~~
3216 ~~499.001-499.081~~.

3217 (e) The holder of the permit, or its agents, employees, or
3218 independent contractors, has distributed any prescription ~~legend~~
3219 drug without written request, when a written request is required
3220 by this section.

3221 (f) The holder of the permit has in its employ, or uses as
3222 agent or independent contractor for the purpose of distributing
3223 or disposing of drugs, any person who has:

3224 1. Violated the requirements of this section or any rule
3225 adopted under this section.

3226 2. Been convicted in any of the courts of this state, the
3227 United States, or any other state of a felony or any other crime
3228 involving moral turpitude or involving those drugs named or
3229 described in chapter 893.

3230 (15) A person may not possess a prescription drug sample
3231 unless:

3232 (a) The drug sample was prescribed to her or him as
3233 evidenced by the label required in s. 465.0276(5).

3234 (b) She or he is the employee of a complimentary drug
3235 distributor that holds a permit issued under this part ~~ss.~~
3236 ~~499.001-499.081~~.

3237 (c) She or he is a person to whom prescription drug samples
3238 may be distributed pursuant to this section.



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3239 (d) He or she is an officer or employee of a federal,
3240 state, or local government acting within the scope of his or her
3241 employment.

3242 Section 21. Subsections (2) and (3) of section 499.029,
3243 Florida Statutes, are amended to read:

3244 499.029 Cancer Drug Donation Program.--

3245 (2) There is created a Cancer Drug Donation Program within
3246 the department ~~of Health~~ for the purpose of authorizing and
3247 facilitating the donation of cancer drugs and supplies to
3248 eligible patients.

3249 (3) As used in this section:

3250 (a) "Cancer drug" means a prescription drug that has been
3251 approved under s. 505 of the federal Food, Drug, and Cosmetic Act
3252 and is used to treat cancer or its side effects or is used to
3253 treat the side effects of a prescription drug used to treat
3254 cancer or its side effects. "Cancer drug" does not include a
3255 substance listed in Schedule II, Schedule III, Schedule IV, or
3256 Schedule V of s. 893.03.

3257 (b) "Closed drug delivery system" means a system in which
3258 the actual control of the unit-dose medication package is
3259 maintained by the facility rather than by the individual patient.

3260 ~~(c) "Department" means the Department of Health.~~

3261 (c) ~~(d)~~ "Donor" means a patient or patient representative
3262 who donates cancer drugs or supplies needed to administer cancer
3263 drugs that have been maintained within a closed drug delivery
3264 system; health care facilities, nursing homes, hospices, or
3265 hospitals with closed drug delivery systems; or pharmacies, drug
3266 manufacturers, medical device manufacturers or suppliers, or
3267 wholesalers of drugs or supplies, in accordance with this
3268 section. "Donor" includes a physician licensed under chapter 458



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3269 or chapter 459 who receives cancer drugs or supplies directly
3270 from a drug manufacturer, wholesale distributor ~~drug wholesaler~~,
3271 or pharmacy.

3272 (d) ~~(e)~~ "Eligible patient" means a person who the department
3273 determines is eligible to receive cancer drugs from the program.

3274 (e) ~~(k)~~ "Participant facility" means a class II hospital
3275 pharmacy that has elected to participate in the program and that
3276 accepts donated cancer drugs and supplies under the rules adopted
3277 by the department for the program.

3278 (f) ~~(n)~~ "Prescribing practitioner" means a physician
3279 licensed under chapter 458 or chapter 459 or any other medical
3280 professional with authority under state law to prescribe cancer
3281 medication.

3282 ~~(o) "Prescription drug" means a drug as defined in s.~~
3283 ~~465.003(8).~~

3284 (g) ~~(p)~~ "Program" means the Cancer Drug Donation Program
3285 created by this section.

3286 (h) ~~(q)~~ "Supplies" means any supplies used in the
3287 administration of a cancer drug.

3288 Section 22. Subsection (1) of section 499.03, Florida
3289 Statutes, is amended to read:

3290 499.03 Possession of certain drugs without prescriptions
3291 unlawful; exemptions and exceptions.--

3292 (1) A person may not possess, or possess with intent to
3293 sell, dispense, or deliver, any habit-forming, toxic, harmful, or
3294 new drug subject to s. 499.003(32) ~~s. 499.003(29)~~, or
3295 prescription legend ~~legend~~ drug as defined in s. 499.003(42) ~~s.~~
3296 ~~499.003(25)~~, unless the possession of the drug has been obtained
3297 by a valid prescription of a practitioner licensed by law to
3298 prescribe the drug. However, this section does not apply to the



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3299 delivery of such drugs to persons included in any of the classes
3300 named in this subsection, or to the agents or employees of such
3301 persons, for use in the usual course of their businesses or
3302 practices or in the performance of their official duties, as the
3303 case may be; nor does this section apply to the possession of
3304 such drugs by those persons or their agents or employees for such
3305 use:

3306 (a) A licensed pharmacist or any person under the licensed
3307 pharmacist's supervision while acting within the scope of the
3308 licensed pharmacist's practice;

3309 (b) A licensed practitioner authorized by law to prescribe
3310 prescription legend ~~legend~~ drugs or any person under the licensed
3311 practitioner's supervision while acting within the scope of the
3312 licensed practitioner's practice;

3313 (c) A qualified person who uses prescription legend ~~legend~~ drugs
3314 for lawful research, teaching, or testing, and not for resale;

3315 (d) A licensed hospital or other institution that procures
3316 such drugs for lawful administration or dispensing by
3317 practitioners;

3318 (e) An officer or employee of a federal, state, or local
3319 government; or

3320 (f) A person that holds a valid permit issued by the
3321 department pursuant to this part ~~ss. 499.001-499.081~~ which
3322 authorizes that person to possess prescription drugs.

3323 Section 23. Section 499.032, Florida Statutes, is amended
3324 to read:

3325 499.032 Phenylalanine; prescription
3326 required.--Phenylalanine restricted formula is declared to be a
3327 prescription ~~legend~~ drug and may be dispensed only upon the



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3328 prescription of a practitioner authorized by law to prescribe
3329 prescription ~~medicinal~~ drugs.

3330 Section 24. Subsection (1) of section 499.033, Florida
3331 Statutes, is amended to read:

3332 499.033 Ephedrine; prescription required.--Ephedrine is
3333 declared to be a prescription drug.

3334 (1) Except as provided in subsection (2), any product that
3335 contains any quantity of ephedrine, a salt of ephedrine, an
3336 optical isomer of ephedrine, or a salt of an optical isomer of
3337 ephedrine may be dispensed only upon the prescription of a duly
3338 licensed practitioner authorized by the laws of the state to
3339 prescribe prescription ~~medicinal~~ drugs.

3340 Section 25. Subsections (1) and (3) of section 499.039,
3341 Florida Statutes, are amended to read:

3342 499.039 Sale, distribution, or transfer of harmful chemical
3343 substances; penalties; authority for enforcement.--It is unlawful
3344 for a person to sell, deliver, or give to a person under the age
3345 of 18 years any compound, liquid, or chemical containing toluol,
3346 hexane, trichloroethylene, acetone, toluene, ethyl acetate,
3347 methyl ethyl ketone, trichloroethane, isopropanol, methyl
3348 isobutyl ketone, ethylene glycol monomethyl ether acetate,
3349 cyclohexanone, nitrous oxide, diethyl ether, alkyl nitrites
3350 (butyl nitrite), or any similar substance for the purpose of
3351 inducing by breathing, inhaling, or ingesting a condition of
3352 intoxication or which is intended to distort or disturb the
3353 auditory, visual, or other physical or mental processes.

3354 (1) On the first violation of this section, the department
3355 may issue a warning according to s. 499.002(5) ~~s. 499.071~~, if the
3356 violation has not caused temporary or permanent physical or
3357 mental injury to the user.



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3358 (3) The department ~~of Health~~ shall adopt rules to implement
3359 this section.

3360 Section 26. Section 499.04, Florida Statutes, is amended to
3361 read:

3362 499.04 Fee authority.--The department may collect fees for
3363 all drug, device, and cosmetic applications, permits, product
3364 registrations, and free-sale certificates. The total amount of
3365 fees collected from all permits, applications, product
3366 registrations, and free-sale certificates must be adequate to
3367 fund the expenses incurred by the department in carrying out this
3368 part ss. 499.001-499.081. The department shall, by rule,
3369 establish a schedule of fees that are within the ranges provided
3370 in this section and shall adjust those fees from time to time
3371 based on the costs associated with administering this part ss.
3372 499.001-499.081. The fees are payable to the department to be
3373 deposited into the Florida Drug, Device, and Cosmetic Trust Fund
3374 for the sole purpose of carrying out the provisions of this part
3375 ss. 499.001-499.081.

3376 Section 27. Subsections (1) through (5), (8), and (10) of
3377 section 499.041, Florida Statutes, are amended to read:

3378 499.041 Schedule of fees for drug, device, and cosmetic
3379 applications and permits, product registrations, and free-sale
3380 certificates.--

3381 (1) The department shall assess applicants requiring a
3382 manufacturing permit an annual fee within the ranges established
3383 in this section for the specific type of manufacturer.

3384 (a) The fee for a prescription drug manufacturer
3385 ~~manufacturer's~~ permit may not be less than \$500 or more than \$750
3386 annually.



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3387 (b) The fee for a device manufacturer ~~manufacturer's~~ permit
3388 may not be less than \$500 or more than \$600 annually.

3389 (c) The fee for a cosmetic manufacturer ~~manufacturer's~~
3390 permit may not be less than \$250 or more than \$400 annually.

