



CHAMBER ACTION

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The Committee on Health Care recommends the following:

Committee Substitute

Remove the entire bill and insert:

A bill to be entitled

An act relating to the distribution of prescription drugs; providing a popular name; providing legislative findings and intent with respect to a report by the Seventeenth Statewide Grand Jury; amending s. 499.003, F.S.; defining additional terms, including the terms "contraband legend drug," "pedigree paper," and "repackager"; amending s. 499.005, F.S.; prohibiting the purchase or sale of prescription drugs in wholesale distribution in exchange for currency; clarifying provisions prohibiting the transfer of legend drugs from or to any person not authorized to possess such drugs; prohibiting additional acts concerning the distribution of prescription drugs; creating s. 499.0051, F.S.; providing that failure to maintain or deliver pedigree papers, failure to authenticate pedigree papers, forgery of pedigree papers, purchase of legend drugs from an unlicensed person, sale of legend drugs to an unlicensed person, possession or sale of contraband legend drugs and possession with intent



29 | to sell or deliver contraband legend drugs, and forgery of
 30 | prescription labels or legend drug labels are felony
 31 | offenses; providing penalties; creating s. 499.0052, F.S.;
 32 | providing that trafficking in contraband legend drugs is a
 33 | felony offense; providing penalties; providing enhanced
 34 | penalties if the defendant is a corporation or not a
 35 | natural person; creating s. 499.00523, F.S.; providing
 36 | that the sale or purchase of a contraband legend drug
 37 | resulting in great bodily harm is a first-degree felony;
 38 | creating s. 499.00525, F.S.; providing that the sale or
 39 | purchase of a contraband legend drug resulting in death is
 40 | a first-degree felony; amending s. 499.006, F.S.;
 41 | providing that a legend drug that is unaccompanied by a
 42 | proper pedigree paper or that has been in the possession
 43 | of an unauthorized person is an adulterated drug; amending
 44 | s. 499.007, F.S.; revising labeling requirements to
 45 | conform to federal law; amending s. 499.01, F.S.;
 46 | authorizing issuance of prescription drug manufacturer
 47 | permits to the addresses of certain pharmacies;
 48 | prohibiting issuance of local occupational licenses to
 49 | establishments not exhibiting a current permit; providing
 50 | expiration dates for prescription drug wholesaler permits
 51 | and out-of-state prescription drug wholesaler permits;
 52 | requiring that prescription drug repackagers, nonresident
 53 | prescription drug manufacturers, and freight forwarders
 54 | obtain a permit from the Department of Health in order to
 55 | do business; revising application requirements; providing
 56 | for revocation of permit for failure to comply with



57 requirements prohibiting transfer of a permit; amending s.
58 499.012, F.S.; excluding the transfer of prescription
59 drugs within a hospital from the definition of wholesale
60 distribution; providing bond requirements for prescription
61 drug wholesalers and out-of-state prescription drug
62 wholesalers; deleting provisions authorizing the
63 department to grant out-of-state wholesalers reciprocity;
64 requiring freight forwarders and nonresident prescription
65 drug manufacturers to obtain a permit; providing
66 requirements; providing requirements for the permitting of
67 prescription drug wholesalers, out-of-state prescription
68 drug wholesalers, and retail pharmacy drug wholesalers;
69 requiring prescription drug wholesalers and out-of-state
70 prescription drug wholesalers to designate a
71 representative; providing criteria for designation as a
72 representative; amending s. 499.0121, F.S.; requiring
73 pedigree papers for the transfer and sale of legend drugs;
74 providing documentation requirements for the shipment of
75 prescription drugs; providing requirements for wholesale
76 drug distributors with respect to the exercise of due
77 diligence; creating s. 499.01211, F.S.; creating the Drug
78 Wholesaler Advisory Council within the Department of
79 Health; providing for membership of the council and terms
80 of office; requiring the council to review rules and make
81 recommendations to the secretary of the department;
82 amending s. 499.0122, F.S.; conforming cross references;
83 amending s. 499.013, F.S.; providing requirements for
84 repackagers of drugs, devices, and cosmetics; requiring



