

By Senator Peaden

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1 A bill to be entitled
2 An act relating to prescription drugs; amending ss.
3 409.9201 and 465.0265, F.S.; conforming cross-references;
4 amending s. 499.002, F.S.; requiring the Department of
5 Health to administer and enforce ch. 499, F.S.;
6 authorizing the department to administer oaths, take
7 depositions, issue and serve subpoenas, and compel the
8 attendance of witnesses and the production of books,
9 papers, documents, or other evidence; requiring the
10 appropriate prosecuting officer to initiate proceedings;
11 providing that the department is not required to report
12 minor violations under certain circumstances; providing
13 that certain carriers engaged in interstate commerce are
14 not subject to ch. 499, F.S., under certain circumstances;
15 amending s. 499.003, F.S.; revising and providing
16 definitions; repealing s. 499.004, F.S., relating to the
17 administration and enforcement by the department of
18 provisions governing the repackaging and distribution of
19 drugs; amending s. 499.005, F.S.; conforming provisions to
20 changes made by the act; amending s. 499.0051, F.S.;
21 substituting the phrase "legend drug" for the phrase
22 "prescription drug" with regard to criminal acts;
23 providing that trafficking in contraband prescription
24 drugs is a third-degree felony; providing that it is a
25 first-degree felony to sell or purchase contraband
26 prescription drugs resulting in great bodily harm or
27 death; prohibiting the violation of s. 499.005, F.S.,
28 related to certain prohibited acts regarding devices and
29 cosmetics; providing penalties; providing an exception for

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30 certain persons or entities with regard to the
31 dissemination of false advertisement; providing that the
32 misbranding or adulteration of drugs is a first-degree
33 felony; prohibiting false or misleading advertisement and
34 failure to maintain records related to drugs; providing
35 penalties; providing that it is a third-degree felony to
36 refuse to allow the department to inspect certain
37 establishments or vehicles, to sell, purchase, or trade
38 drug samples, to fail to maintain records or obtain
39 certain permits relating to prescription drugs, or to
40 possess adulterated or misbranded prescription drugs
41 outside a designated quarantine area; providing that it is
42 a second-degree felony to commit certain other violations;
43 repealing s. 499.0053, F.S., relating to the department's
44 power to administer oaths, take depositions, and issue and
45 serve subpoenas; repealing s. 499.00535, F.S., relating to
46 the sale or purchase of contraband legend drugs resulting
47 in great bodily harm; amending s. 499.0054, F.S.;
48 requiring the department to review a representation made
49 in an advertisement to determine whether it is false or
50 misleading; providing exceptions to classifying certain
51 advertisements as false or misleading; repealing s.
52 499.00545, F.S., relating to the sale or purchase of
53 contraband legend drugs resulting in death; repealing s.
54 499.0055, F.S., relating to false or misleading
55 advertisement; repealing s. 499.0057, F.S., relating to
56 certain advertisement exemptions; amending s. 499.006,
57 F.S.; conforming provisions; amending s. 499.007, F.S.;
58 conforming provisions; providing that a drug or device is

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59 | misbranded if it is an active pharmaceutical ingredient in
60 | bulk form and does not bear a label containing certain
61 | information; amending ss. 499.008 and 499.009, F.S.;
62 | conforming provisions; amending s. 499.01, F.S.; providing
63 | requirements for obtaining a permit to operate as a drug
64 | manufacturer, a drug repackager, a drug wholesale
65 | distributor, a restricted prescription drug distributor, a
66 | freight forwarder, a drug retail establishment, a medical
67 | gas wholesale distributor or manufacturer, or a device
68 | manufacturer; providing requirements for such permits;
69 | deleting certain permit requirements; amending s. 499.012,
70 | F.S.; providing application requirements for persons and
71 | establishments to obtain a permit; requiring the
72 | department to consider certain factors in reviewing the
73 | qualifications of persons who apply for certain permits;
74 | providing for the renewal of a permit; authorizing the
75 | department to adopt rules for applying for a permit;
76 | providing for the expiration of certain permits;
77 | prohibiting the renewal of certain permits under certain
78 | conditions; requiring that a permit be conspicuously
79 | posted; deleting the definition of certain terms and
80 | redefining them in s. 499.003, F.S.; providing
81 | requirements and additional information for a permit
82 | application for a prescription drug wholesale distributor
83 | or an out-of-state prescription drug wholesale
84 | distributor; authorizing the department to deny or refuse
85 | to renew a permit for a prescription drug wholesale
86 | distributor or an out-of-state prescription drug wholesale
87 | distributor under certain conditions; conforming

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88 provisions; deleting the department's authorization to
89 adopt rules governing recordkeeping, storage, and handling
90 with respect to the distribution of certain prescription
91 drugs; amending s. 499.01201, F.S.; conforming provisions;
92 amending s. 499.0121, F.S.; requiring the department to
93 adopt rules requiring manufacturers and repackagers of
94 medical devices, certain drugs, or cosmetics to maintain
95 certain records; directing the department to adopt rules
96 requiring a wholesale distributor to maintain pedigree
97 papers separate and distinct from other required records;
98 deleting a requirement that a person who is engaged in the
99 wholesale distribution of a prescription drug and who is
100 not the manufacturer of that drug provide to the person
101 who receives the drug a pedigree paper; deleting the
102 department's requirement to adopt rules with regard to
103 recordkeeping by affiliated groups; conforming cross-
104 references; amending s. 499.01211, F.S.; conforming
105 provisions and cross-references; creating s. 499.01213,
106 F.S.; requiring a person who is engaged in the wholesale
107 distribution of a prescription drug to provide to the
108 person who receives the drug a pedigree paper; providing
109 for required information in a pedigree paper; requiring a
110 wholesale distributor to maintain and make available to
111 the department certain information; providing exceptions
112 to the requirement of a pedigree paper; repealing s.
113 499.0122, F.S., relating to medical oxygen and veterinary
114 legend drug retail establishments; repealing s. 499.013,
115 F.S., relating to manufacturers and repackagers of drugs,
116 devices, and cosmetics; repealing s. 499.014, F.S.,

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117 relating to the distribution of legend drugs by hospitals,
118 health care entities, charitable organizations, and return
119 or destruction companies; amending ss. 499.015, 499.024,
120 499.028, 499.029, 499.03, and 499.05, F.S.; conforming
121 provisions and cross-references; amending ss. 499.032 and
122 499.033, F.S.; conforming a provision to changes made by
123 the act; amending s. 499.039, F.S.; conforming a provision
124 and cross-reference; amending ss. 499.04 and 499.041,
125 F.S.; conforming provisions to changes made by the act;
126 amending s. 499.05, F.S.; conforming provisions; requiring
127 the department to adopt rules with regard to procedures
128 and forms relating to pedigree paper requirements,
129 manufacturing practices, information required from retail
130 establishments, recordkeeping, storage, and handling with
131 respect to the distribution of certain prescription drugs,
132 concerning alternatives to compliance with the requirement
133 of certain pedigree papers, and concerning the return of
134 prescription drugs purchased before a specified date;
135 amending s. 499.051, 499.052, 499.055, and 499.06, F.S.;
136 conforming provisions; amending s. 499.062, F.S.;
137 conforming a provision; requiring an officer or employee
138 of the department to give notice that an article is the
139 subject of a seizure; requiring the officer or employee to
140 warn persons not to remove or dispose of the article;
141 providing a penalty; requiring the department to petition
142 the court for an order of condemnation or sale of a seized
143 article; requiring the proceeds of the sale of drugs,
144 devices, or cosmetics to be deposited in the Florida Drug,
145 Device, and Cosmetic Trust Fund within the department;

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146 requiring the department officer or employee to remove the
147 tag from the seized article under certain circumstances;
148 repealing s. 499.063, F.S., relating to seizure of a drug,
149 device, or cosmetic; repealing s. 499.064, F.S., relating
150 to condemnation, sale, and release of a seized article;
151 amending ss. 499.065 and 499.066 F.S.; conforming
152 provisions; amending s. 499.0661, F.S.; deleting the
153 definition of the term "permittee"; conforming provisions;
154 amending s. 499.067, F.S.; conforming provisions and
155 cross-references; repealing s. 499.069, F.S., relating to
156 criminal punishment for violations of s. 499.005, F.S.,
157 related to devices and cosmetics; repealing s. 499.0691,
158 F.S., relating to criminal punishment for violations
159 related to drugs and dissemination of false advertisement;
160 repealing s. 499.07, F.S., relating to the duty of the
161 prosecuting officer; repealing s. 499.071, F.S., relating
162 to the issuance of warnings for minor violations;
163 repealing s. 499.081, F.S., relating to the exemption of
164 carriers in interstate commerce; amending s. 895.02, F.S.,
165 conforming cross-references; amending s. 921.0022, F.S.;
166 conforming cross-references and provisions; providing an
167 effective date.

168
169 Be It Enacted by the Legislature of the State of Florida:

170
171 Section 1. Paragraph (a) of subsection (1) of section
172 409.9201, Florida Statutes, is amended to read:

173 409.9201 Medicaid fraud.--

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

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175 (a) "Legend drug" means any drug, including, but not
176 limited to, finished dosage forms or active ingredients that are
177 subject to, defined by, or described by s. 503(b) of the Federal
178 Food, Drug, and Cosmetic Act or by s. 499.007(13) or s.
179 465.003(8), ~~s. 499.007(12), or s. 499.0122(1)(b) or (c).~~

180
181 The value of individual items of the legend drugs or goods or
182 services involved in distinct transactions committed during a
183 single scheme or course of conduct, whether involving a single
184 person or several persons, may be aggregated when determining the
185 punishment for the offense.

186 Section 2. Subsection (3) of section 465.0265, Florida
187 Statutes, is amended to read:

188 465.0265 Centralized prescription filling.--

189 (3) The filling, delivery, and return of a prescription by
190 one pharmacy for another pursuant to this section shall not be
191 construed as the filling of a transferred prescription as set
192 forth in s. 465.026 or as a wholesale distribution as set forth
193 in s. 499.003(60) ~~s. 499.012(1)(a).~~

194 Section 3. Section 499.002, Florida Statutes, is amended to
195 read:

196 499.002 Purpose, administration, enforcement, and exemption
197 ~~of ss. 499.001-499.081.--Sections 499.001-499.081 are intended~~
198 ~~to:~~

199 (1) This part is intended to:

200 (a) Safeguard the public health and promote the public
201 welfare by protecting the public from injury by product use and
202 by merchandising deceit involving drugs, devices, and cosmetics.

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203 (b)~~(2)~~ Provide uniform legislation to be administered so
204 far as practicable in conformity with the provisions of, and
205 regulations issued under the authority of, the Federal Food,
206 Drug, and Cosmetic Act and that portion of the Federal Trade
207 Commission Act which expressly prohibits the false advertisement
208 of drugs, devices, and cosmetics.

209 (c)~~(3)~~ Promote thereby uniformity of such state and federal
210 laws, and their administration and enforcement, throughout the
211 United States.

212 (2) The department shall administer and enforce this part
213 to prevent fraud, adulteration, misbranding, or false advertising
214 in the preparation, manufacture, repackaging, or distribution of
215 drugs, devices, and cosmetics.

216 (3) For the purpose of any investigation or proceeding
217 conducted by the department under this part, the department may
218 administer oaths, take depositions, issue and serve subpoenas,
219 and compel the attendance of witnesses and the production of
220 books, papers, documents, or other evidence. The department shall
221 exercise this power on its own initiative. Challenges to, and
222 enforcement of, the subpoenas and orders shall be handled as
223 provided in s. 120.569.

224 (4) Each state attorney, county attorney, or municipal
225 attorney to whom the department or its designated agent reports
226 any violation of this part shall cause appropriate proceedings to
227 be instituted in the proper courts without delay and to be
228 prosecuted in the manner required by law.

229 (5) This part does not require the department to report,
230 for the institution of proceedings under this part, minor
231 violations of this part when it believes that the public interest

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232 will be adequately served in the circumstances by a suitable
233 written notice or warning.

234 (6) Carriers engaged in interstate commerce are not subject
235 to this part if they are engaged in the usual course of business
236 as carriers.

237 Section 4. Section 499.003, Florida Statutes, is amended to
238 read:

239 499.003 Definitions of terms used in this part ~~ss. 499.001-~~
240 ~~499.081.~~--As used in this part ~~ss. 499.001-499.081~~, the term:

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

245 (2) "Affiliated group" means an affiliated group as defined
246 by s. 1504 of the Internal Revenue Code of 1986, as amended,
247 which is composed of chain drug entities, including at least 50
248 retail pharmacies, warehouses, or repackagers, which are members
249 of the same affiliated group, if the affiliated group:

250 (a) Discloses to the department the names of all its
251 members; and

252 (b) Agrees in writing to provide records on prescription
253 drug purchases by members of the affiliated group no later than
254 48 hours after the department requests such records, regardless
255 of the location where the records are stored.

256 (3)-(2) "Affiliated party" means:

257 (a) A director, officer, trustee, partner, or committee
258 member of a permittee or applicant or a subsidiary or service
259 corporation of the permittee or applicant;

260 (b) A person who, directly or indirectly, manages,

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261 controls, or oversees the operation of a permittee or applicant,
262 regardless of whether such person is a partner, shareholder,
263 manager, member, officer, director, independent contractor, or
264 employee of the permittee or applicant;

265 (c) A person who has filed or is required to file a
266 personal information statement pursuant to s. 499.012(9) ~~s.~~
267 ~~499.012(4)~~ or is required to be identified in an application for
268 a permit or to renew a permit pursuant to s. 499.012(8) ~~s.~~
269 ~~499.012(3)~~; or

270 (d) The five largest natural shareholders that own at least
271 5 percent of the permittee or applicant.

272 ~~(4)(3)~~ "Applicant" means a person applying for a permit or
273 certification under this part ~~ss. 499.001-499.081~~.

274 ~~(5)(4)~~ "Authenticate" means to affirmatively verify before
275 any distribution of a prescription ~~legend~~ drug occurs that each
276 transaction listed on the pedigree paper has occurred.

277 (6) "Authorized recipient" means a person authorized by law
278 to purchase, possess, administer, dispense, or receive
279 prescription drugs and a person authorized by law to administer
280 the drug as defined in s. 465.003. An authorized recipient
281 includes an entity of which a person authorized by law to
282 administer the drug, as defined in s. 465.003, is a member,
283 officer, employee, or agent, including, but not limited to, a
284 professional corporation or a professional limited liability
285 company described in chapter 621 of the Business Organizations
286 Code.

287 ~~(7)(5)~~ "Certificate of free sale" means a document prepared
288 by the department which certifies a drug, device, or cosmetic,
289 that is registered with the department, as one that can be

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290 | legally sold in the state.

291 | (8) "Chain pharmacy warehouse" means a wholesale
292 | distributor permitted pursuant to s. 499.01 which maintains a
293 | physical location for prescription drugs that functions solely as
294 | a central warehouse to perform intracompany transfers of such
295 | drugs to members of its affiliated group.

296 | (9)~~(6)~~ "Closed pharmacy" means a pharmacy that is licensed
297 | under chapter 465 and purchases prescription drugs for use by a
298 | limited patient population and not for wholesale distribution or
299 | sale to the public. The term does not include retail pharmacies.

300 | (10) "Co-licensed product" means a prescription drug in
301 | which two or more parties have the right to engage in the
302 | manufacturing or marketing or both of such drug consistent with
303 | the FDA's implementation of the Prescription Drug Marketing Act
304 | of 1987, Public Law 100-293.

305 | (11) "Co-licensee" means a party or parties to a co-
306 | licensed product.

307 | (12)~~(7)~~ "Color" includes black, white, and intermediate
308 | grays.

309 | (13)~~(8)~~ "Color additive" means, with the exception of any
310 | material that has been or hereafter is exempt under the federal
311 | act, a material that:

312 | (a) Is a dye pigment, or other substance, made by a process
313 | of synthesis or similar artifice, or extracted, isolated, or
314 | otherwise derived, with or without intermediate or final change
315 | of identity from a vegetable, animal, mineral, or other source;
316 | or

317 | (b) When added or applied to a drug or cosmetic or to the
318 | human body, or any part thereof, is capable alone, or through

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319 reaction with other substances, of imparting color thereto;
320
321 ~~except that the term does not include any material which has been~~
322 ~~or hereafter is exempt under the federal act.~~

323 (14)~~(9)~~ "Compressed medical gas" means any liquefied or
324 vaporized gas that is a prescription drug, whether it is alone or
325 in combination with other gases.

326 (15)~~(10)~~ "Contraband prescription ~~legend~~ drug" means any
327 adulterated drug, as defined in s. 499.006, or any counterfeit
328 drug, as defined in this section, and also means any prescription
329 ~~legend~~ drug for which a pedigree paper does not exist, or for
330 which the pedigree paper in existence has been forged,
331 counterfeited, falsely created, or contains any altered, false,
332 or misrepresented matter.

333 (16)~~(11)~~ "Cosmetic" means, with the exception of soap, an
334 article that is:

335 (a) Intended to be rubbed, poured, sprinkled, or sprayed
336 on; introduced into; or otherwise applied to the human body or
337 any part thereof for cleansing, beautifying, promoting
338 attractiveness, or altering the appearance; or

339 (b) Intended for use as a component of any such article;
340
341 ~~except that the term does not include soap.~~

342 (17)~~(12)~~ "Counterfeit drug, counterfeit device, or
343 counterfeit cosmetic" means a drug, device, or cosmetic which, or
344 the container, seal, or labeling of which, without authorization,
345 bears the trademark, trade name, or other identifying mark,
346 imprint, or device, or any likeness thereof, of a drug, device,
347 or cosmetic manufacturer, processor, packer, or distributor other

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348 than the person that in fact manufactured, processed, packed, or
349 distributed that drug, device, or cosmetic and which thereby
350 falsely purports or is represented to be the product of, or to
351 have been packed or distributed by, that other drug, device, or
352 cosmetic manufacturer, processor, packer, or distributor.

353 (18)~~(13)~~ "Department" means the Department of Health.

354 (19)~~(14)~~ "Device" means any instrument, apparatus,
355 implement, machine, contrivance, implant, in vitro reagent, or
356 other similar or related article, including its components,
357 parts, or accessories, which is:

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

360 (b) Intended for use in the diagnosis, cure, mitigation,
361 treatment, therapy, or prevention of disease in humans or other
362 animals, or

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

365
366 and which does not achieve any of its principal intended purposes
367 through chemical action within or on the body of humans or other
368 animals and which is not dependent upon being metabolized for the
369 achievement of any of its principal intended purposes.

370 (20)~~(15)~~ "Distribute or distribution" means to sell; offer
371 to sell; give away; transfer, whether by passage of title,
372 physical movement, or both; deliver; or offer to deliver. The
373 term does not mean: ~~to administer or dispense.~~

374 (a) The administration or dispensing of a prescription
375 drug; or

376 (b) Intracompany sales by a manufacturer of prescription

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377 drugs manufactured by that manufacturer or by a co-licensee,
378 meaning any transaction or transfer between any division,
379 subsidiary, parent, or affiliated or related company under common
380 ownership and control of a corporate entity or any transaction or
381 transfer between co-licensed entities of co-licensed products.

382 (21) "Drop shipment" means the sale of a prescription drug
383 from a manufacturer to a wholesale distributor, where the
384 wholesale distributor takes title to, but not possession of, the
385 prescription drug and the manufacturer of the prescription drug
386 ships the prescription drug directly to a chain pharmacy
387 warehouse or a person authorized by law to purchase prescription
388 drugs for the purpose of administering or dispensing the drug, as
389 defined in s. 465.003.

390 ~~(16) "Diverted from the legal channels of distribution for~~
391 ~~prescription drugs" means an adulterated drug pursuant to s.~~
392 ~~499.006(10).~~

393 ~~(22)(17)~~ "Drug" means an article that is:

394 (a) Recognized in the current edition of the United States
395 Pharmacopoeia and National Formulary, official Homeopathic
396 Pharmacopoeia of the United States, or any supplement to any of
397 those publications;

398 (b) Intended for use in the diagnosis, cure, mitigation,
399 treatment, therapy, or prevention of disease in humans or other
400 animals;

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

403 (d) Intended for use as a component of any article
404 specified in paragraph (a), paragraph (b), or paragraph (c), but
405 does not include devices or their components, parts, or

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406 accessories.

407 (23)~~(18)~~ "Establishment" means a place of business at one
408 general physical location.

409 (24)~~(19)~~ "Federal act" means the Federal Food, Drug, and
410 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

411 (25)~~(20)~~ "Freight forwarder" means a person who receives
412 prescription legend drugs that ~~which~~ are owned by another person
413 and designated by that person for export, and who exports those
414 prescription legend drugs.

415 (26) "Health care clinic" means a health care clinic
416 licensed under part X of chapter 400.

417 (27)~~(21)~~ "Health care entity" means a closed pharmacy or
418 any person, organization, or business entity that provides
419 diagnostic, medical, surgical, or dental treatment or care, or
420 chronic or rehabilitative care, but does not include any
421 wholesale distributor or retail pharmacy licensed under state law
422 to deal in prescription drugs.

423 (28) "Health care facility" means a health care facility
424 licensed under chapter 395.

425 (29) "Hospice" means a corporation licensed under part IV
426 of chapter 400.

427 (30) "Hospital" means a facility as defined in s. 395.002
428 and licensed under chapter 395.

429 (31)~~(22)~~ "Immediate container" does not include package
430 liners.

431 (32) "Intracompany transfer" means any sale, purchase,
432 trade, transfer, or distribution of prescription drugs between
433 any division, subsidiary, parent, or affiliated or related
434 company under common ownership and control of a corporate entity

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435 or any transaction or transfer between co-licensed entities of a
436 co-licensed product.

437 ~~(33)-(23)~~ "Label" means a display of written, printed, or
438 graphic matter upon the immediate container of any drug, device,
439 or cosmetic. A requirement made by or under authority of this
440 part ss. 499.001-499.081 or rules adopted under this part ~~these~~
441 ~~sections~~ that any word, statement, or other information appear on
442 the label is not complied with unless such word, statement, or
443 other information also appears on the outside container or
444 wrapper, if any, of the retail package of such drug, device, or
445 cosmetic or is easily legible through the outside container or
446 wrapper.

447 ~~(34)-(24)~~ "Labeling" means all labels and other written,
448 printed, or graphic matters:

449 (a) Upon a drug, device, or cosmetic, or any of its
450 containers or wrappers; or

451 (b) Accompanying or related to such drug, device, or
452 cosmetic.

453 ~~(25) "Legend drug," "prescription drug," or "medicinal~~
454 ~~drug" means any drug, including, but not limited to, finished~~
455 ~~dosage forms, or active ingredients subject to, defined by, or~~
456 ~~described by s. 503(b) of the Federal Food, Drug, and Cosmetic~~
457 ~~Act or s. 465.003(8), s. 499.007(12), or s. 499.0122(1)(b) or~~
458 ~~(c).~~

459 ~~(26) "Legend drug label" means any display of written,~~
460 ~~printed, or graphic matter upon the immediate container of any~~
461 ~~legend drug prior to its dispensing to an individual patient~~
462 ~~pursuant to a prescription of a practitioner authorized by law to~~
463 ~~prescribe.~~

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464 ~~(35)-(27)~~ "Manufacture" means the preparation, deriving,
465 compounding, propagation, processing, producing, or fabrication
466 of any drug, device, or cosmetic.

467 ~~(36)-(28)~~ "Manufacturer" means a person who prepares,
468 derives, manufactures, or produces a drug, device, or cosmetic,
469 or any division, subsidiary, parent, or affiliated or related
470 company under common ownership and control of that person, or a
471 co-licensee of that person. The term excludes pharmacies that are
472 operating in compliance with pharmacy practice standards as
473 defined in chapter 465 and rules adopted under that chapter.

474 ~~(37)-(29)~~ "New drug" means:

475 (a) Any drug the composition of which is such that the drug
476 is not generally recognized, among experts qualified by
477 scientific training and experience to evaluate the safety and
478 effectiveness of drugs, as safe and effective for use under the
479 conditions prescribed, recommended, or suggested in the labeling
480 of that drug; or

481 (b) Any drug the composition of which is such that the
482 drug, as a result of investigations to determine its safety and
483 effectiveness for use under certain conditions, has been
484 recognized for use under such conditions, but which drug has not,
485 other than in those investigations, been used to a material
486 extent or for a material time under such conditions.

487 ~~(38)~~ "Normal distribution chain" means a wholesale
488 distribution of a prescription drug where the wholesale
489 distributor purchases and receives the specific unit of the
490 prescription drug directly from the manufacturer and distributes
491 the prescription drug directly, or through any intracompany
492 transfers, to a chain pharmacy warehouse or a person authorized

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493 by law to purchase prescription drugs for the purpose of
494 administering or dispensing the drug, as defined in s. 465.003.

495 (39) "Nursing home" means a facility licensed under part II
496 of chapter 400.

497 ~~(40)-(30)~~ "Official compendium" means the current edition of
498 the official United States Pharmacopoeia and National Formulary,
499 or any supplement thereto.

500 ~~(41)-(31)~~ "Pedigree paper" means:

501 ~~(a) Effective July 1, 2006, a document in written or~~
502 ~~electronic form approved by the department which contains of~~
503 ~~Health and containing information required by s. 499.01211~~
504 ~~regarding the sale and that records each distribution of any~~
505 ~~given prescription legend drug, from sale by a pharmaceutical~~
506 ~~manufacturer, through acquisition and sale by any wholesaler or~~
507 ~~repackager, until final sale to a pharmacy or other person~~
508 ~~administering or dispensing the drug. The information required to~~
509 ~~be included on the form approved by the department pursuant to~~
510 ~~this paragraph must at least detail the amount of the legend~~
511 ~~drug; its dosage form and strength; its lot numbers; the name and~~
512 ~~address of each owner of the legend drug and his or her~~
513 ~~signature; its shipping information, including the name and~~
514 ~~address of each person certifying delivery or receipt of the~~
515 ~~legend drug; an invoice number, a shipping document number, or~~
516 ~~another number uniquely identifying the transaction; and a~~
517 ~~certification that the recipient wholesaler has authenticated the~~
518 ~~pedigree papers. If the manufacturer or repackager has uniquely~~
519 ~~serialized the individual legend drug unit, that identifier must~~
520 ~~also be included on the form approved pursuant to this paragraph.~~
521 ~~It must also include the name, address, telephone number and, if~~

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

524 ~~(b) A statement, under oath, in written or electronic form,~~
525 ~~confirming that a wholesale distributor purchases and receives~~
526 ~~the specific unit of the prescription drug directly from the~~
527 ~~manufacturer of the prescription drug and distributes the~~
528 ~~prescription drug directly, or through an intracompany transfer,~~
529 ~~to a chain pharmacy warehouse or a person authorized by law to~~
530 ~~purchase prescription drugs for the purpose of administering or~~
531 ~~dispensing the drug, as defined in s. 465.003. For purposes of~~
532 ~~this subsection, the term "chain pharmacy warehouse" means a~~
533 ~~wholesale distributor permitted pursuant to s. 499.01 that~~
534 ~~maintains a physical location for prescription drugs that~~
535 ~~functions solely as a central warehouse to perform intracompany~~
536 ~~transfers of such drugs to a member of its affiliated group as~~
537 ~~described in s. 499.0121(6)(f)1.~~

538 ~~1. The information required to be included pursuant to this~~
539 ~~paragraph must include:~~

540 ~~a. The following statement: "This wholesale distributor~~
541 ~~purchased the specific unit of the prescription drug directly~~
542 ~~from the manufacturer."~~

543 ~~b. The manufacturer's national drug code identifier and the~~
544 ~~name and address of the wholesaler and the purchaser of the~~
545 ~~prescription drug.~~

546 ~~c. The name of the prescription drug as it appears on the~~
547 ~~label.~~

548 ~~d. The quantity, dosage form, and strength of the~~
549 ~~prescription drug.~~

550 ~~2. The wholesale distributor must also maintain and make~~

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551 | ~~available to the department, upon request, the point of origin of~~
552 | ~~the prescription drugs, including intracompany transfers; the~~
553 | ~~date of the shipment from the manufacturer to the wholesale~~
554 | ~~distributor; the lot numbers of such drugs; and the invoice~~
555 | ~~numbers from the manufacturer.~~

556

557 | ~~The department may adopt rules and forms relating to the~~
558 | ~~requirements of this subsection.~~

559 | (42) "Permittee" means any person holding a permit issued
560 | pursuant to s. 499.012.

561 | (43)~~(32)~~ "Person" means any individual, child, joint
562 | venture, syndicate, fiduciary, partnership, corporation, division
563 | of a corporation, firm, trust, business trust, company, estate,
564 | public or private institution, association, organization, group,
565 | city, county, city and county, political subdivision of this
566 | state, other governmental agency within this state, and any
567 | representative, agent, or agency of any of the foregoing, or any
568 | other group or combination of the foregoing.

569 | (44) "Pharmacist" means a person licensed under chapter
570 | 465.

571 | (45) "Pharmacy" means an entity licensed under chapter 465.

572 | (46)~~(33)~~ "Prepackaged drug product" means a drug that
573 | originally was in finished packaged form sealed by a manufacturer
574 | and that is placed in a properly labeled container by a pharmacy
575 | or practitioner authorized to dispense pursuant to chapter 465
576 | for the purpose of dispensing in the establishment in which the
577 | prepackaging occurred.

578 | (47) "Prescribing practitioner" means a physician licensed
579 | under chapter 458 or chapter 459 or any other medical

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580 professional with authority under state law to prescribe cancer
581 medication.

582 (48) "Prescription drug" means a prescription or legend
583 drug, including, but not limited to, finished dosage forms or
584 active ingredients subject to, defined by, or described by s.
585 503(b) of the Federal Food, Drug, and Cosmetic Act or s.
586 465.003(8), s. 499.007(13), s. 499.003(11), s. 499.003(47), or s.
587 499.003(54).

588 (49) "Prescription drug label" means any display of
589 written, printed, or graphic matter upon the immediate container
590 of any prescription drug prior to its dispensing to an individual
591 patient pursuant to a prescription of a practitioner authorized
592 by law to prescribe.

593 (50)-~~(34)~~ "Prescription label" means any display of written,
594 printed, or graphic matter upon the immediate container of any
595 prescription ~~legend~~ drug dispensed pursuant to a prescription of
596 a practitioner authorized by law to prescribe.

597 (51)-~~(35)~~ "Prescription medical oxygen" means oxygen USP
598 which is a drug that can only be sold on the order or
599 prescription of a practitioner authorized by law to prescribe.
600 The label of prescription medical oxygen must comply with current
601 labeling requirements for oxygen under the Federal Food, Drug,
602 and Cosmetic Act.

603 (52) "Primary wholesale distributor" means any wholesale
604 distributor that:

605 (a) Purchased 90 percent or more of the total dollar volume
606 of its purchases of prescription drugs directly from
607 manufacturers in the previous year; and

608 (b)1. Directly purchased prescription drugs from not fewer

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609 than 50 different prescription drug manufacturers in the previous
610 year; or

611 2. Has, or is a member of an affiliated group, as defined
612 in s. 1504 of the Internal Revenue Code, which has no fewer than
613 250 employees.

614 (53) "Directly from a manufacturer" or "directly from
615 manufacturers" means:

616 (a) Purchases made by the wholesale distributor directly
617 from the manufacturer of prescription drugs; and

618 (b) Transfers from a member of an affiliated group, as
619 defined in s. 1504 of the Internal Revenue Code, of which the
620 wholesale distributor is a member, if:

621 1. The affiliated group purchases 90 percent or more of the
622 total dollar volume of its purchases of prescription drugs from
623 the manufacturer in the previous year; and

624 2. The wholesale distributor discloses to the department
625 the names of all members of the affiliated group of which the
626 wholesale distributor is a member and the affiliated group agrees
627 in writing to provide records on prescription drug purchases by
628 the members of the affiliated group no later than 48 hours after
629 the department requests access to such records, regardless of the
630 location where the records are stored.

631 (54)-(36) "Proprietary drug," or "OTC drug," means a patent
632 or over-the-counter drug in its unbroken, original package, which
633 drug is sold to the public by, or under the authority of, the
634 manufacturer or primary distributor thereof, is not misbranded
635 under the provisions of this part ss. ~~499.001-499.081~~, and can be
636 purchased without a prescription.

637 (55)-(37) "Repackage" includes repacking or otherwise

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638 changing the container, wrapper, or labeling to further the
639 distribution of the drug, device, or cosmetic.

640 ~~(56)-(38)~~ "Repackager" means a person who repackages. The
641 term excludes pharmacies that are operating in compliance with
642 pharmacy practice standards as defined in chapter 465 and rules
643 adopted under that chapter.

644 (57) "Retail pharmacy" means a community pharmacy licensed
645 under chapter 465 which purchases prescription drugs at fair
646 market prices and provides prescription services to the public.

647 (58) "Secondary wholesale distributor" means a wholesale
648 distributor that is not a primary wholesaler.

649 ~~(59)-(39)~~ "Veterinary prescription drug" means a
650 prescription ~~legend~~ drug intended solely for veterinary use. The
651 label of the drug must bear the statement, "Caution: Federal law
652 restricts this drug to sale by or on the order of a licensed
653 veterinarian."

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

657 (60) "Wholesale distribution" means distribution of
658 prescription drugs to persons other than a consumer or patient,
659 but does not include:

660 (a) Any of the following activities, which is not a
661 violation of s. 499.005(21) if such activity is conducted in
662 accordance with s. 499.01(2)(g):

663 1. The purchase or other acquisition by a hospital or other
664 health care entity that is a member of a group purchasing
665 organization of a prescription drug for its own use from the
666 group purchasing organization or from other hospitals or health

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667 care entities that are members of that organization.