3391 (d) The fee for an over-the-counter drug manufacturer
3392 ~~manufacturer's~~ permit may not be less than \$300 or more than \$400
3393 annually.

3394 (e) The fee for a compressed medical gas manufacturer
3395 ~~manufacturer's~~ permit may not be less than \$400 or more than \$500
3396 annually.

3397 (f) The fee for a prescription drug repackager ~~repackager's~~
3398 permit may not be less than \$500 or more than \$750 annually.

3399 (g) A manufacturer may not be required to pay more than one
3400 fee per establishment to obtain an additional manufacturing
3401 permit, but each manufacturer must pay the highest fee applicable
3402 to his or her operation in each establishment.

3403 (2) The department shall assess an applicant that is
3404 required to have a wholesaling permit an annual fee within the
3405 ranges established in this section for the specific type of
3406 wholesaling.

3407 (a) The fee for a prescription drug wholesale distributor
3408 ~~wholesaler's~~ permit may not be less than \$300 or more than \$800
3409 annually.

3410 (b) The fee for a compressed medical gas wholesale
3411 distributor ~~wholesaler's~~ permit may not be less than \$200 or more
3412 than \$300 annually.

3413 (c) The fee for an out-of-state prescription drug wholesale
3414 distributor ~~wholesaler's~~ permit may not be less than \$300 or more
3415 than \$800 annually.



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3416 (d) The fee for a nonresident prescription drug
3417 manufacturer ~~manufacturer's~~ permit may not be less than \$300 or
3418 more than \$500 annually.

3419 (e) The fee for a retail pharmacy drug wholesale
3420 distributor ~~wholesaler's~~ permit may not be less than \$35 or more
3421 than \$50 annually.

3422 (f) The fee for a freight forwarder ~~forwarder's~~ permit may
3423 not be less than \$200 or more than \$300 annually.

3424 (g) The fee for a veterinary prescription drug wholesale
3425 distributor ~~wholesaler's~~ permit may not be less than \$300 or more
3426 than \$500 annually.

3427 (h) The fee for a limited prescription drug veterinary
3428 wholesale distributor ~~wholesaler's~~ permit may not be less than
3429 \$300 or more than \$500 annually.

3430 (i) The fee for a third part logistics provider permit may
3431 not be less than \$200 or more than \$300 annually.

3432 (3) The department shall assess an applicant that is
3433 required to have a retail establishment permit an annual fee
3434 within the ranges established in this section for the specific
3435 type of retail establishment.

3436 (a) The fee for a veterinary prescription legend ~~legend~~ drug
3437 retail establishment permit may not be less than \$200 or more
3438 than \$300 annually.

3439 (b) The fee for a medical oxygen retail establishment
3440 permit may not be less than \$200 or more than \$300 annually.

3441 (c) The fee for a health care clinic establishment permit
3442 may not be less than \$125 or more than \$250 annually.

3443 (4) The department shall assess an applicant that is
3444 required to have a restricted prescription drug distributor



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3445 ~~distributor's~~ permit an annual fee of not less than \$200 or more
3446 than \$300.

3447 (5) In addition to the fee charged for a permit required by
3448 this part ~~ss. 499.001-499.081~~, the department shall assess
3449 applicants an initial application fee of \$150 for each new permit
3450 issued by the department which requires an onsite inspection.

3451 (8) The department shall assess an out-of-state
3452 prescription drug wholesale distributor ~~wholesaler~~ applicant or
3453 permittee an onsite inspection fee of not less than \$1,000 or
3454 more than \$3,000 annually, to be based on the actual cost of the
3455 inspection if an onsite inspection is performed by agents of the
3456 department.

3457 (10) The department shall assess other fees as provided in
3458 this part ~~ss. 499.001-499.081~~.

3459 Section 28. Section 499.05, Florida Statutes, is amended;
3460 subsection (3) of section 499.013, Florida Statutes, is
3461 redesignated as paragraph (k) of subsection (1) of that section
3462 and amended; paragraph (b) of subsection (2) of section 499.0122,
3463 Florida Statutes, is redesignated as paragraph (l) of subsection
3464 (1) of that section and amended; and subsection (12) of section
3465 499.012, Florida Statutes, is redesignated as paragraph (m) of
3466 subsection (1) of that section and amended, to read:

3467 499.05 Rules.--

3468 (1) The department shall adopt rules to implement and
3469 enforce this part ~~ss. 499.001-499.081~~ with respect to:

3470 (a) The definition of terms used in this part ~~ss. 499.001-~~
3471 ~~499.081~~, and used in the rules adopted under this part ~~ss.~~
3472 ~~499.001-499.081~~, when the use of the term is not its usual and
3473 ordinary meaning.



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- 3474 (b) Labeling requirements for drugs, devices, and
3475 cosmetics.
- 3476 (c) The establishment of fees authorized in this part ss.
3477 ~~499.001-499.081~~.
- 3478 (d) The identification of permits that require an initial
3479 application and onsite inspection or other prerequisites for
3480 permitting which demonstrate that the establishment and person
3481 are in compliance with the requirements of this part ss. ~~499.001-~~
3482 ~~499.081~~.
- 3483 (e) The application processes and forms for product
3484 registration.
- 3485 (f) Procedures for requesting and issuing certificates of
3486 free sale.
- 3487 (g) Inspections and investigations conducted under s.
3488 499.051, and the identification of information claimed to be a
3489 trade secret and exempt from the public records law as provided
3490 in s. 499.051(7).
- 3491 (h) The establishment of a range of penalties, as provided
3492 in s. 499.066 ~~s. 499.006~~; requirements for notifying persons of
3493 the potential impact of a violation of this part ss. ~~499.001-~~
3494 ~~499.081~~; and a process for the uncontested settlement of alleged
3495 violations.
- 3496 (i) Additional conditions that qualify as an emergency
3497 medical reason under s. 499.003(53)(b)2. ~~s. 499.012(1)(a)2.b.~~
- 3498 (j) Procedures and forms relating to the pedigree paper
3499 requirement of s. 499.01212.
- 3500 ~~(k)(3) The department may adopt such rules as are necessary~~
3501 ~~for~~ The protection of the public health, safety, and welfare
3502 regarding good manufacturing practices that manufacturers and
3503 repackagers must follow to ensure the safety of the products.



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3504 ~~(1)(b)~~ The department shall adopt rules relating to
3505 Information required from each retail establishment pursuant to
3506 s. 499.012(3) ~~s. 499.01(4)~~, including requirements for
3507 prescriptions or orders.

3508 ~~(m)(12)~~ The department may adopt rules governing The
3509 recordkeeping, storage, and handling with respect to each of the
3510 distributions of prescription drugs specified in s.
3511 499.003(53)(a)-(d) subparagraphs (1)(a)1-4.

3512 (n) Alternatives to compliance with s. 499.01212 for a
3513 prescription drug in the inventory of a permitted prescription
3514 drug wholesale distributor as of June 30, 2006, and the return of
3515 a prescription drug purchased prior to July 1, 2006. The
3516 department may specify time limits for such alternatives.

3517 (2) With respect to products in interstate commerce, those
3518 rules must not be inconsistent with rules and regulations of
3519 federal agencies unless specifically otherwise directed by the
3520 Legislature.

3521 (3) The department shall adopt rules regulating
3522 recordkeeping for and the storage, handling, and distribution of
3523 medical devices and over-the-counter drugs to protect the public
3524 from adulterated products.

3525 Section 29. Section 499.051, Florida Statutes, is amended
3526 to read:

3527 499.051 Inspections and investigations.--

3528 (1) The agents of the department ~~of Health~~ and of the
3529 Department of Law Enforcement, after they present proper
3530 identification, may inspect, monitor, and investigate any
3531 establishment permitted pursuant to this part ~~ss. 499.001-499.081~~
3532 during business hours for the purpose of enforcing this part ~~ss.~~



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3533 ~~499.001-499.081~~, chapters 465, 501, and 893, and the rules of the
3534 department that protect the public health, safety, and welfare.

3535 (2) In addition to the authority set forth in subsection
3536 (1), the department and any duly designated officer or employee
3537 of the department may enter and inspect any other establishment
3538 for the purpose of determining compliance with this part ~~ss.~~
3539 ~~499.001-499.081~~ and rules adopted under this part ~~those sections~~
3540 regarding any drug, device, or cosmetic product.

3541 (3) Any application for a permit or product registration or
3542 for renewal of such permit or registration made pursuant to this
3543 part ~~ss. 499.001-499.081~~ and rules adopted under this part ~~those~~
3544 ~~sections~~ constitutes permission for any entry or inspection of
3545 the premises in order to verify compliance with this part ~~those~~
3546 ~~sections~~ and rules; to discover, investigate, and determine the
3547 existence of compliance; or to elicit, receive, respond to, and
3548 resolve complaints and violations.

3549 (4) Any application for a permit made pursuant to s.
3550 499.012 ~~ss. 499.01 and 499.012~~ and rules adopted under that
3551 section ~~those sections~~ constitutes permission for agents of the
3552 department ~~of Health~~ and the Department of Law Enforcement, after
3553 presenting proper identification, to inspect, review, and copy
3554 any financial document or record related to the manufacture,
3555 repackaging, or distribution of a drug as is necessary to verify
3556 compliance with this part ~~ss. 499.001-499.081~~ and the rules
3557 adopted by the department to administer this part ~~those sections~~,
3558 in order to discover, investigate, and determine the existence of
3559 compliance, or to elicit, receive, respond to, and resolve
3560 complaints and violations.

3561 (5) The authority to inspect under this section includes
3562 the authority to access, review, and copy any and all financial



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3563 documents related to the activity of manufacturing, repackaging,
3564 or distributing prescription drugs.