85 | that a repackager obtain a permit from the department;
86 | amending s. 499.014, F.S.; specifying that certain
87 | restricted distributors are exempt from the requirements
88 | concerning pedigree papers; amending ss. 499.015, 499.024,
89 | and 499.03, F.S.; conforming cross references; amending s.
90 | 499.041, F.S.; revising the schedule of fees for permits;
91 | amending s. 499.05, F.S.; conforming a cross reference;
92 | amending s. 499.051, F.S.; extending the authority of the
93 | Department of Health to inspect pharmacies and retail
94 | pharmacy wholesalers; authorizing the department and the
95 | Department of Law Enforcement to inspect certain financial
96 | documents and records; amending s. 499.055, F.S.;
97 | requiring the Department of Health to establish a website
98 | listing certain wholesaler permit holders and pending
99 | enforcement actions; creating s. 499.065, F.S.;
100 | authorizing the department to enter and inspect all
101 | permitted facilities at any reasonable time; authorizing
102 | the department to seize and destroy prescription drugs
103 | representing a threat to public health; authorizing the
104 | department to close facilities that represent an imminent
105 | danger to public health; amending s. 499.066, F.S.;
106 | providing for enforcement actions by the department;
107 | creating s. 499.0661, F.S.; providing for the department
108 | to issue cease and desist orders; providing for the
109 | department to order the removal of certain persons from
110 | involvement with certain drug wholesalers; amending s.
111 | 499.067, F.S.; specifying additional grounds for denial of
112 | a permit or certification; amending s. 499.069, F.S.;



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113 | revising certain penalty provisions; creating s. 499.0691,
114 | F.S.; providing criminal penalties for violations related
115 | to drugs or false advertisement; amending s. 921.0022,
116 | F.S., relating to the offense severity ranking chart of
117 | the Criminal Punishment Code; conforming provisions to
118 | changes made by the act; amending s. 895.02, F.S.;
119 | including certain violations of part I of ch. 499, F.S.,
120 | within the definition of racketeering activity; amending
121 | ss. 16.56 and 905.34, F.S.; authorizing criminal
122 | violations of part I of ch. 499, F.S., to be prosecuted by
123 | the Office of Statewide Prosecution and heard by a
124 | statewide grand jury; providing for severability;
125 | providing effective dates.

126

127 | Be It Enacted by the Legislature of the State of Florida:

128

129 | Section 1. This act shall be known by the popular name the
130 | "Prescription Drug Protection Act."

131 | Section 2. Legislative findings and intent.--Based on the
132 | report of the Seventeenth Statewide Grand Jury in its First
133 | Interim Report, the Legislature finds that prescription drugs
134 | brought into the state by wholesalers are being relabeled and
135 | falsely represented as being of a higher dosage by other
136 | wholesalers in order to charge higher prices for those drugs and
137 | that counterfeit substances labeled as genuine pharmaceuticals
138 | are being distributed, thereby causing an extreme danger that
139 | persons eventually receiving the drugs by prescription are
140 | receiving ineffective drugs in nontherapeutic doses, or even



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141 receiving dangerous or unwholesome substances, with the result
142 that the health and well-being of the public is at risk. The
143 Statewide Grand Jury also found that the lack of an effective
144 pedigree paper requirement has resulted in the inability of
145 prescription drug users to have confidence in the purity and
146 efficacy of the drugs they use. The Statewide Grand Jury further
147 noted that present laws do not allow effective criminal
148 prosecution of persons involved in such false representations.
149 It is the intent of the Legislature that the statutory changes
150 and recommendations outlined in the Statewide Grand Jury's
151 report be implemented as provided by this act.