668 2. The sale, purchase, or trade of a prescription drug or
669 an offer to sell, purchase, or trade a prescription drug by a
670 charitable organization described in s. 501(c)(3) of the Internal
671 Revenue Code of 1986, as amended and revised, to a nonprofit
672 affiliate of the organization to the extent otherwise permitted
673 by law.

674 3. The sale, purchase, or trade of a prescription drug or
675 an offer to sell, purchase, or trade a prescription drug among
676 hospitals or other health care entities that are under common
677 control. For purposes of this section, "common control" means the
678 power to direct or cause the direction of the management and
679 policies of a person or an organization, whether by ownership of
680 stock, by voting rights, by contract, or otherwise.

681 4. The sale, purchase, trade, or other transfer of a
682 prescription drug from or for any federal, state, or local
683 government agency or any entity eligible to purchase prescription
684 drugs at public health services prices pursuant to Pub. L. No.
685 102-585, s. 602 to a contract provider or its subcontractor for
686 eligible patients of the agency or entity under the following
687 conditions:

688 a. The agency or entity must obtain written authorization
689 for the sale, purchase, trade, or other transfer of a
690 prescription drug under this sub-subparagraph from the State
691 Surgeon General or his or her designee.

692 b. The contract provider or subcontractor must be
693 authorized by law to administer or dispense prescription drugs.

694 c. In the case of a subcontractor, the agency or entity
695 must be a party to and execute the subcontract.

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696 d. A contract provider or subcontractor must maintain
697 separate and apart from other prescription drug inventory any
698 prescription drugs of the agency or entity in its possession.

699 e. The contract provider or subcontractor must maintain and
700 produce immediately for inspection all records of movement or
701 transfer of all the prescription drugs belonging to the agency or
702 entity, including, but not limited to, the records of receipt and
703 disposition of prescription drugs. Each contractor and
704 subcontractor dispensing or administering these drugs must
705 maintain and produce records documenting the dispensing or
706 administration. Records that are required to be maintained
707 include, but are not limited to, a perpetual inventory itemizing
708 drugs received and drugs dispensed by prescription number or
709 administered by patient identifier, which must be submitted to
710 the agency or entity quarterly.

711 f. The contract provider or subcontractor may administer or
712 dispense the prescription drugs only to the eligible patients of
713 the agency or entity or must return the prescription drugs to the
714 agency or entity. The contract provider or subcontractor must
715 require proof from each person seeking to fill a prescription or
716 obtain treatment that the person is an eligible patient of the
717 agency or entity and must, at a minimum, maintain a copy of this
718 proof as part of the records of the contractor or subcontractor
719 required under sub-subparagraph e.

720 g. In addition to the departmental inspection authority set
721 forth in s. 499.051, the establishment of the contract provider
722 and subcontractor and all records pertaining to prescription
723 drugs subject to this sub-subparagraph shall be subject to
724 inspection by the agency or entity. All records relating to

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725 prescription drugs of a manufacturer under this subparagraph are
726 subject to audit by the manufacturer of those drugs, without
727 identifying individual patient information.

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

731 1. The sale, purchase, or trade of a prescription drug
732 among federal, state, or local government health care entities
733 that are under common control and are authorized to purchase such
734 prescription drug.

735 2. The sale, purchase, or trade of a prescription drug or
736 an offer to sell, purchase, or trade a prescription drug for
737 emergency medical reasons. For purposes of this sub-subparagraph,
738 the term "emergency medical reasons" includes transfers of
739 prescription drugs by a retail pharmacy to another retail
740 pharmacy to alleviate a temporary shortage.

741 3. The transfer of a prescription drug acquired by a
742 medical director on behalf of a licensed emergency medical
743 services provider to that emergency medical services provider and
744 its transport vehicles for use in accordance with the provider's
745 license under chapter 401.

746 4. The revocation of a sale or the return of a prescription
747 drug to the person's prescription drug wholesale supplier.

748 5. The donation of a prescription drug by a health care
749 entity to a charitable organization that has been granted an
750 exemption under s. 501(c)(3) of the Internal Revenue Code of
751 1986, as amended, and that is authorized to possess prescription
752 drugs.

753 6. The transfer of a prescription drug by a person

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754 authorized to purchase or receive prescription drugs to a person
755 licensed or permitted to handle reverse distributions or
756 destruction under the laws of the jurisdiction in which the
757 person handling the reverse distribution or destruction receives
758 the drug.

759 7. The transfer of a prescription drug by a hospital or
760 other health care entity to a person licensed under this chapter
761 to repackage prescription drugs for the purpose of repackaging
762 the prescription drug for use by that hospital or other health
763 care entity and other health care entities that are under common
764 control, if ownership of the prescription drugs remains with the
765 hospital or other health care entity at all times. In addition to
766 the recordkeeping requirements of s. 499.0121(6), the hospital or
767 health care entity that transfers prescription drugs pursuant to
768 this subparagraph must reconcile all drugs transferred and
769 returned and resolve any discrepancies in a timely manner.

770 (c) The distribution of prescription drug samples by
771 manufacturers' representatives or distributors' representatives
772 conducted in accordance with s. 499.028.

773 (d) The sale, purchase, or trade of blood and blood
774 components intended for transfusion. As used in this
775 subparagraph, the term "blood" means whole blood collected from a
776 single donor and processed for transfusion or further
777 manufacturing, and the term "blood components" means that part of
778 the blood separated by physical or mechanical means.

779 (e) The lawful dispensing of a prescription drug in
780 accordance with chapter 465.

781 (f) The sale, purchase, or trade of a prescription drug
782 between pharmacies as a result of a sale, transfer, merger, or

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783 consolidation of all or part of the business of the pharmacies
784 from or with another pharmacy, whether accomplished as a purchase
785 and sale of stock or of business assets.

786 (g) The intracompany sale of prescription drugs, meaning
787 any transaction or transfer between any division, subsidiary,
788 parent, or affiliated or related company under common ownership
789 and control of a corporate entity or any transaction or transfer
790 between co-licensed entities of a co-licensed product.

791 (61) "Wholesale distributor" means any person engaged in
792 wholesale distribution of prescription drugs in or into this
793 state, including, but not limited to, manufacturers; repackagers;
794 own-label distributors; jobbers; private-label distributors;
795 brokers; warehouses, including manufacturers' and distributors'
796 warehouses, chain drug warehouses, and wholesale drug warehouses;
797 independent wholesale drug traders; exporters; retail pharmacies;
798 and the agents thereof that conduct wholesale distributions.

799 Section 5. Section 499.004, Florida Statutes, is repealed.

800 Section 6. Section 499.005, Florida Statutes, is amended to
801 read:

802 499.005 Prohibited acts.--It is unlawful for a person to
803 perform or cause the performance of any of the following acts in
804 this state:

805 (1) The manufacture, repackaging, sale, delivery, or
806 holding or offering for sale of any drug, device, or cosmetic
807 that is adulterated or misbranded or has otherwise been rendered
808 unfit for human or animal use.

809 (2) The adulteration or misbranding of any drug, device, or
810 cosmetic.

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811 (3) The receipt of any drug, device, or cosmetic that is
812 adulterated or misbranded, and the delivery or proffered delivery
813 of such drug, device, or cosmetic, for pay or otherwise.

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

817 (5) The dissemination of any false or misleading
818 advertisement of a drug, device, or cosmetic.

819 (6) The refusal or constructive refusal:

820 (a) To allow the department to enter or inspect an
821 establishment in which drugs, devices, or cosmetics are
822 manufactured, processed, repackaged, sold, brokered, or held;

823 (b) To allow inspection of any record of that
824 establishment;

825 (c) To allow the department to enter and inspect any
826 vehicle that is being used to transport drugs, devices, or
827 cosmetics; or

828 (d) To allow the department to take samples of any drug,
829 device, or cosmetic.

830 (7) The purchase or sale of prescription drugs for
831 wholesale distribution in exchange for currency, as defined in s.
832 560.103(6).

833 (8) Committing any act that causes a drug, device, or
834 cosmetic to be a counterfeit drug, device, or cosmetic; or
835 selling, dispensing, or holding for sale a counterfeit drug,
836 device, or cosmetic.

837 (9) The alteration, mutilation, destruction, obliteration,
838 or removal of the whole or any part of the labeling of a drug,
839 device, or cosmetic, or the doing of any other act with respect

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840 to a drug, device, or cosmetic, if the act is done while the
841 drug, device, or cosmetic is held for sale and the act results in
842 the drug, device, or cosmetic being misbranded.

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

848 (11) The use, on the labeling of any drug or in any
849 advertisement relating to such drug, of any representation or
850 suggestion that an application of the drug is effective when it
851 is not or that the drug complies with this part ~~ss. 499.001-~~
852 ~~499.081~~ when it does not.

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

855 (13) The sale, delivery, holding, or offering for sale of
856 any self-testing kits designed to tell persons their status
857 concerning human immunodeficiency virus or acquired immune
858 deficiency syndrome or related disorders or conditions. This
859 prohibition does ~~shall~~ not apply to home access HIV test kits
860 approved for distribution and sale by the United States Food and
861 Drug Administration.

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

865 (15) The sale or transfer of a prescription ~~legend~~ drug to
866 a person that is not authorized under the law of the jurisdiction
867 in which the person receives the drug to purchase or possess

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868 prescription ~~legend~~ drugs from the person selling or transferring
869 the prescription ~~legend~~ drug.

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

873 (17) The sale, purchase, or trade, or the offer to sell,
874 purchase, or trade, a drug sample as defined in s. 499.028; the
875 distribution of a drug sample in violation of s. 499.028; or the
876 failure to otherwise comply with s. 499.028.

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

880 (19) Providing the department with false or fraudulent
881 records, or making false or fraudulent statements, regarding any
882 matter within the provisions of this chapter.

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

886 (21) The wholesale distribution of any prescription drug
887 that was:

888 (a) Purchased by a public or private hospital or other
889 health care entity; or

890 (b) Donated or supplied at a reduced price to a charitable
891 organization.

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

895 (23) Obtaining or attempting to obtain a prescription drug
896 or device by fraud, deceit, misrepresentation or subterfuge, or

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897 engaging in misrepresentation or fraud in the distribution of a
898 drug or device.

899 (24) The distribution of a legend device to the patient or
900 ultimate consumer without a prescription or order from a
901 practitioner licensed by law to use or prescribe the device.

902 (25) Charging a dispensing fee for dispensing,
903 administering, or distributing a prescription drug sample.

904 (26) Removing a pharmacy's dispensing label from a
905 dispensed prescription drug with the intent to further distribute
906 the prescription drug.

907 (27) Distributing a prescription drug that was previously
908 dispensed by a licensed pharmacy, unless such distribution was
909 authorized in chapter 465 or the rules adopted under chapter 465.

910 (28) Failure to acquire ~~obtain~~ or deliver ~~pass on~~ a
911 pedigree paper where required under this part.

912 (29) The receipt of a prescription drug pursuant to a
913 wholesale distribution without ~~either~~ first receiving a pedigree
914 paper that was attested to as accurate and complete by the
915 wholesale distributor, where required under this part ~~or~~
916 ~~complying with the provisions of s. 499.0121(6)(d)5.~~

917 Section 7. Section 499.0051, Florida Statutes, is amended
918 to read:

919 499.0051 Criminal acts ~~involving contraband or adulterated~~
920 ~~drugs.--~~

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

922 (a) A person, other than a manufacturer, engaged in the
923 wholesale distribution of prescription ~~legend~~ drugs who fails to
924 deliver to another person complete and accurate pedigree papers
925 concerning a prescription ~~legend~~ drug or contraband prescription

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926 ~~legend~~ drug prior to transferring the prescription ~~legend~~ drug or
927 contraband prescription ~~legend~~ drug to another person commits a
928 felony of the third degree, punishable as provided in s. 775.082,
929 s. 775.083, or s. 775.084.

930 (b) A person engaged in the wholesale distribution of
931 prescription ~~legend~~ drugs who fails to acquire complete and
932 accurate pedigree papers concerning a prescription ~~legend~~ drug or
933 contraband prescription ~~legend~~ drug prior to obtaining the ~~legend~~
934 drug or contraband prescription ~~legend~~ drug from another person
935 commits a felony of the third degree, punishable as provided in
936 s. 775.082, s. 775.083, or s. 775.084.

937 (c) Any person who knowingly destroys, alters, conceals, or
938 fails to maintain complete and accurate pedigree papers
939 concerning any prescription ~~legend~~ drug or contraband
940 prescription ~~legend~~ drug in his or her possession commits a
941 felony of the third degree, punishable as provided in s. 775.082,
942 s. 775.083, or s. 775.084.

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

945 (a) A person engaged in the wholesale distribution of
946 prescription ~~legend~~ drugs who is in possession of pedigree papers
947 concerning legend drugs or contraband prescription ~~legend~~ drugs
948 and who fails to authenticate the matters contained in the
949 pedigree papers and who nevertheless attempts to further
950 distribute prescription ~~legend~~ drugs or contraband prescription
951 ~~legend~~ drugs commits a felony of the third degree, punishable as
952 provided in s. 775.082, s. 775.083, or s. 775.084.

953 (b) A person in possession of pedigree papers concerning
954 prescription ~~legend~~ drugs or contraband prescription ~~legend~~ drugs

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955 | who falsely swears or certifies that he or she has authenticated
956 | the matters contained in the pedigree papers commits a felony of
957 | the third degree, punishable as provided in s. 775.082, s.
958 | 775.083, or s. 775.084.

959 | (c) Authentication of pedigree for a prescription drug
960 | included in a sealed, medical convenience kit shall be limited to
961 | verifying the transaction and pedigree information received and
962 | assuming that the kit contains what is included in the
963 | accompanying pedigree. Such verification shall satisfy the
964 | requirements of the statute for those products.

965 | (3) KNOWING FORGERY OF PEDIGREE PAPERS.--A person who
966 | knowingly forges, counterfeits, or falsely creates any pedigree
967 | paper; who falsely represents any factual matter contained on any
968 | pedigree paper; or who knowingly omits to record material
969 | information required to be recorded in a pedigree paper, commits
970 | a felony of the second degree, punishable as provided in s.
971 | 775.082, s. 775.083, or s. 775.084.

972 | (4) KNOWING PURCHASE OR RECEIPT OF ~~LEGEND~~ DRUG
973 | FROM UNAUTHORIZED PERSON.--A person who knowingly purchases or
974 | receives from a person not authorized to distribute prescription
975 | ~~legend~~ drugs under this chapter a prescription ~~legend~~ drug in a
976 | wholesale distribution transaction commits a felony of the second
977 | degree, punishable as provided in s. 775.082, s. 775.083, or s.
978 | 775.084.

979 | (5) KNOWING SALE OR TRANSFER OF ~~LEGEND~~ DRUG TO
980 | UNAUTHORIZED PERSON.--A person who knowingly sells or transfers
981 | to a person not authorized to purchase or possess prescription
982 | ~~legend~~ drugs, under the law of the jurisdiction in which the
983 | person receives the drug, a prescription ~~legend~~ drug in a

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984 wholesale distribution transaction commits a felony of the second
985 degree, punishable as provided in s. 775.082, s. 775.083, or s.
986 775.084.

987 (6) KNOWING SALE OR DELIVERY, OR POSSESSION WITH INTENT TO
988 SELL, CONTRABAND PRESCRIPTION ~~LEGEND~~ DRUGS.--A person who is
989 knowingly in actual or constructive possession of any amount of
990 contraband prescription ~~legend~~ drugs, who knowingly sells or
991 delivers, or who possesses with intent to sell or deliver any
992 amount of contraband prescription ~~legend~~ drugs, commits a felony
993 of the second degree, punishable as provided in s. 775.082, s.
994 775.083, or s. 775.084.

995 (7) TRAFFICKING IN CONTRABAND PRESCRIPTION DRUGS.--A person
996 who knowingly sells, purchases, manufactures, delivers, or brings
997 into this state, or who is knowingly in actual or constructive
998 possession of any amount of contraband prescription drugs valued
999 at \$25,000 or more, commits a felony of the first degree,
1000 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

1001 (a) Upon conviction, each defendant shall be ordered to pay
1002 a mandatory fine according to the following schedule:

1003 1. If the value of contraband prescription drugs involved
1004 is \$25,000 or more, but less than \$100,000, the defendant shall
1005 pay a mandatory fine of \$25,000. If the defendant is a
1006 corporation or other person that is not a natural person, it
1007 shall pay a mandatory fine of \$75,000.

1008 2. If the value of contraband prescription drugs involved
1009 is \$100,000 or more, but less than \$250,000, the defendant shall
1010 pay a mandatory fine of \$100,000. If the defendant is a
1011 corporation or other person that is not a natural person, it
1012 shall pay a mandatory fine of \$300,000.

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1013 3. If the value of contraband prescription drugs involved
1014 is \$250,000 or more, the defendant shall pay a mandatory fine of
1015 \$200,000. If the defendant is a corporation or other person that
1016 is not a natural person, it shall pay a mandatory fine of
1017 \$600,000.

1018 (b) As used in this section, the term "value" means the
1019 market value of the property at the time and place of the offense
1020 or, if such cannot be satisfactorily ascertained, the cost of
1021 replacement of the property within a reasonable time after the
1022 offense. Amounts of value of separate contraband prescription
1023 drugs involved in distinct transactions for the distribution of
1024 the contraband prescription drugs committed pursuant to one
1025 scheme or course of conduct, whether involving the same person or
1026 several persons, may be aggregated in determining the punishment
1027 of the offense.

1028 (8) ~~(7)~~ FORGERY OF PRESCRIPTION LABELS OR PRESCRIPTION
1029 ~~LEGEND~~ DRUG LABELS.--A person who knowingly forges, counterfeits,
1030 or falsely creates any prescription label or prescription legend
1031 drug label, or who falsely represents any factual matter
1032 contained on any prescription label or prescription legend drug
1033 label, commits a felony of the first degree, punishable as
1034 provided in s. 775.082, s. 775.083, or s. 775.084.

1035 (9) SALE OR PURCHASE OF CONTRABAND PRESCRIPTION DRUGS
1036 RESULTING IN GREAT BODILY HARM.--A person who knowingly sells,
1037 purchases, manufactures, delivers, or brings into this state, or
1038 who is knowingly in actual or constructive possession of any
1039 amount of contraband prescription drugs, and whose acts in
1040 violation of this section result in great bodily harm to a
1041 person, commits a felony of the first degree, as provided in s.

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1042 775.082, s. 775.083, or s. 775.084.

1043 (10) SALE OR PURCHASE OF CONTRABAND PRESCRIPTION DRUGS
1044 RESULTING IN DEATH.--A person who knowingly manufactures, sells,
1045 purchases, delivers, or brings into this state, or who is
1046 knowingly in actual or constructive possession of any amount of
1047 contraband prescription drugs, and whose acts in violation of
1048 this section result in the death of a person, commits a felony of
1049 the first degree, punishable by a term of years not exceeding
1050 life, as provided in s. 775.082, s. 775.083, or s. 775.084.

1051 (11) VIOLATIONS OF S. 499.005 RELATED TO DEVICES AND
1052 COSMETICS; DISSEMINATION OF FALSE ADVERTISEMENT.--Any person who
1053 violates any of the provisions of s. 499.005 with respect to a
1054 device or cosmetic commits a misdemeanor of the second degree,
1055 punishable as provided in s. 775.082 or s. 775.083; but, if the
1056 violation is committed after a conviction of such person under
1057 this section has become final, such person is guilty of a
1058 misdemeanor of the first degree, punishable as provided in s.
1059 775.082 or s. 775.083 or as otherwise provided in this part,
1060 except that any person who violates s. 499.005(8) or s.
1061 499.005(10) with respect to a device or cosmetic commits a felony
1062 of the third degree, punishable as provided in s. 775.082, s.
1063 775.083, or s. 775.084, or as otherwise provided in this part. A
1064 publisher, radio broadcast licensee, or agency or medium for the
1065 dissemination of an advertisement, except the manufacturer,
1066 wholesaler, or seller of the article to which a false
1067 advertisement relates, is not liable under this section by reason
1068 of the dissemination by him or her of such false advertisement,
1069 unless he or she has refused, on the request of the department,
1070 to furnish to the department the name and post office address of

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1071 the manufacturer, wholesaler, seller, or advertising agency that
1072 asked him or her to disseminate such advertisement.

1073 (12) ADULTERATED AND MISBRANDED DRUGS; FALSE ADVERTISEMENT;
1074 FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS.--Any person who
1075 violates any of the following provisions commits a misdemeanor of
1076 the second degree, punishable as provided in s. 775.082 or s.
1077 775.083; but, if the violation is committed after a conviction of
1078 such person under this section has become final, such person
1079 commits a misdemeanor of the first degree, punishable as provided
1080 in s. 775.082 or s. 775.083, or as otherwise provided in this
1081 part:

1082 (a) The manufacture, repackaging, sale, delivery, or
1083 holding or offering for sale of any drug that is adulterated or
1084 misbranded or has otherwise been rendered unfit for human or
1085 animal use.

1086 (b) The adulteration or misbranding of any drug intended
1087 for further distribution.

1088 (c) The receipt of any drug that is adulterated or
1089 misbranded, and the delivery or proffered delivery of such drug,
1090 for pay or otherwise.

1091 (d) The dissemination of any false or misleading
1092 advertisement of a drug.

1093 (e) The use, on the labeling of any drug or in any
1094 advertisement relating to such drug, of any representation or
1095 suggestion that an application of the drug is effective when it
1096 is not or that the drug complies with this part when it does not.

1097 (f) The purchase or receipt of a compressed medical gas
1098 from a person that is not authorized under this chapter to
1099 distribute compressed medical gases.

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- 1100 (g) Charging a dispensing fee for dispensing,
1101 administering, or distributing a prescription drug sample.
- 1102 (h) The failure to maintain records related to a drug as
1103 required by this part and rules adopted under this part, except
1104 for pedigree papers, invoices, or shipping documents related to
1105 prescription drugs.
- 1106 (i) The possession of any drug in violation of this part,
1107 except if the violation relates to a deficiency in pedigree
1108 papers.
- 1109 (13) REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR
1110 TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO
1111 PRESCRIPTION DRUGS.--Any person who violates any of the following
1112 provisions commits a felony of the third degree, punishable as
1113 provided in s. 775.082, s. 775.083, or s. 775.084, or as
1114 otherwise provided in this part.
- 1115 (a) The refusal or constructive refusal to allow:
- 1116 1. The department to enter or inspect an establishment in
1117 which drugs are manufactured, processed, repackaged, sold,
1118 brokered, or held;
- 1119 2. Inspection of any record of that establishment;
- 1120 3. The department to enter and inspect any vehicle that is
1121 being used to transport drugs; or
- 1122 4. The department to take samples of any drug.
- 1123 (b) The sale, purchase, or trade, or the offer to sell,
1124 purchase, or trade, a drug sample as defined in s. 499.028; the
1125 distribution of a drug sample in violation of s. 499.028; or the
1126 failure to otherwise comply with s. 499.028.
- 1127 (c) Providing the department with false or fraudulent
1128 records, or making false or fraudulent statements, regarding any

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1129 matter within the provisions of this chapter related to a drug.

1130 (d) The failure to receive, maintain, or provide invoices
1131 and shipping documents, other than pedigree papers, if
1132 applicable, related to the distribution of a prescription drug.

1133 (e) The importation of a prescription drug for wholesale
1134 distribution, except as provided by s. 801(d) of the Federal
1135 Food, Drug, and Cosmetic Act.

1136 (f) The wholesale distribution of any prescription drug
1137 that was:

1138 1. Purchased by a public or private hospital or other
1139 health care entity; or

1140 2. Donated or supplied at a reduced price to a charitable
1141 organization.

1142 (g) The failure to obtain a permit as a prescription drug
1143 wholesale distributor or nonresident manufacturer when a permit
1144 is required by this part for that activity.

1145 (h) Knowingly possessing any adulterated or misbranded
1146 prescription drug outside of a designated quarantine area.

1147 (i) The purchase or sale of a prescription drug for
1148 wholesale distribution in exchange for currency, as defined in s.
1149 560.103(6).

1150 (14) OTHER VIOLATIONS.--Any person who violates any of the
1151 following provisions commits a felony of the second degree,
1152 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,
1153 or as otherwise provided in this part.

1154 (a) Knowingly manufacturing, repackaging, selling,
1155 delivering, or holding or offering for sale any drug that is
1156 adulterated or misbranded or has otherwise been rendered unfit
1157 for human or animal use.

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1158 (b) Knowingly adulterating a drug that is intended for
1159 further distribution.

1160 (c) Knowingly receiving a drug that is adulterated and
1161 delivering or proffering delivery of such drug for pay or
1162 otherwise.

1163 (d) Committing any act that causes a drug to be a
1164 counterfeit drug, or selling, dispensing, or knowingly holding
1165 for sale a counterfeit drug.

1166 (e) Forging, counterfeiting, simulating, or falsely
1167 representing any drug, or, without the authority of the
1168 manufacturer, using any mark, stamp, tag, label, or other
1169 identification device authorized or required by rules adopted
1170 under this part.

1171 (f) Knowingly obtaining or attempting to obtain a
1172 prescription drug for wholesale distribution by fraud, deceit,
1173 misrepresentation, or subterfuge, or engaging in
1174 misrepresentation or fraud in the distribution of a drug.

1175 (g) Removing a pharmacy's dispensing label from a dispensed
1176 prescription drug with the intent to further distribute the
1177 prescription drug.

1178 (h) Knowingly distributing a prescription drug that was
1179 previously dispensed by a licensed pharmacy, unless such
1180 distribution was authorized in chapter 465 or the rules adopted
1181 under chapter 465.

1182 (15) FALSE ADVERTISEMENT.--A publisher, radio broadcast
1183 licensee, or agency or medium for the dissemination of an
1184 advertisement, except the manufacturer, repackager, wholesale
1185 distributor, or seller of the article to which a false
1186 advertisement relates, is not liable under subsection (12),

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1187 subsection (13), or subsection (14) by reason of the
1188 dissemination by him or her of such false advertisement, unless
1189 he or she has refused, on the request of the department, to
1190 furnish to the department the name and post office address of the
1191 manufacturer, repackager, wholesaler, seller, or advertising
1192 agency that asked him or her to disseminate such advertisement.

1193 Section 8. Section 499.0053, Florida Statutes, is repealed.

1194 Section 9. Section 499.00535, Florida Statutes, is
1195 repealed.

1196 Section 10. Section 499.0054, Florida Statutes, is amended
1197 to read:

1198 499.0054 Advertising and labeling of drugs, devices, and
1199 cosmetics; exemptions.--

1200 (1) It is a violation of the Florida Drug and Cosmetic Act
1201 to perform or cause the performance of any of the following acts:

1202 (a)~~(1)~~ The dissemination of any false advertisement of any
1203 drug, device, or cosmetic. An advertisement is false if it is
1204 false or misleading in any way.

1205 (b)~~(2)~~ The distribution in commerce of any drug, device, or
1206 cosmetic, if its labeling or advertising is in violation of ss.
1207 499.001-499.081.

1208 (c)~~(3)~~ The manufacturing, repackaging, packaging, selling,
1209 delivery, holding, or offering for sale of any drug, device, or
1210 cosmetic for which the advertising or labeling is false or
1211 misleading.

1212 (d)~~(4)~~ The advertising of any drug, device, or cosmetic
1213 that is adulterated or misbranded.

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1214 (e)~~(5)~~ The receiving in commerce of any drug, device, or
1215 cosmetic that is falsely advertised or labeled or the delivering
1216 or proffering for delivery of any such drug, device, or cosmetic.

1217 (f)~~(6)~~ The advertising or labeling of any product
1218 containing ephedrine, a salt of ephedrine, an isomer of
1219 ephedrine, or a salt of an isomer of ephedrine, for the
1220 indication of stimulation, mental alertness, weight loss,
1221 appetite control, energy, or other indications not approved by
1222 the pertinent United States Food and Drug Administration Over-
1223 the-Counter Final or Tentative Final Monograph or approved new
1224 drug application under the federal act. In determining compliance
1225 with this requirement, the department may consider the following
1226 factors:

1227 1.~~(a)~~ The packaging of the product.

1228 2.~~(b)~~ The name and labeling of the product.

1229 3.~~(c)~~ The manner of distribution, advertising, and
1230 promotion of the product, including verbal representations at the
1231 point of sale.

1232 4.~~(d)~~ The duration, scope, and significance of abuse of the
1233 particular product.

1234 (g)~~(7)~~ The advertising of any drug or device represented to
1235 have any effect in any of the following conditions, disorders,
1236 diseases, or processes:

1237 1.~~(a)~~ Blood disorders.

1238 2.~~(b)~~ Bone or joint diseases.

1239 3.~~(c)~~ Kidney diseases or disorders.

1240 4.~~(d)~~ Cancer.

1241 5.~~(e)~~ Diabetes.

1242 6.~~(f)~~ Gall bladder diseases or disorders.

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- 1243 7.~~(g)~~ Heart and vascular diseases.
- 1244 8.~~(h)~~ High blood pressure.
- 1245 9.~~(i)~~ Diseases or disorders of the ear or auditory
1246 apparatus, including hearing loss or deafness.
- 1247 10.~~(j)~~ Mental disease or mental retardation.
- 1248 11.~~(k)~~ Paralysis.
- 1249 12.~~(l)~~ Prostate gland disorders.
- 1250 13.~~(m)~~ Conditions of the scalp affecting hair loss.
- 1251 14.~~(n)~~ Baldness.
- 1252 15.~~(o)~~ Endocrine disorders.
- 1253 16.~~(p)~~ Sexual impotence.
- 1254 17.~~(q)~~ Tumors.
- 1255 18.~~(r)~~ Venereal diseases.
- 1256 19.~~(s)~~ Varicose ulcers.
- 1257 20.~~(t)~~ Breast enlargement.
- 1258 21.~~(u)~~ Purifying blood.
- 1259 22.~~(v)~~ Metabolic disorders.
- 1260 23.~~(w)~~ Immune system disorders or conditions affecting the
1261 immune system.
- 1262 24.~~(x)~~ Extension of life expectancy.
- 1263 25.~~(y)~~ Stress and tension.
- 1264 26.~~(z)~~ Brain stimulation or performance.
- 1265 27.~~(aa)~~ The body's natural defense mechanisms.
- 1266 28.~~(bb)~~ Blood flow.
- 1267 29.~~(cc)~~ Depression.
- 1268 30.~~(dd)~~ Human immunodeficiency virus or acquired immune
1269 deficiency syndrome or related disorders or conditions.

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1270 (h)~~(8)~~ The representation or suggestion in labeling or
1271 advertising that an article is approved under this part ~~ss.~~
1272 ~~499.001-499.081~~, when such is not the case.

1273 (2) In determining whether an advertisement is false or
1274 misleading, the department shall review the representations made
1275 or suggested by statement, word, design, device, sound, or any
1276 combination thereof within the advertisement and the extent to
1277 which the advertisement fails to reveal material facts with
1278 respect to consequences that can result from the use of the drug,
1279 device, or cosmetic to which the advertisement relates under the
1280 conditions of use prescribed in the labeling or advertisement.

1281 (3) (a) An advertisement that is not prohibited under
1282 paragraph (1) (a) is not prohibited under paragraph (1) (g) if it
1283 is disseminated:

1284 1. To the public solely to advertise the product for those
1285 indications that are safe and effective indications and the
1286 product is safe and effective for self-medication, as established
1287 by the United States Food and Drug Administration; or

1288 2. Only to members of the medical, dental, pharmaceutical,
1289 or veterinary professions or appears only in the scientific
1290 periodicals of these professions.

1291 (b) Compliance with this part and the rules adopted under
1292 this part does not create any legal presumption that a drug or
1293 device is safe or effective.

1294 Section 11. Section 499.00545, Florida Statutes, is
1295 repealed.

1296 Section 12. Section 499.0055, Florida Statutes, is
1297 repealed.

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1298 Section 13. Section 499.0057, Florida Statutes, is
1299 repealed.

1300 Section 14. Section 499.006, Florida Statutes, is amended
1301 to read:

1302 499.006 Adulterated drug or device.--A drug or device is
1303 adulterated:

1304 (1) If it consists in whole or in part of any filthy,
1305 putrid, or decomposed substance;

1306 (2) If it has been produced, prepared, packed, or held
1307 under conditions whereby it could have been contaminated with
1308 filth or rendered injurious to health;

1309 (3) If it is a drug and the methods used in, or the
1310 facilities or controls used for, its manufacture, processing,
1311 packing, or holding do not conform to, or are not operated or
1312 administered in conformity with, current good manufacturing
1313 practices to assure that the drug meets the requirements of this
1314 part ss. ~~499.001-499.081~~ and that the drug has the identity and
1315 strength, and meets the standard of quality and purity, which it
1316 purports or is represented to possess;

1317 (4) If it is a drug and its container is composed, in whole
1318 or in part, of any poisonous or deleterious substance which could
1319 render the contents injurious to health;

1320 (5) If it is a drug and it bears or contains, for the
1321 purpose of coloring only, a color additive that is unsafe within
1322 the meaning of the federal act; or, if it is a color additive,
1323 the intended use of which in or on drugs is for the purpose of
1324 coloring only, and it is unsafe within the meaning of the federal
1325 act;

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1326 (6) If it purports to be, or is represented as, a drug the
1327 name of which is recognized in the official compendium, and its
1328 strength differs from, or its quality or purity falls below, the
1329 standard set forth in such compendium. The determination as to
1330 strength, quality, or purity must be made in accordance with the
1331 tests or methods of assay set forth in such compendium, or, when
1332 such tests or methods of assay are absent or inadequate, in
1333 accordance with those tests or methods of assay prescribed under
1334 authority of the federal act. A drug defined in the official
1335 compendium is not adulterated under this subsection merely
1336 because it differs from the standard of strength, quality, or
1337 purity set forth for that drug in such compendium if its
1338 difference in strength, quality, or purity from such standard is
1339 plainly stated on its label;

1340 (7) If it is not subject to subsection (6) and its strength
1341 differs from, or its purity or quality falls below the standard
1342 of, that which it purports or is represented to possess;

1343 (8) If it is a drug:

1344 (a) With which any substance has been mixed or packed so as
1345 to reduce the quality or strength of the drug; or

1346 (b) For which any substance has been substituted wholly or
1347 in part;

1348 (9) If it is a drug or device for which the expiration date
1349 has passed;

1350 (10) If it is a legend drug for which the required pedigree
1351 paper is nonexistent, fraudulent, or incomplete under the
1352 requirements of this part ~~ss. 499.001-499.081~~ or applicable
1353 rules, or that has been purchased, held, sold, or distributed at

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1354 any time by a person not authorized under federal or state law to
1355 do so; or

1356 (11) If it is a prescription drug subject to, defined by,
1357 or described by s. 503(b) of the Federal Food, Drug, and Cosmetic
1358 Act which has been returned by a veterinarian to a limited
1359 prescription drug veterinary wholesaler.