3565 (6) The authority to inspect under this section includes
3566 the authority to secure:

3567 (a) Samples or specimens of any drug, device, or cosmetic;
3568 or

3569 (b) Such other evidence as is needed for any action to
3570 enforce this part ~~ss. 499.001-499.081~~ and the rules adopted under
3571 this part ~~those sections~~.

3572 (7) The complaint and all information obtained pursuant to
3573 the investigation by the department are confidential and exempt
3574 from ~~the provisions of~~ s. 119.07(1) and s. 24(a), Art. I of the
3575 State Constitution until the investigation and the enforcement
3576 action are completed. However, trade secret information contained
3577 therein as defined by s. 812.081(1)(c) shall remain confidential
3578 and exempt from the provisions of s. 119.07(1) and s. 24(a), Art.
3579 I of the State Constitution, as long as the information is
3580 retained by the department. This subsection does not prohibit the
3581 department from using such information for regulatory or
3582 enforcement proceedings under this chapter or from providing such
3583 information to any law enforcement agency or any other regulatory
3584 agency. However, the receiving agency shall keep such records
3585 confidential and exempt as provided in this subsection. In
3586 addition, this subsection is not intended to prevent compliance
3587 with the provisions of s. 499.01212 ~~s. 499.0121(6)(d)~~, and the
3588 pedigree papers required in that section ~~subsection~~ shall not be
3589 deemed a trade secret.

3590 Section 30. Section 499.052, Florida Statutes, is amended
3591 to read:



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3592 499.052 Records of interstate shipment.--For the purpose of
3593 enforcing this part ss. 499.001-499.081, carriers engaged in
3594 interstate commerce and persons receiving drugs, devices, or
3595 cosmetics in interstate commerce must, upon the request, in the
3596 manner set out below, by an officer or employee duly designated
3597 by the department, permit the officer or employee to have access
3598 to and to copy all records showing the movement in interstate
3599 commerce of any drug, device, or cosmetic, and the quantity,
3600 shipper, and consignee thereof.

3601 Section 31. Subsection (4) of section 499.055, Florida
3602 Statutes, is amended to read:

3603 499.055 Reports and dissemination of information by
3604 department.--

3605 (4) The department shall publish on the department's
3606 website and update at least monthly:

3607 (a) A list of the prescription drug wholesale distributors
3608 ~~wholesalers~~, out-of-state prescription drug wholesale
3609 distributors ~~wholesalers~~, and retail pharmacy drug wholesale
3610 distributors ~~wholesalers~~ against whom the department has
3611 initiated enforcement action pursuant to this part ss. 499.001-
3612 ~~499.081~~ to suspend or revoke a permit, seek an injunction, or
3613 otherwise file an administrative complaint and the permit number
3614 of each such wholesale distributor ~~wholesaler~~.

3615 (b) A list of the prescription drug wholesale distributors
3616 ~~wholesalers~~, out-of-state prescription drug wholesale
3617 distributors ~~wholesalers~~, and retail pharmacy drug wholesale
3618 distributors ~~wholesalers~~ to which the department has issued a
3619 permit, including the date on which each permit will expire.

3620 (c) A list of the prescription drug wholesale distributor
3621 ~~wholesalers~~, out-of-state prescription drug wholesale distributor



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3622 ~~wholesalers~~, and retail pharmacy drug wholesale distributor
3623 ~~wholesalers~~ permits that have been returned to the department,
3624 were suspended, were revoked, have expired, or were not renewed
3625 in the previous year.

3626 Section 32. Subsections (1) and (3) of section 499.06,
3627 Florida Statutes, are amended to read:

3628 499.06 Embargoing, detaining, or destroying article or
3629 processing equipment which is in violation of law or rule.--

3630 (1) When a duly authorized agent of the department finds,
3631 or has probable cause to believe, that any drug, device, or
3632 cosmetic is in violation of any provision of this part ss.
3633 ~~499.001-499.081~~ or any rule adopted under this part ~~such sections~~
3634 so as to be dangerous, unwholesome, or fraudulent within the
3635 meaning of this part ss. ~~499.001-499.081~~, she or he may issue and
3636 enforce a stop-sale, stop-use, removal, or hold order, which
3637 order gives notice that such article or processing equipment is,
3638 or is suspected of being, in violation and has been detained or
3639 embargoed, and which order warns all persons not to remove, use,
3640 or dispose of such article or processing equipment by sale or
3641 otherwise until permission for removal, use, or disposal is given
3642 by such agent or the court. It is unlawful for any person to
3643 remove, use, or dispose of such detained or embargoed article or
3644 processing equipment by sale or otherwise without such
3645 permission; and such act is a felony of the second degree,
3646 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3647 (3) If the court finds that the detained or embargoed
3648 article or processing equipment is in violation, such article or
3649 processing equipment shall, after entry of the court order, be
3650 destroyed or made sanitary at the expense of the claimant
3651 thereof, under the supervision of such agent; and all court



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3652 costs, fees, and storage and other proper expenses shall be taxed
3653 against the claimant of such article or processing equipment or
3654 her or his agent. However, when the violation can be corrected by
3655 proper labeling of the article or sanitizing of the processing
3656 equipment, and after such costs, fees, and expenses have been
3657 paid and a good and sufficient bond, conditioned that such
3658 article be so labeled or processed or such processing equipment
3659 be so sanitized, has been executed, the court may by order direct
3660 that such article or processing equipment be delivered to the
3661 claimant thereof for such labeling, processing, or sanitizing,
3662 under the supervision of an agent of the department. The expense
3663 of such supervision shall be paid by the claimant. Such bond
3664 shall be returned to the claimant of the article or processing
3665 equipment upon representation to the court by the department that
3666 the article or processing equipment is no longer in violation of
3667 this part ss. 499.001-499.081 and that the expenses of such
3668 supervision have been paid.

3669 Section 33. Section 499.062, Florida Statutes, is amended;
3670 section 499.063, Florida Statutes, is redesignated as section (2)
3671 of that section and amended; and section 499.064, Florida
3672 Statutes, is redesignated as paragraphs (a) and (b) of subsection
3673 (2) of that section and amended, to read:

3674 499.062 ~~Cause for~~ Seizure and condemnation of drugs,
3675 devices, or cosmetics.--

3676 (1) Any article of any drug, device, or cosmetic that is
3677 adulterated or misbranded under this part ss. 499.001-499.081 is
3678 subject to seizure and condemnation by the department or by its
3679 duly authorized agents designated for that purpose in regard to
3680 drugs, devices, or cosmetics.



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3681 ~~(2) 499.063 Seizure; procedure; prohibition on sale or~~
3682 ~~disposal of article; penalty.~~ Whenever a duly authorized officer
3683 or employee of the department finds cause, or has probable cause
3684 to believe that cause exists, for the seizure of any drug,
3685 device, or cosmetic, as set out in this part ss. 499.001-499.081,
3686 he or she shall affix to the article a tag, stamp, or other
3687 appropriate marking, giving notice that the article is, or is
3688 suspected of being, subject to seizure under this part ss.
3689 ~~499.001-499.081~~ and that the article has been detained and seized
3690 by the department. Such officer or employee shall also warn all
3691 persons not to remove or dispose of the article, by sale or
3692 otherwise, until permission is given by the department or the
3693 court. Any person who violates this subsection ~~section~~ is guilty
3694 of a felony of the second degree, punishable as provided in s.
3695 775.082, s. 775.083, or s. 775.084.

3696 ~~(a) 499.064 Condemnation and sale; release of seized~~
3697 ~~article.~~ ~~(1)~~ When any article detained or seized under this
3698 subsection s. 499.063 has been found by the department to be
3699 subject to seizure and condemnation ~~under s. 499.063~~, the
3700 department shall petition the court for an order of condemnation
3701 or sale, as the court directs. The proceeds of the sale of drugs,
3702 devices, and cosmetics, less the legal costs and charges, shall
3703 be deposited into the Florida Drug, Device, and Cosmetic Trust
3704 Fund.

3705 ~~(b) (2)~~ If the department finds that any article seized
3706 under this subsection s. 499.063 was not subject to seizure ~~under~~
3707 ~~that section~~, the department or the designated officer or
3708 employee shall remove the tag or marking.

3709 Section 34. Section 499.065, Florida Statutes, is amended
3710 to read:



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3711 499.065 Inspections; imminent danger.--

3712 (1) Notwithstanding s. 499.051, the department shall
3713 inspect each prescription drug wholesale distributor
3714 establishment, prescription drug repackager establishment,
3715 veterinary prescription drug wholesale distributor establishment,
3716 limited prescription drug veterinary wholesale distributor
3717 ~~wholesaler~~ establishment, and retail pharmacy drug wholesale
3718 distributor ~~wholesaler~~ establishment that is required to be
3719 permitted under this part ~~chapter~~ as often as necessary to ensure
3720 compliance with applicable laws and rules. The department shall
3721 have the right of entry and access to these facilities at any
3722 reasonable time.

3723 (2) To protect the public from prescription drugs that are
3724 adulterated or otherwise unfit for human or animal consumption,
3725 the department may examine, sample, seize, and stop the sale or
3726 use of prescription drugs to determine the condition of those
3727 drugs. The department may immediately seize and remove any
3728 prescription drugs if the State Surgeon General or his or her
3729 designee determines that the prescription drugs represent a
3730 threat to the public health. The owner of any property seized
3731 under this section may, within 10 days after the seizure, apply
3732 to a court of competent jurisdiction for whatever relief is
3733 appropriate. At any time after 10 days, the department may
3734 destroy the drugs as contraband.