152 Section 3. Section 499.003, Florida Statutes, is amended
153 to read:

154 499.003 Definitions of terms used in ss. 499.001-
155 499.081.--As used in ss. 499.001-499.081, the term:

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

160 (2) "Affiliated party" means:

161 (a) A director, officer, trustee, partner, or committee
162 member of a permittee or applicant or a subsidiary or service
163 corporation of the permittee or applicant;

164 (b) A person who, directly or indirectly, manages,
165 controls, or oversees the operation of a permittee or applicant,
166 regardless of whether such person is a partner, shareholder,
167 manager, member, officer, director, independent contractor, or
168 employee of the permittee or applicant;



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169 (c) A person who has filed or is required to file a
170 personal information statement pursuant to s. 499.012(4) or is
171 required to be identified in an application for a permit or to
172 renew a permit pursuant to s. 499.012(3); or

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

175 (3) "Applicant" means a person applying for a permit or
176 certification under ss. 499.001-499.081.

177 (4) "Authenticate" means to affirmatively verify before
178 any distribution of a legend drug occurs that each transaction
179 listed on the pedigree paper has occurred.

180 (5)(2) "Certificate of free sale" means a document
181 prepared by the department which certifies a drug, device, or
182 cosmetic, that is registered with the department, as one that
183 can be legally sold in the state.

184 (6)(3) "Closed pharmacy" means a pharmacy that is licensed
185 under chapter 465 and purchases prescription drugs for use by a
186 limited patient population and not for wholesale distribution or
187 sale to the public. The term does not include retail
188 pharmacies.

189 (7)(4) "Color" includes black, white, and intermediate
190 grays.

191 (8)(5) "Color additive" means a material that:

192 (a) Is a dye pigment, or other substance, made by a
193 process of synthesis or similar artifice, or extracted,
194 isolated, or otherwise derived, with or without intermediate or
195 final change of identity from a vegetable, animal, mineral, or
196 other source; or



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

200
201 except that the term does not include any material which has
202 been or hereafter is exempt under the federal act.

203 (9)~~(6)~~ "Compressed medical gas" means any liquefied or
204 vaporized gas that is a prescription drug, whether it is alone
205 or in combination with other gases.

206 (10) "Contraband legend drug" means any:

207 (a) Adulterated drug, as defined in s. 499.006;

208 (b) Counterfeit drug, as defined in this section; or

209 (c) Legend drug for which a pedigree paper does not exist
210 or for which the pedigree paper in existence has been forged,
211 counterfeited, falsely created or contains any altered, false,
212 or misrepresented matter.

213 (11)~~(7)~~ "Cosmetic" means an article that is:

214 (a) Intended to be rubbed, poured, sprinkled, or sprayed
215 on; introduced into; or otherwise applied to the human body or
216 any part thereof for cleansing, beautifying, promoting
217 attractiveness, or altering the appearance; or

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

219
220 except that the term does not include soap.

221 (12)~~(8)~~ "Counterfeit drug, counterfeit device, or
222 counterfeit cosmetic" means a drug, device, or cosmetic which,
223 or the container, seal, or labeling of which, without
224 authorization, bears the trademark, trade name, or other



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225 identifying mark, imprint, or device, or any likeness thereof,
226 of a drug, device, or cosmetic manufacturer, processor, packer,
227 or distributor other than the person that in fact manufactured,
228 processed, packed, or distributed that drug, device, or cosmetic
229 and which thereby falsely purports or is represented to be the
230 product of, or to have been packed or distributed by, that other
231 drug, device, or cosmetic manufacturer, processor, packer, or
232 distributor.

233 (13)~~(9)~~ "Department" means the Department of Health.

234 (14)~~(10)~~ "Device" means any instrument, apparatus,
235 implement, machine, contrivance, implant, in vitro reagent, or
236 other similar or related article, including its components,
237 parts, or accessories, which is:

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

240 (b) Intended for use in the diagnosis, cure, mitigation,
241 treatment, therapy, or prevention of disease in humans or other
242 animals, or

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

245

246 and which does not achieve any of its principal intended
247 purposes through chemical action within or on the body of humans
248 or other animals and which is not dependent upon being
249 metabolized for the achievement of any of its principal intended
250 purposes.