1360 Section 15. Section 499.007, Florida Statutes, is amended
1361 to read:

1362 499.007 Misbranded drug or device.--A drug or device is
1363 misbranded:

1364 (1) If its labeling is in any way false or misleading.

1365 (2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a
1366 label containing:

1367 (a) The name and place of business of the manufacturer,
1368 repackager, or distributor of the finished dosage form of the
1369 drug. For the purpose of this paragraph, the finished dosage form
1370 of a prescription medicinal drug is that form of the drug which
1371 is, or is intended to be, dispensed or administered to the
1372 patient and requires no further manufacturing or processing other
1373 than packaging, reconstitution, and labeling; and

1374 (b) An accurate statement of the quantity of the contents
1375 in terms of weight, measure, or numerical count; however, under
1376 this section, reasonable variations are permitted, and the
1377 department shall establish by rule exemptions for small packages.

1378 (3) If it is an active pharmaceutical ingredient in bulk
1379 form and does not bear a label containing:

1380 (a) The name and place of business of the manufacturer,
1381 repackager, or distributor; and

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1382 (b) An accurate statement of the quantity of the contents
1383 in terms of weight, measure, or numerical count.

1384 (4)~~(3)~~ If any word, statement, or other information
1385 required by or under this part ~~ss. 499.001-499.081~~ to appear on
1386 the label or labeling is not prominently placed thereon with such
1387 conspicuousness as compared with other words, statements,
1388 designs, or devices in the labeling, and in such terms, as to
1389 render the word, statement, or other information likely to be
1390 read and understood under customary conditions of purchase and
1391 use.

1392 (5)~~(4)~~ If it is a drug and is not designated solely by a
1393 name recognized in an official compendium and, ~~unless~~ its label
1394 does not bear ~~bears~~:

1395 (a) The common or usual name of the drug, if any; and

1396 (b) In case it is fabricated from two or more ingredients,
1397 the common or usual name and quantity of each active ingredient.

1398 (6)~~(5)~~ If ~~Unless~~ its labeling does not bear ~~bears~~:

1399 (a) Adequate directions for use; and

1400 (b) Adequate warnings against use in those pathological
1401 conditions in which its use may be dangerous to health or against
1402 use by children if its use may be dangerous to health, or against
1403 unsafe dosage or methods or duration of administration or
1404 application, in such manner and form as are necessary for the
1405 protection of users.

1406 (7)~~(6)~~ If it purports to be a drug the name of which is
1407 recognized in the official compendium, and ~~unless~~ it is not
1408 packaged and labeled as prescribed therein; however, the method
1409 of packaging may be modified with the consent of the department.

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1410 (8)~~(7)~~ If it has been found by the department to be a drug
1411 liable to deterioration, and ~~unless~~ it is not packaged in such
1412 form and manner, and its label bears a statement of such
1413 precautions, as the department by rule requires as necessary to
1414 protect the public health. Such rule may not be established for
1415 any drug recognized in an official compendium until the
1416 department has informed the appropriate body charged with the
1417 revision of such compendium of the need for such packaging or
1418 labeling requirements and that body has failed within a
1419 reasonable time to prescribe such requirements.

1420 (9)~~(8)~~ If it is:

1421 (a) A drug and its container or finished dosage form is so
1422 made, formed, or filled as to be misleading;

1423 (b) An imitation of another drug; or

1424 (c) Offered for sale under the name of another drug.

1425 (10)~~(9)~~ If it is dangerous to health when used in the
1426 dosage or with the frequency or duration prescribed, recommended,
1427 or suggested in the labeling of the drug.

1428 (11)~~(10)~~ If it is, purports to be, or is represented as a
1429 drug composed wholly or partly of insulin, and ~~unless~~:

1430 (a) It is not from a batch with respect to which a
1431 certificate has been issued pursuant to s. 506 of the federal
1432 act; and

1433 (b) The certificate is in effect with respect to the drug.

1434 (12)~~(11)~~ If it is, purports to be, or is represented as a
1435 drug composed wholly or partly of any kind of antibiotic
1436 requiring certification under the federal act, and ~~unless~~:

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1437 (a) It is not from a batch with respect to which a
1438 certificate has been issued pursuant to s. 507 of the federal
1439 act; and

1440 (b) The certificate is in effect with respect to the drug.~~†~~

1441

1442 However, this subsection does not apply to any drug or class of
1443 drugs exempted by regulations adopted under s. 507(c) or (d) of
1444 the federal act.

1445 ~~(13)-(12)~~ If it is a drug intended for use by humans which
1446 is a habit-forming drug or which, because of its toxicity or
1447 other potentiality for harmful effect, or the method of its use,
1448 or the collateral measures necessary to its use, is not safe for
1449 use except under the supervision of a practitioner licensed by
1450 law to administer such drugs; or which is limited by an effective
1451 application under s. 505 of the federal act to use under the
1452 professional supervision of a practitioner licensed by law to
1453 prescribe such drug, if ~~unless~~ it is not dispensed only:

1454 (a) Upon the written prescription of a practitioner
1455 licensed by law to prescribe such drug;

1456 (b) Upon an oral prescription of such practitioner, which
1457 is reduced promptly to writing and filled by the pharmacist; or

1458 (c) By refilling any such written or oral prescription, if
1459 such refilling is authorized by the prescriber either in the
1460 original prescription or by oral order which is reduced promptly
1461 to writing and filled by the pharmacist.

1462

1463 This subsection does not relieve any person from any requirement
1464 prescribed by law with respect to controlled substances as
1465 defined in the applicable federal and state laws.

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1466 (14)~~(13)~~ If it is a drug that is subject to paragraph
1467 (13) (a) ~~(12) (a)~~, and if, at any time before it is dispensed, its
1468 label does not ~~fails to~~ bear the statement:

1469 (a) "Caution: Federal Law Prohibits Dispensing Without
1470 Prescription";

1471 (b) "Rx Only";

1472 (c) The prescription symbol followed by the word "Only"; or

1473 (d) "Caution: State Law Prohibits Dispensing Without
1474 Prescription."

1475 (15)~~(14)~~ If it is a drug that is not subject to paragraph
1476 (13) (a) ~~(12) (a)~~, if at any time before it is dispensed its label
1477 bears the statement of caution required in subsection (14) ~~(13)~~.

1478 (16)~~(15)~~ If it is a color additive, the intended use of
1479 which in or on drugs is for the purpose of coloring only, and
1480 ~~unless~~ its packaging and labeling are not in conformity with the
1481 packaging and labeling requirements that apply to such color
1482 additive and are prescribed under the federal act.

1483
1484 A drug dispensed by filling or refilling a written or oral
1485 prescription of a practitioner licensed by law to prescribe such
1486 drug is exempt from the requirements of this section, except
1487 subsections (1), (9)~~(8)~~, (11)~~(10)~~, and (12)~~(11)~~ and the packaging
1488 requirements of subsections (7)~~(6)~~ and (8)~~(7)~~, if the drug bears
1489 a label that contains the name and address of the dispenser or
1490 seller, the prescription number and the date the prescription was
1491 written or filled, the name of the prescriber and the name of the
1492 patient, and the directions for use and cautionary statements.
1493 This exemption does not apply to any drug dispensed in the course
1494 of the conduct of a business of dispensing drugs pursuant to

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1495 diagnosis by mail or to any drug dispensed in violation of
1496 subsection (13) ~~(12)~~. The department may, by rule, exempt drugs
1497 subject to ss. 499.062-499.064 from subsection (13) ~~(12)~~ if
1498 compliance with that subsection is not necessary to protect the
1499 public health, safety, and welfare.

1500 Section 16. Section 499.008, Florida Statutes, is amended
1501 to read:

1502 499.008 Adulterated cosmetics.--A cosmetic is adulterated:

1503 (1) If it bears or contains any poisonous or deleterious
1504 substance that is injurious to users under the conditions of use
1505 prescribed in the labeling or advertisement thereof or under such
1506 conditions of use as are customary or usual. ~~+~~ However, this
1507 subsection does not apply to coal-tar hair dye:

1508 (a) The label of which bears the following legend
1509 conspicuously displayed thereon: "Caution: This product contains
1510 ingredients which may cause skin irritation on certain
1511 individuals, and a preliminary test according to accompanying
1512 directions should first be made. This product must not be used
1513 for dyeing the eyelashes or eyebrows; to do so may cause
1514 blindness"; and

1515 (b) The labeling of which bears adequate directions for
1516 such preliminary testing.

1517
1518 ~~For the purposes of this subsection and subsection (4), the term~~
1519 ~~"hair dye" does not include eyelash dyes or eyebrow dyes.~~

1520 (2) If it consists in whole or in part of any filthy,
1521 putrid, or decomposed substance.

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1522 (3) If it has been produced, prepared, packed, or held
1523 under conditions whereby it could have become contaminated with
1524 filth or whereby it could have been rendered injurious to health.

1525 (4) If it is not a hair dye and it is, or it bears or
1526 contains, a color additive that is unsafe within the meaning of
1527 the federal act.

1528
1529 For the purposes of subsections (1) and (4), the term "hair dye"
1530 does not include eyelash dyes or eyebrow dyes.

1531 Section 17. Section 499.009, Florida Statutes, is amended
1532 to read:

1533 499.009 Misbranded cosmetics.--A cosmetic is misbranded:

1534 (1) If its labeling is false or misleading in any
1535 particular.

1536 (2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a
1537 label containing:

1538 (a) The name and place of business of the manufacturer,
1539 packer, or distributor;

1540 (b) An accurate statement of the quantity of the contents
1541 in terms of weight, measure, or numerical count; however, under
1542 this paragraph reasonable variations are permitted, and the
1543 department shall establish by rule exemptions for small packages;
1544 and

1545 (c) A declaration of ingredients in descending order of
1546 predominance, or as otherwise required by federal law.

1547 (3) If any word, statement, or other information required
1548 by or under authority of this part ~~ss. 499.001-499.081~~ to appear
1549 on the label or labeling is not prominently placed thereon with
1550 such conspicuousness as compared with other words, statements,

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1551 designs, or devices in the labeling, and in such terms, as to
1552 render the word, statement, or other information likely to be
1553 read and understood by an individual under customary conditions
1554 of purchase and use.

1555 (4) If its container is so made, formed, or filled as to be
1556 misleading.

1557 (5) ~~Unless,~~ If it is a color additive, its packaging and
1558 labeling are not in conformity with the packaging and labeling
1559 requirements applicable to that color additive prescribed under
1560 the federal act. This subsection does not apply to packages of
1561 color additives that, with respect to their use for cosmetics,
1562 are marketed and intended for use only in or on hair dyes.

1563 Section 18. Section 499.01, Florida Statutes, is amended to
1564 read:

1565 499.01 ~~Permits; applications; renewal; general~~
1566 ~~requirements.--~~

1567 (1) Prior to operating, a permit is required for each
1568 person and establishment that intends to operate as:

1569 (a) A prescription drug manufacturer;

1570 (b) A prescription drug repackager;

1571 (c) A nonresident prescription drug manufacturer;

1572 (d) A prescription drug wholesale distributor;

1573 (e) An out-of-state prescription drug wholesale

1574 distributor;

1575 (f) A retail pharmacy drug wholesale distributor;

1576 (g) A restricted prescription drug distributor;

1577 (h) A complimentary drug distributor;

1578 (i) A freight forwarder;

1579 (j) A veterinary prescription drug retail establishment;

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- 1580 (k) A veterinary prescription drug wholesale distributor;
1581 (l) A limited prescription drug veterinary wholesale
1582 distributor;
1583 (m) A medical oxygen retail establishment;
1584 (n) A compressed medical gas wholesale distributor;
1585 (o) A compressed medical gas manufacturer;
1586 (p) ~~(e)~~ An over-the-counter drug manufacturer;
1587 ~~(d) A compressed medical gas manufacturer;~~
1588 (q) ~~(e)~~ A device manufacturer; or
1589 (r) ~~(f)~~ A cosmetic manufacturer.
1590 ~~(g) A prescription drug wholesaler;~~
1591 ~~(h) A veterinary prescription drug wholesaler;~~
1592 ~~(i) A compressed medical gas wholesaler;~~
1593 ~~(j) An out-of-state prescription drug wholesaler;~~
1594 ~~(k) A nonresident prescription drug manufacturer;~~
1595 ~~(l) A freight forwarder;~~
1596 ~~(m) A retail pharmacy drug wholesaler;~~
1597 ~~(n) A veterinary legend drug retail establishment;~~
1598 ~~(o) A medical oxygen retail establishment;~~
1599 ~~(p) A complimentary drug distributor;~~
1600 ~~(q) A restricted prescription drug distributor; or~~
1601 ~~(r) A limited prescription drug veterinary wholesaler.~~
1602 (2) The following types of permits are established:
1603 (a) Prescription drug manufacturer permit.--A prescription
1604 drug manufacturer permit is required for any person that
1605 manufactures a prescription drug in this state.
1606 1. A person that operates an establishment permitted as a
1607 prescription drug manufacturer may engage in wholesale
1608 distribution of prescription drugs manufactured at that

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1609 establishment and shall comply with all the provisions of this
1610 part and the rules adopted under this part which apply to a
1611 wholesale distributor.

1612 2. A prescription drug manufacturer shall comply with all
1613 appropriate state and federal good manufacturing practices.

1614 (b) Prescription drug repackager permit.--A prescription
1615 drug repackager permit is required for any person that repackages
1616 a prescription drug in this state.

1617 1. A person that operates an establishment permitted as a
1618 prescription drug repackager may engage in wholesale distribution
1619 of prescription drugs repackaged at that establishment and must
1620 comply with all the provisions of this part and the rules adopted
1621 under this part which apply to a wholesale distributor.

1622 2. A prescription drug repackager shall comply with all
1623 appropriate state and federal good manufacturing practices.

1624 (c) Nonresident prescription drug manufacturer permit.--A
1625 nonresident prescription drug manufacturer permit is required for
1626 any person that is a manufacturer of prescription drugs, or the
1627 distribution point for a manufacturer of prescription drugs, and
1628 located outside of this state, or that is an entity to whom an
1629 approved new drug application has been issued by the United
1630 States Food and Drug Administration, or the contracted
1631 manufacturer of the approved new drug application holder, and
1632 located outside the United States, which engages in the wholesale
1633 distribution in this state of the prescription drugs it
1634 manufactures or is responsible for manufacturing. Each such
1635 manufacturer or entity must be permitted by the department and
1636 comply with all the provisions required of a wholesale
1637 distributor under this part, except s. 499.01213.

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1638 1. A person that distributes prescription drugs that it did
1639 not manufacture must also obtain an out-of-state prescription
1640 drug wholesale distributor permit pursuant to this section to
1641 engage in the wholesale distribution of the prescription drugs
1642 manufactured by another person and comply with the requirements
1643 of an out-of-state prescription drug wholesale distributor.

1644 2. Any such person must comply with the licensing or
1645 permitting requirements of the jurisdiction in which the
1646 establishment is located and the federal act, and any product
1647 wholesaled into this state must comply with this part. If a
1648 person intends to import prescription drugs from a foreign
1649 country into this state, the nonresident prescription drug
1650 manufacturer must provide to the department a list identifying
1651 each prescription drug it intends to import and document approval
1652 by the United States Food and Drug Administration for such
1653 importation.

1654 (d) A prescription drug wholesale distributor permit.--A
1655 prescription drug wholesale distributor is a wholesale
1656 distributor that may engage in the wholesale distribution of
1657 prescription drugs. A prescription drug wholesale distributor
1658 that applies to the department for a new permit or the renewal of
1659 a permit must submit a bond of \$100,000, or other equivalent
1660 means of security acceptable to the department, such as an
1661 irrevocable letter of credit or a deposit in a trust account or
1662 financial institution, payable to the Florida Drug, Device, and
1663 Cosmetic Trust Fund. The purpose of the bond is to secure payment
1664 of any administrative penalties imposed by the department and any
1665 fees and costs incurred by the department regarding that permit
1666 which are authorized under state law and which the permittee

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1667 fails to pay within 30 days after the fine or costs become final.
1668 The department may make a claim against such bond or security
1669 until 1 year after the permittee's license ceases to be valid or
1670 until 60 days after any administrative or legal proceeding
1671 authorized in this part which involves the permittee is
1672 concluded, including any appeal, whichever occurs later. The
1673 department may adopt rules for issuing a prescription drug
1674 wholesale distributor-broker permit to a person who engages in
1675 the wholesale distribution of prescription drugs and does not
1676 take physical possession of any prescription drugs.

1677 (e) An out-of-state prescription drug wholesale distributor
1678 permit.--An out-of-state prescription drug wholesale distributor
1679 is a wholesale distributor located outside this state which
1680 engages in the wholesale distribution of prescription drugs into
1681 this state and which must be permitted by the department and
1682 comply with all the provisions required of a wholesale
1683 distributor under this part. An out-of-state prescription drug
1684 wholesale distributor that applies to the department for a new
1685 permit or the renewal of a permit must submit a bond of \$100,000,
1686 or other equivalent means of security acceptable to the
1687 department, such as an irrevocable letter of credit or a deposit
1688 in a trust account or financial institution, payable to the
1689 Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the
1690 bond is to secure payment of any administrative penalties imposed
1691 by the department and any fees and costs incurred by the
1692 department regarding that permit which are authorized under state
1693 law and which the permittee fails to pay within 30 days after the
1694 fine or costs become final. The department may make a claim
1695 against such bond or security until 1 year after the permittee's

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1696 license ceases to be valid or until 60 days after any
1697 administrative or legal proceeding authorized in this part which
1698 involves the permittee is concluded, including any appeal,
1699 whichever occurs later.

1700 1. The out-of-state prescription drug wholesale distributor
1701 must maintain at all times a license or permit to engage in the
1702 wholesale distribution of prescription drugs in compliance with
1703 laws of the state in which it is a resident.

1704 2. An out-of-state prescription drug wholesale distributor
1705 permit is not required for an intracompany sale or transfer of a
1706 prescription drug from an out-of-state establishment that is duly
1707 licensed as a prescription drug wholesale distributor, in its
1708 state of residence, to a licensed prescription drug wholesale
1709 distributor in this state, if both wholesaler distributors
1710 conduct wholesale distributions of prescription drugs under the
1711 same business name. The recordkeeping requirements of ss.
1712 499.0121(6) and 499.01213 must be followed for this transaction.

1713 (f) A retail pharmacy wholesale distributor permit.--A
1714 retail pharmacy wholesale distributor is a retail pharmacy
1715 engaged in wholesale distribution of prescription drugs within
1716 this state under the following conditions:

1717 1. The pharmacy must obtain a retail pharmacy wholesaler
1718 distributor permit pursuant to this part and the rules adopted
1719 under this part.

1720 2. The wholesale distribution activity does not exceed 30
1721 percent of the total annual purchases of prescription drugs. If
1722 the wholesale distribution activity exceeds the 30-percent
1723 maximum, the pharmacy must obtain a prescription drug wholesaler
1724 distributor permit.

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1725 3. The transfer of prescription drugs that appear in any
1726 schedule contained in chapter 893 is subject to chapter 893 and
1727 the federal Comprehensive Drug Abuse Prevention and Control Act
1728 of 1970.

1729 4. The transfer is between a retail pharmacy and another
1730 retail pharmacy, or a Modified Class II institutional pharmacy,
1731 or a health care practitioner licensed in this state and
1732 authorized by law to dispense or prescribe prescription drugs.

1733 5. All records of sales of prescription drugs subject to
1734 this section must be maintained separate and distinct from other
1735 records and comply with the recordkeeping requirements of this
1736 part.

1737 (g) Restricted prescription drug distributor permit.--A
1738 restricted prescription drug distributor permit is required for
1739 any person that engages in the distribution of a prescription
1740 drug, which distribution is not considered "wholesale
1741 distribution" under s. 499.003(60)(a).

1742 1. A person who engages in the receipt or distribution of a
1743 prescription drug in this state for the purpose of processing its
1744 return or its destruction must obtain a permit as a restricted
1745 prescription drug distributor if such person is not the person
1746 initiating the return, the prescription drug wholesale supplier
1747 of the person initiating the return, or the manufacturer of the
1748 drug.

1749 2. Storage, handling, and recordkeeping of these
1750 distributions must comply with the requirements for wholesale
1751 distributors under s. 499.0121, except those set forth in s.
1752 499.01213.

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1753 3. A person who applies for a permit as a restricted
1754 prescription drug distributor, or for the renewal of such a
1755 permit, shall provide to the department the information required
1756 under s. 499.012.

1757 4. The department may adopt rules regarding the
1758 distribution of prescription drugs by hospitals, health care
1759 entities, charitable organizations, or other persons not involved
1760 in wholesale distribution, which rules are necessary for the
1761 protection of the public health, safety, and welfare.

1762 (h) Complimentary drug distributor permit.--A complimentary
1763 drug distributor permit is required for any person that engages
1764 in the distribution of a complimentary drug, subject to the
1765 requirements of s. 499.028.

1766 (i) Freight forwarder permit.--A freight forwarder permit
1767 is required for any person that engages in the distribution of a
1768 prescription drug as a freight forwarder unless the person is a
1769 common carrier. The storage, handling, and recordkeeping of such
1770 distributions must comply with the requirements for wholesale
1771 distributors under s. 499.0121, except those set forth in s.
1772 499.01213. A freight forwarder must provide the source of the
1773 prescription drugs with a validated airway bill, bill of lading,
1774 or other appropriate documentation to evidence the exportation of
1775 the product.

1776 (j) Veterinary prescription drug retail establishment
1777 permit.--A veterinary prescription drug retail establishment
1778 permit is required for any person that sells veterinary
1779 prescription drugs to the public, but does not include a pharmacy
1780 licensed under chapter 465.

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1781 1. The sale to the public must be based on a valid written
1782 order from a veterinarian licensed in this state who has a valid
1783 client-veterinarian relationship with the purchaser's animal.

1784 2. Veterinary prescription drugs may not be sold in excess
1785 of the amount clearly indicated on the order or beyond the date
1786 indicated on the order.

1787 3. An order may not be valid for more than 1 year.

1788 4. A veterinary prescription drug retail establishment may
1789 not purchase, sell, trade, or possess human prescription drugs or
1790 any controlled substance as defined in chapter 893.

1791 5. A veterinary prescription drug retail establishment must
1792 sell a veterinary prescription drug in the original, sealed
1793 manufacturer's container with all labeling intact and legible.
1794 The department may adopt by rule additional labeling requirements
1795 for the sale of a veterinary prescription drug.

1796 6. A veterinary prescription drug retail establishment must
1797 comply with all of the wholesale distribution requirements of s.
1798 499.0121.

1799 7. A prescription drug sold by a veterinary prescription
1800 drug retail establishment pursuant to a practitioner's order may
1801 not be returned into the retail establishment's inventory.

1802 (k) A veterinary prescription drug wholesale distributor
1803 permit.--A veterinary prescription drug wholesale distributor
1804 permit is required for any person that engages in the
1805 distribution of veterinary prescription drugs in or into this
1806 state. A veterinary prescription drug wholesale distributor that
1807 also distributes prescription drugs subject to, defined by, or
1808 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
1809 Act which it did not manufacture must obtain a permit as a

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1810 prescription drug wholesale distributor, an out-of-state
1811 prescription drug wholesale distributor, or a limited
1812 prescription drug veterinary wholesale distributor in lieu of the
1813 veterinary prescription drug wholesale distributor permit. A
1814 veterinary prescription drug wholesale distributor must comply
1815 with the requirements for wholesale distributors under s.
1816 499.0121, except those set forth in s. 499.01213.

1817 (1) Limited prescription drug veterinary wholesale
1818 distributor permit.--Unless engaging in the activities of and
1819 permitted as a prescription drug manufacturer, nonresident
1820 prescription drug manufacturer, prescription drug wholesale
1821 distributor, or out-of-state prescription drug wholesale
1822 distributor, a limited prescription drug veterinary wholesale
1823 distributor permit is required for any person that engages in the
1824 distribution in or into this state of veterinary prescription
1825 drugs and prescription drugs subject to, defined by, or described
1826 by s. 503(b) of the Federal Food, Drug, and Cosmetic Act under
1827 the following conditions:

1828 1. The person is engaged in the business of wholesaling
1829 prescription and veterinary legend drugs to persons:

1830 a. Licensed as veterinarians practicing on a full-time
1831 basis;

1832 b. Regularly and lawfully engaged in instruction in
1833 veterinary medicine;

1834 c. Regularly and lawfully engaged in law enforcement
1835 activities;

1836 d. For use in research not involving clinical use; or

1837 e. For use in chemical analysis or physical testing or for
1838 purposes of instruction in law enforcement activities, research,

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1839 or testing.

1840 2. No more than 30 percent of total annual prescription
1841 drug sales may be prescription drugs approved for human use which
1842 are subject to, defined by, or described by s. 503(b) of the
1843 Federal Food, Drug, and Cosmetic Act.

1844 3. The person does not distribute in any state prescription
1845 drugs subject to, defined by, or described by s. 503(b) of the
1846 Federal Food, Drug, and Cosmetic Act to any person who is
1847 authorized to sell, distribute, purchase, trade, or use these
1848 drugs on or for humans.

1849 4. A limited prescription drug veterinary wholesale
1850 distributor that applies to the department for a new permit or
1851 the renewal of a permit must submit a bond of \$20,000, or other
1852 equivalent means of security acceptable to the department, such
1853 as an irrevocable letter of credit or a deposit in a trust
1854 account or financial institution, payable to the Florida Drug,
1855 Device, and Cosmetic Trust Fund. The purpose of the bond is to
1856 secure payment of any administrative penalties imposed by the
1857 department and any fees and costs incurred by the department
1858 regarding that permit which are authorized under state law and
1859 which the permittee fails to pay within 30 days after the fine or
1860 costs become final. The department may make a claim against such
1861 bond or security until 1 year after the permittee's license
1862 ceases to be valid or until 60 days after any administrative or
1863 legal proceeding authorized in this part which involves the
1864 permittee is concluded, including any appeal, whichever occurs
1865 later.

1866 5. A limited prescription drug veterinary wholesale
1867 distributor must maintain at all times a license or permit to

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1868 engage in the wholesale distribution of prescription drugs in
1869 compliance with laws of the state in which it is a resident.

1870 6. A limited prescription drug veterinary wholesale
1871 distributor must comply with the requirements for wholesale
1872 distributors under s. 499.0121, except that a limited
1873 prescription drug veterinary wholesale distributor is not
1874 required to provide a pedigree paper as required by s. 499.01213
1875 upon the wholesale distribution of a prescription drug to a
1876 veterinarian.

1877 7. A limited prescription drug veterinary wholesale
1878 distributor may not return to inventory for subsequent wholesale
1879 distribution any prescription drug subject to, defined by, or
1880 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
1881 Act which has been returned by a veterinarian.

1882 8. A limited prescription drug veterinary wholesale
1883 distributor permit is not required for an intracompany sale or
1884 transfer of a prescription drug from an out-of-state
1885 establishment that is duly licensed to engage in the wholesale
1886 distribution of prescription drugs in its state of residence to a
1887 licensed limited prescription drug veterinary wholesale
1888 distributor in this state if both wholesale distributors conduct
1889 wholesale distributions of prescription drugs under the same
1890 business name. The recordkeeping requirements of ss. 499.0121(6)
1891 and 499.01213 must be followed for this transaction.

1892 (m) Medical oxygen retail establishment permit.--A medical
1893 oxygen retail establishment permit is required for any person
1894 that sells medical oxygen to patients only. The sale must be
1895 based on an order from a practitioner authorized by law to

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1896 prescribe. The term does not include a pharmacy licensed under
1897 chapter 465.

1898 1. A medical oxygen retail establishment may not possess,
1899 purchase, sell, or trade any prescription drug other than medical
1900 oxygen.

1901 2. A medical oxygen retail establishment may refill medical
1902 oxygen for an individual patient based on an order from a
1903 practitioner authorized by law to prescribe. A medical oxygen
1904 retail establishment that refills medical oxygen must comply with
1905 all appropriate state and federal good manufacturing practices.

1906 3. A medical oxygen retail establishment must comply with
1907 all of the wholesale distribution requirements of s. 499.0121.

1908 4. Prescription medical oxygen sold by a medical oxygen
1909 retail establishment pursuant to a practitioner's order may not
1910 be returned into the retail establishment's inventory.

1911 (n) A compressed medical gas wholesaler distributor
1912 permit.--A compressed medical gas wholesale distributor is a
1913 wholesale distributor that is limited to the wholesale
1914 distribution of compressed medical gases to other than the
1915 consumer or patient. The compressed medical gas must be in the
1916 original sealed container that was purchased by that wholesale
1917 distributor. A compressed medical gas wholesale distributor may
1918 not possess or engage in the wholesale distribution of any
1919 prescription drug other than compressed medical gases. The
1920 department shall adopt rules that govern the wholesale
1921 distribution of prescription medical oxygen for emergency use.
1922 With respect to the emergency use of prescription medical oxygen,
1923 those rules may not be inconsistent with rules and regulations of

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1924 federal agencies unless the Legislature specifically directs
1925 otherwise.

1926 (o) Compressed medical gas manufacturer permit.--A
1927 compressed medical gas manufacturer permit is required for any
1928 person that engages in the manufacture of compressed medical
1929 gases or repackages compressed medical gases from one container
1930 to another.

1931 1. A compressed medical gas manufacturer may not
1932 manufacture or possess any prescription drug other than
1933 compressed medical gases.

1934 2. A compressed medical gas manufacturer may engage in
1935 wholesale distribution of compressed medical gases manufactured
1936 at that establishment and must comply with all the provisions of
1937 this part and the rules adopted under this part which apply to a
1938 wholesale distributor.

1939 3. A compressed medical gas manufacturer must comply with
1940 all appropriate state and federal good manufacturing practices.

1941 (p) Over-the-counter drug manufacturer permit.-- An over-
1942 the-counter drug manufacturer permit is required for any person
1943 that engages in the manufacture or repackaging of an over-the-
1944 counter drug.

1945 1. An over-the-counter drug manufacturer may not possess or
1946 purchase prescription drugs.

1947 2. A pharmacy is exempt from obtaining an over-the-counter
1948 drug manufacturer's permit if it is operating in compliance with
1949 pharmacy practice standards as defined in chapter 465 and the
1950 rules adopted under that chapter.

1951 3. An over-the-counter drug manufacturer must comply with
1952 all appropriate state and federal good manufacturing practices.

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1953 (q) Device manufacturer permit.--A device manufacturer
1954 permit is required for any person that engages in the
1955 manufacture, repackaging, or assembly of medical devices for
1956 human use in this state, except that a permit is not required if
1957 the person is engaged only in manufacturing, repackaging, or
1958 assembling a medical device pursuant to a practitioner's order
1959 for a specific patient.

1960 1. A manufacturer or repackager of medical devices in this
1961 state must comply with all appropriate state and federal good
1962 manufacturing practices and quality system rules.

1963 2. The department shall adopt rules related to storage,
1964 handling, and recordkeeping requirements for manufacturers of
1965 medical devices for human use.

1966 (r) Cosmetic manufacturer permit.--A cosmetic manufacturer
1967 permit is required for any person that manufactures or repackages
1968 cosmetics in this state. A person that only labels or changes the
1969 labeling of a cosmetic but does not open the container sealed by
1970 the manufacturer of the product is exempt from obtaining a permit
1971 under this paragraph.