3735 (3) The department may determine that a prescription drug
3736 wholesale distributor establishment, prescription drug repackager
3737 establishment, veterinary prescription drug wholesale distributor
3738 establishment, limited prescription drug veterinary wholesale
3739 distributor ~~wholesaler~~ establishment, or retail pharmacy drug
3740 wholesale distributor ~~wholesaler~~ establishment that is required



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3741 to be permitted under this part ~~chapter~~ is an imminent danger to
3742 the public health and shall require its immediate closure if the
3743 establishment fails to comply with applicable laws and rules and,
3744 because of the failure, presents an imminent threat to the
3745 public's health, safety, or welfare. Any establishment so deemed
3746 and closed shall remain closed until allowed by the department or
3747 by judicial order to reopen.

3748 (4) For purposes of this section, a refusal to allow entry
3749 to the department for inspection at reasonable times, or a
3750 failure or refusal to provide the department with required
3751 documentation for purposes of inspection, constitutes an imminent
3752 danger to the public health.

3753 Section 35. Subsections (1) through (4) of section 499.066,
3754 Florida Statutes, are amended to read:

3755 499.066 Penalties; remedies.--In addition to other
3756 penalties and other enforcement provisions:

3757 (1) The department may institute such suits or other legal
3758 proceedings as are required to enforce any provision of this part
3759 ~~ss. 499.001-499.081~~. If it appears that a person has violated any
3760 provision of this part ~~ss. 499.001-499.081~~ for which criminal
3761 prosecution is provided, the department may provide the
3762 appropriate state attorney or other prosecuting agency having
3763 jurisdiction with respect to such prosecution with the relevant
3764 information in the department's possession.

3765 (2) If any person engaged in any activity covered by this
3766 part ~~ss. 499.001-499.081~~ violates any provision of this part
3767 ~~those sections~~, any rule adopted under this part ~~those sections~~,
3768 or a cease and desist order as provided by this part ~~those~~
3769 ~~sections~~, the department may obtain an injunction in the circuit
3770 court of the county in which the violation occurred or in which



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3771 the person resides or has its principal place of business, and
3772 may apply in that court for such temporary and permanent orders
3773 as the department considers necessary to restrain the person from
3774 engaging in any such activities until the person complies with
3775 this part ss. 499.001-499.081, the rules adopted under this part
3776 ~~those sections~~, and the orders of the department authorized by
3777 this part ~~those sections~~ or to mandate compliance with this part
3778 ~~ss. 499.001-499.081~~, the rules adopted under this part ~~those~~
3779 ~~sections~~, and any order or permit issued by the department under
3780 this part ~~those sections~~.

3781 (3) The department may impose an administrative fine, not
3782 to exceed \$5,000 per violation per day, for the violation of any
3783 provision of this part ss. 499.001-499.081 or rules adopted under
3784 this part ~~those sections~~. Each day a violation continues
3785 constitutes a separate violation, and each separate violation is
3786 subject to a separate fine. All amounts collected pursuant to
3787 this section shall be deposited into the Florida Drug, Device,
3788 and Cosmetic Trust Fund and are appropriated for the use of the
3789 department in administering this part ss. 499.001-499.081. In
3790 determining the amount of the fine to be levied for a violation,
3791 the department shall consider:

3792 (a) The severity of the violation;

3793 (b) Any actions taken by the person to correct the
3794 violation or to remedy complaints; and

3795 (c) Any previous violations.

3796 (4) The department shall deposit any rewards, fines, or
3797 collections that are due the department and which derive from
3798 joint enforcement activities with other state and federal
3799 agencies which relate to this part ss. 499.001-499.081, chapter
3800 893, or the federal act, into the Florida Drug, Device, and



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3801 Cosmetic Trust Fund. The proceeds of those rewards, fines, and
3802 collections are appropriated for the use of the department in
3803 administering this part ~~ss. 499.001-499.081~~.

3804 Section 36. Section 499.0661, Florida Statutes, is amended
3805 to read:

3806 499.0661 Cease and desist orders; removal of certain
3807 persons.--

3808 (1) ~~(2)~~ CEASE AND DESIST ORDERS.--

3809 (a) In addition to any authority otherwise provided in this
3810 chapter, the department may issue and serve a complaint stating
3811 charges upon any permittee or upon any affiliated party, whenever
3812 the department has reasonable cause to believe that the person or
3813 individual named therein is engaging in or has engaged in conduct
3814 that is:

3815 1. An act that demonstrates a lack of fitness or
3816 trustworthiness to engage in the business authorized under the
3817 permit issued pursuant to this part ~~ss. 499.001-499.081~~, is
3818 hazardous to the public health, or constitutes business
3819 operations that are a detriment to the public health;

3820 2. A violation of any provision of this part ~~ss. 499.001-~~
3821 ~~499.081~~;

3822 3. A violation of any rule of the department;

3823 4. A violation of any order of the department; or

3824 5. A breach of any written agreement with the department.

3825 (b) The complaint must contain a statement of facts and
3826 notice of opportunity for a hearing pursuant to ss. 120.569 and
3827 120.57.

3828 (c) If a hearing is not requested within the time allowed
3829 by ss. 120.569 and 120.57, or if a hearing is held and the
3830 department finds that any of the charges are proven, the



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3831 department may enter an order directing the permittee or the
3832 affiliated party named in the complaint to cease and desist from
3833 engaging in the conduct complained of and take corrective action
3834 to remedy the effects of past improper conduct and assure future
3835 compliance.

3836 (d) A contested or default cease and desist order is
3837 effective when reduced to writing and served upon the permittee
3838 or affiliated party named therein. An uncontested cease and
3839 desist order is effective as agreed.

3840 (e) Whenever the department finds that conduct described in
3841 paragraph (a) is likely to cause an immediate threat to the
3842 public health, it may issue an emergency cease and desist order
3843 requiring the permittee or any affiliated party to immediately
3844 cease and desist from engaging in the conduct complained of and
3845 to take corrective and remedial action. The emergency order is
3846 effective immediately upon service of a copy of the order upon
3847 the permittee or affiliated party named therein and remains
3848 effective for 90 days. If the department begins nonemergency
3849 cease and desist proceedings under this subsection, the emergency
3850 order remains effective until the conclusion of the proceedings
3851 under ss. 120.569 and 120.57.

3852 ~~(2)(3)~~ REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.--

3853 (a) The department may issue and serve a complaint stating
3854 charges upon any affiliated party and upon the permittee involved
3855 whenever the department has reason to believe that an affiliated
3856 party is engaging in or has engaged in conduct that constitutes:

3857 1. An act that demonstrates a lack of fitness or
3858 trustworthiness to engage in the business authorized under the
3859 permit issued pursuant to this part ~~ss. 499.001-499.081~~, is



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3860 hazardous to the public health, or constitutes business
3861 operations that are a detriment to the public health;
3862 2. A willful violation of this part ~~ss. 499.001-499.081~~;
3863 however, if the violation constitutes a misdemeanor, a complaint
3864 may not be served as provided in this section until the
3865 affiliated party is notified in writing of the matter of the
3866 violation and has been afforded a reasonable period of time, as
3867 set forth in the notice, to correct the violation and has failed
3868 to do so;

3869 3. A violation of any other law involving fraud or moral
3870 turpitude which constitutes a felony;

3871 4. A willful violation of any rule of the department;

3872 5. A willful violation of any order of the department; or

3873 6. A material misrepresentation of fact, made knowingly and
3874 willfully or made with reckless disregard for the truth of the
3875 matter.

3876 (b) The complaint must contain a statement of facts and
3877 notice of opportunity for a hearing pursuant to ss. 120.569 and
3878 120.57.

3879 (c) If a hearing is not requested within the time allotted
3880 by ss. 120.569 and 120.57, or if a hearing is held and the
3881 department finds that any of the charges in the complaint are
3882 proven true, the department may enter an order removing the
3883 affiliated party or restricting or prohibiting participation by
3884 the person in the affairs of that permittee or of any other
3885 permittee.

3886 (d) A contested or default order of removal, restriction,
3887 or prohibition is effective when reduced to writing and served on
3888 the permittee and the affiliated party. An uncontested order of
3889 removal, restriction, or prohibition is effective as agreed.



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3890 (e)1. The chief executive officer, designated
3891 representative, or the person holding the equivalent office, of a
3892 permittee shall promptly notify the department if she or he has
3893 actual knowledge that any affiliated party is charged with a
3894 felony in a state or federal court.

3895 2. Whenever any affiliated party is charged with a felony
3896 in a state or federal court or with the equivalent of a felony in
3897 the courts of any foreign country with which the United States
3898 maintains diplomatic relations, and the charge alleges violation
3899 of any law involving prescription drugs, pharmaceuticals, fraud,
3900 theft, or moral turpitude, the department may enter an emergency
3901 order suspending the affiliated party or restricting or
3902 prohibiting participation by the affiliated party in the affairs
3903 of the particular permittee or of any other permittee upon
3904 service of the order upon the permittee and the affiliated party
3905 charged. The order must contain notice of opportunity for a
3906 hearing pursuant to ss. 120.569 and 120.57, where the affiliated
3907 party may request a postsuspension hearing to show that continued
3908 service to or participation in the affairs of the permittee does
3909 not pose a threat to the public health or the interests of the
3910 permittee and does not threaten to impair public confidence in
3911 the permittee. In accordance with applicable departmental rules,
3912 the department shall notify the affiliated party whether the
3913 order suspending or prohibiting the person from participation in
3914 the affairs of a permittee will be rescinded or otherwise
3915 modified. The emergency order remains in effect, unless otherwise
3916 modified by the department, until the criminal charge is disposed
3917 of. The acquittal of the person charged, or the final, unappealed
3918 dismissal of all charges against the person, dissolves the
3919 emergency order but does not prohibit the department from



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3920 instituting proceedings under paragraph (a). If the person
3921 charged is convicted or pleads guilty or nolo contendere, whether
3922 or not an adjudication of guilt is entered by the court, the
3923 emergency order shall become final.