251 (15)~~(11)~~ "Distribute" or "distribution" means to sell;
252 offer to sell; give away; transfer, whether by passage of title,



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253 physical movement, or both; deliver; or offer to deliver. The
254 term does not mean to administer or dispense.

255 (16) "Diverted from the legal channels of distribution for
256 prescription drugs" means an adulterated drug pursuant to s.
257 499.006(10).

258 (17)~~(12)~~ "Drug" means an article that is:

259 (a) Recognized in the current edition of the United States
260 Pharmacopoeia and National Formulary, official Homeopathic
261 Pharmacopoeia of the United States, or any supplement to any of
262 those publications;

263 (b) Intended for use in the diagnosis, cure, mitigation,
264 treatment, therapy, or prevention of disease in humans or other
265 animals;

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

268 (d) Intended for use as a component of any article
269 specified in paragraph (a), paragraph (b), or paragraph (c), but
270 does not include devices or their components, parts, or
271 accessories.

272 (18)~~(13)~~ "Establishment" means a place of business at one
273 general physical location.

274 (19)~~(14)~~ "Federal act" means the Federal Food, Drug, and
275 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

276 (20) "Freight forwarder" means a person who receives
277 legend drugs which are owned by another person and designated by
278 that person for export, and exports those legend drugs.

279 (21)~~(15)~~ "Health care entity" means a closed pharmacy or
280 any person, organization, or business entity that provides



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281 diagnostic, medical, surgical, or dental treatment or care, or
282 chronic or rehabilitative care, but does not include any
283 wholesale distributor or retail pharmacy licensed under state
284 law to deal in prescription drugs.

285 (22)~~(16)~~ "Immediate container" does not include package
286 liners.

287 (23)~~(17)~~ "Label" means a display of written, printed, or
288 graphic matter upon the immediate container of any drug, device,
289 or cosmetic. A requirement made by or under authority of ss.
290 499.001-499.081 or rules adopted under those sections that any
291 word, statement, or other information appear on the label is not
292 complied with unless such word, statement, or other information
293 also appears on the outside container or wrapper, if any, of the
294 retail package of such drug, device, or cosmetic or is easily
295 legible through the outside container or wrapper.

296 (24)~~(18)~~ "Labeling" means all labels and other written,
297 printed, or graphic matters:

298 (a) Upon a drug, device, or cosmetic, or any of its
299 containers or wrappers; or

300 (b) Accompanying or related to such drug, device, or
301 cosmetic.

302 (25)~~(19)~~ "Legend drug," "prescription drug," or "medicinal
303 drug" means any drug, including, but not limited to, finished
304 dosage forms, or active ingredients subject to, defined by, or
305 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
306 Act or s. 465.003(8), s. 499.007(12), or s. 499.0122(1)(b) or
307 (c).



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308 (26) "Legend drug label" means any display of written,
309 printed, or graphic matter upon the immediate container of any
310 legend drug prior to its dispensing to an individual patient
311 pursuant to a prescription of a practitioner authorized by law
312 to prescribe.

313 (27)~~(20)~~ "Manufacture" means the preparation, deriving,
314 compounding, propagation, processing, producing, or fabrication
315 of any drug, device, or cosmetic. ~~The term includes repackaging~~
316 ~~or otherwise changing the container, wrapper, or labeling to~~
317 ~~further the distribution of the drug, device, or cosmetic.~~

318 (28)~~(21)~~ "Manufacturer" means a person who prepares,
319 derives, manufactures, or produces a drug, device, or cosmetic.
320 The term excludes pharmacies that are operating in compliance
321 with pharmacy practice standards as defined in chapter 465 and
322 rules adopted under that chapter.