1972 ~~(2) (a) A permit issued pursuant to ss. 499.001-499.081 may~~
1973 ~~be issued only to a natural person who is at least 18 years of~~
1974 ~~age or to an applicant that is not a natural person if each~~
1975 ~~person who, directly or indirectly, manages, controls, or~~
1976 ~~oversees the operation of that applicant is at least 18 years of~~
1977 ~~age.~~

1978 ~~(b) An establishment that is a place of residence may not~~
1979 ~~receive a permit and may not operate under ss. 499.001-499.081.~~

1980 ~~(c) A person that applies for or renews a permit to~~
1981 ~~manufacture or distribute legend drugs may not use a name~~

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1982 ~~identical to the name used by any other establishment or licensed~~
1983 ~~person authorized to purchase prescription drugs in this state,~~
1984 ~~except that a restricted drug distributor permit issued to a~~
1985 ~~health care entity will be issued in the name in which the~~
1986 ~~institutional pharmacy permit is issued and a retail pharmacy~~
1987 ~~drug wholesaler will be issued a permit in the name of its retail~~
1988 ~~pharmacy permit.~~

1989 ~~(d) A permit for a prescription drug manufacturer,~~
1990 ~~prescription drug repackager, prescription drug wholesaler,~~
1991 ~~limited prescription drug veterinary wholesaler, or retail~~
1992 ~~pharmacy wholesaler may not be issued to the address of a health~~
1993 ~~care entity or to a pharmacy licensed under chapter 465, except~~
1994 ~~as provided in this paragraph. The department may issue a~~
1995 ~~prescription drug manufacturer permit to an applicant at the same~~
1996 ~~address as a licensed nuclear pharmacy, which is a health care~~
1997 ~~entity, for the purpose of manufacturing prescription drugs used~~
1998 ~~in positron emission tomography or other radiopharmaceuticals, as~~
1999 ~~listed in a rule adopted by the department pursuant to this~~
2000 ~~paragraph. The purpose of this exemption is to assure~~
2001 ~~availability of state-of-the-art pharmaceuticals that would pose~~
2002 ~~a significant danger to the public health if manufactured at a~~
2003 ~~separate establishment address from the nuclear pharmacy from~~
2004 ~~which the prescription drugs are dispensed. The department may~~
2005 ~~also issue a retail pharmacy wholesaler permit to the address of~~
2006 ~~a community pharmacy licensed under chapter 465 which does not~~
2007 ~~meet the definition of a closed pharmacy in s. 499.003.~~

2008 ~~(e) A county or municipality may not issue an occupational~~
2009 ~~license for any licensing period beginning on or after October 1,~~
2010 ~~2003, for any establishment that requires a permit pursuant to~~

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2011 ~~ss. 499.001-499.081, unless the establishment exhibits a current~~
2012 ~~permit issued by the department for the establishment. Upon~~
2013 ~~presentation of the requisite permit issued by the department, an~~
2014 ~~occupational license may be issued by the municipality or county~~
2015 ~~in which application is made. The department shall furnish to~~
2016 ~~local agencies responsible for issuing occupational licenses a~~
2017 ~~current list of all establishments licensed pursuant to ss.~~
2018 ~~499.001-499.081.~~

2019 ~~(3) Notwithstanding subsection (7), a permitted person in~~
2020 ~~good standing may change the type of permit issued to that person~~
2021 ~~by completing a new application for the requested permit, paying~~
2022 ~~the amount of the difference in the permit fees if the fee for~~
2023 ~~the new permit is more than the fee for the original permit, and~~
2024 ~~meeting the applicable permitting conditions for the new permit~~
2025 ~~type. The new permit expires on the expiration date of the~~
2026 ~~original permit being changed; however, a new permit for a~~
2027 ~~prescription drug wholesaler, an out-of-state prescription drug~~
2028 ~~wholesaler, or a retail pharmacy drug wholesaler shall expire on~~
2029 ~~the expiration date of the original permit or 1 year after the~~
2030 ~~date of issuance of the new permit, whichever is earlier. A~~
2031 ~~refund may not be issued if the fee for the new permit is less~~
2032 ~~than the fee that was paid for the original permit.~~

2033 ~~(4) A written application for a permit or to renew a permit~~
2034 ~~must be filed with the department on forms furnished by the~~
2035 ~~department. The department shall establish, by rule, the form and~~
2036 ~~content of the application to obtain or renew a permit. The~~
2037 ~~applicant must submit to the department with the application a~~
2038 ~~statement that swears or affirms that the information is true and~~
2039 ~~correct.~~

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2040 ~~(5) (a) Except for a permit for a prescription drug~~
2041 ~~wholesaler or an out-of-state prescription drug wholesaler, an~~
2042 ~~application for a permit must include:~~

2043 ~~1. The name, full business address, and telephone number of~~
2044 ~~the applicant;~~

2045 ~~2. All trade or business names used by the applicant;~~

2046 ~~3. The address, telephone numbers, and the names of contact~~
2047 ~~persons for each facility used by the applicant for the storage,~~
2048 ~~handling, and distribution of prescription drugs;~~

2049 ~~4. The type of ownership or operation, such as a~~
2050 ~~partnership, corporation, or sole proprietorship; and~~

2051 ~~5. The names of the owner and the operator of the~~
2052 ~~establishment, including:~~

2053 ~~a. If an individual, the name of the individual;~~

2054 ~~b. If a partnership, the name of each partner and the name~~
2055 ~~of the partnership;~~

2056 ~~c. If a corporation, the name and title of each corporate~~
2057 ~~officer and director, the corporate names, and the name of the~~
2058 ~~state of incorporation;~~

2059 ~~d. If a sole proprietorship, the full name of the sole~~
2060 ~~proprietor and the name of the business entity;~~

2061 ~~e. If a limited liability company, the name of each member,~~
2062 ~~the name of each manager, the name of the limited liability~~
2063 ~~company, and the name of the state in which the limited liability~~
2064 ~~company was organized; and~~

2065 ~~f. Any other relevant information that the department~~
2066 ~~requires.~~

2067 ~~(b) Upon approval of the application by the department and~~
2068 ~~payment of the required fee, the department shall issue a permit~~

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2069 ~~to the applicant, if the applicant meets the requirements of ss.~~
2070 ~~499.001-499.081 and rules adopted under those sections.~~

2071 ~~(c) Any change in information required under paragraph (a)~~
2072 ~~must be submitted to the department before the change occurs.~~

2073 ~~(d) The department shall consider, at a minimum, the~~
2074 ~~following factors in reviewing the qualifications of persons to~~
2075 ~~be permitted under ss. 499.001-499.081:~~

2076 ~~1. The applicant's having been found guilty, regardless of~~
2077 ~~adjudication, in a court of this state or other jurisdiction, of~~
2078 ~~a violation of a law that directly relates to a drug, device, or~~
2079 ~~cosmetic. A plea of nolo contendere constitutes a finding of~~
2080 ~~guilt for purposes of this subparagraph.~~

2081 ~~2. The applicant's having been disciplined by a regulatory~~
2082 ~~agency in any state for any offense that would constitute a~~
2083 ~~violation of ss. 499.001-499.081.~~

2084 ~~3. Any felony conviction of the applicant under a federal,~~
2085 ~~state, or local law;~~

2086 ~~4. The applicant's past experience in manufacturing or~~
2087 ~~distributing drugs, devices, or cosmetics;~~

2088 ~~5. The furnishing by the applicant of false or fraudulent~~
2089 ~~material in any application made in connection with manufacturing~~
2090 ~~or distributing drugs, devices, or cosmetics;~~

2091 ~~6. Suspension or revocation by a federal, state, or local~~
2092 ~~government of any permit currently or previously held by the~~
2093 ~~applicant for the manufacture or distribution of any drugs,~~
2094 ~~devices, or cosmetics;~~

2095 ~~7. Compliance with permitting requirements under any~~
2096 ~~previously granted permits;~~

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2097 ~~8. Compliance with requirements to maintain or make~~
2098 ~~available to the state permitting authority or to federal, state,~~
2099 ~~or local law enforcement officials those records required under~~
2100 ~~this section; and~~

2101 ~~9. Any other factors or qualifications the department~~
2102 ~~considers relevant to and consistent with the public health and~~
2103 ~~safety.~~

2104 ~~(6) Except for permits for prescription drug wholesalers or~~
2105 ~~out-of-state prescription drug wholesalers:~~

2106 ~~(a) The department shall adopt rules for the biennial~~
2107 ~~renewal of permits.~~

2108 ~~(b) The department shall renew a permit upon receipt of the~~
2109 ~~renewal application and renewal fee if the applicant meets the~~
2110 ~~requirements established under ss. 499.001-499.081 and the rules~~
2111 ~~adopted under those sections.~~

2112 ~~(c) A permit, unless sooner suspended or revoked,~~
2113 ~~automatically expires 2 years after the last day of the~~
2114 ~~anniversary month in which the permit was originally issued. A~~
2115 ~~permit issued under ss. 499.001-499.081 may be renewed by making~~
2116 ~~application for renewal on forms furnished by the department and~~
2117 ~~paying the appropriate fees. If a renewal application and fee are~~
2118 ~~submitted and postmarked after the expiration date of the permit,~~
2119 ~~the permit may be renewed only upon payment of a late renewal~~
2120 ~~delinquent fee of \$100, plus the required renewal fee, not later~~
2121 ~~than 60 days after the expiration date.~~

2122 ~~(d) Failure to renew a permit in accordance with this~~
2123 ~~section precludes any future renewal of that permit. If a permit~~
2124 ~~issued pursuant to this section has expired and cannot be~~
2125 ~~renewed, before an establishment may engage in activities that~~

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2126 ~~require a permit under ss. 499.001-499.081, the establishment~~
2127 ~~must submit an application for a new permit, pay the applicable~~
2128 ~~application fee, the initial permit fee, and all applicable~~
2129 ~~penalties, and be issued a new permit by the department.~~

2130 ~~(7) A permit issued by the department is nontransferable.~~
2131 ~~Each permit is valid only for the person or governmental unit to~~
2132 ~~which it is issued and is not subject to sale, assignment, or~~
2133 ~~other transfer, voluntarily or involuntarily; nor is a permit~~
2134 ~~valid for any establishment other than the establishment for~~
2135 ~~which it was originally issued.~~

2136 ~~(a) A person permitted under ss. 499.001-499.081 must~~
2137 ~~notify the department before making a change of address. The~~
2138 ~~department shall set a change of location fee not to exceed \$100.~~

2139 ~~(b)1. An application for a new permit is required when a~~
2140 ~~majority of the ownership or controlling interest of a permitted~~
2141 ~~establishment is transferred or assigned or when a lessee agrees~~
2142 ~~to undertake or provide services to the extent that legal~~
2143 ~~liability for operation of the establishment will rest with the~~
2144 ~~lessee. The application for the new permit must be made before~~
2145 ~~the date of the sale, transfer, assignment, or lease.~~

2146 ~~2. A permittee that is authorized to distribute legend~~
2147 ~~drugs may transfer such drugs to the new owner or lessee under~~
2148 ~~subparagraph 1. only after the new owner or lessee has been~~
2149 ~~approved for a permit to distribute legend drugs.~~

2150 ~~(c) If an establishment permitted under ss. 499.001-499.081~~
2151 ~~closes, the owner must notify the department in writing before~~
2152 ~~the effective date of closure and must:~~

2153 ~~1. Return the permit to the department;~~

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2154 ~~2. If the permittee is authorized to distribute legend~~
2155 ~~drugs, indicate the disposition of such drugs, including the~~
2156 ~~name, address, and inventory, and provide the name and address of~~
2157 ~~a person to contact regarding access to records that are required~~
2158 ~~to be maintained under ss. 499.001-499.081. Transfer of ownership~~
2159 ~~of legend drugs may be made only to persons authorized to possess~~
2160 ~~legend drugs under ss. 499.001-499.081.~~

2161
2162 ~~The department may revoke the permit of any person that fails to~~
2163 ~~comply with the requirements of this subsection.~~

2164 ~~(8) A permit must be posted in a conspicuous place on the~~
2165 ~~licensed premises.~~

2166 Section 19. Section 499.012, Florida Statutes, is amended
2167 to read:

2168 499.012 Permit application ~~Wholesale distribution;~~
2169 ~~definitions; permits; applications; general requirements.--~~

2170 (1) (a) A permit issued pursuant to this part may be issued
2171 only to a natural person who is at least 18 years of age or to an
2172 applicant that is not a natural person if each person who,
2173 directly or indirectly, manages, controls, or oversees the
2174 operation of that applicant is at least 18 years of age.

2175 (b) An establishment that is a place of residence may not
2176 receive a permit and may not operate under this part.

2177 (c) A person that applies for or renews a permit to
2178 manufacture or distribute prescription drugs may not use a name
2179 identical to the name used by any other establishment or licensed
2180 person authorized to purchase prescription drugs in this state,
2181 except that a restricted drug distributor permit issued to a
2182 health care entity will be issued in the name in which the

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2183 institutional pharmacy permit is issued and a retail pharmacy
2184 drug wholesale distributor will be issued a permit in the name of
2185 its retail pharmacy permit.

2186 (d) A permit for a prescription drug manufacturer,
2187 prescription drug repackager, prescription drug wholesale
2188 distributor, limited prescription drug veterinary wholesale
2189 distributor, or retail pharmacy wholesale distributor may not be
2190 issued to the address of a health care entity or to a pharmacy
2191 licensed under chapter 465, except as provided in this paragraph.
2192 The department may issue a prescription drug manufacturer permit
2193 to an applicant at the same address as a licensed nuclear
2194 pharmacy, which is a health care entity, for the purpose of
2195 manufacturing prescription drugs used in positron emission
2196 tomography or other radiopharmaceuticals, as listed in a rule
2197 adopted by the department pursuant to this paragraph. The purpose
2198 of this exemption is to assure availability of state-of-the-art
2199 pharmaceuticals that would pose a significant danger to the
2200 public health if manufactured at a separate establishment address
2201 from the nuclear pharmacy from which the prescription drugs are
2202 dispensed. The department may also issue a retail pharmacy
2203 wholesale distributor permit to the address of a community
2204 pharmacy licensed under chapter 465 which does not meet the
2205 definition of a closed pharmacy in s. 499.003.

2206 (e) A county or municipality may not issue an occupational
2207 license for any licensing period beginning on or after October 1,
2208 2003, for any establishment that requires a permit pursuant to
2209 this part unless the establishment exhibits a current permit
2210 issued by the department for the establishment. Upon presentation
2211 of the requisite permit issued by the department, an occupational

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2212 license may be issued by the municipality or county in which
2213 application is made. The department shall furnish to local
2214 agencies responsible for issuing occupational licenses a current
2215 list of all establishments licensed pursuant to this part.

2216 (2) Notwithstanding subsection (6), a permitted person in
2217 good standing may change the type of permit issued to that person
2218 by completing a new application for the requested permit, paying
2219 the amount of the difference in the permit fees if the fee for
2220 the new permit is more than the fee for the original permit, and
2221 meeting the applicable permitting conditions for the new permit
2222 type. The new permit expires on the expiration date of the
2223 original permit being changed; however, a new permit for a
2224 prescription drug wholesale distributor, an out-of-state
2225 prescription drug wholesale distributor, or a retail pharmacy
2226 drug wholesale distributor shall expire on the expiration date of
2227 the original permit or 1 year after the date of issuance of the
2228 new permit, whichever is earlier. A refund may not be issued if
2229 the fee for the new permit is less than the fee that was paid for
2230 the original permit.

2231 (3) A written application for a permit or to renew a permit
2232 must be filed with the department on forms furnished by the
2233 department. The department shall establish, by rule, the form and
2234 content of the application to obtain or renew a permit. The
2235 applicant must submit to the department with the application a
2236 statement that swears or affirms that the information is true and
2237 correct.

2238 (4) (a) Except for a permit for a prescription drug
2239 wholesale distributor or an out-of-state prescription drug
2240 wholesale distributor, an application for a permit must include:

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- 2241 1. The name, full business address, and telephone number of
2242 the applicant;
- 2243 2. All trade or business names used by the applicant;
- 2244 3. The address, telephone numbers, and the names of contact
2245 persons for each facility used by the applicant for the storage,
2246 handling, and distribution of prescription drugs;
- 2247 4. The type of ownership or operation, such as a
2248 partnership, corporation, or sole proprietorship; and
- 2249 5. The names of the owner and the operator of the
2250 establishment, including:
- 2251 a. If an individual, the name of the individual;
- 2252 b. If a partnership, the name of each partner and the name
2253 of the partnership;
- 2254 c. If a corporation, the name and title of each corporate
2255 officer and director, the corporate names, and the name of the
2256 state of incorporation;
- 2257 d. If a sole proprietorship, the full name of the sole
2258 proprietor and the name of the business entity;
- 2259 e. If a limited liability company, the name of each member,
2260 the name of each manager, the name of the limited liability
2261 company, and the name of the state in which the limited liability
2262 company was organized; and
- 2263 f. Any other relevant information that the department
2264 requires.
- 2265 (b) Upon approval of the application by the department and
2266 payment of the required fee, the department shall issue a permit
2267 to the applicant, if the applicant meets the requirements of this
2268 part and rules adopted under this part.
- 2269 (c) Any change in information required under paragraph (a)

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2270 | must be submitted to the department before the change occurs.

2271 | (d) The department shall consider, at a minimum, the
2272 | following factors in reviewing the qualifications of persons to
2273 | be permitted under this part:

2274 | 1. The applicant's having been found guilty, regardless of
2275 | adjudication, in a court of this state or other jurisdiction, of
2276 | a violation of a law that directly relates to a drug, device, or
2277 | cosmetic. A plea of nolo contendere constitutes a finding of
2278 | guilt for purposes of this subparagraph.

2279 | 2. The applicant's having been disciplined by a regulatory
2280 | agency in any state for any offense that would constitute a
2281 | violation of this part.

2282 | 3. Any felony conviction of the applicant under a federal,
2283 | state, or local law;

2284 | 4. The applicant's past experience in manufacturing or
2285 | distributing drugs, devices, or cosmetics;

2286 | 5. The furnishing by the applicant of false or fraudulent
2287 | material in any application made in connection with manufacturing
2288 | or distributing drugs, devices, or cosmetics;

2289 | 6. Suspension or revocation by a federal, state, or local
2290 | government of any permit currently or previously held by the
2291 | applicant for the manufacture or distribution of any drugs,
2292 | devices, or cosmetics;

2293 | 7. Compliance with permitting requirements under any
2294 | previously granted permits;

2295 | 8. Compliance with requirements to maintain or make
2296 | available to the state permitting authority or to federal, state,
2297 | or local law enforcement officials those records required under
2298 | this section; and

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2299 9. Any other factors or qualifications the department
2300 considers relevant to and consistent with the public health and
2301 safety.

2302 (5) Except for a permit for a prescription drug wholesaler
2303 distributor or an out-of-state prescription drug wholesaler
2304 distributor:

2305 (a) The department shall adopt rules for the biennial
2306 renewal of permits.

2307 (b) The department shall renew a permit upon receipt of the
2308 renewal application and renewal fee if the applicant meets the
2309 requirements established under this part and the rules adopted
2310 under this part.

2311 (c) A permit, unless sooner suspended or revoked,
2312 automatically expires 2 years after the last day of the
2313 anniversary month in which the permit was originally issued. A
2314 permit issued under this part may be renewed by making
2315 application for renewal on forms furnished by the department and
2316 paying the appropriate fees. If a renewal application and fee are
2317 submitted and postmarked after the expiration date of the permit,
2318 the permit may be renewed only upon payment of a late renewal
2319 delinquent fee of \$100, plus the required renewal fee, not later
2320 than 60 days after the expiration date.

2321 (d) Failure to renew a permit in accordance with this
2322 section precludes any future renewal of that permit. If a permit
2323 issued pursuant to this section has expired and cannot be
2324 renewed, before an establishment may engage in activities that
2325 require a permit under this part the establishment must submit an
2326 application for a new permit, pay the applicable application fee,

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2327 the initial permit fee, and all applicable penalties, and be
2328 issued a new permit by the department.

2329 (6) A permit issued by the department is nontransferable.
2330 Each permit is valid only for the person or governmental unit to
2331 which it is issued and is not subject to sale, assignment, or
2332 other transfer, voluntarily or involuntarily; nor is a permit
2333 valid for any establishment other than the establishment for
2334 which it was originally issued.

2335 (a) A person permitted under this part must notify the
2336 department before making a change of address. The department
2337 shall set a change of location fee not to exceed \$100.

2338 (b)1. An application for a new permit is required when a
2339 majority of the ownership or controlling interest of a permitted
2340 establishment is transferred or assigned or when a lessee agrees
2341 to undertake or provide services to the extent that legal
2342 liability for operation of the establishment will rest with the
2343 lessee. The application for the new permit must be made before
2344 the date of the sale, transfer, assignment, or lease.

2345 2. A permittee that is authorized to distribute
2346 prescription drugs may transfer such drugs to the new owner or
2347 lessee under subparagraph 1. only after the new owner or lessee
2348 has been approved for a permit to distribute prescription drugs.

2349 (c) If an establishment permitted under this part closes,
2350 the owner must notify the department in writing before the
2351 effective date of closure and must:

2352 1. Return the permit to the department;

2353 2. If the permittee is authorized to distribute
2354 prescription drugs, indicate the disposition of such drugs,
2355 including the name, address, and inventory, and provide the name

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2356 and address of a person to contact regarding access to records
2357 that are required to be maintained under this part. Transfer of
2358 ownership of prescription drugs may be made only to persons
2359 authorized to possess prescription drugs under this part.

2360
2361 The department may revoke the permit of any person that fails to
2362 comply with the requirements of this subsection.

2363 (7) A permit must be posted in a conspicuous place on the
2364 licensed premises.

2365 ~~(1) As used in this section, the term:~~

2366 ~~(a) "Wholesale distribution" means distribution of~~
2367 ~~prescription drugs to persons other than a consumer or patient,~~
2368 ~~but does not include:~~

2369 ~~1. Any of the following activities, which is not a~~
2370 ~~violation of s. 499.005(21) if such activity is conducted in~~
2371 ~~accordance with s. 499.014:~~

2372 ~~a. The purchase or other acquisition by a hospital or other~~
2373 ~~health care entity that is a member of a group purchasing~~
2374 ~~organization of a prescription drug for its own use from the~~
2375 ~~group purchasing organization or from other hospitals or health~~
2376 ~~care entities that are members of that organization.~~

2377 ~~b. The sale, purchase, or trade of a prescription drug or~~
2378 ~~an offer to sell, purchase, or trade a prescription drug by a~~
2379 ~~charitable organization described in s. 501(c)(3) of the Internal~~
2380 ~~Revenue Code of 1986, as amended and revised, to a nonprofit~~
2381 ~~affiliate of the organization to the extent otherwise permitted~~
2382 ~~by law.~~

2383 ~~e. The sale, purchase, or trade of a prescription drug or~~
2384 ~~an offer to sell, purchase, or trade a prescription drug among~~

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2385 ~~hospitals or other health care entities that are under common~~
2386 ~~control. For purposes of this section, "common control" means the~~
2387 ~~power to direct or cause the direction of the management and~~
2388 ~~policies of a person or an organization, whether by ownership of~~
2389 ~~stock, by voting rights, by contract, or otherwise.~~

2390 ~~d. The sale, purchase, trade, or other transfer of a~~
2391 ~~prescription drug from or for any federal, state, or local~~
2392 ~~government agency or any entity eligible to purchase prescription~~
2393 ~~drugs at public health services prices pursuant to Pub. L. No.~~
2394 ~~102-585, s. 602 to a contract provider or its subcontractor for~~
2395 ~~eligible patients of the agency or entity under the following~~
2396 ~~conditions:~~

2397 ~~(I) The agency or entity must obtain written authorization~~
2398 ~~for the sale, purchase, trade, or other transfer of a~~
2399 ~~prescription drug under this sub-subparagraph from the State~~
2400 ~~Surgeon General or his or her designee.~~

2401 ~~(II) The contract provider or subcontractor must be~~
2402 ~~authorized by law to administer or dispense prescription drugs.~~

2403 ~~(III) In the case of a subcontractor, the agency or entity~~
2404 ~~must be a party to and execute the subcontract.~~

2405 ~~(IV) A contract provider or subcontractor must maintain~~
2406 ~~separate and apart from other prescription drug inventory any~~
2407 ~~prescription drugs of the agency or entity in its possession.~~

2408 ~~(V) The contract provider and subcontractor must maintain~~
2409 ~~and produce immediately for inspection all records of movement or~~
2410 ~~transfer of all the prescription drugs belonging to the agency or~~
2411 ~~entity, including, but not limited to, the records of receipt and~~
2412 ~~disposition of prescription drugs. Each contractor and~~
2413 ~~subcontractor dispensing or administering these drugs must~~

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2414 ~~maintain and produce records documenting the dispensing or~~
2415 ~~administration. Records that are required to be maintained~~
2416 ~~include, but are not limited to, a perpetual inventory itemizing~~
2417 ~~drugs received and drugs dispensed by prescription number or~~
2418 ~~administered by patient identifier, which must be submitted to~~
2419 ~~the agency or entity quarterly.~~

2420 ~~(VI) The contract provider or subcontractor may administer~~
2421 ~~or dispense the prescription drugs only to the eligible patients~~
2422 ~~of the agency or entity or must return the prescription drugs for~~
2423 ~~or to the agency or entity. The contract provider or~~
2424 ~~subcontractor must require proof from each person seeking to fill~~
2425 ~~a prescription or obtain treatment that the person is an eligible~~
2426 ~~patient of the agency or entity and must, at a minimum, maintain~~
2427 ~~a copy of this proof as part of the records of the contractor or~~
2428 ~~subcontractor required under sub-sub-subparagraph (V).~~

2429 ~~(VII) In addition to the departmental inspection authority~~
2430 ~~set forth in s. 499.051, the establishment of the contract~~
2431 ~~provider and subcontractor and all records pertaining to~~
2432 ~~prescription drugs subject to this sub-subparagraph shall be~~
2433 ~~subject to inspection by the agency or entity. All records~~
2434 ~~relating to prescription drugs of a manufacturer under this sub-~~
2435 ~~subparagraph shall be subject to audit by the manufacturer of~~
2436 ~~those drugs, without identifying individual patient information.~~

2437 ~~2. Any of the following activities, which is not a~~
2438 ~~violation of s. 499.005(21) if such activity is conducted in~~
2439 ~~accordance with rules established by the department:~~

2440 ~~a. The sale, purchase, or trade of a prescription drug~~
2441 ~~among federal, state, or local government health care entities~~

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2442 ~~that are under common control and are authorized to purchase such~~
2443 ~~prescription drug.~~

2444 ~~b. The sale, purchase, or trade of a prescription drug or~~
2445 ~~an offer to sell, purchase, or trade a prescription drug for~~
2446 ~~emergency medical reasons. For purposes of this sub-subparagraph,~~
2447 ~~the term "emergency medical reasons" includes transfers of~~
2448 ~~prescription drugs by a retail pharmacy to another retail~~
2449 ~~pharmacy to alleviate a temporary shortage.~~

2450 ~~e. The transfer of a prescription drug acquired by a~~
2451 ~~medical director on behalf of a licensed emergency medical~~
2452 ~~services provider to that emergency medical services provider and~~
2453 ~~its transport vehicles for use in accordance with the provider's~~
2454 ~~license under chapter 401.~~

2455 ~~d. The revocation of a sale or the return of a prescription~~
2456 ~~drug to the person's prescription drug wholesale supplier.~~

2457 ~~e. The donation of a prescription drug by a health care~~
2458 ~~entity to a charitable organization that has been granted an~~
2459 ~~exemption under s. 501(c)(3) of the Internal Revenue Code of~~
2460 ~~1986, as amended, and that is authorized to possess prescription~~
2461 ~~drugs.~~

2462 ~~f. The transfer of a prescription drug by a person~~
2463 ~~authorized to purchase or receive prescription drugs to a person~~
2464 ~~licensed or permitted to handle reverse distributions or~~
2465 ~~destruction under the laws of the jurisdiction in which the~~
2466 ~~person handling the reverse distribution or destruction receives~~
2467 ~~the drug.~~

2468 ~~g. The transfer of a prescription drug by a hospital or~~
2469 ~~other health care entity to a person licensed under this chapter~~
2470 ~~to repackage prescription drugs for the purpose of repackaging~~

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2471 ~~the prescription drug for use by that hospital, or other health~~
2472 ~~care entity and other health care entities that are under common~~
2473 ~~control, if ownership of the prescription drugs remains with the~~
2474 ~~hospital or other health care entity at all times. In addition to~~
2475 ~~the recordkeeping requirements of s. 499.0121(6), the hospital or~~
2476 ~~health care entity that transfers prescription drugs pursuant to~~
2477 ~~this sub-subparagraph must reconcile all drugs transferred and~~
2478 ~~returned and resolve any discrepancies in a timely manner.~~

2479 ~~3. The distribution of prescription drug samples by~~
2480 ~~manufacturers' representatives or distributors' representatives~~
2481 ~~conducted in accordance with s. 499.028.~~

2482 ~~4. The sale, purchase, or trade of blood and blood~~
2483 ~~components intended for transfusion. As used in this~~
2484 ~~subparagraph, the term "blood" means whole blood collected from a~~
2485 ~~single donor and processed either for transfusion or further~~
2486 ~~manufacturing, and the term "blood components" means that part of~~
2487 ~~the blood separated by physical or mechanical means.~~

2488 ~~5. The lawful dispensing of a prescription drug in~~
2489 ~~accordance with chapter 465.~~

2490 ~~6. The sale, purchase, or trade of a prescription drug~~
2491 ~~between pharmacies as a result of a sale, transfer, merger, or~~
2492 ~~consolidation of all or part of the business of the pharmacies~~
2493 ~~from or with another pharmacy, whether accomplished as a purchase~~
2494 ~~and sale of stock or of business assets.~~

2495 ~~(b) "Wholesale distributor" means any person engaged in~~
2496 ~~wholesale distribution of prescription drugs in or into this~~
2497 ~~state, including, but not limited to, manufacturers; repackagers;~~
2498 ~~own-label distributors; jobbers; private-label distributors;~~
2499 ~~brokers; warehouses, including manufacturers' and distributors'~~

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2500 ~~warehouses, chain drug warehouses, and wholesale drug warehouses;~~
2501 ~~independent wholesale drug traders; exporters; retail pharmacies;~~
2502 ~~and the agents thereof that conduct wholesale distributions.~~

2503 ~~(c) "Retail pharmacy" means a community pharmacy licensed~~
2504 ~~under chapter 465 that purchases prescription drugs at fair~~
2505 ~~market prices and provides prescription services to the public.~~

2506 ~~(d) "Primary wholesaler" means any wholesale distributor~~
2507 ~~that:~~

2508 ~~1. Purchased 90 percent or more of the total dollar volume~~
2509 ~~of its purchases of prescription drugs directly from~~
2510 ~~manufacturers in the previous year; and~~

2511 ~~2.a. Directly purchased prescription drugs from not fewer~~
2512 ~~than 50 different prescription drug manufacturers in the previous~~
2513 ~~year; or~~

2514 ~~b. Has, or the affiliated group, as defined in s. 1504 of~~
2515 ~~the Internal Revenue Code, of which the wholesale distributor is~~
2516 ~~a member has, not fewer than 250 employees.~~

2517 ~~(e) "Directly from a manufacturer" means:~~

2518 ~~1. Purchases made by the wholesale distributor directly~~
2519 ~~from the manufacturer of prescription drugs; and~~

2520 ~~2. Transfers from a member of an affiliated group, as~~
2521 ~~defined in s. 1504 of the Internal Revenue Code, of which the~~
2522 ~~wholesale distributor is a member, if:~~

2523 ~~a. The affiliated group purchases 90 percent or more of the~~
2524 ~~total dollar volume of its purchases of prescription drugs from~~
2525 ~~the manufacturer in the previous year; and~~

2526 ~~b. The wholesale distributor discloses to the department~~
2527 ~~the names of all members of the affiliated group of which the~~
2528 ~~wholesale distributor is a member and the affiliated group agrees~~

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2529 ~~in writing to provide records on prescription drug purchases by~~
2530 ~~the members of the affiliated group not later than 48 hours after~~
2531 ~~the department requests access to such records, regardless of the~~
2532 ~~location where the records are stored.~~

2533 ~~(f) "Secondary wholesaler" means a wholesale distributor~~
2534 ~~that is not a primary wholesaler.~~

2535 ~~(2) The following types of wholesaler permits are~~
2536 ~~established:~~

2537 ~~(a) A prescription drug wholesaler's permit. A~~
2538 ~~prescription drug wholesaler is a wholesale distributor that may~~
2539 ~~engage in the wholesale distribution of prescription drugs. A~~
2540 ~~prescription drug wholesaler that applies to the department for a~~
2541 ~~new permit or the renewal of a permit must submit a bond of~~
2542 ~~\$100,000, or other equivalent means of security acceptable to the~~
2543 ~~department, such as an irrevocable letter of credit or a deposit~~
2544 ~~in a trust account or financial institution, payable to the~~
2545 ~~Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the~~
2546 ~~bond is to secure payment of any administrative penalties imposed~~
2547 ~~by the department and any fees and costs incurred by the~~
2548 ~~department regarding that permit which are authorized under state~~
2549 ~~law and which the permittee fails to pay 30 days after the fine~~
2550 ~~or costs become final. The department may make a claim against~~
2551 ~~such bond or security until 1 year after the permittee's license~~
2552 ~~ceases to be valid or until 60 days after any administrative or~~
2553 ~~legal proceeding authorized in ss. 499.001-499.081 which involves~~
2554 ~~the permittee is concluded, including any appeal, whichever~~
2555 ~~occurs later. The department may adopt rules for issuing a~~
2556 ~~prescription drug wholesaler broker permit to a person who~~

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2557 ~~engages in the wholesale distribution of prescription drugs and~~
2558 ~~does not take physical possession of any prescription drugs.~~

2559 ~~(b) A compressed medical gas wholesaler's permit. A~~
2560 ~~compressed medical gas wholesaler is a wholesale distributor that~~
2561 ~~is limited to the wholesale distribution of compressed medical~~
2562 ~~gases to other than the consumer or patient. The compressed~~
2563 ~~medical gas must be in the original sealed container that was~~
2564 ~~purchased by that wholesaler. A compressed medical gas wholesaler~~
2565 ~~may not possess or engage in the wholesale distribution of any~~
2566 ~~prescription drug other than compressed medical gases. The~~
2567 ~~department shall adopt rules that govern the wholesale~~
2568 ~~distribution of prescription medical oxygen for emergency use.~~
2569 ~~With respect to the emergency use of prescription medical oxygen,~~
2570 ~~those rules may not be inconsistent with rules and regulations of~~
2571 ~~federal agencies unless the Legislature specifically directs~~
2572 ~~otherwise.~~

2573 ~~(c) An out-of-state prescription drug wholesaler's~~
2574 ~~permit. An out-of-state prescription drug wholesaler is a~~
2575 ~~wholesale distributor located outside this state which engages in~~
2576 ~~the wholesale distribution of prescription drugs into this state~~
2577 ~~and which must be permitted by the department and comply with all~~
2578 ~~the provisions required of a wholesale distributor under ss.~~
2579 ~~499.001-499.081. An out-of-state prescription drug wholesaler~~
2580 ~~that applies to the department for a new permit or the renewal of~~
2581 ~~a permit must submit a bond of \$100,000, or other equivalent~~
2582 ~~means of security acceptable to the department, such as an~~
2583 ~~irrevocable letter of credit or a deposit in a trust account or~~
2584 ~~financial institution, payable to the Florida Drug, Device, and~~
2585 ~~Cosmetic Trust Fund. The purpose of the bond is to secure payment~~