3924 (f) Any affiliated party removed pursuant to this section
3925 is not eligible for reemployment by the permittee or to be an
3926 affiliated party of any permittee except upon the written consent
3927 of the department. Any affiliated party who is removed,
3928 restricted, or prohibited from participating in the affairs of a
3929 permittee pursuant to this section may petition the department
3930 for modification or termination of the removal, restriction, or
3931 prohibition.

3932 Section 37. Section 499.067, Florida Statutes, is amended
3933 to read:

3934 499.067 Denial, suspension, or revocation of permit,
3935 certification, or registration.--

3936 (1) (a) The department may deny, suspend, or revoke a permit
3937 if it finds that there has been a substantial failure to comply
3938 with this part ~~ss. 499.001-499.081~~ or chapter 465, chapter 501,
3939 or chapter 893, the rules adopted under this part ~~any of those~~
3940 ~~sections~~ or those chapters, any final order of the department, or
3941 applicable federal laws or regulations or other state laws or
3942 rules governing drugs, devices, or cosmetics.

3943 (b) The department may deny an application for a permit or
3944 certification, or suspend or revoke a permit or certification, if
3945 the department finds that:

3946 1. The applicant is not of good moral character or that it
3947 would be a danger or not in the best interest of the public
3948 health, safety, and welfare if the applicant were issued a permit
3949 or certification.



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3950 2. The applicant has not met the requirements for the
3951 permit or certification.

3952 3. The applicant is not eligible for a permit or
3953 certification for any of the reasons enumerated in s. 499.012 ~~s.~~
3954 ~~499.01~~ or ~~s. 499.012(5)~~.

3955 4. The applicant, permittee, or person certified under s.
3956 499.012(16) ~~s. 499.012(11)~~ demonstrates any of the conditions
3957 enumerated in s. 499.012 ~~s. 499.01~~ or ~~s. 499.012(5)~~.

3958 5. The applicant, permittee, or person certified under s.
3959 499.012(16) ~~s. 499.012(11)~~ has committed any violation of ss.
3960 499.005-499.0054.

3961 (2) The department may deny, suspend, or revoke any
3962 registration required by the provisions of this part ~~ss. 499.001-~~
3963 ~~499.081~~ for the violation of any provision of this part ~~ss.~~
3964 ~~499.001-499.081~~ or of any rules adopted under this part ~~those~~
3965 ~~sections~~.

3966 (3) The department may revoke or suspend a permit:

3967 (a) If the permit was obtained by misrepresentation or
3968 fraud or through a mistake of the department;

3969 (b) If the permit was procured, or attempted to be
3970 procured, for any other person by making or causing to be made
3971 any false representation; or

3972 (c) If the permittee has violated any provision of this
3973 part ~~ss. 499.001-499.081~~ or rules adopted under this part ~~those~~
3974 ~~sections~~.

3975 (4) If any permit issued under this part ~~ss. 499.001-~~
3976 ~~499.081~~ is revoked or suspended, the owner, manager, operator, or
3977 proprietor of the establishment shall cease to operate as the
3978 permit authorized, from the effective date of the suspension or
3979 revocation until the person is again registered with the



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3980 department and possesses the required permit. If a permit is
3981 revoked or suspended, the owner, manager, or proprietor shall
3982 remove all signs and symbols that identify the operation as
3983 premises permitted as a drug wholesaling establishment; drug,
3984 device, or cosmetic manufacturing establishment; or retail
3985 establishment. The department shall determine the length of time
3986 for which the permit is to be suspended. If a permit is revoked,
3987 the person that owns or operates the establishment may not apply
3988 for any permit under this part ~~ss. 499.001-499.081~~ for a period
3989 of 1 year after the date of the revocation. A revocation of a
3990 permit may be permanent if the department considers that to be in
3991 the best interest of the public health.

3992 (5) The department may deny, suspend, or revoke a permit
3993 issued under this part ~~ss. 499.001-499.081~~ which authorizes the
3994 permittee to purchase prescription drugs, if any owner, officer,
3995 employee, or other person who participates in administering or
3996 operating the establishment has been found guilty of any
3997 violation of this part ~~ss. 499.001-499.081~~ or chapter 465,
3998 chapter 501, or chapter 893, any rules adopted under this part
3999 ~~any of those sections~~ or those chapters, or any federal or state
4000 drug law, regardless of whether the person has been pardoned, had
4001 her or his civil rights restored, or had adjudication withheld.

4002 (6) The department shall deny, suspend, or revoke the
4003 permit of any person or establishment if the assignment, sale,
4004 transfer, or lease of an establishment permitted under this part
4005 ~~ss. 499.001-499.081~~ will avoid an administrative penalty, civil
4006 action, or criminal prosecution.

4007 (7) Notwithstanding s. 120.60(5), if a permittee fails to
4008 comply with s. 499.012(6) ~~s. 499.01(7)~~, the department may revoke
4009 the permit of the permittee and shall provide notice of the



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4010 intended agency action by posting a notice at the department's
4011 headquarters and by mailing a copy of the notice of intended
4012 agency action by certified mail to the most recent mailing
4013 address on record with the department and, if the permittee is
4014 not a natural person, to the permittee's registered agent on file
4015 with the Department of State.

4016 Section 38. Paragraph (a) of subsection (1) of section
4017 409.9201, Florida Statutes, is amended to read:

4018 409.9201 Medicaid fraud.--

4019 (1) As used in this section, the term:

4020 (a) "Prescription Legend ~~Legend~~ drug" means any drug, including,
4021 but not limited to, finished dosage forms or active ingredients
4022 that are subject to, defined by, or described by s. 503(b) of the
4023 Federal Food, Drug, and Cosmetic Act or by s. 465.003(8), s.
4024 499.007(13) ~~s. 499.007(12)~~, or s. 499.003(45) or (52) ~~s.~~
4025 ~~499.0122(1)(b) or (c)~~.

4026
4027 The value of individual items of the legend drugs or goods or
4028 services involved in distinct transactions committed during a
4029 single scheme or course of conduct, whether involving a single
4030 person or several persons, may be aggregated when determining the
4031 punishment for the offense.

4032 Section 39. Paragraph (c) of subsection (9) of section
4033 460.403, Florida Statutes, is amended to read:

4034 460.403 Definitions.--As used in this chapter, the term:

4035 (9)

4036 (c)1. Chiropractic physicians may adjust, manipulate, or
4037 treat the human body by manual, mechanical, electrical, or
4038 natural methods; by the use of physical means or physiotherapy,
4039 including light, heat, water, or exercise; by the use of



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4040 acupuncture; or by the administration of foods, food
4041 concentrates, food extracts, and items for which a prescription
4042 is not required and may apply first aid and hygiene, but
4043 chiropractic physicians are expressly prohibited from prescribing
4044 or administering to any person any legend drug except as
4045 authorized under subparagraph 2., from performing any surgery
4046 except as stated herein, or from practicing obstetrics.

4047 2. Notwithstanding the prohibition against prescribing and
4048 administering legend drugs under subparagraph 1. or s.
4049 499.01(2)(m) ~~s. 499.0122~~, pursuant to board rule chiropractic
4050 physicians may order, store, and administer, for emergency
4051 purposes only at the chiropractic physician's office or place of
4052 business, prescription medical oxygen and may also order, store,
4053 and administer the following topical anesthetics in aerosol form:

4054 a. Any solution consisting of 25 percent ethylchloride and
4055 75 percent dichlorodifluoromethane.

4056 b. Any solution consisting of 15 percent
4057 dichlorodifluoromethane and 85 percent
4058 trichloromonofluoromethane.

4059
4060 However, this paragraph does not authorize a chiropractic
4061 physician to prescribe medical oxygen as defined in chapter 499.

4062 Section 40. Subsection (3) of section 465.0265, Florida
4063 Statutes, is amended to read:

4064 465.0265 Centralized prescription filling.--

4065 (3) The filling, delivery, and return of a prescription by
4066 one pharmacy for another pursuant to this section shall not be
4067 construed as the filling of a transferred prescription as set
4068 forth in s. 465.026 or as a wholesale distribution as set forth
4069 in s. 499.003(53) ~~s. 499.012(1)(a)~~.



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4070 Section 41. Section 794.075, Florida Statutes, is amended
4071 to read:

4072 794.075 Sexual predators; erectile dysfunction drugs.--

4073 (1) A person may not possess a prescription drug, as
4074 defined in s. 499.003(42) ~~s. 499.003(25)~~, for the purpose of
4075 treating erectile dysfunction if the person is designated as a
4076 sexual predator under s. 775.21.

4077 (2) A person who violates a provision of this section for
4078 the first time commits a misdemeanor of the second degree,
4079 punishable as provided in s. 775.082 or s. 775.083. A person who
4080 violates a provision of this section a second or subsequent time
4081 commits a misdemeanor of the first degree, punishable as provided
4082 in s. 775.082 or s. 775.083.

4083 Section 42. Paragraph (a) of subsection (1) of section
4084 895.02, Florida Statutes, is amended to read:

4085 895.02 Definitions.--As used in ss. 895.01-895.08, the
4086 term:

4087 (1) "Racketeering activity" means to commit, to attempt to
4088 commit, to conspire to commit, or to solicit, coerce, or
4089 intimidate another person to commit:

4090 (a) Any crime that is chargeable by indictment or
4091 information under the following provisions of the Florida
4092 Statutes:

4093 1. Section 210.18, relating to evasion of payment of
4094 cigarette taxes.