323 (29)~~(22)~~ "New drug" means:

324 (a) Any drug the composition of which is such that the
325 drug is not generally recognized, among experts qualified by
326 scientific training and experience to evaluate the safety and
327 effectiveness of drugs, as safe and effective for use under the
328 conditions prescribed, recommended, or suggested in the labeling
329 of that drug; or

330 (b) Any drug the composition of which is such that the
331 drug, as a result of investigations to determine its safety and
332 effectiveness for use under certain conditions, has been
333 recognized for use under such conditions, but which drug has
334 not, other than in those investigations, been used to a material
335 extent or for a material time under such conditions.



336 ~~(30)~~~~(23)~~ "Official compendium" means the current edition
337 of the official United States Pharmacopoeia and National
338 Formulary, or any supplement thereto.

339 (31) "Pedigree paper" means:

340 (a) A document required pursuant to s. 499.0121(6)(d) or
341 (e); or

342 (b) Effective July 1, 2006, a document in a form approved
343 by the department and containing information that records each
344 distribution of any given legend drug, from sale by a
345 pharmaceutical manufacturer, through acquisition and sale by any
346 wholesaler or repackager, until final sale to a pharmacy or
347 other person administering or dispensing the drug. The
348 information required to be included on a legend drug's pedigree
349 paper must at least detail the amount of the legend drug, its
350 dosage form and strength, its lot numbers, the name and address
351 of each owner of the legend drug and his or her signature, its
352 shipping information, including the name and address of each
353 person certifying delivery or receipt of the legend drug, and a
354 certification that the recipient has authenticated the pedigree
355 papers. It must also include the name, address, telephone number
356 and, if available, e-mail contact information of each wholesaler
357 involved in the chain of the legend drug's custody. The
358 department shall adopt rules and a form relating to the
359 requirements of this paragraph no later than 90 days after the
360 effective date of this act.

361 ~~(32)~~~~(24)~~ "Person" means any individual, child, joint
362 venture, syndicate, fiduciary, partnership, corporation,
363 division of a corporation, firm, trust, business trust, company,



364 estate, public or private institution, association,
 365 organization, group, city, county, city and county, political
 366 subdivision of this state, other governmental agency within this
 367 state, and any representative, agent, or agency of any of the
 368 foregoing, or any other group or combination of the foregoing.

369 (33)~~(25)~~ "Prepackaged drug product" means a drug that
 370 originally was in finished packaged form sealed by a
 371 manufacturer and that is placed in a properly labeled container
 372 by a pharmacy or practitioner authorized to dispense pursuant to
 373 chapter 465 for the purpose of dispensing in the establishment
 374 in which the prepackaging occurred.

375 (34) "Prescription label" means any display of written,
 376 printed, or graphic matter upon the immediate container of any
 377 legend drug dispensed pursuant to a prescription of a
 378 practitioner authorized by law to prescribe.

379 (35)~~(26)~~ "Prescription medical oxygen" means oxygen USP
 380 which is a drug that can only be sold on the order or
 381 prescription of a practitioner authorized by law to prescribe.
 382 The label of prescription medical oxygen must comply with
 383 current labeling requirements for oxygen under the Federal Food,
 384 Drug, and Cosmetic Act.

385 (36)~~(27)~~ "Proprietary drug," or "OTC drug," means a patent
 386 or over-the-counter drug in its unbroken, original package,
 387 which drug is sold to the public by, or under the authority of,
 388 the manufacturer or primary distributor thereof, is not
 389 misbranded under the provisions of ss. 499.001-499.081, and can
 390 be purchased without a prescription.



391 (37) "Repackage" includes repacking or otherwise changing
 392 the container, wrapper, or labeling to further the distribution
 393 of a drug, device, or cosmetic.

394 (38) "Repackager" means a person who repackages. The term
 395 excludes pharmacies that are operating in compliance with
 396 pharmacy practice standards as defined in chapter 465 and rules
 397 adopted under that chapter.