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2586 ~~of any administrative penalties imposed by the department and any~~
2587 ~~fees and costs incurred by the department regarding that permit~~
2588 ~~which are authorized under state law and which the permittee~~
2589 ~~fails to pay 30 days after the fine or costs become final. The~~
2590 ~~department may make a claim against such bond or security until 1~~
2591 ~~year after the permittee's license ceases to be valid or until 60~~
2592 ~~days after any administrative or legal proceeding authorized in~~
2593 ~~ss. 499.001-499.081 which involves the permittee is concluded,~~
2594 ~~including any appeal, whichever occurs later.~~

2595 ~~1. The out-of-state drug wholesaler must maintain at all~~
2596 ~~times a license or permit to engage in the wholesale distribution~~
2597 ~~of prescription drugs in compliance with laws of the state in~~
2598 ~~which it is a resident.~~

2599 ~~2. An out-of-state prescription drug wholesaler's permit is~~
2600 ~~not required for an intracompany sale or transfer of a~~
2601 ~~prescription drug from an out-of-state establishment that is duly~~
2602 ~~licensed as a prescription drug wholesaler, in its state of~~
2603 ~~residence, to a licensed prescription drug wholesaler in this~~
2604 ~~state, if both wholesalers conduct wholesale distributions of~~
2605 ~~prescription drugs under the same business name. The~~
2606 ~~recordkeeping requirements of s. 499.0121(6) must be followed for~~
2607 ~~this transaction.~~

2608 ~~(d) A retail pharmacy wholesaler's permit.--A retail~~
2609 ~~pharmacy wholesaler is a retail pharmacy engaged in wholesale~~
2610 ~~distribution of prescription drugs within this state under the~~
2611 ~~following conditions:~~

2612 ~~1. The pharmacy must obtain a retail pharmacy wholesaler's~~
2613 ~~permit pursuant to ss. 499.001-499.081 and the rules adopted~~
2614 ~~under those sections.~~

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2615 2. ~~The wholesale distribution activity does not exceed 30~~
2616 ~~percent of the total annual purchases of prescription drugs. If~~
2617 ~~the wholesale distribution activity exceeds the 30 percent~~
2618 ~~maximum, the pharmacy must obtain a prescription drug~~
2619 ~~wholesaler's permit.~~

2620 3. ~~The transfer of prescription drugs that appear in any~~
2621 ~~schedule contained in chapter 893 is subject to chapter 893 and~~
2622 ~~the federal Comprehensive Drug Abuse Prevention and Control Act~~
2623 ~~of 1970.~~

2624 4. ~~The transfer is between a retail pharmacy and another~~
2625 ~~retail pharmacy, or a Modified Class II institutional pharmacy,~~
2626 ~~or a health care practitioner licensed in this state and~~
2627 ~~authorized by law to dispense or prescribe prescription drugs.~~

2628 5. ~~All records of sales of prescription drugs subject to~~
2629 ~~this section must be maintained separate and distinct from other~~
2630 ~~records and comply with the recordkeeping requirements of ss.~~
2631 ~~499.001-499.081.~~

2632 (c) ~~Nonresident prescription drug manufacturer permit. A~~
2633 ~~nonresident prescription drug manufacturer permit is required for~~
2634 ~~any person that is a manufacturer of prescription drugs, or the~~
2635 ~~distribution point for a manufacturer of prescription drugs, and~~
2636 ~~located outside of this state, or that is an entity to whom an~~
2637 ~~approved new drug application has been issued by the United~~
2638 ~~States Food and Drug Administration, or the contracted~~
2639 ~~manufacturer of the approved new drug application holder, and~~
2640 ~~located outside the United States, which engages in the wholesale~~
2641 ~~distribution in this state of the prescription drugs it~~
2642 ~~manufactures or is responsible for manufacturing. Each such~~
2643 ~~manufacturer or entity must be permitted by the department and~~

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2644 ~~comply with all the provisions required of a wholesale~~
2645 ~~distributor under ss. 499.001-499.081, except s. 499.0121(6)(d).~~

2646 ~~1. A person that distributes prescription drugs that it did~~
2647 ~~not manufacture must also obtain an out-of-state prescription~~
2648 ~~drug wholesaler permit pursuant to this section to engage in the~~
2649 ~~wholesale distribution of the prescription drugs manufactured by~~
2650 ~~another person and comply with the requirements of an out-of-~~
2651 ~~state prescription drug wholesaler.~~

2652 ~~2. Any such person must comply with the licensing or~~
2653 ~~permitting requirements of the jurisdiction in which the~~
2654 ~~establishment is located and the federal act, and any product~~
2655 ~~wholesaled into this state must comply with ss. 499.001-499.081.~~
2656 ~~If a person intends to import prescription drugs from a foreign~~
2657 ~~country into this state, the nonresident prescription drug~~
2658 ~~manufacturer must provide to the department a list identifying~~
2659 ~~each prescription drug it intends to import and document approval~~
2660 ~~by the United States Food and Drug Administration for such~~
2661 ~~importation.~~

2662 ~~(f) Freight forwarder permit.--A freight forwarder permit~~
2663 ~~is required for any person that engages in the distribution of a~~
2664 ~~legend drug as a freight forwarder unless the person is a common~~
2665 ~~carrier. The storage, handling, and recordkeeping of such~~
2666 ~~distributions must comply with the requirements for wholesale~~
2667 ~~distributors under s. 499.0121, except those set forth in s.~~
2668 ~~499.0121(6)(d). A freight forwarder must provide the source of~~
2669 ~~the legend drugs with a validated airway bill, bill of lading, or~~
2670 ~~other appropriate documentation to evidence the exportation of~~
2671 ~~the product.~~

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2672 ~~(g) A veterinary prescription drug wholesaler permit. A~~
2673 ~~veterinary prescription drug wholesaler permit is required for~~
2674 ~~any person that engages in the distribution of veterinary~~
2675 ~~prescription drugs in or into this state. A veterinary~~
2676 ~~prescription drug wholesaler that also distributes prescription~~
2677 ~~drugs subject to, defined by, or described by s. 503(b) of the~~
2678 ~~Federal Food, Drug, and Cosmetic Act which it did not manufacture~~
2679 ~~must obtain a permit as a prescription drug wholesaler, an out-~~
2680 ~~of-state prescription drug wholesaler, or a limited prescription~~
2681 ~~drug veterinary wholesaler in lieu of the veterinary prescription~~
2682 ~~drug wholesaler permit. A veterinary prescription drug wholesaler~~
2683 ~~must comply with the requirements for wholesale distributors~~
2684 ~~under s. 499.0121, except those set forth in s. 499.0121(6)(d).~~

2685 ~~(h) Limited prescription drug veterinary wholesaler~~
2686 ~~permit. Unless engaging in the activities of and permitted as a~~
2687 ~~prescription drug manufacturer, nonresident prescription drug~~
2688 ~~manufacturer, prescription drug wholesaler, or out-of-state~~
2689 ~~prescription drug wholesaler, a limited prescription drug~~
2690 ~~veterinary wholesaler permit is required for any person that~~
2691 ~~engages in the distribution in or into this state of veterinary~~
2692 ~~prescription drugs and prescription drugs subject to, defined by,~~
2693 ~~or described by s. 503(b) of the Federal Food, Drug, and Cosmetic~~
2694 ~~Act under the following conditions:~~

2695 ~~1. The person is engaged in the business of wholesaling~~
2696 ~~prescription and veterinary legend drugs to persons:~~

2697 ~~a. Licensed as veterinarians practicing on a full-time~~
2698 ~~basis;~~

2699 ~~b. Regularly and lawfully engaged in instruction in~~
2700 ~~veterinary medicine;~~

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2701 ~~e. Regularly and lawfully engaged in law enforcement~~
2702 ~~activities;~~

2703 ~~d. For use in research not involving clinical use; or~~
2704 ~~e. For use in chemical analysis or physical testing or for~~
2705 ~~purposes of instruction in law enforcement activities, research,~~
2706 ~~or testing.~~

2707 ~~2. No more than 30 percent of total annual prescription~~
2708 ~~drug sales may be prescription drugs approved for human use which~~
2709 ~~are subject to, defined by, or described by s. 503(b) of the~~
2710 ~~Federal Food, Drug, and Cosmetic Act.~~

2711 ~~3. The person is not permitted, licensed, or otherwise~~
2712 ~~authorized in any state to wholesale prescription drugs subject~~
2713 ~~to, defined by, or described by s. 503(b) of the Federal Food,~~
2714 ~~Drug, and Cosmetic Act to any person who is authorized to sell,~~
2715 ~~distribute, purchase, trade, or use these drugs on or for humans.~~

2716 ~~4. A limited prescription drug veterinary wholesaler that~~
2717 ~~applies to the department for a new permit or the renewal of a~~
2718 ~~permit must submit a bond of \$20,000, or other equivalent means~~
2719 ~~of security acceptable to the department, such as an irrevocable~~
2720 ~~letter of credit or a deposit in a trust account or financial~~
2721 ~~institution, payable to the Florida Drug, Device, and Cosmetic~~
2722 ~~Trust Fund. The purpose of the bond is to secure payment of any~~
2723 ~~administrative penalties imposed by the department and any fees~~
2724 ~~and costs incurred by the department regarding that permit which~~
2725 ~~are authorized under state law and which the permittee fails to~~
2726 ~~pay 30 days after the fine or costs become final. The department~~
2727 ~~may make a claim against such bond or security until 1 year after~~
2728 ~~the permittee's license ceases to be valid or until 60 days after~~
2729 ~~any administrative or legal proceeding authorized in ss. 499.001-~~

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2730 ~~499.081 which involves the permittee is concluded, including any~~
2731 ~~appeal, whichever occurs later.~~

2732 ~~5. A limited prescription drug veterinary wholesaler must~~
2733 ~~maintain at all times a license or permit to engage in the~~
2734 ~~wholesale distribution of prescription drugs in compliance with~~
2735 ~~laws of the state in which it is a resident.~~

2736 ~~6. A limited prescription drug veterinary wholesaler must~~
2737 ~~comply with the requirements for wholesale distributors under s.~~
2738 ~~499.0121, except that a limited prescription drug veterinary~~
2739 ~~wholesaler is not required to provide a pedigree paper as~~
2740 ~~required by s. 499.0121(6)(d) upon the wholesale distribution of~~
2741 ~~a prescription drug to a veterinarian.~~

2742 ~~7. A limited prescription drug veterinary wholesaler may~~
2743 ~~not return to inventory for subsequent wholesale distribution any~~
2744 ~~prescription drug subject to, defined by, or described by s.~~
2745 ~~503(b) of the Federal Food, Drug, and Cosmetic Act which has been~~
2746 ~~returned by a veterinarian.~~

2747 ~~8. An out-of-state prescription drug wholesaler's permit or~~
2748 ~~a limited prescription drug veterinary wholesaler permit is not~~
2749 ~~required for an intracompany sale or transfer of a prescription~~
2750 ~~drug from an out-of-state establishment that is duly licensed to~~
2751 ~~engage in the wholesale distribution of prescription drugs in its~~
2752 ~~state of residence to a licensed limited prescription drug~~
2753 ~~veterinary wholesaler in this state if both wholesalers conduct~~
2754 ~~wholesale distributions of prescription drugs under the same~~
2755 ~~business name. The recordkeeping requirements of s. 499.0121(6)~~
2756 ~~must be followed for this transaction.~~

2757 ~~(8)(3)~~ An application for a permit or to renew a permit for
2758 a prescription drug wholesale distributor ~~wholesaler~~ or an out-

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2759 of-state prescription drug wholesale distributor ~~wholesaler~~
2760 submitted to the department must include:

2761 (a) The name, full business address, and telephone number
2762 of the applicant.

2763 (b) All trade or business names used by the applicant.

2764 (c) The address, telephone numbers, and the names of
2765 contact persons for each facility used by the applicant for the
2766 storage, handling, and distribution of prescription drugs.

2767 (d) The type of ownership or operation, such as a
2768 partnership, corporation, or sole proprietorship.

2769 (e) The names of the owner and the operator of the
2770 establishment, including:

2771 1. If an individual, the name of the individual.

2772 2. If a partnership, the name of each partner and the name
2773 of the partnership.

2774 3. If a corporation:

2775 a. The name, address, and title of each corporate officer
2776 and director.

2777 b. The name and address of the corporation, resident agent
2778 of the corporation, the resident agent's address, and the
2779 corporation's state of incorporation.

2780 c. The name and address of each shareholder of the
2781 corporation that owns 5 percent or more of the outstanding stock
2782 of the corporation.

2783 4. If a sole proprietorship, the full name of the sole
2784 proprietor and the name of the business entity.

2785 5. If a limited liability company:

2786 a. The name and address of each member.

2787 b. The name and address of each manager.

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2788 c. The name and address of the limited liability company,
2789 the resident agent of the limited liability company, and the name
2790 of the state in which the limited liability company was
2791 organized.

2792 (f) If applicable, the name and address of each member of
2793 the affiliated group of which the applicant is a member.

2794 (g)1. For an application for a new permit, the estimated
2795 annual dollar volume of prescription drug sales of the applicant,
2796 the estimated annual percentage of the applicant's total company
2797 sales that are prescription drugs, the applicant's estimated
2798 annual total dollar volume of purchases of prescription drugs,
2799 and the applicant's estimated annual total dollar volume of
2800 prescription drug purchases directly from manufacturers.

2801 2. For an application to renew a permit, the total dollar
2802 volume of prescription drug sales in the previous year, the total
2803 dollar volume of prescription drug sales made in the previous 6
2804 months, the percentage of total company sales that were
2805 prescription drugs in the previous year, the total dollar volume
2806 of purchases of prescription drugs in the previous year, and the
2807 total dollar volume of prescription drug purchases directly from
2808 manufacturers in the previous year.

2809
2810 Such portions of the information required pursuant to this
2811 paragraph which are a trade secret, as defined in s. 812.081,
2812 shall be maintained by the department as trade secret information
2813 is required to be maintained under s. 499.051.

2814 (h) The tax year of the applicant.

2815 (i) A copy of the deed for the property on which
2816 applicant's establishment is located, if the establishment is

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2817 | owned by the applicant, or a copy of the applicant's lease for
2818 | the property on which applicant's establishment is located that
2819 | has an original term of not less than 1 calendar year, if the
2820 | establishment is not owned by the applicant.

2821 | (j) A list of all licenses and permits issued to the
2822 | applicant by any other state which authorize the applicant to
2823 | purchase or possess prescription drugs.

2824 | (k) The name of the manager of the establishment that is
2825 | applying for the permit or to renew the permit, the next four
2826 | highest ranking employees responsible for prescription drug
2827 | wholesale operations for the establishment, and the name of all
2828 | affiliated parties for the establishment, together with the
2829 | personal information statement and fingerprints required pursuant
2830 | to subsection (9) ~~(4)~~ for each of such persons.

2831 | (l) The name of each of the applicant's designated
2832 | representatives as required by subsection (16) ~~(11)~~, together
2833 | with the personal information statement and fingerprints required
2834 | pursuant to subsection (9) ~~(4)~~ for each such person.

2835 | (m) For an applicant that is a secondary wholesaler, each
2836 | of the following:

2837 | 1. A personal background information statement containing
2838 | the background information and fingerprints required pursuant to
2839 | subsection (9) ~~(4)~~ for each person named in the applicant's
2840 | response to paragraphs (k) and (l) and for each affiliated party
2841 | of the applicant.

2842 | 2. If any of the five largest shareholders of the
2843 | corporation seeking the permit is a corporation, the name,
2844 | address, and title of each corporate officer and director of each
2845 | such corporation; the name and address of such corporation; the

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2846 name of such corporation's resident agent, such corporation's
2847 resident agent's address, and such corporation's state of its
2848 incorporation; and the name and address of each shareholder of
2849 such corporation that owns 5 percent or more of the stock of such
2850 corporation.

2851 3. The name and address of all financial institutions in
2852 which the applicant has an account which is used to pay for the
2853 operation of the establishment or to pay for drugs purchased for
2854 the establishment, together with the names of all persons that
2855 are authorized signatories on such accounts. The portions of the
2856 information required pursuant to this subparagraph which are a
2857 trade secret, as defined in s. 812.081, shall be maintained by
2858 the department as trade secret information is required to be
2859 maintained under s. 499.051.

2860 4. The sources of all funds and the amounts of such funds
2861 used to purchase or finance purchases of prescription drugs or to
2862 finance the premises on which the establishment is to be located.

2863 5. If any of the funds identified in subparagraph 4. were
2864 borrowed, copies of all promissory notes or loans used to obtain
2865 such funds.

2866 (n) Any other relevant information that the department
2867 requires, including, but not limited to, any information related
2868 to whether the applicant satisfies the definition of a primary
2869 wholesaler or a secondary wholesaler.

2870 (9)~~(4)~~(a) Each person required by subsection (8)~~(3)~~ to
2871 provide a personal information statement and fingerprints shall
2872 provide the following information to the department on forms
2873 prescribed by the department:

2874 1. The person's places of residence for the past 7 years.

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- 2875 2. The person's date and place of birth.
- 2876 3. The person's occupations, positions of employment, and
2877 offices held during the past 7 years.
- 2878 4. The principal business and address of any business,
2879 corporation, or other organization in which each such office of
2880 the person was held or in which each such occupation or position
2881 of employment was carried on.
- 2882 5. Whether the person has been, during the past 7 years,
2883 the subject of any proceeding for the revocation of any license
2884 and, if so, the nature of the proceeding and the disposition of
2885 the proceeding.
- 2886 6. Whether, during the past 7 years, the person has been
2887 enjoined, either temporarily or permanently, by a court of
2888 competent jurisdiction from violating any federal or state law
2889 regulating the possession, control, or distribution of
2890 prescription drugs, together with details concerning any such
2891 event.
- 2892 7. A description of any involvement by the person with any
2893 business, including any investments, other than the ownership of
2894 stock in a publicly traded company or mutual fund, during the
2895 past 7 years, which manufactured, administered, prescribed,
2896 distributed, or stored pharmaceutical products and any lawsuits
2897 in which such businesses were named as a party.
- 2898 8. A description of any felony criminal offense of which
2899 the person, as an adult, was found guilty, regardless of whether
2900 adjudication of guilt was withheld or whether the person pled
2901 guilty or nolo contendere. A criminal offense committed in
2902 another jurisdiction which would have been a felony in this state
2903 must be reported. If the person indicates that a criminal

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2904 conviction is under appeal and submits a copy of the notice of
2905 appeal of that criminal offense, the applicant must, within 15
2906 days after the disposition of the appeal, submit to the
2907 department a copy of the final written order of disposition.

2908 9. A photograph of the person taken in the previous 30
2909 days.

2910 10. A set of fingerprints for the person on a form and
2911 under procedures specified by the department, together with
2912 payment of an amount equal to the costs incurred by the
2913 department for the criminal record check of the person.

2914 11. The name, address, occupation, and date and place of
2915 birth for each member of the person's immediate family who is 18
2916 years of age or older. As used in this subparagraph, the term
2917 "member of the person's immediate family" includes the person's
2918 spouse, children, parents, siblings, the spouses of the person's
2919 children, and the spouses of the person's siblings.

2920 12. Any other relevant information that the department
2921 requires.

2922 (b) The information required pursuant to paragraph (a)
2923 shall be provided under oath.

2924 (c) The department shall submit the fingerprints provided
2925 by a person for initial licensure to the Department of Law
2926 Enforcement for a statewide criminal record check and for
2927 forwarding to the Federal Bureau of Investigation for a national
2928 criminal record check of the person. The department shall submit
2929 the fingerprints provided by a person as a part of a renewal
2930 application to the Department of Law Enforcement for a statewide
2931 criminal record check, and for forwarding to the Federal Bureau
2932 of Investigation for a national criminal record check, for the

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2933 initial renewal of a permit after January 1, 2004; for any
2934 subsequent renewal of a permit, the department shall submit the
2935 required information for a statewide and national criminal record
2936 check of the person. Any person who as a part of an initial
2937 permit application or initial permit renewal after January 1,
2938 2004, submits to the department a set of fingerprints required
2939 for the criminal record check required in this paragraph shall
2940 not be required to provide a subsequent set of fingerprints for a
2941 criminal record check to the department, if the person has
2942 undergone a criminal record check as a condition of the issuance
2943 of an initial permit or the initial renewal of a permit of an
2944 applicant after January 1, 2004.

2945 (10)~~(5)~~ The department may deny an application for a permit
2946 or refuse to renew a permit for a prescription drug wholesale
2947 distributor ~~wholesaler~~ or an out-of-state prescription drug
2948 wholesale distributor ~~wholesaler~~ if:

2949 (a) The applicant has not met the requirements for the
2950 permit.

2951 (b) The management, officers, or directors of the applicant
2952 or any affiliated party are found by the department to be
2953 incompetent or untrustworthy.

2954 (c) The applicant is so lacking in experience in managing a
2955 wholesale distributor as to make the issuance of the proposed
2956 permit hazardous to the public health.

2957 (d) The applicant is so lacking in experience in managing a
2958 wholesale distributor as to jeopardize the reasonable promise of
2959 successful operation of the wholesale distributor.

2960 (e) The applicant is lacking in experience in the
2961 distribution of prescription drugs.

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2962 (f) The applicant's past experience in manufacturing or
2963 distributing prescription drugs indicates that the applicant
2964 poses a public health risk.

2965 (g) The applicant is affiliated directly or indirectly
2966 through ownership, control, or other business relations, with any
2967 person or persons whose business operations are or have been
2968 detrimental to the public health.

2969 (h) The applicant, or any affiliated party, has been found
2970 guilty of or has pleaded guilty or nolo contendere to any felony
2971 or crime punishable by imprisonment for 1 year or more under the
2972 laws of the United States, any state, or any other country,
2973 regardless of whether adjudication of guilt was withheld.

2974 (i) The applicant or any affiliated party has been charged
2975 with a felony in a state or federal court and the disposition of
2976 that charge is pending during the application review or renewal
2977 review period.

2978 (j) The applicant has furnished false or fraudulent
2979 information or material in any application made in this state or
2980 any other state in connection with obtaining a permit or license
2981 to manufacture or distribute drugs, devices, or cosmetics.

2982 (k) That a federal, state, or local government permit
2983 currently or previously held by the applicant, or any affiliated
2984 party, for the manufacture or distribution of any drugs, devices,
2985 or cosmetics has been disciplined, suspended, or revoked and has
2986 not been reinstated.

2987 (l) The applicant does not possess the financial or
2988 physical resources to operate in compliance with the permit being
2989 sought, this chapter, and the rules adopted under this chapter.

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2990 (m) The applicant or any affiliated party receives,
2991 directly or indirectly, financial support and assistance from a
2992 person who was an affiliated party of a permittee whose permit
2993 was subject to discipline or was suspended or revoked, other than
2994 through the ownership of stock in a publicly traded company or a
2995 mutual fund.

2996 (n) The applicant or any affiliated party receives,
2997 directly or indirectly, financial support and assistance from a
2998 person who has been found guilty of any violation of this part
2999 ~~ss. 499.001-499.081~~ or chapter 465, chapter 501, or chapter 893,
3000 any rules adopted under any of this part or those ~~sections or~~
3001 chapters, any federal or state drug law, or any felony where the
3002 underlying facts related to drugs, regardless of whether the
3003 person has been pardoned, had her or his civil rights restored,
3004 or had adjudication withheld, other than through the ownership of
3005 stock in a publicly traded company or a mutual fund.

3006 (o) The applicant for renewal of a permit under s.
3007 499.01(2)(d) ~~paragraph (2)(a)~~ or s. 499.01(2)(e) ~~paragraph (2)(e)~~
3008 has not actively engaged in the wholesale distribution of
3009 prescription drugs, as demonstrated by the regular and systematic
3010 distribution of prescription drugs throughout the year as
3011 evidenced by not fewer than 12 wholesale distributions in the
3012 previous year and not fewer than three wholesale distributions in
3013 the previous 6 months.

3014 (p) Information obtained in response to s. 499.01(2)(d)
3015 ~~paragraph (2)(a)~~ or s. 499.01(2)(e) ~~paragraph (2)(e)~~ demonstrates
3016 it would not be in the best interest of the public health,
3017 safety, and welfare to issue a permit.

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3018 (q) The applicant does not possess the financial standing
3019 and business experience for the successful operation of the
3020 applicant.

3021 (r) The applicant or any affiliated party has failed to
3022 comply with the requirements for manufacturing or distributing
3023 prescription drugs under this part ss. 499.001-499.081, similar
3024 federal laws, similar laws in other states, or the rules adopted
3025 under such laws.

3026 ~~(11)(6)~~ Upon approval of the application by the department
3027 and payment of the required fee, the department shall issue or
3028 renew a prescription drug wholesaler or an out-of-state
3029 prescription drug wholesaler permit to the applicant.

3030 ~~(12)(7)~~ For a permit ~~permits~~ for a prescription drug
3031 wholesale distributor ~~wholesalers~~ or an out-of-state prescription
3032 drug wholesale distributor ~~wholesalers~~:

3033 (a) The department shall adopt rules for the annual renewal
3034 of permits. At least 90 days before the expiration of a permit,
3035 the department shall forward a permit renewal notification and
3036 renewal application to the prescription drug wholesale
3037 distributor ~~wholesaler~~ or out-of-state prescription drug
3038 wholesale distributor ~~wholesaler~~ at the mailing address of the
3039 permitted establishment on file with the department. The permit
3040 renewal notification must state conspicuously the date on which
3041 the permit for the establishment will expire and that the
3042 establishment may not operate unless the permit for the
3043 establishment is renewed timely.

3044 (b) A permit, unless sooner suspended or revoked,
3045 automatically expires 1 year after the last day of the
3046 anniversary month in which the permit was originally issued. A

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3047 permit may be renewed by making application for renewal on forms
3048 furnished by the department and paying the appropriate fees. If a
3049 renewal application and fee are submitted and postmarked after 45
3050 days prior to the expiration date of the permit, the permit may
3051 be renewed only upon payment of a late renewal fee of \$100, plus
3052 the required renewal fee. A permittee that has submitted a
3053 renewal application in accordance with this paragraph may
3054 continue to operate under its permit, unless the permit is
3055 suspended or revoked, until final disposition of the renewal
3056 application.

3057 (c) Failure to renew a permit in accordance with this
3058 section precludes any future renewal of that permit. If a permit
3059 issued pursuant to this section has expired and cannot be
3060 renewed, before an establishment may engage in activities that
3061 require a permit under this part ~~ss. 499.001-499.081~~, the
3062 establishment must submit an application for a new permit; pay
3063 the applicable application fee, initial permit fee, and all
3064 applicable penalties; and be issued a new permit by the
3065 department.

3066 (13) ~~(8)~~ A person that engages in wholesale distribution of
3067 prescription drugs in this state must have a wholesale
3068 distributor's permit issued by the department, except as noted in
3069 this section. Each establishment must be separately permitted
3070 except as noted in this subsection.

3071 (a) A separate establishment permit is not required when a
3072 permitted prescription drug wholesale distributor ~~wholesaler~~
3073 consigns a prescription drug to a pharmacy that is permitted
3074 under chapter 465 and located in this state, provided that:

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3075 1. The consignor wholesale distributor ~~wholesaler~~ notifies
3076 the department in writing of the contract to consign prescription
3077 drugs to a pharmacy along with the identity and location of each
3078 consignee pharmacy;

3079 2. The pharmacy maintains its permit under chapter 465;

3080 3. The consignor wholesale distributor ~~wholesaler~~, which
3081 has no legal authority to dispense prescription drugs, complies
3082 with all wholesale distribution requirements of s. 499.0121 and
3083 s. 499.01213 with respect to the consigned drugs and maintains
3084 records documenting the transfer of title or other completion of
3085 the wholesale distribution of the consigned prescription drugs;

3086 4. The distribution of the prescription drug is otherwise
3087 lawful under this chapter and other applicable law;

3088 5. Open packages containing prescription drugs within a
3089 pharmacy are the responsibility of the pharmacy, regardless of
3090 how the drugs are titled; and

3091 6. The pharmacy dispenses the consigned prescription drug
3092 in accordance with the limitations of its permit under chapter
3093 465 or returns the consigned prescription drug to the consignor
3094 wholesale distributor ~~wholesaler~~. In addition, a person who holds
3095 title to prescription drugs may transfer the drugs to a person
3096 permitted or licensed to handle the reverse distribution or
3097 destruction of drugs. Any other distribution by and means of the
3098 consigned prescription drug by any person, not limited to the
3099 consignor wholesaler or consignee pharmacy, to any other person
3100 is prohibited.

3101 (b) A wholesale distributor's permit is not required for
3102 the one-time transfer of title of a pharmacy's lawfully acquired
3103 prescription drug inventory by a pharmacy with a valid permit

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3104 issued under chapter 465 to a consignor prescription drug
3105 wholesale distributor ~~wholesaler~~, permitted under this chapter,
3106 in accordance with a written consignment agreement between the
3107 pharmacy and that wholesale distributor ~~wholesaler~~ if: the
3108 permitted pharmacy and the permitted prescription drug wholesale
3109 distributor ~~wholesaler~~ comply with all of the provisions of
3110 paragraph (a) and the prescription drugs continue to be within
3111 the permitted pharmacy's inventory for dispensing in accordance
3112 with the limitations of the pharmacy permit under chapter 465. A
3113 consignor drug wholesale distributor ~~wholesaler~~ may not use the
3114 pharmacy as a wholesale distributor through which it distributes
3115 the prescription ~~legend~~ drugs to other pharmacies. Nothing in
3116 this section is intended to prevent a wholesale ~~drug~~ distributor
3117 from obtaining this inventory in the event of nonpayment by the
3118 pharmacy.

3119 (c) The department shall require information from each
3120 wholesale distributor as part of the permit and renewal of such
3121 permit, as required under ~~s. 499.01~~ or this section.

3122 (14)~~(9)~~ Personnel employed in wholesale distribution must
3123 have appropriate education and experience to enable them to
3124 perform their duties in compliance with state permitting
3125 requirements.

3126 (15)~~(10)~~ The name of a permittee or establishment on a
3127 prescription drug wholesale distributor ~~wholesaler~~ permit or an
3128 out-of-state prescription drug wholesale distributor ~~wholesaler~~
3129 permit may not include any indicia of attainment of any
3130 educational degree, any indicia that the permittee or
3131 establishment possesses a professional license, or any name or
3132 abbreviation that the department determines is likely to cause

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3133 confusion or mistake or that the department determines is
3134 deceptive, including that of any other entity authorized to
3135 purchase prescription drugs.

3136 ~~(16)~~~~(11)~~(a) Each establishment that is issued an initial or
3137 renewal permit as a prescription drug wholesale distributor
3138 ~~wholesaler~~ or an out-of-state prescription drug wholesale
3139 distributor ~~wholesaler~~ must designate in writing to the
3140 department at least one natural person to serve as the designated
3141 representative of the wholesale distributor ~~wholesaler~~. Such
3142 person must have an active certification as a designated
3143 representative from the department.

3144 (b) To be certified as a designated representative, a
3145 natural person must:

3146 1. Submit an application on a form furnished by the
3147 department and pay the appropriate fees;

3148 2. Be at least 18 years of age;

3149 3. Have not less than 2 years of verifiable full-time work
3150 experience in a pharmacy licensed in this state or another state,
3151 where the person's responsibilities included, but were not
3152 limited to, recordkeeping for prescription drugs, or have not
3153 less than 2 years of verifiable full-time managerial experience
3154 with a prescription drug wholesale distributor ~~wholesaler~~
3155 licensed in this state or in another state;

3156 4. Receive a passing score of at least 75 percent on an
3157 examination given by the department regarding federal laws
3158 governing distribution of prescription drugs and this part ss.
3159 ~~499.001-499.081~~ and the rules adopted by the department governing
3160 the wholesale distribution of prescription drugs. This
3161 requirement shall be effective 1 year after the results of the

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3162 initial examination are mailed to the persons that took the
3163 examination. The department shall offer such examinations at
3164 least four times each calendar year; and

3165 5. Provide the department with a personal information
3166 statement and fingerprints pursuant to subsection (9) ~~(4)~~.

3167 (c) The department may deny an application for
3168 certification as a designated representative or may suspend or
3169 revoke a certification of a designated representative pursuant to
3170 s. 499.067.

3171 (d) A designated representative:

3172 1. Must be actively involved in and aware of the actual
3173 daily operation of the wholesale distributor.

3174 2. Must be employed full time in a managerial position by
3175 the wholesale distributor.

3176 3. Must be physically present at the establishment during
3177 normal business hours, except for time periods when absent due to
3178 illness, family illness or death, scheduled vacation, or other
3179 authorized absence.

3180 4. May serve as a designated representative for only one
3181 wholesale distributor at any one time.

3182 (e) A wholesale distributor must notify the department when
3183 a designated representative leaves the employ of the wholesale
3184 distributor. Such notice must be provided to the department
3185 within 10 business days after the last day of designated
3186 representative's employment with the wholesale distributor.

3187 (f) A wholesale distributor may not operate under a
3188 prescription drug wholesale distributor ~~wholesaler~~ permit or an
3189 out-of-state prescription drug wholesale distributor ~~wholesaler~~
3190 permit for more than 10 business days after the designated

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3191 representative leaves the employ of the wholesale distributor,
3192 unless the wholesale distributor employs another designated
3193 representative and notifies the department within 10 business
3194 days of the identity of the new designated representative.