4095 2. Section 403.727(3)(b), relating to environmental
4096 control.

4097 3. Section 409.920 or s. 409.9201, relating to Medicaid
4098 fraud.

4099 4. Section 414.39, relating to public assistance fraud.



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- 4100 5. Section 440.105 or s. 440.106, relating to workers'
4101 compensation.
- 4102 6. Section 443.071(4), relating to creation of a fictitious
4103 employer scheme to commit unemployment compensation fraud.
- 4104 7. Section 465.0161, relating to distribution of medicinal
4105 drugs without a permit as an Internet pharmacy.
- 4106 8. Section 499.0051 ~~Sections 499.0051, 499.0052, 499.00535,~~
4107 ~~499.00545, and 499.0691,~~ relating to crimes involving contraband
4108 and adulterated drugs.
- 4109 9. Part IV of chapter 501, relating to telemarketing.
- 4110 10. Chapter 517, relating to sale of securities and
4111 investor protection.
- 4112 11. Section 550.235, s. 550.3551, or s. 550.3605, relating
4113 to dogracing and horseracing.
- 4114 12. Chapter 550, relating to jai alai frontons.
- 4115 13. Section 551.109, relating to slot machine gaming.
- 4116 14. Chapter 552, relating to the manufacture, distribution,
4117 and use of explosives.
- 4118 15. Chapter 560, relating to money transmitters, if the
4119 violation is punishable as a felony.
- 4120 16. Chapter 562, relating to beverage law enforcement.
- 4121 17. Section 624.401, relating to transacting insurance
4122 without a certificate of authority, s. 624.437(4)(c)1., relating
4123 to operating an unauthorized multiple-employer welfare
4124 arrangement, or s. 626.902(1)(b), relating to representing or
4125 aiding an unauthorized insurer.
- 4126 18. Section 655.50, relating to reports of currency
4127 transactions, when such violation is punishable as a felony.
- 4128 19. Chapter 687, relating to interest and usurious
4129 practices.



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- 4130 | 20. Section 721.08, s. 721.09, or s. 721.13, relating to
4131 | real estate timeshare plans.
- 4132 | 21. Chapter 782, relating to homicide.
- 4133 | 22. Chapter 784, relating to assault and battery.
- 4134 | 23. Chapter 787, relating to kidnapping or human
4135 | trafficking.
- 4136 | 24. Chapter 790, relating to weapons and firearms.
- 4137 | 25. Section 796.03, s. 796.035, s. 796.04, s. 796.045, s.
4138 | 796.05, or s. 796.07, relating to prostitution and sex
4139 | trafficking.
- 4140 | 26. Chapter 806, relating to arson.
- 4141 | 27. Section 810.02(2)(c), relating to specified burglary of
4142 | a dwelling or structure.
- 4143 | 28. Chapter 812, relating to theft, robbery, and related
4144 | crimes.
- 4145 | 29. Chapter 815, relating to computer-related crimes.
- 4146 | 30. Chapter 817, relating to fraudulent practices, false
4147 | pretenses, fraud generally, and credit card crimes.
- 4148 | 31. Chapter 825, relating to abuse, neglect, or
4149 | exploitation of an elderly person or disabled adult.
- 4150 | 32. Section 827.071, relating to commercial sexual
4151 | exploitation of children.
- 4152 | 33. Chapter 831, relating to forgery and counterfeiting.
- 4153 | 34. Chapter 832, relating to issuance of worthless checks
4154 | and drafts.
- 4155 | 35. Section 836.05, relating to extortion.
- 4156 | 36. Chapter 837, relating to perjury.
- 4157 | 37. Chapter 838, relating to bribery and misuse of public
4158 | office.
- 4159 | 38. Chapter 843, relating to obstruction of justice.



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4160 39. Section 847.011, s. 847.012, s. 847.013, s. 847.06, or
4161 s. 847.07, relating to obscene literature and profanity.

4162 40. Section 849.09, s. 849.14, s. 849.15, s. 849.23, or s.
4163 849.25, relating to gambling.

4164 41. Chapter 874, relating to criminal street gangs.

4165 42. Chapter 893, relating to drug abuse prevention and
4166 control.

4167 43. Chapter 896, relating to offenses related to financial
4168 transactions.

4169 44. Sections 914.22 and 914.23, relating to tampering with
4170 a witness, victim, or informant, and retaliation against a
4171 witness, victim, or informant.

4172 45. Sections 918.12 and 918.13, relating to tampering with
4173 jurors and evidence.

4174 Section 43. Paragraphs (d), (f), (h), (i), and (j) of
4175 subsection (3) of section 921.0022, Florida Statutes, are amended
4176 to read:

4177 921.0022 Criminal Punishment Code; offense severity ranking
4178 chart.--

4179 (3) OFFENSE SEVERITY RANKING CHART

4180 (d) LEVEL 4

4181

Florida	Felony	Description
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Statute	Degree	
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4182

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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4183	499.0051(1)	3rd	Failure to maintain or deliver pedigree papers.
4184	499.0051(2)	3rd	Failure to authenticate pedigree papers.
4185	499.0051(6)	2nd	<u>Knowing</u> sale or delivery, or possession with intent to sell, contraband <u>prescription</u> legend drugs.
4186	784.07(2)(b)	3rd	Battery of law enforcement officer, firefighter, intake officer, etc.
4187	784.074(1)(c)	3rd	Battery of sexually violent predators facility staff.
4188	784.075	3rd	Battery on detention or commitment facility staff.
4189	784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
4190	784.08(2)(c)	3rd	Battery on a person 65 years of age or older.
4191	784.081(3)	3rd	Battery on specified official or employee.

4192



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4193	784.082 (3)	3rd	Battery by detained person on visitor or other detainee.
4194	784.083 (3)	3rd	Battery on code inspector.
4195	784.085	3rd	Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.
4196	787.03 (1)	3rd	Interference with custody; wrongly takes minor from appointed guardian.
4197	787.04 (2)	3rd	Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
4198	787.04 (3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
4199	790.115 (1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
4200	790.115 (2) (b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school property.
4201	790.115 (2) (c)	3rd	Possessing firearm on school property.



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4202	800.04 (7) (d)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
4203	810.02 (4) (a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
4204	810.02 (4) (b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
4205	810.06	3rd	Burglary; possession of tools.
4206	810.08 (2) (c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
4207	812.014 (2) (c) 3.	3rd	Grand theft, 3rd degree \$10,000 or more but less than \$20,000.
4208	812.014 (2) (c) 4.- 10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
4209	812.0195 (2)	3rd	Dealing in stolen property by use of the Internet; property stolen \$300 or more.
4210	817.563 (1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03 (5) drugs.



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4211	817.568 (2) (a)	3rd	Fraudulent use of personal identification information.
4212	817.625 (2) (a)	3rd	Fraudulent use of scanning device or reencoder.
4213	828.125 (1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
4214	837.02 (1)	3rd	Perjury in official proceedings.
4215	837.021 (1)	3rd	Make contradictory statements in official proceedings.
4216	838.022	3rd	Official misconduct.
4217	839.13 (2) (a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
4218	839.13 (2) (c)	3rd	Falsifying records of the Department of Children and Family Services.
4219	843.021	3rd	Possession of a concealed handcuff key by a person in custody.
4220	843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.



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4221	843.15(1)(a)	3rd	Failure to appear while on bail for felony (bond estreature or bond jumping).
4222	874.05(1)	3rd	Encouraging or recruiting another to join a criminal street gang.
4223	893.13(2)(a)1.	2nd	Purchase of cocaine (or other s. 893.03(1)(a), (b), or (d), (2)(a), (2)(b), or (2)(c)4. drugs).
4224	914.14(2)	3rd	Witnesses accepting bribes.
4225	914.22(1)	3rd	Force, threaten, etc., witness, victim, or informant.
4226	914.23(2)	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
4227	918.12	3rd	Tampering with jurors.
4228	934.215	3rd	Use of two-way communications device to facilitate commission of a crime.

4229 (f) LEVEL 6

4230

Florida Felony Description
Statute Degree

4231

316.193(2)(b) 3rd Felony DUI, 4th or subsequent



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conviction.

4232

499.0051 (3) 2nd Knowing forgery of pedigree papers.

4233

499.0051 (4) 2nd Knowing purchase or receipt of
prescription ~~legend~~ drug from
unauthorized person.

4234

499.0051 (5) 2nd Knowing sale or transfer of prescription
~~legend~~ drug to unauthorized person.

4235

775.0875 (1) 3rd Taking firearm from law enforcement
officer.

4236

784.021 (1) (a) 3rd Aggravated assault; deadly weapon
without intent to kill.

4237

784.021 (1) (b) 3rd Aggravated assault; intent to commit
felony.

4238

784.041 3rd Felony battery; domestic battery by
strangulation.

4239

784.048 (3) 3rd Aggravated stalking; credible threat.

4240

784.048 (5) 3rd Aggravated stalking of person under 16.

4241

784.07 (2) (c) 2nd Aggravated assault on law enforcement
officer.

4242

Bill No. HB 7049, 1st Eng.



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4243	784.074(1)(b)	2nd	Aggravated assault on sexually violent predators facility staff.
4244	784.08(2)(b)	2nd	Aggravated assault on a person 65 years of age or older.
4245	784.081(2)	2nd	Aggravated assault on specified official or employee.
4246	784.082(2)	2nd	Aggravated assault by detained person on visitor or other detainee.
4247	784.083(2)	2nd	Aggravated assault on code inspector.
4248	787.02(2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.
4249	790.115(2)(d)	2nd	Discharging firearm or weapon on school property.
4250	790.161(2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.
4251	790.164(1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
	790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.