398 ~~(39)~~~~(28)~~ "Veterinary prescription drug" means a legend
 399 drug intended solely for veterinary use. The label of the drug
 400 must bear the statement, "Caution: Federal law restricts this
 401 drug to sale by or on the order of a licensed veterinarian."

402 Section 4. Section 499.005, Florida Statutes, is amended
 403 to read:

404 499.005 Prohibited acts.--It is unlawful for a person to
 405 perform or cause the performance of any of the following acts in
 406 this state:

407 (1) The manufacture, repackaging, sale, delivery, or
 408 holding or offering for sale of any drug, device, or cosmetic
 409 that is adulterated or misbranded or has otherwise been rendered
 410 unfit for human or animal use.

411 (2) The adulteration or misbranding of any drug, device,
 412 or cosmetic.

413 (3) The receipt of any drug, device, or cosmetic that is
 414 adulterated or misbranded, and the delivery or proffered
 415 delivery of such drug, device, or cosmetic, for pay or
 416 otherwise.



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417 (4) The sale, distribution, purchase, trade, holding, or
418 offering of any drug, device, or cosmetic in violation of ss.
419 499.001-499.081.

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

422 (6) The refusal or constructive refusal:

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

426 (b) To allow inspection of any record of that
427 establishment;

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

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

433 (7) The purchase or sale of prescription drugs for
434 wholesale distribution in exchange for currency, as defined in
435 s. 560.103(6). ~~The giving of a false guaranty or false~~
436 ~~undertaking with respect to a drug, device, or cosmetic, except~~
437 ~~by a person who relied on a guaranty or undertaking to the same~~
438 ~~effect signed by, and containing the name and address of, the~~
439 ~~person residing in this state from whom she or he received in~~
440 ~~good faith the drug, device, or cosmetic.~~

441 (8) Committing any act that causes a drug, device, or
442 cosmetic to be a counterfeit drug, device, or cosmetic; or
443 selling, dispensing, or holding for sale a counterfeit drug,
444 device, or cosmetic.



445 (9) The alteration, mutilation, destruction, obliteration,
446 or removal of the whole or any part of the labeling of a drug,
447 device, or cosmetic, or the doing of any other act with respect
448 to a drug, device, or cosmetic, if the act is done while the
449 drug, device, or cosmetic is held for sale and the act results
450 in the drug, device, or cosmetic being misbranded.

451 (10) Forging; counterfeiting; simulating; falsely
452 representing any drug, device, or cosmetic; or, without the
453 authority of the manufacturer, using any mark, stamp, tag,
454 label, or other identification device authorized or required by
455 rules adopted under ss. 499.001-499.081.

456 (11) The use, on the labeling of any drug or in any
457 advertisement relating to such drug, of any representation or
458 suggestion that an application of the drug is effective when it
459 is not or that the drug complies with ss. 499.001-499.081 when
460 it does not.

461 (12) The possession of any drug in violation of ss.
462 499.001-499.081.

463 (13) The sale, delivery, holding, or offering for sale of
464 any self-testing kits designed to tell persons their status
465 concerning human immunodeficiency virus or acquired immune
466 deficiency syndrome or related disorders or conditions. This
467 prohibition shall not apply to home access HIV test kits
468 approved for distribution and sale by the United States Food and
469 Drug Administration.

470 (14) The purchase or receipt of a legend drug from a
471 person that is not authorized under this chapter to distribute
472 legend drugs to that purchaser or recipient.



473 (15) The sale or transfer of a legend drug to a person
 474 that is not authorized under the law of the jurisdiction in
 475 which the person receives the drug to purchase or possess legend
 476 drugs from the person selling or transferring the legend drug.

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

480 (17) The sale, purchase, or trade, or the offer to sell,
 481 purchase, or trade, a drug sample as defined in s. 499.028; the
 482 distribution of a drug sample in violation of s. 499.028; or the
 483 failure to otherwise comply with s. 499.028.