3195 ~~(12) The department may adopt rules governing the~~
3196 ~~recordkeeping, storage, and handling with respect to each of the~~
3197 ~~distributions of prescription drugs specified in subparagraphs~~
3198 ~~(1)(a)1.-4.~~

3199 Section 20. Section 499.01201, Florida Statutes, is amended
3200 to read:

3201 499.01201 Agency for Health Care Administration review and
3202 use of statute and rule violation or compliance
3203 data.--Notwithstanding any other provisions of law to the
3204 contrary, the Agency for Health Care Administration may not:

3205 (1) Review or use any violation or alleged violation of s.
3206 499.0121(6) or s. 499.01213, or any rules adopted under those
3207 sections ~~that section~~, as a ground for denying or withholding any
3208 payment of a Medicaid reimbursement to a pharmacy licensed under
3209 chapter 465; or

3210 (2) Review or use compliance with s. 499.0121(6) or s.
3211 499.01213, or any rules adopted under those sections ~~that~~
3212 ~~section~~, as the subject of any audit of Medicaid-related records
3213 held by a pharmacy licensed under chapter 465.

3214 Section 21. Section 499.0121, Florida Statutes, is amended
3215 to read:

3216 499.0121 Storage and handling of prescription drugs;
3217 recordkeeping.--The department shall adopt rules to implement
3218 this section as necessary to protect the public health, safety,
3219 and welfare. Such rules shall include, but not be limited to,

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3220 requirements for the storage and handling of prescription drugs
3221 and for the establishment and maintenance of prescription drug
3222 distribution records.

3223 (1) ESTABLISHMENTS.--An establishment at which prescription
3224 drugs are stored, warehoused, handled, held, offered, marketed,
3225 or displayed must:

3226 (a) Be of suitable size and construction to facilitate
3227 cleaning, maintenance, and proper operations;

3228 (b) Have storage areas designed to provide adequate
3229 lighting, ventilation, temperature, sanitation, humidity, space,
3230 equipment, and security conditions;

3231 (c) Have a quarantine area for storage of prescription
3232 drugs that are outdated, damaged, deteriorated, misbranded, or
3233 adulterated, or that are in immediate or sealed, secondary
3234 containers that have been opened;

3235 (d) Be maintained in a clean and orderly condition; and

3236 (e) Be free from infestation by insects, rodents, birds, or
3237 vermin of any kind.

3238 (2) SECURITY.--

3239 (a) An establishment that is used for wholesale drug
3240 distribution must be secure from unauthorized entry.

3241 1. Access from outside the premises must be kept to a
3242 minimum and be well-controlled.

3243 2. The outside perimeter of the premises must be well-
3244 lighted.

3245 3. Entry into areas where prescription drugs are held must
3246 be limited to authorized personnel.

3247 (b) An establishment that is used for wholesale drug
3248 distribution must be equipped with:

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3249 1. An alarm system to detect entry after hours; however,
3250 the department may exempt by rule establishments that only hold a
3251 permit as prescription drug wholesaler distributor-brokers
3252 ~~wholesaler-brokers~~ and establishments that only handle medical
3253 oxygen; and

3254 2. A security system that will provide suitable protection
3255 against theft and diversion. When appropriate, the security
3256 system must provide protection against theft or diversion that is
3257 facilitated or hidden by tampering with computers or electronic
3258 records.

3259 (c) Any vehicle that contains prescription drugs must be
3260 secure from unauthorized access to the prescription drugs in the
3261 vehicle.

3262 (3) STORAGE.--All prescription drugs shall be stored at
3263 appropriate temperatures and under appropriate conditions in
3264 accordance with requirements, if any, in the labeling of such
3265 drugs, or with requirements in the official compendium.

3266 (a) If no storage requirements are established for a
3267 prescription drug, the drug may be held at "controlled" room
3268 temperature, as defined in the official compendium, to help
3269 ensure that its identity, strength, quality, and purity are not
3270 adversely affected.

3271 (b) Appropriate manual, electromechanical, or electronic
3272 temperature and humidity recording equipment, devices, or logs
3273 must be used to document proper storage of prescription drugs.

3274 (c) The recordkeeping requirements in subsection (6) must
3275 be followed for all stored prescription drugs.

3276 (4) EXAMINATION OF MATERIALS AND RECORDS.--

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3277 (a) Upon receipt, each outside shipping container must be
3278 visually examined for identity and to prevent the acceptance of
3279 contaminated prescription drugs that are otherwise unfit for
3280 distribution. This examination must be adequate to reveal
3281 container damage that would suggest possible contamination or
3282 other damage to the contents.

3283 (b) Each outgoing shipment must be carefully inspected for
3284 identity of the prescription drug products and to ensure that
3285 there is no delivery of prescription drugs that have expired or
3286 been damaged in storage or held under improper conditions.

3287 (c) The recordkeeping requirements in subsection (6) must
3288 be followed for all incoming and outgoing prescription drugs.

3289 (d) Upon receipt, a wholesale distributor ~~wholesaler~~ must
3290 review records required under this section for the acquisition of
3291 prescription drugs for accuracy and completeness, considering the
3292 total facts and circumstances surrounding the transactions and
3293 the wholesale distributors involved. This includes authenticating
3294 each transaction listed on a pedigree paper, as defined in s.
3295 499.003(41) ~~s. 499.001(31)~~.

3296 (5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.--

3297 (a)1. Prescription drugs that are outdated, damaged,
3298 deteriorated, misbranded, or adulterated must be quarantined and
3299 physically separated from other prescription drugs until they are
3300 destroyed or returned to their supplier. A quarantine section
3301 must be separate and apart from other sections where prescription
3302 drugs are stored so that prescription drugs in this section are
3303 not confused with usable prescription drugs.

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3304 2. Prescription drugs must be examined at least every 12
3305 months, and drugs for which the expiration date has passed must
3306 be removed and quarantined.

3307 (b) Any prescription drugs of which the immediate or sealed
3308 outer containers or sealed secondary containers have been opened
3309 or used must be identified as such and must be quarantined and
3310 physically separated from other prescription drugs until they are
3311 either destroyed or returned to the supplier.

3312 (c) If the conditions under which a prescription drug has
3313 been returned cast doubt on the drug's safety, identity,
3314 strength, quality, or purity, the drug must be destroyed or
3315 returned to the supplier, unless examination, testing, or other
3316 investigation proves that the drug meets appropriate standards of
3317 safety, identity, strength, quality, and purity. In determining
3318 whether the conditions under which a drug has been returned cast
3319 doubt on the drug's safety, identity, strength, quality, or
3320 purity, the wholesale ~~drug~~ distributor must consider, among other
3321 things, the conditions under which the drug has been held,
3322 stored, or shipped before or during its return and the conditions
3323 of the drug and its container, carton, or labeling, as a result
3324 of storage or shipping.

3325 (d) The recordkeeping requirements in subsection (6) must
3326 be followed for all outdated, damaged, deteriorated, misbranded,
3327 or adulterated prescription drugs.

3328 (6) RECORDKEEPING.--The department shall adopt rules that
3329 require keeping such records of prescription drugs as are
3330 necessary for the protection of the public health.

3331 (a) Wholesale drug distributors must establish and maintain
3332 inventories and records of all transactions regarding the receipt

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3333 and distribution or other disposition of prescription drugs.
3334 These records must provide a complete audit trail from receipt to
3335 sale or other disposition, be readily retrievable for inspection,
3336 and include, at a minimum, the following information:

- 3337 1. The source of the drugs, including the name and
3338 principal address of the seller or transferor, and the address of
3339 the location from which the drugs were shipped;
- 3340 2. The name, principal address, and state license permit or
3341 registration number of the person authorized to purchase
3342 prescription drugs;
- 3343 3. The name, strength, dosage form, and quantity of the
3344 drugs received and distributed or disposed of;
- 3345 4. The dates of receipt and distribution or other
3346 disposition of the drugs; and
- 3347 5. Any financial documentation supporting the transaction.

3348 (b) Inventories and records must be made available for
3349 inspection and photocopying by authorized federal, state, or
3350 local officials for a period of 2 years following disposition of
3351 the drugs or 3 years after the creation of the records, whichever
3352 period is longer.

3353 (c) Records described in this section that are kept at the
3354 inspection site or that can be immediately retrieved by computer
3355 or other electronic means must be readily available for
3356 authorized inspection during the retention period. Records that
3357 are kept at a central location outside of this state and that are
3358 not electronically retrievable must be made available for
3359 inspection within 2 working days after a request by an authorized
3360 official of a federal, state, or local law enforcement agency.
3361 Records that are maintained at a central location within this

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3362 state must be maintained at an establishment that is permitted
3363 pursuant to this part ~~ss. 499.001-499.081~~ and must be readily
3364 available.

3365 (d) Each manufacturer or repackager of medical devices,
3366 over-the-counter drugs, or cosmetics must maintain records that
3367 include the name and principal address of the seller or
3368 transferor of the product, the address of the location from which
3369 the product was shipped, the date of the transaction, the name
3370 and quantity of the product involved, and the name and principal
3371 address of the person who purchased the product.

3372 (e) A wholesale distributor must maintain pedigree papers
3373 separate and distinct from other records required under this
3374 chapter.

3375 ~~(d)1. Effective July 1, 2006, each person who is engaged in~~
3376 ~~the wholesale distribution of a prescription drug and who is not~~
3377 ~~the manufacturer of that drug must, before each wholesale~~
3378 ~~distribution of such drug, provide to the person who receives the~~
3379 ~~drug a pedigree paper as defined in s. 499.003(31).~~

3380 ~~2. A repackager must comply with this paragraph.~~

3381 ~~3. The pedigree paper requirements in this paragraph do not~~
3382 ~~apply to compressed medical gases or veterinary legend drugs.~~

3383 ~~4. Each wholesale distributor of prescription drugs must~~
3384 ~~maintain separate and distinct from other required records all~~
3385 ~~statements that are required under subparagraph 1.~~

3386 ~~5. Subparagraph 1. is satisfied when a wholesale~~
3387 ~~distributor takes title to, but not possession of, a prescription~~
3388 ~~drug and the prescription drug's manufacturer ships the~~
3389 ~~prescription drug directly to a person authorized by law to~~
3390 ~~purchase prescription drugs for the purpose of administering or~~

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3391 ~~dispensing the drug, as defined in s. 465.003, or a member of an~~
3392 ~~affiliated group, as described in paragraph (f), with the~~
3393 ~~exception of a repackager.~~

3394 ~~a. The wholesale distributor must deliver to the recipient~~
3395 ~~of the prescription drug, within 14 days after the shipment~~
3396 ~~notification from the manufacturer, an invoice and the following~~
3397 ~~sworn statement: "This wholesale distributor purchased the~~
3398 ~~specific unit of the prescription drug listed on the invoice~~
3399 ~~directly from the manufacturer, and the specific unit of~~
3400 ~~prescription drug was shipped by the manufacturer directly to a~~
3401 ~~person authorized by law to administer or dispense the legend~~
3402 ~~drug, as defined in s. 465.003, Florida Statutes, or a member of~~
3403 ~~an affiliated group, as described in s. 499.0121(6) (f), Florida~~
3404 ~~Statutes, with the exception of a repackager." The invoice must~~
3405 ~~contain a unique cross-reference to the shipping document sent by~~
3406 ~~the manufacturer to the recipient of the prescription drug.~~

3407 ~~b. The manufacturer of the prescription drug shipped~~
3408 ~~directly to the recipient under this section must provide and the~~
3409 ~~recipient of the prescription drug must acquire, within 14 days~~
3410 ~~after receipt of the prescription drug, a shipping document from~~
3411 ~~the manufacturer that contains, at a minimum:~~

3412 ~~(I) The name and address of the manufacturer, including the~~
3413 ~~point of origin of the shipment, and the names and addresses of~~
3414 ~~the wholesaler and the purchaser.~~

3415 ~~(II) The name of the prescription drug as it appears on the~~
3416 ~~label.~~

3417 ~~(III) The quantity, dosage form, and strength of the~~
3418 ~~prescription drug.~~

3419 ~~(IV) The date of the shipment from the manufacturer.~~

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3420 ~~e. The wholesale distributor must also maintain and make~~
3421 ~~available to the department, upon request, the lot number of such~~
3422 ~~drug if not contained in the shipping document acquired by the~~
3423 ~~recipient.~~

3424 ~~6. Failure of the manufacturer to provide, the recipient to~~
3425 ~~acquire, or the wholesale distributor to deliver, the~~
3426 ~~documentation required under subparagraph 5. shall constitute~~
3427 ~~failure to acquire or deliver a pedigree paper under s. 499.0051.~~
3428 ~~Forgery by the manufacturer, the recipient, or the wholesale~~
3429 ~~distributor of the documentation required to be acquired or~~
3430 ~~delivered under subparagraph 5. shall constitute forgery of a~~
3431 ~~pedigree paper under s. 499.0051.~~

3432 ~~7. The department may, by rule, specify alternatives to~~
3433 ~~compliance with subparagraph 1. for a prescription drug in the~~
3434 ~~inventory of a permitted prescription drug wholesaler as of June~~
3435 ~~30, 2006, and the return of a prescription drug purchased prior~~
3436 ~~to July 1, 2006. The department may specify time limits for such~~
3437 ~~alternatives.~~

3438 (7)(e) NOTIFICATION REQUIRED.--Each wholesale distributor,
3439 except for a manufacturer, shall annually provide the department
3440 with a written list of all wholesale distributors and
3441 manufacturers from whom the wholesale distributor purchases
3442 prescription drugs. A wholesale distributor, except a
3443 manufacturer, shall notify the department not later than 10 days
3444 after any change to either list. Such portions of the information
3445 required pursuant to this paragraph which are a trade secret, as
3446 defined in s. 812.081, shall be maintained by the department as
3447 trade secret information is required to be maintained under s.
3448 499.051.

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3449 ~~(f)1. This paragraph applies only to an affiliated group,~~
3450 ~~as defined by s. 1504 of the Internal Revenue Code of 1986, as~~
3451 ~~amended, which is composed of chain drug entities, including at~~
3452 ~~least 50 retail pharmacies, warehouses, or repackagers, which are~~
3453 ~~members of the same affiliated group, if the affiliated group:~~

3454 ~~a. Discloses to the department the names of all its~~
3455 ~~members; and~~

3456 ~~b. Agrees in writing to provide records on prescription~~
3457 ~~drug purchases by members of the affiliated group not later than~~
3458 ~~48 hours after the department requests such records, regardless~~
3459 ~~of the location where the records are stored.~~

3460 ~~2. Each warehouse within the affiliated group must comply~~
3461 ~~with all applicable federal and state drug wholesale permit~~
3462 ~~requirements and must purchase, receive, hold, and distribute~~
3463 ~~prescription drugs only to a retail pharmacy or warehouse within~~
3464 ~~the affiliated group. Such a warehouse is exempt from providing a~~
3465 ~~pedigree paper in accordance with paragraph (d) to its affiliated~~
3466 ~~group member warehouse or retail pharmacy, provided that:~~

3467 ~~a. Any affiliated group member that purchases or receives a~~
3468 ~~prescription drug from outside the affiliated group must receive~~
3469 ~~a pedigree paper if the prescription drug is distributed in or~~
3470 ~~into this state and a pedigree paper is required under this~~
3471 ~~section and must authenticate the documentation as required in~~
3472 ~~subsection (4), regardless of whether the affiliated group member~~
3473 ~~is directly subject to regulation under this chapter; and~~

3474 ~~b. The affiliated group makes available to the department~~
3475 ~~on request all records related to the purchase or acquisition of~~
3476 ~~prescription drugs by members of the affiliated group, regardless~~

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3477 ~~of the location where the records are stored, if the prescription~~
3478 ~~drugs were distributed in or into this state.~~

3479 ~~3. If a repackager repackages prescription drugs solely for~~
3480 ~~distribution to its affiliated group members for the exclusive~~
3481 ~~distribution to and among retail pharmacies that are members of~~
3482 ~~the affiliated group to which the repackager is a member:~~

3483 ~~a. The repackager must:~~

3484 ~~(I) In lieu of the written statement required by paragraph~~
3485 ~~(d), for all repackaged prescription drugs distributed in or into~~
3486 ~~this state, state in writing under oath with each distribution of~~
3487 ~~a repackaged prescription drug to an affiliated group member~~
3488 ~~warehouse or repackager: "All repackaged prescription drugs are~~
3489 ~~purchased by the affiliated group directly from the manufacturer~~
3490 ~~or from a prescription drug wholesaler that purchased the~~
3491 ~~prescription drugs directly from the manufacturer.";~~

3492 ~~(II) Purchase all prescription drugs it repackages:~~

3493 ~~(A) Directly from the manufacturer; or~~

3494 ~~(B) From a prescription drug wholesaler that purchased the~~
3495 ~~prescription drugs directly from the manufacturer; and~~

3496 ~~(III) Maintain records in accordance with this section to~~
3497 ~~document that it purchased the prescription drugs directly from~~
3498 ~~the manufacturer or that its prescription drug wholesale supplier~~
3499 ~~purchased the prescription drugs directly from the manufacturer.~~

3500 ~~b. All members of the affiliated group must provide to~~
3501 ~~agents of the department on request records of purchases by all~~
3502 ~~members of the affiliated group of prescription drugs that have~~
3503 ~~been repackaged, regardless of the location where the records are~~
3504 ~~stored or where the repackager is located.~~

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3505 (8)~~(7)~~ WRITTEN POLICIES AND PROCEDURES.--Wholesale drug
3506 distributors must establish, maintain, and adhere to written
3507 policies and procedures, which must be followed for the receipt,
3508 security, storage, inventory, and distribution of prescription
3509 drugs, including policies and procedures for identifying,
3510 recording, and reporting losses or thefts, and for correcting all
3511 errors and inaccuracies in inventories. Wholesale drug
3512 distributors must include in their written policies and
3513 procedures:

3514 (a) A procedure whereby the oldest approved stock of a
3515 prescription drug product is distributed first. The procedure may
3516 permit deviation from this requirement, if the deviation is
3517 temporary and appropriate.

3518 (b) A procedure to be followed for handling recalls and
3519 withdrawals of prescription drugs. Such procedure must be
3520 adequate to deal with recalls and withdrawals due to:

3521 1. Any action initiated at the request of the Food and Drug
3522 Administration or any other federal, state, or local law
3523 enforcement or other government agency, including the department.

3524 2. Any voluntary action by the manufacturer or repackager
3525 to remove defective or potentially defective drugs from the
3526 market; or

3527 3. Any action undertaken to promote public health and
3528 safety by replacing existing merchandise with an improved product
3529 or new package design.

3530 (c) A procedure to ensure that wholesale drug distributors
3531 prepare for, protect against, and handle any crisis that affects
3532 security or operation of any facility if a strike, fire, flood,

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3533 or other natural disaster, or a local, state, or national
3534 emergency, occurs.

3535 (d) A procedure to ensure that any outdated prescription
3536 drugs are segregated from other drugs and either returned to the
3537 manufacturer or repackager or destroyed. This procedure must
3538 provide for written documentation of the disposition of outdated
3539 prescription drugs. This documentation must be maintained for 2
3540 years after disposition of the outdated drugs.

3541 (9)~~(8)~~ RESPONSIBLE PERSONS.--Wholesale drug distributors
3542 must establish and maintain lists of officers, directors,
3543 managers, designated representatives, and other persons in charge
3544 of wholesale drug distribution, storage, and handling, including
3545 a description of their duties and a summary of their
3546 qualifications.

3547 (10)~~(9)~~ COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.--A
3548 wholesale drug distributor must operate in compliance with
3549 applicable federal, state, and local laws and regulations.

3550 (a) A wholesale drug distributor must allow the department
3551 and authorized federal, state, and local officials to enter and
3552 inspect its premises and delivery vehicles, and to audit its
3553 records and written operating procedures, at reasonable times and
3554 in a reasonable manner, to the extent authorized by law.

3555 (b) A wholesale drug distributor that deals in controlled
3556 substances must register with the Drug Enforcement Administration
3557 and must comply with all applicable state, local, and federal
3558 laws. A wholesale drug distributor that distributes any substance
3559 controlled under chapter 893 must notify the department when
3560 registering with the Drug Enforcement Administration pursuant to
3561 that chapter and must provide the department with its DEA number.

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3562 (11)~~(10)~~ SALVAGING AND REPROCESSING.--A wholesale drug
3563 distributor is subject to any applicable federal, state, or local
3564 laws or regulations that relate to prescription drug product
3565 salvaging or reprocessing.

3566 (12)~~(11)~~ SHIPPING AND TRANSPORTATION.--The person
3567 responsible for shipment and transportation of a prescription
3568 drug in a wholesale distribution may use a common carrier; its
3569 own vehicle or employee acting within the scope of employment if
3570 authorized under s. 499.03 for the possession of prescription
3571 drugs in this state; or, in the case of a prescription drug
3572 intended for domestic distribution, an independent contractor who
3573 must be the agent of the authorized seller or recipient
3574 responsible for shipping and transportation as set forth in a
3575 written contract between the parties. A person selling a
3576 prescription drug for export must obtain documentation, such as a
3577 validated airway bill, bill of lading, or other appropriate
3578 documentation that the prescription drug was exported. A person
3579 responsible for shipping or transporting prescription drugs is
3580 not required to maintain documentation from a common carrier that
3581 the designated recipient received the prescription drugs;
3582 however, the person must obtain such documentation from the
3583 common carrier and make it available to the department upon
3584 request of the department.

3585 (13)~~(12)~~ DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing
3586 any prescription drugs from another wholesale drug distributor, a
3587 prescription drug wholesale distributor ~~wholesaler~~, an out-of-
3588 state prescription drug wholesale distributor ~~wholesaler~~, or a
3589 prescription drug repackager must:

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3590 (a) Enter an agreement with the selling wholesale drug
3591 distributor by which the selling wholesale ~~drug~~ distributor will
3592 indemnify the purchasing wholesale ~~drug~~ distributor for any loss
3593 caused to the purchasing wholesale ~~drug~~ distributor related to
3594 the purchase of drugs from the selling wholesale ~~drug~~ distributor
3595 which are determined to be counterfeit or to have been
3596 distributed in violation of any federal or state law governing
3597 the distribution of drugs.

3598 (b) Determine that the selling wholesale drug distributor
3599 has insurance coverage of not less than the greater of 1 percent
3600 of the amount of total dollar volume of the prescription drug
3601 sales reported to the department under s. 499.012(8)(g) ~~s.~~
3602 ~~499.012(3)(g)~~ or \$500,000; however the coverage need not exceed
3603 \$2 million.

3604 (c) Obtain information from the selling wholesale ~~drug~~
3605 distributor, including the length of time the selling wholesale
3606 ~~drug~~ distributor has been licensed in this state, a copy of the
3607 selling wholesale ~~drug~~ distributor's licenses or permits, and
3608 background information concerning the ownership of the selling
3609 wholesale ~~drug~~ distributor, including the experience of the
3610 wholesale distributor in the wholesale distribution of
3611 prescription drugs.

3612 (d) Verify that the selling wholesale ~~drug~~ distributor's
3613 Florida permit is valid.

3614 (e) Inspect the selling wholesale ~~drug~~ distributor's
3615 licensed establishment to document that it has a policies and
3616 procedures manual relating to the distribution of drugs, the
3617 appropriate temperature controlled environment for drugs
3618 requiring temperature control, an alarm system, appropriate

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3619 | access restrictions, and procedures to ensure that records
3620 | related to the wholesale distribution of prescription drugs are
3621 | maintained as required by law:

3622 | 1. Before purchasing any drug from the wholesale drug
3623 | distributor, and at least once each subsequent year; or

3624 | 2. Before purchasing any drug from the wholesale drug
3625 | distributor, and each subsequent year obtain a complete copy of
3626 | the most recent inspection report for the establishment which was
3627 | prepared by the department or the regulatory authority
3628 | responsible for wholesale ~~drug~~ distributors in the state in which
3629 | the establishment is located.

3630 | Section 22. Section 499.01211, Florida Statutes, is amended
3631 | to read:

3632 | 499.01211 Drug Wholesaler Advisory Council.--

3633 | (1) There is created the Drug Wholesaler Advisory Council
3634 | within the department. The council shall meet at least once each
3635 | calendar quarter. Staff for the council shall be provided by the
3636 | department. The council shall consist of 11 members who shall
3637 | serve without compensation. The council shall elect a chairperson
3638 | and a vice chairperson annually.

3639 | (2) The State Surgeon General, or his or her designee, and
3640 | the Secretary of Health Care Administration, or her or his
3641 | designee, shall be members of the council. The State Surgeon
3642 | General shall appoint nine additional members to the council who
3643 | shall be appointed to a term of 4 years each, as follows:

3644 | (a) Three different persons each of whom is employed by a
3645 | different prescription drug wholesaler licensed under this
3646 | chapter which operates nationally and is a primary wholesale

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3647 distributor ~~wholesaler~~, as defined in s. 499.003(52) ~~s.~~
3648 ~~499.012(1)(d)~~.

3649 (b) One person employed by a prescription drug wholesaler
3650 licensed under this chapter which is a secondary wholesale
3651 distributor ~~wholesaler~~, as defined in s. 499.003(58) ~~s.~~
3652 ~~499.012(1)(f)~~.

3653 (c) One person employed by a retail pharmacy chain located
3654 in this state.

3655 (d) One person who is a member of the Board of Pharmacy and
3656 is a pharmacist licensed under chapter 465.

3657 (e) One person who is a physician licensed pursuant to
3658 chapter 458 or chapter 459.

3659 (f) One person who is an employee of a hospital licensed
3660 pursuant to chapter 395 and is a pharmacist licensed pursuant to
3661 chapter 465.

3662 (g) One person who is an employee of a pharmaceutical
3663 manufacturer.

3664 (3) The council shall review this part ~~ss. 499.001-499.081~~
3665 and the rules adopted to administer this part ~~ss. 499.001-499.081~~
3666 annually, provide input to the department regarding all proposed
3667 rules to administer this part ~~ss. 499.001-499.081~~, make
3668 recommendations to the department to improve the protection of
3669 the prescription drugs and public health, make recommendations to
3670 improve coordination with other states' regulatory agencies and
3671 the federal government concerning the wholesale distribution of
3672 drugs, and make recommendations to minimize the impact of
3673 regulation of the wholesale distribution industry while ensuring
3674 protection of the public health.

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3675 Section 23. Section 499.01213, Florida Statutes, is created
3676 to read:

3677 499.01213 Pedigree paper.--

3678 (1) APPLICATION.--Each person who is engaged in the
3679 wholesale distribution of a prescription drug, with the exception
3680 of the manufacturer of the prescription drug, must, before each
3681 wholesale distribution of such drug, provide to the person who
3682 receives the drug a pedigree paper.

3683 (2) FORMAT.--A pedigree paper must contain the following
3684 information:

3685 (a) For the wholesale distribution of a prescription drug
3686 within the normal distribution chain:

3687 1. The following statement, under oath, which may be
3688 included on the invoice for the transaction and does not require
3689 a signature: "This wholesale distributor purchased the specific
3690 unit of the prescription drug directly from the manufacturer."

3691 2. The manufacturer's national drug code identifier and the
3692 name and address of the wholesale distributor and the purchaser
3693 of the prescription drug.

3694 3. The name of the prescription drug as it appears on the
3695 label.

3696 4. The quantity, dosage form, and strength of the
3697 prescription drug.

3698
3699 The wholesale distributor must also maintain and make available
3700 to the department, upon request, the point of origin of the
3701 prescription drug, including intracompany transfers; the date of
3702 the shipment from the manufacturer to the wholesale distributor;

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3703 the lot numbers of such drug; and the invoice numbers from the
3704 manufacturer.

3705 (b) For all other wholesale distributions of prescription
3706 drugs:

3707 1. The quantity, dosage form, and strength of the
3708 prescription drug.

3709 2. The lot numbers of the prescription drug.

3710 3. The name and address of each owner of the prescription
3711 drug and his or her signature.

3712 4. The shipping information, including the name and address
3713 of each person certifying delivery or receipt of the prescription
3714 drug.

3715 5. An invoice number, a shipping document number, or
3716 another number uniquely identifying the transaction.

3717 6. A certification that the recipient wholesale distributor
3718 has authenticated the pedigree papers.

3719 7. The unique serialization of the prescription drug, if
3720 the manufacturer or repackager has uniquely serialized the
3721 individual prescription drug unit.

3722 8. The name, address, telephone number and, if available,
3723 e-mail contact information of each wholesale distributor involved
3724 in the chain of the prescription drug's custody.

3725 (3) EXCEPTIONS.--A pedigree paper is not required for:

3726 (a) The wholesale distribution of a compressed medical gas.

3727 (b) The wholesale distribution of a veterinary prescription
3728 drug.

3729 (c) A drop shipment, provided that:

3730 1. The wholesale distributor delivers to the recipient of
3731 the prescription drug, within 14 days after the shipment

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3732 notification from the manufacturer, an invoice and the following
3733 sworn statement: "This wholesale distributor purchased the
3734 specific unit of the prescription drug listed on the invoice
3735 directly from the manufacturer, and the specific unit of
3736 prescription drug was shipped by the manufacturer directly to a
3737 person authorized by law to administer or dispense the legend
3738 drug, as defined in s. 465.003, or a member of an affiliated
3739 group, with the exception of a repackager." The invoice must
3740 contain a unique cross-reference to the shipping document sent by
3741 the manufacturer to the recipient of the prescription drug.

3742 2. The manufacturer of the prescription drug shipped
3743 directly to the recipient provides, and the recipient of the
3744 prescription drug acquires, within 14 days after receipt of the
3745 prescription drug, a shipping document from the manufacturer that
3746 contains, at a minimum:

3747 a. The name and address of the manufacturer, including the
3748 point of origin of the shipment, and the names and addresses of
3749 the wholesaler and the purchaser.

3750 b. The name of the prescription drug as it appears on the
3751 label.

3752 c. The quantity, dosage form, and strength of the
3753 prescription drug.

3754 d. The date of the shipment from the manufacturer.

3755 3. The wholesale distributor maintains and makes available
3756 to the department, upon request, the lot number of such drug if
3757 not contained in the shipping document acquired by the recipient.

3758
3759 Failure of the manufacturer to provide, the recipient to acquire,
3760 or the wholesale distributor to deliver the documentation

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3761 required under paragraph (c), including manufacturer notification
3762 to the wholesaler, shall constitute failure to acquire or deliver
3763 a pedigree paper under ss. 499.005(28) and 499.0051. Forgery by
3764 the manufacturer, the recipient, or the wholesale distributor of
3765 the documentation required to be acquired or delivered under
3766 subparagraph (2)(b)5. shall constitute forgery of a pedigree
3767 paper under s. 499.0051.

3768 4. The wholesale distributor that takes title to, but not
3769 possession of, the prescription drug is not a member of the
3770 affiliated group that receives the prescription drug directly
3771 from the manufacturer.

3772 (d) The wholesale distribution of a prescription drug by a
3773 warehouse within an affiliated group to a warehouse or retail
3774 pharmacy within its affiliated group, provided that:

3775 1. Any affiliated group member that purchases or receives a
3776 prescription drug from outside the affiliated group must receive
3777 a pedigree paper if the prescription drug is distributed in or
3778 into this state and a pedigree paper is required under this
3779 section and must authenticate the documentation as required in s.
3780 499.0121(4), regardless of whether the affiliated group member is
3781 directly subject to regulation under this chapter; and

3782 2. The affiliated group makes available to the department
3783 on request all records related to the purchase or acquisition of
3784 prescription drugs by members of the affiliated group, regardless
3785 of the location where the records are stored, if the prescription
3786 drugs were distributed in or into this state.

3787 (e) The repackaging of prescription drugs by a repackager
3788 solely for distribution to its affiliated group members for the
3789 exclusive distribution to and among retail pharmacies that are

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3790 members of the affiliated group to which the repackager is a
3791 member.

3792 1. The repackager must:

3793 a. For all repackaged prescription drugs distributed in or
3794 into this state, state in writing under oath with each
3795 distribution of a repackaged prescription drug to an affiliated
3796 group member warehouse or repackager: "All repackaged
3797 prescription drugs are purchased by the affiliated group directly
3798 from the manufacturer or from a prescription drug wholesale
3799 distributor that purchased the prescription drugs directly from
3800 the manufacturer."

3801 b. Purchase all prescription drugs it repackages:

3802 (I) Directly from the manufacturer; or

3803 (II) From a prescription drug wholesaler that purchased the
3804 prescription drugs directly from the manufacturer; and

3805 c. Maintain records in accordance with this section to
3806 document that it purchased the prescription drugs directly from
3807 the manufacturer or that its prescription drug wholesale supplier
3808 purchased the prescription drugs directly from the manufacturer.

3809 2. All members of the affiliated group must provide to
3810 agents of the department on request records of purchases by all
3811 members of the affiliated group of prescription drugs that have
3812 been repackaged, regardless of the location where the records are
3813 stored or where the repackager is located.

3814 Section 24. Section 499.0122, Florida Statutes, is
3815 repealed.

3816 Section 25. Section 499.013, Florida Statutes, is repealed.

3817 Section 26. Section 499.014, Florida Statutes, is repealed.

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3818 Section 27. Subsections (1), (3), (4), (6), and (8) of
3819 section 499.015, Florida Statutes, are amended to read:

3820 499.015 Registration of drugs, devices, and cosmetics;
3821 issuance of certificates of free sale.--

3822 (1)(a) Except for those persons exempted from the
3823 definition of manufacturer in s. 499.003(36) ~~s. 499.003(28)~~, any
3824 person who manufactures, packages, repackages, labels, or
3825 relabels a drug, device, or cosmetic in this state must register
3826 such drug, device, or cosmetic biennially with the department;
3827 pay a fee in accordance with the fee schedule provided by s.
3828 499.041; and comply with this section. The registrant must list
3829 each separate and distinct drug, device, or cosmetic at the time
3830 of registration.