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4252	794.011 (8) (a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
4253	794.05 (1)	2nd	Unlawful sexual activity with specified minor.
4254	800.04 (5) (d)	3rd	Lewd or lascivious molestation; victim 12 years of age or older but less than 16 years; offender less than 18 years.
4255	800.04 (6) (b)	2nd	Lewd or lascivious conduct; offender 18 years of age or older.
4256	806.031 (2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
4257	810.02 (3) (c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
4258	812.014 (2) (b) 1.	2nd	Property stolen \$20,000 or more, but less than \$100,000, grand theft in 2nd degree.
4259	812.014 (6)	2nd	Theft; property stolen \$3,000 or more; coordination of others.
4260	812.015 (9) (a)	2nd	Retail theft; property stolen \$300 or more; second or subsequent conviction.
4261			



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4262	812.015 (9) (b)	2nd	Retail theft; property stolen \$3,000 or more; coordination of others.
4263	812.13 (2) (c)	2nd	Robbery, no firearm or other weapon (strong-arm robbery).
4264	817.034 (4) (a) 1.	1st	Communications fraud, value greater than \$50,000.
4265	817.4821 (5)	2nd	Possess cloning paraphernalia with intent to create cloned cellular telephones.
4266	825.102 (1)	3rd	Abuse of an elderly person or disabled adult.
4267	825.102 (3) (c)	3rd	Neglect of an elderly person or disabled adult.
4268	825.1025 (3)	3rd	Lewd or lascivious molestation of an elderly person or disabled adult.
4269	825.103 (2) (c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than \$20,000.
4270	827.03 (1)	3rd	Abuse of a child.
4271	827.03 (3) (c)	3rd	Neglect of a child.



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4272	827.071(2)&(3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
4273	836.05	2nd	Threats; extortion.
4274	836.10	2nd	Written threats to kill or do bodily injury.
4275	843.12	3rd	Aids or assists person to escape.
4276	847.0135(2)	3rd	Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.
4277	914.23	2nd	Retaliation against a witness, victim, or informant, with bodily injury.
4278	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.
4279	944.40	2nd	Escapes.
4280	944.46	3rd	Harboring, concealing, aiding escaped prisoners.
	944.47(1)(a)5.	2nd	Introduction of contraband (firearm,



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weapon, or explosive) into correctional facility.

4281

951.22 (1) 3rd Intoxicating drug, firearm, or weapon introduced into county facility.

4282

4283 (h) LEVEL 8

4284

Florida Statute	Felony Degree	Description
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4285

316.193 (3) (c) 3.a.	2nd	DUI manslaughter.
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4286

316.1935 (4) (b)	1st	Aggravated fleeing or attempted eluding with serious bodily injury or death.
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4287

327.35 (3) (c) 3.	2nd	Vessel BUI manslaughter.
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4288

<u>499.0051 (8)</u>	1st	<u>Knowing</u> forgery of prescription labels or <u>prescription legend</u> drug labels.
499.0051 (7)		

4289

<u>499.0051 (7)</u>	1st	<u>Knowing</u> trafficking in contraband <u>prescription legend</u> drugs.
499.0052		

4290

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.
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4291	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.
4292	655.50 (10) (b) 2.	2nd	Failure to report financial transactions totaling or exceeding \$20,000, but less than \$100,000 by financial institutions.
4293	777.03 (2) (a)	1st	Accessory after the fact, capital felony.
4294	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.
4295	782.051 (2)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony not enumerated in s. 782.04 (3).
4296	782.071 (1) (b)	1st	Committing vehicular homicide and failing to render aid or give information.



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4297	782.072 (2)	1st	Committing vessel homicide and failing to render aid or give information.
4298	790.161 (3)	1st	Discharging a destructive device which results in bodily harm or property damage.
4299	794.011 (5)	2nd	Sexual battery, victim 12 years or over, offender does not use physical force likely to cause serious injury.
4300	794.08 (3)	2nd	Female genital mutilation, removal of a victim younger than 18 years of age from this state.
4301	800.04 (4)	2nd	Lewd or lascivious battery.
4302	806.01 (1)	1st	Maliciously damage dwelling or structure by fire or explosive, believing person in structure.
4303	810.02 (2) (a)	1st, PBL	Burglary with assault or battery.
4304	810.02 (2) (b)	1st, PBL	Burglary; armed with explosives or dangerous weapon.
4305	810.02 (2) (c)	1st	Burglary of a dwelling or structure causing structural damage or \$1,000



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4306			or more property damage.
	812.014 (2) (a) 2.	1st	Property stolen; cargo valued at \$50,000 or more, grand theft in 1st degree.
4307			
	812.13 (2) (b)	1st	Robbery with a weapon.
4308			
	812.135 (2) (c)	1st	Home-invasion robbery, no firearm, deadly weapon, or other weapon.
4309			
	817.568 (6)	2nd	Fraudulent use of personal identification information of an individual under the age of 18.
4310			
	825.102 (2)	2nd	Aggravated abuse of an elderly person or disabled adult.
4311			
	825.1025 (2)	2nd	Lewd or lascivious battery upon an elderly person or disabled adult.
4312			
	825.103 (2) (a)	1st	Exploiting an elderly person or disabled adult and property is valued at \$100,000 or more.
4313			
	837.02 (2)	2nd	Perjury in official proceedings relating to prosecution of a capital felony.
4314			
	837.021 (2)	2nd	Making contradictory statements in



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4315 official proceedings relating to
prosecution of a capital felony.

860.121(2)(c) 1st Shooting at or throwing any object in
path of railroad vehicle resulting in
great bodily harm.

4316 860.16 1st Aircraft piracy.

4317 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).

4318 893.13(2)(b) 1st Purchase in excess of 10 grams of any
substance specified in s.
893.03(1)(a) or (b).

4319 893.13(6)(c) 1st Possess in excess of 10 grams of any
substance specified in s.
893.03(1)(a) or (b).

4320 893.135(1)(a)2. 1st Trafficking in cannabis, more than
2,000 lbs., less than 10,000 lbs.

4321 893.135(1)(b)1.b. 1st Trafficking in cocaine, more than 200
grams, less than 400 grams.

4322 893.135(1)(c)1.b. 1st Trafficking in illegal drugs, more
than 14 grams, less than 28 grams.

4323



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4324	893.135(1)(d)1.b.	1st	Trafficking in phencyclidine, more than 200 grams, less than 400 grams.
4325	893.135(1)(e)1.b.	1st	Trafficking in methaqualone, more than 5 kilograms, less than 25 kilograms.
4326	893.135(1)(f)1.b.	1st	Trafficking in amphetamine, more than 28 grams, less than 200 grams.
4327	893.135(1)(g)1.b.	1st	Trafficking in flunitrazepam, 14 grams or more, less than 28 grams.
4328	893.135(1)(h)1.b.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 5 kilograms or more, less than 10 kilograms.
4329	893.135(1)(j)1.b.	1st	Trafficking in 1,4-Butanediol, 5 kilograms or more, less than 10 kilograms.
4330	893.135(1)(k)2.b.	1st	Trafficking in Phenethylamines, 200 grams or more, less than 400 grams.
4331	895.03(1)	1st	Use or invest proceeds derived from pattern of racketeering activity.
	895.03(2)	1st	Acquire or maintain through racketeering activity any interest in or control of any enterprise or real



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4332			property.
4333	895.03 (3)	1st	Conduct or participate in any enterprise through pattern of racketeering activity.
4334	896.101 (5) (b)	2nd	Money laundering, financial transactions totaling or exceeding \$20,000, but less than \$100,000.
4335	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.
4336	(i) LEVEL 9		
4337	Florida Statute	Felony Degree	Description
4338	316.193 (3) (c) 3.b.	1st	DUI manslaughter; failing to render aid or give information.
4339	327.35 (3) (c) 3.b.	1st	BUI manslaughter; failing to render aid or give information.
4340	<u>499.0051 (9)</u> 499.00535	1st	<u>Knowing</u> sale or purchase of contraband <u>prescription</u> legend drugs resulting in great bodily harm.



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4341	560.123 (8) (b) 3.	1st	Failure to report currency or payment instruments totaling or exceeding \$100,000 by money transmitter.
4342	560.125 (5) (c)	1st	Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding \$100,000.
4343	655.50 (10) (b) 3.	1st	Failure to report financial transactions totaling or exceeding \$100,000 by financial institution.
4344	775.0844	1st	Aggravated white collar crime.
4345	782.04 (1)	1st	Attempt, conspire, or solicit to commit premeditated murder.
4346	782.04 (3)	1st, PBL	Accomplice to murder in connection with arson, sexual battery, robbery, burglary, and other specified felonies.
4347	782.051 (1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04 (3).
4348	782.07 (2)	1st	Aggravated manslaughter of an elderly



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4349 person or disabled adult.

4350 787.01(1)(a)1. 1st,PBL Kidnapping; hold for ransom or reward
or as a shield or hostage.

4351 787.01(1)(a)2. 1st,PBL Kidnapping with intent to commit or
facilitate commission of any felony.

4352 787.01(1)(a)4. 1st,PBL Kidnapping with intent to interfere
with performance of any governmental
or political function.

4353 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.

4354 790.161 1st Attempted capital destructive device
offense.

4355 790.166(2) 1st,PBL Possessing, selling, using, or
attempting to use a weapon of mass
destruction.