484 (18) Failure to maintain records as required by ss.
 485 499.001-499.081 and rules adopted under those sections.

486 (19) Providing the department with false or fraudulent
 487 records, or making false or fraudulent statements, regarding any
 488 matter within the provisions of this chapter.

489 (20) The importation of a legend drug except as provided
 490 by s. 801(d) of the Federal Food, Drug, and Cosmetic Act.

491 (21) The wholesale distribution of any prescription drug
 492 that was:

493 (a) Purchased by a public or private hospital or other
 494 health care entity; or

495 (b) Donated or supplied at a reduced price to a charitable
 496 organization.

497 (22) Failure to obtain a permit or registration, or
 498 operating without a valid permit when a permit or registration
 499 is required by ss. 499.001-499.081 for that activity.



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500 (23) Obtaining or attempting to obtain a prescription drug
501 or device by fraud, deceit, misrepresentation or subterfuge, or
502 engaging in misrepresentation or fraud in the distribution of a
503 drug or device.

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

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

509 (26) Removing a pharmacy's dispensing label from a
510 dispensed prescription drug with the intent to further
511 distribute the prescription drug.

512 (27) Distributing a prescription drug that was previously
513 dispensed by a licensed pharmacy, unless such distribution was
514 authorized in chapter 465 or the rules adopted under chapter
515 465.

516 (28) Failure to obtain or pass on a pedigree paper.

517 (29) The receipt of a prescription drug pursuant to a
518 wholesale distribution without first receiving a pedigree paper
519 that was attested to as accurate and complete by the wholesale
520 distributor.

521 Section 5. Section 499.0051, Florida Statutes, is created
522 to read:

523 499.0051 Criminal acts involving contraband or adulterated
524 drugs.--

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

526 (a) A person, other than a manufacturer, engaged in the
527 wholesale distribution of legend drugs who fails to deliver to



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528 another person complete and accurate pedigree papers concerning
529 a legend drug or contraband legend drug prior to transferring
530 the legend drug or contraband legend drug to another person
531 commits a felony of the third degree, punishable as provided in
532 s. 775.082, s. 775.083, or s. 775.084.

533 (b) A person engaged in the wholesale distribution of
534 legend drugs who fails to acquire complete and accurate pedigree
535 papers concerning a legend drug or contraband legend drug prior
536 to obtaining the legend drug or contraband legend drug from
537 another person commits a felony of the third degree, punishable
538 as provided in s. 775.082, s. 775.083, or s. 775.084.

539 (c) Any person who knowingly destroys, alters, conceals,
540 or fails to maintain complete and accurate pedigree papers
541 concerning any legend drug or contraband legend drug in his or
542 her possession commits a felony of the third degree, punishable
543 as provided in s. 775.082, s. 775.083, or s. 775.084.

544 (2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS.--

545 (a)1. A person engaged in the wholesale distribution of
546 legend drugs who is in possession of documents required under s.
547 499.0121(6)(e) and who fails to authenticate the matters
548 contained in the documents and who nevertheless attempts to
549 further distribute legend drugs or contraband legend drugs
550 commits a felony of the third degree, punishable as provided in
551 s. 775.082, s. 775.083, or s. 775.084.

552 2. A person in possession of documents required under s.
553 499.0121(6)(e) who falsely swears or certifies that he or she
554 has authenticated the matters contained in the documents commits



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555 a felony of the third degree, punishable as provided in s.
556 775.082, s. 775.083, or s. 775.084.

557 3. This paragraph expires July 1, 2006.