3831 (b) The department may not register any product that does
3832 not comply with the Federal Food, Drug, and Cosmetic Act, as
3833 amended, or Title 21 C.F.R. Registration of a product by the
3834 department does not mean that the product does in fact comply
3835 with all provisions of the Federal Food, Drug, and Cosmetic Act,
3836 as amended.

3837 (3) Except for those persons exempted from the definition
3838 of manufacturer in s. 499.003(36) ~~s. 499.003(28)~~, a person may
3839 not sell any product that he or she has failed to register in
3840 conformity with this section. Such failure to register subjects
3841 such drug, device, or cosmetic product to seizure and
3842 condemnation as provided in ss. 499.062-499.064, and subjects
3843 such person to the penalties and remedies provided in this part
3844 ~~ss. 499.001-499.081~~.

3845 (4) Unless a registration is renewed, it expires 2 years
3846 after the last day of the month in which it was issued. The

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3847 department may issue a stop-sale notice or order against a person
3848 that is subject to the requirements of this section and that
3849 fails to comply with this section within 31 days after the date
3850 the registration expires. The notice or order shall prohibit such
3851 person from selling or causing to be sold any drugs, devices, or
3852 cosmetics covered by this part ~~ss. 499.001-499.081~~ until he or
3853 she complies with the requirements of this section.

3854 (6) The department may issue a certificate of free sale for
3855 any product that is required to be registered under this part ~~ss.~~
3856 ~~499.001-499.081~~.

3857 (8) Notwithstanding any requirements set forth in this part
3858 ~~ss. 499.001-499.081~~, a manufacturer of medical devices that is
3859 registered with the federal Food and Drug Administration is
3860 exempt from this section and s. 499.041(6) if:

3861 (a) The manufacturer's medical devices are approved for
3862 marketing by, or listed with the federal Food and Drug
3863 Administration in accordance with federal law for commercial
3864 distribution; or

3865 (b) The manufacturer subcontracts with a manufacturer of
3866 medical devices to manufacture components of such devices.

3867 Section 28. Subsections (3), (5), and (6) of section
3868 499.024, Florida Statutes, are amended to read:

3869 499.024 Drug product classification.--The State Surgeon
3870 General shall adopt rules to classify drug products intended for
3871 use by humans which the United States Food and Drug
3872 Administration has not classified in the federal act or the Code
3873 of Federal Regulations.

3874 (3) Any product that falls under the definition of drug
3875 ~~definition, s. 499.003(22) s. 499.003(17)~~, may be classified

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3876 under the authority of this section. This section does not
3877 subject portable emergency oxygen inhalators to classification;
3878 however, this section does not exempt any person from ss. 499.01
3879 and 499.015.

3880 (5) The department may by rule reclassify drugs subject to
3881 this part ~~ss. 499.001-499.081~~ when such classification action is
3882 necessary to protect the public health.

3883 (6) The department may adopt rules that exempt from any
3884 labeling or packaging requirements of this part ~~ss. 499.001-~~
3885 ~~499.081~~ drugs classified under this section if those requirements
3886 are not necessary to protect the public health.

3887 Section 29. Subsections (7), (12), and (15) of section
3888 499.028, Florida Statutes, are amended to read:

3889 499.028 Drug samples or complimentary drugs; starter packs;
3890 permits to distribute.--

3891 (7) A drug manufacturer or distributor must report to the
3892 department any conviction of itself or of its assigns, agents,
3893 employees, or representatives for a violation of s. 503(c)(1) of
3894 the federal act or of this part ~~ss. 499.001-499.081~~ because of
3895 the sale, purchase, or trade of a drug sample or the offer to
3896 sell, purchase, or trade a drug sample.

3897 (12) The department may suspend or revoke a permit issued
3898 under this section, after giving notice and an opportunity to be
3899 heard pursuant to chapter 120, when:

3900 (a) Such permit was obtained by misrepresentation or fraud
3901 or through a mistake of the department.

3902 (b) The holder of the permit has distributed or disposed of
3903 any prescription ~~legend~~ drug, directly or through its agents,

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3904 employees, or independent contractors, to any person not
3905 authorized to possess such drug.

3906 (c) The holder of the permit, or its agents, employees, or
3907 independent contractors, has distributed or possessed any
3908 prescription ~~legend~~ drug except in the usual course of its
3909 business.

3910 (d) The holder of the permit, or its agents, employees, or
3911 independent contractors, has distributed any prescription ~~legend~~
3912 drug that is misbranded or adulterated under this part ~~ss.~~
3913 ~~499.001-499.081~~.

3914 (e) The holder of the permit, or its agents, employees, or
3915 independent contractors, has distributed any prescription ~~legend~~
3916 drug without written request, when a written request is required
3917 by this section.

3918 (f) The holder of the permit has in its employ, or uses as
3919 agent or independent contractor for the purpose of distributing
3920 or disposing of drugs, any person who has:

3921 1. Violated the requirements of this section or any rule
3922 adopted under this section.

3923 2. Been convicted in any of the courts of this state, the
3924 United States, or any other state of a felony or any other crime
3925 involving moral turpitude or involving those drugs named or
3926 described in chapter 893.

3927 (15) A person may not possess a prescription drug sample
3928 unless:

3929 (a) The drug sample was prescribed to her or him as
3930 evidenced by the label required in s. 465.0276(5).

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3931 (b) She or he is the employee of a complimentary drug
3932 distributor that holds a permit issued under this part ~~ss-~~
3933 ~~499.001-499.081~~.

3934 (c) She or he is a person to whom prescription drug samples
3935 may be distributed pursuant to this section.

3936 (d) He or she is an officer or employee of a federal,
3937 state, or local government acting within the scope of his or her
3938 employment.

3939 Section 30. Subsections (2) and (3) of section 499.029,
3940 Florida Statutes, are amended to read:

3941 499.029 Cancer Drug Donation Program.--

3942 (2) There is created a Cancer Drug Donation Program within
3943 the department of ~~Health~~ for the purpose of authorizing and
3944 facilitating the donation of cancer drugs and supplies to
3945 eligible patients.

3946 (3) As used in this section:

3947 (a) "Cancer drug" means a prescription drug that has been
3948 approved under s. 505 of the federal Food, Drug, and Cosmetic Act
3949 and is used to treat cancer or its side effects or is used to
3950 treat the side effects of a prescription drug used to treat
3951 cancer or its side effects. "Cancer drug" does not include a
3952 substance listed in Schedule II, Schedule III, Schedule IV, or
3953 Schedule V of s. 893.03.

3954 (b) "Closed drug delivery system" means a system in which
3955 the actual control of the unit-dose medication package is
3956 maintained by the facility rather than by the individual patient.

3957 ~~(c) "Department" means the Department of Health.~~

3958 (c) ~~(d)~~ "Donor" means a patient or patient representative
3959 who donates cancer drugs or supplies needed to administer cancer

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3960 | drugs that have been maintained within a closed drug delivery
3961 | system; health care facilities, nursing homes, hospices, or
3962 | hospitals with closed drug delivery systems; or pharmacies, drug
3963 | manufacturers, medical device manufacturers or suppliers, or
3964 | wholesalers of drugs or supplies, in accordance with this
3965 | section. "Donor" includes a physician licensed under chapter 458
3966 | or chapter 459 who receives cancer drugs or supplies directly
3967 | from a drug manufacturer, drug wholesaler, or pharmacy.

3968 | (d)~~(e)~~ "Eligible patient" means a person who the department
3969 | determines is eligible to receive cancer drugs from the program.

3970 | (e)~~(f)~~ "Health care facility" means a health care facility
3971 | licensed under chapter 395.

3972 | (f)~~(g)~~ "Health care clinic" means a health care clinic
3973 | licensed under part X of chapter 400.

3974 | (g)~~(h)~~ "Hospice" means a corporation licensed under part IV
3975 | of chapter 400.

3976 | (h)~~(i)~~ "Hospital" means a facility as defined in s. 395.002
3977 | and licensed under chapter 395.

3978 | (i)~~(j)~~ "Nursing home" means a facility licensed under part
3979 | II of chapter 400.

3980 | (j)~~(k)~~ "Participant facility" means a class II hospital
3981 | pharmacy that has elected to participate in the program and that
3982 | accepts donated cancer drugs and supplies under the rules adopted
3983 | by the department for the program.

3984 | (k)~~(l)~~ "Pharmacist" means a person licensed under chapter
3985 | 465.

3986 | (l)~~(m)~~ "Pharmacy" means an entity licensed under chapter
3987 | 465.

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3988 (m) ~~(n)~~ "Prescribing practitioner" means a physician
3989 licensed under chapter 458 or any other medical professional with
3990 authority under state law to prescribe cancer medication.

3991 ~~(o) "Prescription drug" means a drug as defined in s.~~
3992 ~~465.003(8).~~

3993 (n) ~~(p)~~ "Program" means the Cancer Drug Donation Program
3994 created by this section.

3995 (o) ~~(q)~~ "Supplies" means any supplies used in the
3996 administration of a cancer drug.

3997 Section 31. Subsection (1) of section 499.03, Florida
3998 Statutes, is amended to read:

3999 499.03 Possession of certain drugs without prescriptions
4000 unlawful; exemptions and exceptions.--

4001 (1) A person may not possess, or possess with intent to
4002 sell, dispense, or deliver, any habit-forming, toxic, harmful, or
4003 new drug subject to s. 499.003(37) ~~s. 499.003(29)~~, or
4004 prescription ~~legend~~ drug as defined in s. 499.003(48) ~~s.~~
4005 ~~499.003(25)~~, unless the possession of the drug has been obtained
4006 by a valid prescription of a practitioner licensed by law to
4007 prescribe the drug. However, this section does not apply to the
4008 delivery of such drugs to persons included in any of the classes
4009 named in this subsection, or to the agents or employees of such
4010 persons, for use in the usual course of their businesses or
4011 practices or in the performance of their official duties, as the
4012 case may be; nor does this section apply to the possession of
4013 such drugs by those persons or their agents or employees for such
4014 use:

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4015 (a) A licensed pharmacist or any person under the licensed
4016 pharmacist's supervision while acting within the scope of the
4017 licensed pharmacist's practice;

4018 (b) A licensed practitioner authorized by law to prescribe
4019 prescription ~~legend~~ drugs or any person under the licensed
4020 practitioner's supervision while acting within the scope of the
4021 licensed practitioner's practice;

4022 (c) A qualified person who uses prescription ~~legend~~ drugs
4023 for lawful research, teaching, or testing, and not for resale;

4024 (d) A licensed hospital or other institution that procures
4025 such drugs for lawful administration or dispensing by
4026 practitioners;

4027 (e) An officer or employee of a federal, state, or local
4028 government; or

4029 (f) A person that holds a valid permit issued by the
4030 department pursuant to this part ~~ss. 499.001-499.081~~ which
4031 authorizes that person to possess prescription drugs.

4032 Section 32. Section 499.032, Florida Statutes, is amended
4033 to read:

4034 499.032 Phenylalanine; prescription
4035 required.--Phenylalanine restricted formula is declared to be a
4036 prescription ~~legend~~ drug and may be dispensed only upon the
4037 prescription of a practitioner authorized by law to prescribe
4038 prescription ~~medicinal~~ drugs.

4039 Section 33. Subsection (1) of section 499.033, Florida
4040 Statutes, is amended to read:

4041 499.033 Ephedrine; prescription required.--Ephedrine is
4042 declared to be a prescription drug.

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4043 (1) Except as provided in subsection (2), any product that
4044 contains any quantity of ephedrine, a salt of ephedrine, an
4045 optical isomer of ephedrine, or a salt of an optical isomer of
4046 ephedrine may be dispensed only upon the prescription of a duly
4047 licensed practitioner authorized by the laws of the state to
4048 prescribe prescription ~~medicinal~~ drugs.

4049 Section 34. Subsections (1) and (3) of section 499.039,
4050 Florida Statutes, is amended to read:

4051 499.039 Sale, distribution, or transfer of harmful chemical
4052 substances; penalties; authority for enforcement.--It is unlawful
4053 for a person to sell, deliver, or give to a person under the age
4054 of 18 years any compound, liquid, or chemical containing toluol,
4055 hexane, trichloroethylene, acetone, toluene, ethyl acetate,
4056 methyl ethyl ketone, trichloroethane, isopropanol, methyl
4057 isobutyl ketone, ethylene glycol monomethyl ether acetate,
4058 cyclohexanone, nitrous oxide, diethyl ether, alkyl nitrites
4059 (butyl nitrite), or any similar substance for the purpose of
4060 inducing by breathing, inhaling, or ingesting a condition of
4061 intoxication or which is intended to distort or disturb the
4062 auditory, visual, or other physical or mental processes.

4063 (1) On the first violation of this section, the department
4064 may issue a warning according to s. 499.002(5) ~~s. 499.071~~, if the
4065 violation has not caused temporary or permanent physical or
4066 mental injury to the user.

4067 (3) The department ~~of Health~~ shall adopt rules to implement
4068 this section.

4069 Section 35. Section 499.04, Florida Statutes, is amended to
4070 read:

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4071 499.04 Fee authority.--The department may collect fees for
4072 all drug, device, and cosmetic applications, permits, product
4073 registrations, and free-sale certificates. The total amount of
4074 fees collected from all permits, applications, product
4075 registrations, and free-sale certificates must be adequate to
4076 fund the expenses incurred by the department in carrying out this
4077 part ss. ~~499.001-499.081~~. The department shall, by rule,
4078 establish a schedule of fees that are within the ranges provided
4079 in this section and shall adjust those fees from time to time
4080 based on the costs associated with administering this part ss.
4081 ~~499.001-499.081~~. The fees are payable to the department to be
4082 deposited into the Florida Drug, Device, and Cosmetic Trust Fund
4083 for the sole purpose of carrying out the provisions of this part
4084 ss. ~~499.001-499.081~~.

4085 Section 36. Section 499.041, Florida Statutes, is amended
4086 to read:

4087 499.041 Schedule of fees for drug, device, and cosmetic
4088 applications and permits, product registrations, and free-sale
4089 certificates.--

4090 (1) The department shall assess applicants requiring a
4091 manufacturing permit an annual fee within the ranges established
4092 in this section for the specific type of manufacturer.

4093 (a) The fee for a prescription drug manufacturer
4094 ~~manufacturer's~~ permit may not be less than \$500 or more than \$750
4095 annually.

4096 (b) The fee for a device manufacturer ~~manufacturer's~~ permit
4097 may not be less than \$500 or more than \$600 annually.

4098 (c) The fee for a cosmetic manufacturer ~~manufacturer's~~
4099 permit may not be less than \$250 or more than \$400 annually.

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4100 (d) The fee for an over-the-counter drug manufacturer
4101 ~~manufacturer's~~ permit may not be less than \$300 or more than \$400
4102 annually.

4103 (e) The fee for a compressed medical gas manufacturer
4104 ~~manufacturer's~~ permit may not be less than \$400 or more than \$500
4105 annually.

4106 (f) The fee for a prescription drug repackager ~~repackager's~~
4107 permit may not be less than \$500 or more than \$750 annually.

4108 (g) A manufacturer may not be required to pay more than one
4109 fee per establishment to obtain an additional manufacturing
4110 permit, but each manufacturer must pay the highest fee applicable
4111 to his or her operation in each establishment.

4112 (2) The department shall assess an applicant that is
4113 required to have a wholesaling permit an annual fee within the
4114 ranges established in this section for the specific type of
4115 wholesaling.

4116 (a) The fee for a prescription drug wholesale distributor
4117 ~~wholesaler's~~ permit may not be less than \$300 or more than \$800
4118 annually.

4119 (b) The fee for a compressed medical gas wholesale
4120 distributor ~~wholesaler's~~ permit may not be less than \$200 or more
4121 than \$300 annually.

4122 (c) The fee for an out-of-state prescription drug wholesale
4123 distributor ~~wholesaler's~~ permit may not be less than \$300 or more
4124 than \$800 annually.

4125 (d) The fee for a nonresident prescription drug
4126 manufacturer ~~manufacturer's~~ permit may not be less than \$300 or
4127 more than \$500 annually.

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4128 (e) The fee for a retail pharmacy wholesale distributor
4129 ~~wholesaler's~~ permit may not be less than \$35 or more than \$50
4130 annually.

4131 (f) The fee for a freight forwarder ~~forwarder's~~ permit may
4132 not be less than \$200 or more than \$300 annually.

4133 (g) The fee for a veterinary prescription drug wholesaler
4134 distributor ~~wholesaler's~~ permit may not be less than \$300 or more
4135 than \$500 annually.

4136 (h) The fee for a limited prescription drug veterinary
4137 ~~wholesaler's~~ permit may not be less than \$300 or more than \$500
4138 annually.

4139 (3) The department shall assess an applicant that is
4140 required to have a retail establishment permit an annual fee
4141 within the ranges established in this section for the specific
4142 type of retail establishment.

4143 (a) The fee for a veterinary prescription legend ~~legend~~ drug
4144 retail establishment permit may not be less than \$200 or more
4145 than \$300 annually.

4146 (b) The fee for a medical oxygen retail establishment
4147 permit may not be less than \$200 or more than \$300 annually.

4148 (4) The department shall assess an applicant that is
4149 required to have a restricted prescription drug distributor
4150 ~~distributor's~~ permit an annual fee of not less than \$200 or more
4151 than \$300.

4152 (5) In addition to the fee charged for a permit required by
4153 this part ~~ss. 499.001-499.081~~, the department shall assess
4154 applicants an initial application fee of \$150 for each new permit
4155 issued by the department which requires an onsite inspection.

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4156 (6) A person that is required to register drugs, devices,
4157 or cosmetic products under s. 499.015 shall pay an annual product
4158 registration fee of not less than \$5 or more than \$15 for each
4159 separate and distinct product in package form. The registration
4160 fee is in addition to the fee charged for a free-sale
4161 certificate.

4162 (7) The department shall assess an applicant that requests
4163 a free-sale certificate a fee of \$25. A fee of \$2 will be charged
4164 for each signature copy of a free-sale certificate that is
4165 obtained at the same time the free-sale certificate is issued.

4166 (8) The department shall assess an out-of-state
4167 prescription drug wholesale distributor ~~wholesaler~~ applicant or
4168 permittee an onsite inspection fee of not less than \$1,000 or
4169 more than \$3,000 annually, to be based on the actual cost of the
4170 inspection if an onsite inspection is performed by agents of the
4171 department.

4172 (9) The department shall assess each person applying for
4173 certification as a designated representative a fee of \$150, plus
4174 the cost of processing the criminal history record check.

4175 (10) The department shall assess other fees as provided in
4176 this part ~~ss. 499.001-499.081~~.

4177 Section 37. Section 499.05, Florida Statutes, is amended to
4178 read:

4179 499.05 Rules.--

4180 (1) The department shall adopt rules to implement and
4181 enforce this part ~~ss. 499.001-499.081~~ with respect to:

4182 (a) The definition of terms used in this part ~~ss. 499.001-~~
4183 ~~499.081~~, and used in the rules adopted under this part ~~ss.~~

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4184 ~~499.001-499.081~~, when the use of the term is not its usual and
4185 ordinary meaning.

4186 (b) Labeling requirements for drugs, devices, and
4187 cosmetics.

4188 (c) The establishment of fees authorized in this part ~~ss.~~
4189 ~~499.001-499.081~~.

4190 (d) The identification of permits that require an initial
4191 application and onsite inspection or other prerequisites for
4192 permitting which demonstrate that the establishment and person
4193 are in compliance with the requirements of this part ~~ss. 499.001-~~
4194 ~~499.081~~.

4195 (e) The application processes and forms for product
4196 registration.

4197 (f) Procedures for requesting and issuing certificates of
4198 free sale.

4199 (g) Inspections and investigations conducted under s.
4200 499.051, and the identification of information claimed to be a
4201 trade secret and exempt from the public records law as provided
4202 in s. 499.051(7).

4203 (h) The establishment of a range of penalties, as provided
4204 in s. 499.066 ~~s. 499.006~~; requirements for notifying persons of
4205 the potential impact of a violation of this part ~~ss. 499.001-~~
4206 ~~499.081~~; and a process for the uncontested settlement of alleged
4207 violations.

4208 (i) Additional conditions that qualify as an emergency
4209 medical reason under s. 499.003(60)(b)2 ~~s. 499.012(1)(a)2.b.~~

4210 (j) Procedures and forms relating to the pedigree paper
4211 requirements of s. 499.01213.

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4212 (k) The protection of the public health, safety, and
4213 welfare regarding good manufacturing practices that manufacturers
4214 and repackagers must follow to ensure the safety of the products.

4215 (l) Information required from each retail establishment
4216 pursuant to s. 499.012(3), including requirements for
4217 prescriptions or orders.

4218 (m) The recordkeeping, storage, and handling with respect
4219 to each of the distributions of prescription drugs specified in
4220 s. 499.003(60)(a)-(d).

4221 (n) Alternatives to compliance with s. 499.01213 for a
4222 prescription drug in the inventory of a permitted prescription
4223 drug wholesale distributor as of June 30, 2006, and the return of
4224 a prescription drug purchased prior to July 1, 2006. The
4225 department may specify time limits for such alternatives.

4226 (2) With respect to products in interstate commerce, those
4227 rules must not be inconsistent with rules and regulations of
4228 federal agencies unless specifically otherwise directed by the
4229 Legislature.

4230 (3) The department shall adopt rules regulating
4231 recordkeeping for and the storage, handling, and distribution of
4232 medical devices and over-the-counter drugs to protect the public
4233 from adulterated products.

4234 Section 38. Section 499.051, Florida Statutes, is amended
4235 to read:

4236 499.051 Inspections and investigations.--

4237 (1) The agents of the Department of Health and of the
4238 Department of Law Enforcement, after they present proper
4239 identification, may inspect, monitor, and investigate any
4240 establishment permitted pursuant to this part ~~ss. 499.001-499.081~~

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4241 during business hours for the purpose of enforcing this part ~~ss.~~
4242 ~~499.001-499.081~~, chapters 465, 501, and 893, and the rules of the
4243 department that protect the public health, safety, and welfare.

4244 (2) In addition to the authority set forth in subsection
4245 (1), the department and any duly designated officer or employee
4246 of the department may enter and inspect any other establishment
4247 for the purpose of determining compliance with this part ~~ss.~~
4248 ~~499.001-499.081~~ and rules adopted under this part ~~those sections~~
4249 regarding any drug, device, or cosmetic product.

4250 (3) Any application for a permit or product registration or
4251 for renewal of such permit or registration made pursuant to this
4252 part ~~ss. 499.001-499.081~~ and rules adopted under this part ~~those~~
4253 ~~sections~~ constitutes permission for any entry or inspection of
4254 the premises in order to verify compliance with this part ~~those~~
4255 ~~sections~~ and rules; to discover, investigate, and determine the
4256 existence of compliance; or to elicit, receive, respond to, and
4257 resolve complaints and violations.

4258 (4) Any application for a permit made pursuant to s. ~~ss.~~
4259 ~~499.01~~ and 499.012 and rules adopted under that section ~~those~~
4260 ~~sections~~ constitutes permission for agents of the department ~~of~~
4261 ~~Health~~ and the Department of Law Enforcement, after presenting
4262 proper identification, to inspect, review, and copy any financial
4263 document or record related to the manufacture, repackaging, or
4264 distribution of a drug as is necessary to verify compliance with
4265 this part ~~ss. 499.001-499.081~~ and the rules adopted by the
4266 department to administer this part ~~those sections~~, in order to
4267 discover, investigate, and determine the existence of compliance,
4268 or to elicit, receive, respond to, and resolve complaints and
4269 violations.

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4270 (5) The authority to inspect under this section includes
4271 the authority to access, review, and copy any and all financial
4272 documents related to the activity of manufacturing, repackaging,
4273 or distributing prescription drugs.

4274 (6) The authority to inspect under this section includes
4275 the authority to secure:

4276 (a) Samples or specimens of any drug, device, or cosmetic;
4277 or

4278 (b) Such other evidence as is needed for any action to
4279 enforce this part ~~ss. 499.001-499.081~~ and the rules adopted under
4280 this part ~~these sections~~.

4281 (7) The complaint and all information obtained pursuant to
4282 the investigation by the department are confidential and exempt
4283 from the provisions of s. 119.07(1) and s. 24(a), Art. I of the
4284 State Constitution until the investigation and the enforcement
4285 action are completed. However, trade secret information contained
4286 therein as defined by s. 812.081(1)(c) shall remain confidential
4287 and exempt from the provisions of s. 119.07(1) and s. 24(a), Art.
4288 I of the State Constitution, as long as the information is
4289 retained by the department. This subsection does not prohibit the
4290 department from using such information for regulatory or
4291 enforcement proceedings under this chapter or from providing such
4292 information to any law enforcement agency or any other regulatory
4293 agency. However, the receiving agency shall keep such records
4294 confidential and exempt as provided in this subsection. In
4295 addition, this subsection is not intended to prevent compliance
4296 with the provisions of s. 499.01213 ~~s. 499.0121(6)(d)~~, and the
4297 pedigree papers required in that subsection shall not be deemed a
4298 trade secret.

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4299 Section 39. Section 499.052, Florida Statutes, is amended
4300 to read:

4301 499.052 Records of interstate shipment.--For the purpose of
4302 enforcing this part ss. 499.001-499.081, carriers engaged in
4303 interstate commerce and persons receiving drugs, devices, or
4304 cosmetics in interstate commerce must, upon the request, in the
4305 manner set out below, by an officer or employee duly designated
4306 by the department, permit the officer or employee to have access
4307 to and to copy all records showing the movement in interstate
4308 commerce of any drug, device, or cosmetic, and the quantity,
4309 shipper, and consignee thereof.

4310 Section 40. Subsection (4) of section 499.055, Florida
4311 Statutes, is amended to read:

4312 499.055 Reports and dissemination of information by
4313 department.--

4314 (4) The department shall publish on the department's
4315 website and update at least monthly:

4316 (a) A list of the prescription drug wholesale distributors
4317 ~~wholesalers~~, out-of-state prescription drug wholesale
4318 distributors ~~wholesalers~~, and retail pharmacy drug wholesale
4319 distributors ~~wholesalers~~ against whom the department has
4320 initiated enforcement action pursuant to this part ss. 499.001-
4321 ~~499.081~~ to suspend or revoke a permit, seek an injunction, or
4322 otherwise file an administrative complaint and the permit number
4323 of each such wholesale distributor ~~wholesaler~~.

4324 (b) A list of the prescription drug wholesale distributors
4325 ~~wholesalers~~, out-of-state prescription drug wholesale
4326 distributors ~~wholesalers~~, and retail pharmacy drug wholesale

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4327 distributors ~~wholesalers~~ to which the department has issued a
4328 permit, including the date on which each permit will expire.

4329 (c) A list of the prescription drug wholesale distributors'
4330 ~~wholesalers~~, out-of-state prescription drug wholesale
4331 distributors' ~~wholesalers~~, and retail pharmacy drug wholesale
4332 distributors' ~~wholesalers'~~ permits that have been returned to the
4333 department, were suspended, were revoked, have expired, or were
4334 not renewed in the previous year.

4335 Section 41. Subsections (1) and (3) of section 499.06,
4336 Florida Statutes, are amended to read:

4337 499.06 Embargoing, detaining, or destroying article or
4338 processing equipment which is in violation of law or rule.--

4339 (1) When a duly authorized agent of the department finds,
4340 or has probable cause to believe, that any drug, device, or
4341 cosmetic is in violation of any provision of this part ~~ss.~~
4342 ~~499.001-499.081~~ or any rule adopted under this part ~~such sections~~
4343 so as to be dangerous, unwholesome, or fraudulent within the
4344 meaning of this part ~~ss. 499.001-499.081~~, she or he may issue and
4345 enforce a stop-sale, stop-use, removal, or hold order, which
4346 order gives notice that such article or processing equipment is,
4347 or is suspected of being, in violation and has been detained or
4348 embargoed, and which order warns all persons not to remove, use,
4349 or dispose of such article or processing equipment by sale or
4350 otherwise until permission for removal, use, or disposal is given
4351 by such agent or the court. It is unlawful for any person to
4352 remove, use, or dispose of such detained or embargoed article or
4353 processing equipment by sale or otherwise without such
4354 permission; and such act is a felony of the second degree,
4355 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

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4356 (3) If the court finds that the detained or embargoed
4357 article or processing equipment is in violation, such article or
4358 processing equipment shall, after entry of the court order, be
4359 destroyed or made sanitary at the expense of the claimant
4360 thereof, under the supervision of such agent; and all court
4361 costs, fees, and storage and other proper expenses shall be taxed
4362 against the claimant of such article or processing equipment or
4363 her or his agent. However, when the violation can be corrected by
4364 proper labeling of the article or sanitizing of the processing
4365 equipment, and after such costs, fees, and expenses have been
4366 paid and a good and sufficient bond, conditioned that such
4367 article be so labeled or processed or such processing equipment
4368 be so sanitized, has been executed, the court may by order direct
4369 that such article or processing equipment be delivered to the
4370 claimant thereof for such labeling, processing, or sanitizing,
4371 under the supervision of an agent of the department. The expense
4372 of such supervision shall be paid by the claimant. Such bond
4373 shall be returned to the claimant of the article or processing
4374 equipment upon representation to the court by the department that
4375 the article or processing equipment is no longer in violation of
4376 this part ss. 499.001-499.081 and that the expenses of such
4377 supervision have been paid.

4378 Section 42. Section 499.062, Florida Statutes, is amended
4379 to read:

4380 499.062 ~~Cause for~~ Seizure and condemnation of drugs,
4381 devices, or cosmetics.--

4382 (1) Any article of any drug, device, or cosmetic that is
4383 adulterated or misbranded under this part ss. 499.001-499.081 is
4384 subject to seizure and condemnation by the department or by its

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4385 | duly authorized agents designated for that purpose in regard to
4386 | drugs, devices, or cosmetics.

4387 | (2) Whenever a duly authorized officer or employee of the
4388 | department finds cause, or has probable cause to believe that
4389 | cause exists, for the seizure of any drug, device, or cosmetic,
4390 | as set out in this part, he or she shall affix to the article a
4391 | tag, stamp, or other appropriate marking, giving notice that the
4392 | article is, or is suspected of being, subject to seizure under
4393 | this part and that the article has been detained and seized by
4394 | the department. Such officer or employee shall also warn all
4395 | persons not to remove or dispose of the article, by sale or
4396 | otherwise, until permission is given by the department or the
4397 | court. Any person who violates this subsection is guilty of a
4398 | felony of the second degree, punishable as provided in s.
4399 | 775.082, s. 775.083, or s. 775.084.

4400 | (a) When any article detained or seized under this
4401 | subsection has been found by the department to be subject to
4402 | seizure and condemnation, the department shall petition the court
4403 | for an order of condemnation or sale, as the court directs. The
4404 | proceeds of the sale of drugs, devices, and cosmetics, less the
4405 | legal costs and charges, shall be deposited into the Florida
4406 | Drug, Device, and Cosmetic Trust Fund.

4407 | (b) If the department finds that any article seized under
4408 | this subsection was not subject to seizure under that section,
4409 | the department or the designated officer or employee shall remove
4410 | the tag or marking.

4411 | Section 43. Section 499.063, Florida Statutes, is repealed.

4412 | Section 44. Section 499.064, Florida Statutes, is repealed.

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4413 Section 45. Section 499.065, Florida Statutes, is amended
4414 to read:

4415 499.065 Inspections; imminent danger.--

4416 (1) Notwithstanding s. 499.051, the department shall
4417 inspect each prescription drug wholesale distributor
4418 establishment, prescription drug repackager establishment,
4419 veterinary prescription drug wholesale distributor establishment,
4420 limited prescription drug veterinary wholesale distributor
4421 ~~wholesaler~~ establishment, and retail pharmacy drug wholesale
4422 distributor ~~wholesaler~~ establishment that is required to be
4423 permitted under this part ~~chapter~~ as often as necessary to ensure
4424 compliance with applicable laws and rules. The department shall
4425 have the right of entry and access to these facilities at any
4426 reasonable time.

4427 (2) To protect the public from prescription drugs that are
4428 adulterated or otherwise unfit for human or animal consumption,
4429 the department may examine, sample, seize, and stop the sale or
4430 use of prescription drugs to determine the condition of those
4431 drugs. The department may immediately seize and remove any
4432 prescription drugs if the State Surgeon General or his or her
4433 designee determines that the prescription drugs represent a
4434 threat to the public health. The owner of any property seized
4435 under this section may, within 10 days after the seizure, apply
4436 to a court of competent jurisdiction for whatever relief is
4437 appropriate. At any time after 10 days, the department may
4438 destroy the drugs as contraband.

4439 (3) The department may determine that a prescription drug
4440 wholesale distributor establishment, prescription drug repackager
4441 establishment, veterinary prescription drug wholesale distributor

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4442 establishment, limited prescription drug veterinary wholesale
4443 distributor ~~wholesaler~~ establishment, or retail pharmacy drug
4444 wholesale distributor ~~wholesaler~~ establishment that is required
4445 to be permitted under this part ~~chapter~~ is an imminent danger to
4446 the public health and shall require its immediate closure if the
4447 establishment fails to comply with applicable laws and rules and,
4448 because of the failure, presents an imminent threat to the
4449 public's health, safety, or welfare. Any establishment so deemed
4450 and closed shall remain closed until allowed by the department or
4451 by judicial order to reopen.

4452
4453 For purposes of this section, a refusal to allow entry to the
4454 department for inspection at reasonable times, or a failure or
4455 refusal to provide the department with required documentation for
4456 purposes of inspection, constitutes an imminent danger to the
4457 public health.