4356 794.011(2) 1st Attempted sexual battery; victim less
than 12 years of age.

794.011(2) Life Sexual battery; offender younger than



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4357			18 years and commits sexual battery on a person less than 12 years.
	794.011 (4)	1st	Sexual battery; victim 12 years or older, certain circumstances.
4358			
	794.011 (8) (b)	1st	Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial authority.
4359			
	794.08 (2)	1st	Female genital mutilation; victim younger than 18 years of age.
4360			
	800.04 (5) (b)	Life	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
4361			
	812.13 (2) (a)	1st, PBL	Robbery with firearm or other deadly weapon.
4362			
	812.133 (2) (a)	1st, PBL	Carjacking; firearm or other deadly weapon.
4363			
	812.135 (2) (b)	1st	Home-invasion robbery with weapon.
4364			
	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



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			person exercising custodial authority.
4365	827.03 (2)	1st	Aggravated child abuse.
4366	847.0145 (1)	1st	Selling, or otherwise transferring custody or control, of a minor.
4367	847.0145 (2)	1st	Purchasing, or otherwise obtaining custody or control, of a minor.
4368	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.
4369	893.135	1st	Attempted capital trafficking offense.
4370	893.135 (1) (a) 3.	1st	Trafficking in cannabis, more than 10,000 lbs.
4371	893.135 (1) (b) 1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.
4372	893.135 (1) (c) 1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
4373			



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4374	893.135(1)(d)1.c.	1st	Trafficking in phencyclidine, more than 400 grams.
4375	893.135(1)(e)1.c.	1st	Trafficking in methaqualone, more than 25 kilograms.
4376	893.135(1)(f)1.c.	1st	Trafficking in amphetamine, more than 200 grams.
4377	893.135(1)(h)1.c.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 10 kilograms or more.
4378	893.135(1)(j)1.c.	1st	Trafficking in 1,4-Butanediol, 10 kilograms or more.
4379	893.135(1)(k)2.c.	1st	Trafficking in Phenethylamines, 400 grams or more.
4380	896.101(5)(c)	1st	Money laundering, financial instruments totaling or exceeding \$100,000.
4381	896.104(4)(a)3.	1st	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding \$100,000.
4382	(j)	LEVEL 10	
4383			

Florida Felony Description



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	Statute	Degree	
4384	<u>499.0051(10)</u> 499.00545	1st	<u>Knowing</u> sale or purchase of contraband <u>prescription</u> legend drugs resulting in death.
4385	782.04(2)	1st,PBL	Unlawful killing of human; act is homicide, unpremeditated.
4386	787.01(1)(a)3.	1st,PBL	Kidnapping; inflict bodily harm upon or terrorize victim.
4387	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.
4388	782.07(3)	1st	Aggravated manslaughter of a child.
4389	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.
4390	812.135(2)(a)	1st,PBL	Home-invasion robbery with firearm or other deadly weapon.
4391	876.32	1st	Treason against the state.
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4393 Section 44. This act shall take effect July 1, 2008.

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4396 ===== T I T L E A M E N D M E N T =====

4397 And the title is amended as follows:

4398 Delete everything before the enacting clause

4399 and insert:

4400 A bill to be entitled

4401 An act relating to drugs, devices, and cosmetics; amending

4402 and reorganizing provisions in part I of ch. 499, F.S.;

4403 amending s. 499.002, F.S.; expanding the provisions of the

4404 section to include administration and enforcement of,

4405 exemptions from, and purpose of the part; amending and

4406 redesignating ss. 499.004, 499.0053, 499.07, 499.071, and

4407 499.081, F.S., as provisions in that section relating to

4408 such functions to conform; amending s. 499.003, F.S.;

4409 revising and providing definitions; amending and

4410 redesignating provisions in ss. 499.012, 499.029, and

4411 499.0661, F.S., relating to definitions, as provisions of

4412 that section; amending s. 499.005, F.S.; conforming

4413 provisions to changes made by the act, including the

4414 substitution of the term "prescription drug" for the term

4415 "legend drug"; amending s. 499.0051, F.S.; substituting

4416 the term "prescription drug" for the term "legend drug"

4417 with regard to criminal acts; consolidating criminal act

4418 provisions of part I of ch. 499, F.S.; amending and

4419 redesignating ss. 499.0052, 499.00535, 499.00545, 499.069,

4420 and 499.0691, F.S., as criminal offense provisions in that

4421 section; providing penalties; conforming provisions to

4422 changes made by the act; amending s. 499.0054, F.S.,



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4423 relating to advertising and labeling of drugs, devices,
4424 and cosmetics to include certain exemptions; amending and
4425 redesignating ss. 499.0055 and 499.0057, F.S., as
4426 provisions relating to those functions in that section;
4427 amending s. 499.006, F.S.; conforming provisions to
4428 changes made by the act; amending s. 499.007, F.S.;
4429 conforming provisions to changes made by the act;
4430 providing that a drug or device is misbranded if it is an
4431 active pharmaceutical ingredient in bulk form and does not
4432 bear a label containing certain information; amending ss.
4433 499.008 and 499.009, F.S.; conforming provisions to
4434 changes made by the act; amending s. 499.01, F.S.;
4435 providing that the section relates only to permits;
4436 requiring a permit to operate as a third party logistics
4437 provider and a health care clinic establishment; providing
4438 requirements for obtaining a permit to operate in certain
4439 capacities; deleting certain permit requirements;
4440 providing an exemption for a nonresident prescription drug
4441 manufacturer permit; providing requirements for such
4442 exemption; providing requirements for a third party
4443 logistics provider permit and a health care clinic
4444 establishment permit; amending and redesignating
4445 provisions of ss. 499.013, and 499.014, F.S., relating to
4446 such functions as provisions of that section; conforming
4447 provisions and cross-references to changes made by the
4448 act; amending s. 499.012, F.S.; providing that the section
4449 relates to permit application requirements; providing that
4450 a separate establishment permit is not required when a
4451 permitted prescription drug wholesale distributor operates
4452 temporary transit storage facilities for the sole purpose



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4453 of storage; amending the provisions to conform; amending
4454 and redesignating provisions of s. 499.01, F.S., relating
4455 to such functions as provisions of that section;
4456 conforming provisions and cross-references to changes made
4457 by the act; amending s. 499.01201, F.S.; conforming
4458 provisions to changes made by the act; amending s.
4459 499.0121, F.S., relating to storage and handling of
4460 prescription drugs and recordkeeping; directing the
4461 department to adopt rules requiring a wholesale
4462 distributor to maintain pedigree papers separate and
4463 distinct from other required records; deleting a
4464 requirement that a person who is engaged in the wholesale
4465 distribution of a prescription drug and who is not the
4466 manufacturer of that drug provide a pedigree paper to the
4467 person who receives the drug; deleting the department's
4468 requirement to adopt rules with regard to recordkeeping by
4469 affiliated groups; conforming provisions and cross-
4470 references to changes made by the act; amending and
4471 redesignating a provision of s. 499.013, F.S., relating to
4472 such functions as a provision of that section; amending s.
4473 499.01211, F.S.; conforming provisions and cross-
4474 references to changes made by the act; creating s.
4475 499.01212, F.S.; requiring a person who is engaged in the
4476 wholesale distribution of a prescription drug to provide a
4477 pedigree paper to the person who receives the drug;
4478 requiring certain information in a pedigree paper;
4479 requiring a wholesale distributor to maintain and make
4480 available to the department certain information; providing
4481 exceptions to the requirement of a pedigree paper;
4482 repealing s. 499.0122, F.S., relating to medical oxygen



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4483 and veterinary legend drug retail establishments;
4484 repealing s. 499.013, F.S., relating to manufacturers and
4485 repackagers of drugs, devices, and cosmetics; amending ss.
4486 499.015, 499.024, 499.028, 499.029, and 499.03, F.S.;
4487 conforming provisions and cross-references to changes made
4488 by the act; amending ss. 499.032 and 499.033, F.S.;
4489 conforming terminology to changes made by the act;
4490 amending s. 499.039, F.S.; conforming a provision and
4491 cross-reference; amending ss. 499.04, F.S.; conforming
4492 provisions to changes made by the act; amending s.
4493 499.041, F.S.; conforming provisions to changes made by
4494 the act; requiring the department to assess an annual fee
4495 for a third part logistic provider permit and a health
4496 care clinic establishment permit; amending s. 499.05,
4497 F.S.; conforming provisions to changes made by the act;
4498 requiring the department to adopt rules with regard to
4499 procedures and forms relating to pedigree paper
4500 requirements, alternatives to compliance with the
4501 requirement of certain pedigree papers, and the return of
4502 prescription drugs purchased before a specified date;
4503 amending and redesignating provisions of ss. 499.013 and
4504 499.0122, F.S., as provisions relating to rulemaking
4505 functions of that section; amending ss. 499.051, 499.052,
4506 499.055, and 499.06, F.S.; conforming provisions to
4507 changes made by the act; amending s. 499.062, F.S.;
4508 providing that the section relates to seizure and
4509 condemnation of drugs, devices, or cosmetics; conforming a
4510 provision to changes made by the act; amending and
4511 redesignating ss. 499.063 and 499.064, F.S., as provisions
4512 relating to such functions in that section; amending ss.



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4513 | 499.065, 499.066, 499.0661, and 499.067, F.S.; conforming
4514 | provisions and cross-references to changes made by the
4515 | act; amending ss. 409.9201, 460.403, 465.0265, 794.075,
4516 | 895.02, and 921.0022, F.S.; conforming provisions to
4517 | changes made by the act; conforming cross-references to
4518 | changes made by the act; providing an effective date.