4458 Section 46. Subsections (1), (2), (3), and (4) of section
4459 499.066, Florida Statutes, are amended to read:

4460 499.066 Penalties; remedies.--In addition to other
4461 penalties and other enforcement provisions:

4462 (1) The department may institute such suits or other legal
4463 proceedings as are required to enforce any provision of this part
4464 ~~ss. 499.001-499.081~~. If it appears that a person has violated any
4465 provision of this part ~~ss. 499.001-499.081~~ for which criminal
4466 prosecution is provided, the department may provide the
4467 appropriate state attorney or other prosecuting agency having
4468 jurisdiction with respect to such prosecution with the relevant
4469 information in the department's possession.

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4470 (2) If any person engaged in any activity covered by this
4471 part ss. 499.001-499.081 violates any provision of this part
4472 ~~those sections~~, any rule adopted under this part ~~those sections~~,
4473 or a cease and desist order as provided by this part ~~these~~
4474 ~~sections~~, the department may obtain an injunction in the circuit
4475 court of the county in which the violation occurred or in which
4476 the person resides or has its principal place of business, and
4477 may apply in that court for such temporary and permanent orders
4478 as the department considers necessary to restrain the person from
4479 engaging in any such activities until the person complies with
4480 this part ss. 499.001-499.081, the rules adopted under this part
4481 ~~those sections~~, and the orders of the department authorized by
4482 this part ~~those sections~~ or to mandate compliance with this part
4483 ~~ss. 499.001-499.081~~, the rules adopted under this part ~~those~~
4484 ~~sections~~, and any order or permit issued by the department under
4485 this part ~~those sections~~.

4486 (3) The department may impose an administrative fine, not
4487 to exceed \$5,000 per violation per day, for the violation of any
4488 provision of this part ss. 499.001-499.081 or rules adopted under
4489 this part ~~those sections~~. Each day a violation continues
4490 constitutes a separate violation, and each separate violation is
4491 subject to a separate fine. All amounts collected pursuant to
4492 this section shall be deposited into the Florida Drug, Device,
4493 and Cosmetic Trust Fund and are appropriated for the use of the
4494 department in administering this part ss. 499.001-499.081. In
4495 determining the amount of the fine to be levied for a violation,
4496 the department shall consider:

4497 (a) The severity of the violation;

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4498 (b) Any actions taken by the person to correct the
4499 violation or to remedy complaints; and

4500 (c) Any previous violations.

4501 (4) The department shall deposit any rewards, fines, or
4502 collections that are due the department and which derive from
4503 joint enforcement activities with other state and federal
4504 agencies which relate to this part ss. 499.001-499.081, chapter
4505 893, or the federal act, into the Florida Drug, Device, and
4506 Cosmetic Trust Fund. The proceeds of those rewards, fines, and
4507 collections are appropriated for the use of the department in
4508 administering this part ss. 499.001-499.081.

4509 Section 47. Section 499.0661, Florida Statutes, is amended
4510 to read:

4511 499.0661 Cease and desist orders; removal of certain
4512 persons.--

4513 ~~(1) DEFINITION. As used in this section, the term~~
4514 ~~"permittee" means any person holding a permit issued pursuant to~~
4515 ~~s. 499.012.~~

4516 (1)(2) CEASE AND DESIST ORDERS.--

4517 (a) In addition to any authority otherwise provided in this
4518 chapter, the department may issue and serve a complaint stating
4519 charges upon any permittee or upon any affiliated party, whenever
4520 the department has reasonable cause to believe that the person or
4521 individual named therein is engaging in or has engaged in conduct
4522 that is:

4523 1. An act that demonstrates a lack of fitness or
4524 trustworthiness to engage in the business authorized under the
4525 permit issued pursuant to this part ss. 499.001-499.081, is

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4526 hazardous to the public health, or constitutes business
4527 operations that are a detriment to the public health;

4528 2. A violation of any provision of this part ~~ss. 499.001-~~
4529 ~~499.081~~;

4530 3. A violation of any rule of the department;

4531 4. A violation of any order of the department; or

4532 5. A breach of any written agreement with the department.

4533 (b) The complaint must contain a statement of facts and
4534 notice of opportunity for a hearing pursuant to ss. 120.569 and
4535 120.57.

4536 (c) If a hearing is not requested within the time allowed
4537 by ss. 120.569 and 120.57, or if a hearing is held and the
4538 department finds that any of the charges are proven, the
4539 department may enter an order directing the permittee or the
4540 affiliated party named in the complaint to cease and desist from
4541 engaging in the conduct complained of and take corrective action
4542 to remedy the effects of past improper conduct and assure future
4543 compliance.

4544 (d) A contested or default cease and desist order is
4545 effective when reduced to writing and served upon the permittee
4546 or affiliated party named therein. An uncontested cease and
4547 desist order is effective as agreed.

4548 (e) Whenever the department finds that conduct described in
4549 paragraph (a) is likely to cause an immediate threat to the
4550 public health, it may issue an emergency cease and desist order
4551 requiring the permittee or any affiliated party to immediately
4552 cease and desist from engaging in the conduct complained of and
4553 to take corrective and remedial action. The emergency order is
4554 effective immediately upon service of a copy of the order upon

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4555 the permittee or affiliated party named therein and remains
4556 effective for 90 days. If the department begins nonemergency
4557 cease and desist proceedings under this subsection, the emergency
4558 order remains effective until the conclusion of the proceedings
4559 under ss. 120.569 and 120.57.

4560 (2)~~(3)~~ REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.--

4561 (a) The department may issue and serve a complaint stating
4562 charges upon any affiliated party and upon the permittee involved
4563 whenever the department has reason to believe that an affiliated
4564 party is engaging in or has engaged in conduct that constitutes:

4565 1. An act that demonstrates a lack of fitness or
4566 trustworthiness to engage in the business authorized under the
4567 permit issued pursuant to this part ~~ss. 499.001-499.081~~, is
4568 hazardous to the public health, or constitutes business
4569 operations that are a detriment to the public health;

4570 2. A willful violation of this part ~~ss. 499.001-499.081~~;
4571 however, if the violation constitutes a misdemeanor, a complaint
4572 may not be served as provided in this section until the
4573 affiliated party is notified in writing of the matter of the
4574 violation and has been afforded a reasonable period of time, as
4575 set forth in the notice, to correct the violation and has failed
4576 to do so;

4577 3. A violation of any other law involving fraud or moral
4578 turpitude which constitutes a felony;

4579 4. A willful violation of any rule of the department;

4580 5. A willful violation of any order of the department; or

4581 6. A material misrepresentation of fact, made knowingly and
4582 willfully or made with reckless disregard for the truth of the
4583 matter.

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4584 (b) The complaint must contain a statement of facts and
4585 notice of opportunity for a hearing pursuant to ss. 120.569 and
4586 120.57.

4587 (c) If a hearing is not requested within the time allotted
4588 by ss. 120.569 and 120.57, or if a hearing is held and the
4589 department finds that any of the charges in the complaint are
4590 proven true, the department may enter an order removing the
4591 affiliated party or restricting or prohibiting participation by
4592 the person in the affairs of that permittee or of any other
4593 permittee.

4594 (d) A contested or default order of removal, restriction,
4595 or prohibition is effective when reduced to writing and served on
4596 the permittee and the affiliated party. An uncontested order of
4597 removal, restriction, or prohibition is effective as agreed.

4598 (e)1. The chief executive officer, designated
4599 representative, or the person holding the equivalent office, of a
4600 permittee shall promptly notify the department if she or he has
4601 actual knowledge that any affiliated party is charged with a
4602 felony in a state or federal court.

4603 2. Whenever any affiliated party is charged with a felony
4604 in a state or federal court or with the equivalent of a felony in
4605 the courts of any foreign country with which the United States
4606 maintains diplomatic relations, and the charge alleges violation
4607 of any law involving prescription drugs, pharmaceuticals, fraud,
4608 theft, or moral turpitude, the department may enter an emergency
4609 order suspending the affiliated party or restricting or
4610 prohibiting participation by the affiliated party in the affairs
4611 of the particular permittee or of any other permittee upon
4612 service of the order upon the permittee and the affiliated party

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4613 | charged. The order must contain notice of opportunity for a
4614 | hearing pursuant to ss. 120.569 and 120.57, where the affiliated
4615 | party may request a postsuspension hearing to show that continued
4616 | service to or participation in the affairs of the permittee does
4617 | not pose a threat to the public health or the interests of the
4618 | permittee and does not threaten to impair public confidence in
4619 | the permittee. In accordance with applicable departmental rules,
4620 | the department shall notify the affiliated party whether the
4621 | order suspending or prohibiting the person from participation in
4622 | the affairs of a permittee will be rescinded or otherwise
4623 | modified. The emergency order remains in effect, unless otherwise
4624 | modified by the department, until the criminal charge is disposed
4625 | of. The acquittal of the person charged, or the final, unappealed
4626 | dismissal of all charges against the person, dissolves the
4627 | emergency order but does not prohibit the department from
4628 | instituting proceedings under paragraph (a). If the person
4629 | charged is convicted or pleads guilty or nolo contendere, whether
4630 | or not an adjudication of guilt is entered by the court, the
4631 | emergency order shall become final.

4632 | (f) Any affiliated party removed pursuant to this section
4633 | is not eligible for reemployment by the permittee or to be an
4634 | affiliated party of any permittee except upon the written consent
4635 | of the department. Any affiliated party who is removed,
4636 | restricted, or prohibited from participating in the affairs of a
4637 | permittee pursuant to this section may petition the department
4638 | for modification or termination of the removal, restriction, or
4639 | prohibition.

4640 | Section 48. Section 499.067, Florida Statutes, is amended
4641 | to read:

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4642 499.067 Denial, suspension, or revocation of permit,
4643 certification, or registration.--

4644 (1) (a) The department may deny, suspend, or revoke a permit
4645 if it finds that there has been a substantial failure to comply
4646 with this part ~~ss. 499.001-499.081~~ or chapter 465, chapter 501,
4647 or chapter 893, the rules adopted under this part ~~any of those~~
4648 ~~sections~~ or those chapters, any final order of the department, or
4649 applicable federal laws or regulations or other state laws or
4650 rules governing drugs, devices, or cosmetics.

4651 (b) The department may deny an application for a permit or
4652 certification, or suspend or revoke a permit or certification, if
4653 the department finds that:

4654 1. The applicant is not of good moral character or that it
4655 would be a danger or not in the best interest of the public
4656 health, safety, and welfare if the applicant were issued a permit
4657 or certification.

4658 2. The applicant has not met the requirements for the
4659 permit or certification.

4660 3. The applicant is not eligible for a permit or
4661 certification for any of the reasons enumerated in s. 499.012 ~~s.~~
4662 ~~499.01~~ ~~or s. 499.012(5)~~.

4663 4. The applicant, permittee, or person certified under s.
4664 499.012(16) ~~s. 499.012(11)~~ demonstrates any of the conditions
4665 enumerated in s. 499.012 ~~s. 499.01~~ ~~or s. 499.012(5)~~.

4666 5. The applicant, permittee, or person certified under s.
4667 499.012(16) ~~s. 499.012(11)~~ has committed any violation of ss.
4668 499.005-499.0054.

4669 (2) The department may deny, suspend, or revoke any
4670 registration required by the provisions of this part ~~ss. 499.001-~~

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4671 | ~~499.081~~ for the violation of any provision of this part ~~ss.~~
4672 | ~~499.001-499.081~~ or of any rules adopted under this part ~~these~~
4673 | ~~sections.~~

4674 | (3) The department may revoke or suspend a permit:

4675 | (a) If the permit was obtained by misrepresentation or
4676 | fraud or through a mistake of the department;

4677 | (b) If the permit was procured, or attempted to be
4678 | procured, for any other person by making or causing to be made
4679 | any false representation; or

4680 | (c) If the permittee has violated any provision of this
4681 | part ~~ss. 499.001-499.081~~ or rules adopted under this part ~~these~~
4682 | ~~sections.~~

4683 | (4) If any permit issued under this part ~~ss. 499.001-~~
4684 | ~~499.081~~ is revoked or suspended, the owner, manager, operator, or
4685 | proprietor of the establishment shall cease to operate as the
4686 | permit authorized, from the effective date of the suspension or
4687 | revocation until the person is again registered with the
4688 | department and possesses the required permit. If a permit is
4689 | revoked or suspended, the owner, manager, or proprietor shall
4690 | remove all signs and symbols that identify the operation as
4691 | premises permitted as a drug wholesaling establishment; drug,
4692 | device, or cosmetic manufacturing establishment; or retail
4693 | establishment. The department shall determine the length of time
4694 | for which the permit is to be suspended. If a permit is revoked,
4695 | the person that owns or operates the establishment may not apply
4696 | for any permit under this part ~~ss. 499.001-499.081~~ for a period
4697 | of 1 year after the date of the revocation. A revocation of a
4698 | permit may be permanent if the department considers that to be in
4699 | the best interest of the public health.

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4700 (5) The department may deny, suspend, or revoke a permit
4701 issued under this part ~~ss. 499.001-499.081~~ which authorizes the
4702 permittee to purchase prescription drugs, if any owner, officer,
4703 employee, or other person who participates in administering or
4704 operating the establishment has been found guilty of any
4705 violation of this part ~~ss. 499.001-499.081~~ or chapter 465,
4706 chapter 501, or chapter 893, any rules adopted under this part
4707 ~~any of these sections~~ or those chapters, or any federal or state
4708 drug law, regardless of whether the person has been pardoned, had
4709 her or his civil rights restored, or had adjudication withheld.

4710 (6) The department shall deny, suspend, or revoke the
4711 permit of any person or establishment if the assignment, sale,
4712 transfer, or lease of an establishment permitted under this part
4713 ~~ss. 499.001-499.081~~ will avoid an administrative penalty, civil
4714 action, or criminal prosecution.

4715 (7) Notwithstanding s. 120.60(5), if a permittee fails to
4716 comply with s. 499.012(6) ~~s. 499.01(7)~~, the department may revoke
4717 the permit of the permittee and shall provide notice of the
4718 intended agency action by posting a notice at the department's
4719 headquarters and by mailing a copy of the notice of intended
4720 agency action by certified mail to the most recent mailing
4721 address on record with the department and, if the permittee is
4722 not a natural person, to the permittee's registered agent on file
4723 with the Department of State.

4724 Section 49. Section 499.069, Florida Statutes, is repealed.

4725 Section 50. Section 499.0691, Florida Statutes, is
4726 repealed.

4727 Section 51. Section 499.07, Florida Statutes, is repealed.

4728 Section 52. Section 499.071, Florida Statutes, is repealed.

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4729 Section 53. Section 499.081, Florida Statutes, is repealed.

4730 Section 54. Paragraph (a) of subsection (1) of section
4731 895.02, Florida Statutes, is amended to read:

4732 895.02 Definitions.--As used in ss. 895.01-895.08, the
4733 term:

4734 (1) "Racketeering activity" means to commit, to attempt to
4735 commit, to conspire to commit, or to solicit, coerce, or
4736 intimidate another person to commit:

4737 (a) Any crime that is chargeable by indictment or
4738 information under the following provisions of the Florida
4739 Statutes:

4740 1. Section 210.18, relating to evasion of payment of
4741 cigarette taxes.

4742 2. Section 403.727(3)(b), relating to environmental
4743 control.

4744 3. Section 409.920 or s. 409.9201, relating to Medicaid
4745 fraud.

4746 4. Section 414.39, relating to public assistance fraud.

4747 5. Section 440.105 or s. 440.106, relating to workers'
4748 compensation.

4749 6. Section 443.071(4), relating to creation of a fictitious
4750 employer scheme to commit unemployment compensation fraud.

4751 7. Section 465.0161, relating to distribution of medicinal
4752 drugs without a permit as an Internet pharmacy.

4753 8. Section 499.0051 ~~Sections 499.0051, 499.0052, 499.00535,~~
4754 ~~499.00545, and 499.0691,~~ relating to crimes involving
4755 prescription ~~contraband and adulterated~~ drugs.

4756 9. Part IV of chapter 501, relating to telemarketing.

4757 10. Chapter 517, relating to sale of securities and

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- 4758 investor protection.
- 4759 11. Section 550.235, s. 550.3551, or s. 550.3605, relating
- 4760 to dogracing and horseracing.
- 4761 12. Chapter 550, relating to jai alai frontons.
- 4762 13. Section 551.109, relating to slot machine gaming.
- 4763 14. Chapter 552, relating to the manufacture, distribution,
- 4764 and use of explosives.
- 4765 15. Chapter 560, relating to money transmitters, if the
- 4766 violation is punishable as a felony.
- 4767 16. Chapter 562, relating to beverage law enforcement.
- 4768 17. Section 624.401, relating to transacting insurance
- 4769 without a certificate of authority, s. 624.437(4)(c)1., relating
- 4770 to operating an unauthorized multiple-employer welfare
- 4771 arrangement, or s. 626.902(1)(b), relating to representing or
- 4772 aiding an unauthorized insurer.
- 4773 18. Section 655.50, relating to reports of currency
- 4774 transactions, when such violation is punishable as a felony.
- 4775 19. Chapter 687, relating to interest and usurious
- 4776 practices.
- 4777 20. Section 721.08, s. 721.09, or s. 721.13, relating to
- 4778 real estate timeshare plans.
- 4779 21. Chapter 782, relating to homicide.
- 4780 22. Chapter 784, relating to assault and battery.
- 4781 23. Chapter 787, relating to kidnapping or human
- 4782 trafficking.
- 4783 24. Chapter 790, relating to weapons and firearms.
- 4784 25. Section 796.03, s. 796.035, s. 796.04, s. 796.045, s.
- 4785 796.05, or s. 796.07, relating to prostitution and sex
- 4786 trafficking.

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- 4787 26. Chapter 806, relating to arson.
- 4788 27. Section 810.02(2)(c), relating to specified burglary of
4789 a dwelling or structure.
- 4790 28. Chapter 812, relating to theft, robbery, and related
4791 crimes.
- 4792 29. Chapter 815, relating to computer-related crimes.
- 4793 30. Chapter 817, relating to fraudulent practices, false
4794 pretenses, fraud generally, and credit card crimes.
- 4795 31. Chapter 825, relating to abuse, neglect, or
4796 exploitation of an elderly person or disabled adult.
- 4797 32. Section 827.071, relating to commercial sexual
4798 exploitation of children.
- 4799 33. Chapter 831, relating to forgery and counterfeiting.
- 4800 34. Chapter 832, relating to issuance of worthless checks
4801 and drafts.
- 4802 35. Section 836.05, relating to extortion.
- 4803 36. Chapter 837, relating to perjury.
- 4804 37. Chapter 838, relating to bribery and misuse of public
4805 office.
- 4806 38. Chapter 843, relating to obstruction of justice.
- 4807 39. Section 847.011, s. 847.012, s. 847.013, s. 847.06, or
4808 s. 847.07, relating to obscene literature and profanity.
- 4809 40. Section 849.09, s. 849.14, s. 849.15, s. 849.23, or s.
4810 849.25, relating to gambling.
- 4811 41. Chapter 874, relating to criminal street gangs.
- 4812 42. Chapter 893, relating to drug abuse prevention and
4813 control.
- 4814 43. Chapter 896, relating to offenses related to financial
4815 transactions.

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4816 44. Sections 914.22 and 914.23, relating to tampering with
 4817 a witness, victim, or informant, and retaliation against a
 4818 witness, victim, or informant.

4819 45. Sections 918.12 and 918.13, relating to tampering with
 4820 jurors and evidence.

4821 Section 55. Paragraphs (d), (h), (i), and (j) of subsection
 4822 (3) of section 921.0022, Florida Statutes, are amended to read:

4823 921.0022 Criminal Punishment Code; offense severity ranking
 4824 chart.--

4825 (3) OFFENSE SEVERITY RANKING CHART

4826 (d) LEVEL 4

4827

Florida Statute	Felony Degree	Description
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.
499.0051 (1)	3rd	Failure to maintain or deliver pedigree

4829

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4830	499.0051 (2)	3rd	papers.
4831	499.0051 (6)	2nd	Failure to authenticate pedigree papers.
4832	784.07 (2) (b)	3rd	Sale or delivery, or possession with intent to sell, contraband <u>prescription legend</u> drugs.
4833	784.074 (1) (c)	3rd	Battery of law enforcement officer, firefighter, intake officer, etc.
4834	784.075	3rd	Battery of sexually violent predators facility staff.
4835	784.078	3rd	Battery on detention or commitment facility staff.
			Battery of facility

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4836	784.08 (2) (c)	3rd	employee by throwing, tossing, or expelling certain fluids or materials.
4837	784.081 (3)	3rd	Battery on a person 65 years of age or older.
4838	784.082 (3)	3rd	Battery on specified official or employee.
4839	784.083 (3)	3rd	Battery by detained person on visitor or other detainee.
4840	784.085	3rd	Battery on code inspector.
4841	787.03 (1)	3rd	Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.
			Interference with

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4842	787.04 (2)	3rd	custody; wrongly takes minor from appointed guardian.
4843	787.04 (3)	3rd	Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
4844	790.115 (1)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
4845	790.115 (2) (b)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
			Possessing electric weapon or device, destructive device, or other weapon on

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4846	790.115 (2) (c)	3rd	school property.
4847	800.04 (7) (d)	3rd	Possessing firearm on school property.
4848	810.02 (4) (a)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
4849	810.02 (4) (b)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
4850	810.06	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
4851	810.08 (2) (c)	3rd	Burglary; possession of tools.
			Trespass on

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4852	812.014 (2) (c) 3.	3rd	property, armed with firearm or dangerous weapon.
4853	812.014 (2) (c) 4.-10.	3rd	Grand theft, 3rd degree \$10,000 or more but less than \$20,000.
4854	812.0195 (2)	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
4855	817.563 (1)	3rd	Dealing in stolen property by use of the Internet; property stolen \$300 or more.
4856	817.568 (2) (a)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03 (5) drugs.
			Fraudulent use of

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4857	817.625 (2) (a)	3rd	personal identification information. Fraudulent use of scanning device or reencoder.
4858	828.125 (1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
4859	837.02 (1)	3rd	Perjury in official proceedings.
4860	837.021 (1)	3rd	Make contradictory statements in official proceedings.
4861	838.022	3rd	Official misconduct.
4862	839.13 (2) (a)	3rd	Falsifying records of an individual in the care and

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4863	839.13 (2) (c)	3rd	custody of a state agency.
4864	843.021	3rd	Falsifying records of the Department of Children and Family Services.
4865	843.025	3rd	Possession of a concealed handcuff key by a person in custody.
4866	843.15 (1) (a)	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
4867	874.05 (1)	3rd	Failure to appear while on bail for felony (bond estreature or bond jumping).
			Encouraging or

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4868	893.13 (2) (a) 1.	2nd	recruiting another to join a criminal street gang.
4869	914.14 (2)	3rd	Purchase of cocaine (or other s. 893.03 (1) (a), (b), or (d), (2) (a), (2) (b), or (2) (c) 4. drugs).
4870	914.22 (1)	3rd	Witnesses accepting bribes.
4871	914.23 (2)	3rd	Force, threaten, etc., witness, victim, or informant.
4872	918.12	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
4873	934.215	3rd	Tampering with jurors.
			Use of two-way communications

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			device to facilitate commission of a crime.
4874			
4875			
4876	(h)	LEVEL 8	
4877			
	Florida	Felony	Description
	Statute	Degree	
4878			
	316.193 (3) (c) 3.a.	2nd	DUI manslaughter.
4879			
	316.1935 (4) (b)	1st	Aggravated fleeing or attempted eluding with serious bodily injury or death.
4880			
	327.35 (3) (c) 3.	2nd	Vessel BUI manslaughter.
4881			
	<u>499.0051 (8)</u>	1st	Forgery of prescription <u>labels</u> or <u>prescription</u> legend drug labels.
	499.0051 (7)		
4882			
	<u>499.0051 (7)</u>	1st	Trafficking in contraband
	499.0052		

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4883	560.123 (8) (b) 2.	2nd	<u>prescription legend</u> drugs.
4884	560.125 (5) (b)	2nd	Failure to report currency or payment instruments totaling or exceeding \$20,000, but less than \$100,000 by money transmitter.
4885	655.50 (10) (b) 2.	2nd	Money transmitter business by unauthorized person, currency or payment instruments totaling or exceeding \$20,000, but less than \$100,000.
			Failure to report financial transactions totaling or exceeding \$20,000, but less than \$100,000 by

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4886	777.03 (2) (a)	1st	financial institutions.
4887	782.04 (4)	2nd	Accessory after the fact, capital felony.
4888	782.051 (2)	1st	Killing of human without design when engaged in act or attempt of any felony other than arson, sexual battery, robbery, burglary, kidnapping, aircraft piracy, or unlawfully discharging bomb.
4889	782.071 (1) (b)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony not enumerated in s. 782.04(3).
			Committing

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4890	782.072 (2)	1st	vehicular homicide and failing to render aid or give information.
4891	790.161 (3)	1st	Committing vessel homicide and failing to render aid or give information.
4892	794.011 (5)	2nd	Discharging a destructive device which results in bodily harm or property damage.
4893	794.08 (3)	2nd	Sexual battery, victim 12 years or over, offender does not use physical force likely to cause serious injury. Female genital mutilation, removal of a victim younger than 18 years of

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4894	800.04 (4)	2nd	age from this state.
4895	806.01 (1)	1st	Lewd or lascivious battery.
4896	810.02 (2) (a)	1st, PBL	Maliciously damage dwelling or structure by fire or explosive, believing person in structure.
4897	810.02 (2) (b)	1st, PBL	Burglary with assault or battery.
4898	810.02 (2) (c)	1st	Burglary; armed with explosives or dangerous weapon.
4899	812.014 (2) (a) 2.	1st	Burglary of a dwelling or structure causing structural damage or \$1,000 or more property damage.
			Property stolen; cargo valued at

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4900	812.13 (2) (b)	1st	\$50,000 or more, grand theft in 1st degree.
4901	812.135 (2) (c)	1st	Robbery with a weapon.
4902	817.568 (6)	2nd	Home-invasion robbery, no firearm, deadly weapon, or other weapon.
4903	825.102 (2)	2nd	Fraudulent use of personal identification information of an individual under the age of 18.
4904	825.1025 (2)	2nd	Aggravated abuse of an elderly person or disabled adult.
4905			Lewd or lascivious battery upon an elderly person or disabled adult.

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4906	825.103 (2) (a)	1st	Exploiting an elderly person or disabled adult and property is valued at \$100,000 or more.
4907	837.02 (2)	2nd	Perjury in official proceedings relating to prosecution of a capital felony.
4908	837.021 (2)	2nd	Making contradictory statements in official proceedings relating to prosecution of a capital felony.
4909	860.121 (2) (c)	1st	Shooting at or throwing any object in path of railroad vehicle resulting in great bodily harm.

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4910	860.16	1st	Aircraft piracy.
4911	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).
4912	893.13 (2) (b)	1st	Purchase in excess of 10 grams of any substance specified in s. 893.03 (1) (a) or (b).
4913	893.13 (6) (c)	1st	Possess in excess of 10 grams of any substance specified in s. 893.03 (1) (a) or (b).
4914	893.135 (1) (a) 2.	1st	Trafficking in cannabis, more than 2,000 lbs., less than 10,000 lbs.
	893.135 (1) (b) 1.b.	1st	Trafficking in cocaine, more than 200 grams, less

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4915	893.135 (1) (c) 1.b.	1st	than 400 grams.
4916	893.135 (1) (d) 1.b.	1st	Trafficking in illegal drugs, more than 14 grams, less than 28 grams.
4917	893.135 (1) (e) 1.b.	1st	Trafficking in phencyclidine, more than 200 grams, less than 400 grams.
4918	893.135 (1) (f) 1.b.	1st	Trafficking in methaqualone, more than 5 kilograms, less than 25 kilograms.
4919	893.135 (1) (g) 1.b.	1st	Trafficking in amphetamine, more than 28 grams, less than 200 grams.
4920	893.135 (1) (g) 1.b.	1st	Trafficking in flunitrazepam, 14 grams or more, less than 28 grams.

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4921	893.135 (1) (h) 1.b.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 5 kilograms or more, less than 10 kilograms.
4922	893.135 (1) (j) 1.b.	1st	Trafficking in 1,4-Butanediol, 5 kilograms or more, less than 10 kilograms.
4923	893.135 (1) (k) 2.b.	1st	Trafficking in Phenethylamines, 200 grams or more, less than 400 grams.
4924	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

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4925	895.03 (3)	1st	interest in or control of any enterprise or real property.
4926	896.101 (5) (b)	2nd	Conduct or participate in any enterprise through pattern of racketeering activity.
4927	896.104 (4) (a) 2.	2nd	Money laundering, financial transactions totaling or exceeding \$20,000, but less than \$100,000.
			Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding \$20,000

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			but less than \$100,000.
4928			
4929			
4930	(i) LEVEL 9		
4931			
	Florida Statute	Felony Degree	Description
4932	316.193 (3) (c) 3.b.	1st	DUI manslaughter; failing to render aid or give information.
4933	327.35 (3) (c) 3.b.	1st	BUI manslaughter; failing to render aid or give information.
4934	<u>499.0051 (9)</u> 499.00535	1st	Sale or purchase of contraband <u>prescription legend</u> drugs resulting in great bodily harm.
4935	560.123 (8) (b) 3.	1st	Failure to report currency or payment instruments totaling or

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4936	560.125 (5) (c)	1st	exceeding \$100,000 by money transmitter.
4937	655.50 (10) (b) 3.	1st	Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding \$100,000.
4938	775.0844	1st	Failure to report financial transactions totaling or exceeding \$100,000 by financial institution.
4939	782.04 (1)	1st	Aggravated white collar crime. Attempt, conspire, or solicit to commit premeditated murder.
4940			

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4941	782.04 (3)	1st, PBL	Accomplice to murder in connection with arson, sexual battery, robbery, burglary, and other specified felonies.
4942	782.051 (1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04 (3).
4943	782.07 (2)	1st	Aggravated manslaughter of an elderly person or disabled adult.
4944	787.01 (1) (a) 1.	1st, PBL	Kidnapping; hold for ransom or reward or as a shield or hostage.
	787.01 (1) (a) 2.	1st, PBL	Kidnapping with intent to commit or facilitate

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4945	787.01 (1) (a) 4.	1st, PBL	commission of any felony.
4946	787.02 (3) (a)	1st	Kidnapping with intent to interfere with performance of any governmental or political function.
4947	790.161	1st	False imprisonment; child under age 13; perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
4948	790.166 (2)	1st, PBL	Attempted capital destructive device offense.
			Possessing, selling, using, or attempting to use a weapon of mass destruction.

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4949	794.011 (2)	1st	Attempted sexual battery; victim less than 12 years of age.
4950	794.011 (2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.
4951	794.011 (4)	1st	Sexual battery; victim 12 years or older, certain circumstances.
4952	794.011 (8) (b)	1st	Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial authority.
4953	794.08 (2)	1st	Female genital mutilation; victim younger than 18

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4954	800.04 (5) (b)	Life	years of age.
4955	812.13 (2) (a)	1st, PBL	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
4956	812.133 (2) (a)	1st, PBL	Robbery with firearm or other deadly weapon.
4957	812.135 (2) (b)	1st	Carjacking; firearm or other deadly weapon.
4958	817.568 (7)	2nd, PBL	Home-invasion robbery with weapon.
			Fraudulent use of personal identification information of an individual under the age of 18 by his or her parent, legal guardian, or person exercising

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4959	827.03 (2)	1st	custodial authority.
4960	847.0145 (1)	1st	Aggravated child abuse.
4961	847.0145 (2)	1st	Selling, or otherwise transferring custody or control, of a minor.
4962	859.01	1st	Purchasing, or otherwise obtaining custody or control, of a minor. Poisoning or introducing bacteria, radioactive materials, viruses, or chemical compounds into food, drink, medicine, or water with intent to kill or injure another person.

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4963	893.135	1st	Attempted capital trafficking offense.
4964	893.135 (1) (a) 3.	1st	Trafficking in cannabis, more than 10,000 lbs.
4965	893.135 (1) (b) 1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.
4966	893.135 (1) (c) 1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
4967	893.135 (1) (d) 1.c.	1st	Trafficking in phencyclidine, more than 400 grams.
4968	893.135 (1) (e) 1.c.	1st	Trafficking in methaqualone, more than 25 kilograms.
4969	893.135 (1) (f) 1.c.	1st	Trafficking in amphetamine, more

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4970	893.135 (1) (h) 1.c.	1st	than 200 grams.
4971	893.135 (1) (j) 1.c.	1st	Trafficking in gamma- hydroxybutyric acid (GHB), 10 kilograms or more.
4972	893.135 (1) (k) 2.c.	1st	Trafficking in 1,4- Butanediol, 10 kilograms or more.
4973	896.101 (5) (c)	1st	Trafficking in Phenethylamines, 400 grams or more.
4974	896.104 (4) (a) 3.	1st	Money laundering, financial instruments totaling or exceeding \$100,000.
			Structuring transactions to evade reporting or registration requirements, financial transactions

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			totaling or exceeding \$100,000.
4975			
4976			
4977	(j) LEVEL 10		
4978			
	Florida Statute	Felony Degree	Description
4979	<u>499.0051(10)</u> 499.00545	1st	Sale or purchase of contraband <u>prescription legend</u> legend drugs resulting in death.
4980	782.04 (2)	1st, PBL	Unlawful killing of human; act is homicide, unpremeditated.
4981	787.01 (1) (a) 3.	1st, PBL	Kidnapping; inflict bodily harm upon or terrorize victim.
4982	787.01 (3) (a)	Life	Kidnapping; child under age 13, perpetrator also commits aggravated child abuse, sexual

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4983	782.07 (3)	1st	battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
4984	794.011 (3)	Life	Aggravated manslaughter of a child.
4985	812.135 (2) (a)	1st, PBL	Sexual battery; victim 12 years or older, offender uses or threatens to use deadly weapon or physical force to cause serious injury.
4986	876.32	1st	Home-invasion robbery with firearm or other deadly weapon.
4987	Section 56. This act shall take effect July 1, 2008.		
4988			