558 (b) Effective July 1, 2006:

559 1. A person engaged in the wholesale distribution of
560 legend drugs who is in possession of pedigree papers concerning
561 legend drugs or contraband legend drugs and who fails to
562 authenticate the matters contained in the pedigree papers and
563 who nevertheless attempts to further distribute legend drugs or
564 contraband legend drug commits a felony of the third degree,
565 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

566 2. A person in possession of pedigree papers concerning
567 legend drugs or contraband legend drugs who falsely swears or
568 certifies that he or she has authenticated the matters contained
569 in the pedigree papers commits a felony of the third degree,
570 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

571 (3) FORGERY OF PEDIGREE PAPERS.--A person who knowingly
572 forges, counterfeits, or falsely creates any pedigree paper; who
573 falsely represents any factual matter contained on any pedigree
574 paper; or who knowingly omits to record material information
575 required to be recorded in a pedigree paper, commits a felony of
576 the second degree, punishable as provided in s. 775.082, s.
577 775.083, or s. 775.084.

578 (4) PURCHASE OR RECEIPT OF LEGEND DRUG FROM UNAUTHORIZED
579 PERSON.--A person who knowingly purchases or receives from a
580 person not authorized to distribute legend drugs under this
581 chapter a legend drug in a wholesale distribution transaction



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582 commits a felony of the second degree, punishable as provided in
583 s. 775.082, s. 775.083, or s. 775.084.

584 (5) SALE OR TRANSFER OF LEGEND DRUG TO UNAUTHORIZED
585 PERSON.--A person who knowingly sells or transfers to a person
586 not authorized to purchase or possess legend drugs, under the
587 law of the jurisdiction in which the person receives the drug, a
588 legend drug in a wholesale distribution transaction commits a
589 felony of the second degree, punishable as provided in s.
590 775.082, s. 775.083, or s. 775.084.

591 (6) SALE OR DELIVERY, OR POSSESSION WITH INTENT TO SELL,
592 CONTRABAND LEGEND DRUGS.--A person who is knowingly in actual or
593 constructive possession of any amount of contraband legend
594 drugs, who knowingly sells or delivers, or who possesses with
595 intent to sell or deliver any amount of contraband legend drugs,
596 commits a felony of the second degree, punishable as provided in
597 s. 775.082, s. 775.083, or s. 775.084.

598 (7) FORGERY OF PRESCRIPTION OR LEGEND DRUG LABELS.--A
599 person who knowingly forges, counterfeits, or falsely creates
600 any prescription label or legend drug label, or who falsely
601 represents any factual matter contained on any prescription
602 label or legend drug label, commits a felony of the first
603 degree, punishable as provided in s. 775.082, s. 775.083, or s.
604 775.084.

605 Section 6. Section 499.0052, Florida Statutes, is created
606 to read:

607 499.0052 Trafficking in contraband legend drugs.--A person
608 who knowingly sells, purchases, manufactures, delivers, or
609 brings into this state, or who is knowingly in actual or



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610 constructive possession of, any amount of contraband legend
611 drugs valued at \$25,000 or more commits a felony of the first
612 degree, punishable as provided in s. 775.082, s. 775.083, or s.
613 775.084. Upon conviction, each defendant shall be ordered to pay
614 a mandatory fine according to the following schedule:

615 (1) If the value of contraband legend drugs involved is
616 \$25,000 or more, but less than \$100,000, the defendant shall pay
617 a mandatory fine of \$25,000. If the defendant is a corporation
618 or other person that is not a natural person, it shall pay a
619 mandatory fine of \$75,000.

620 (2) If the value of contraband legend drugs involved is
621 \$100,000 or more, but less than \$250,000, the defendant shall
622 pay a mandatory fine of \$100,000. If the defendant is a
623 corporation or other person that is not a natural person, it
624 shall pay a mandatory fine of \$300,000.

625 (3) If the value of contraband legend drugs involved is
626 \$250,000 or more, the defendant shall pay a mandatory fine of
627 \$200,000. If the defendant is a corporation or other person that
628 is not a natural person, it shall pay a mandatory fine of
629 \$600,000.

630
631 As used in this section, the term "value" means the market value
632 of the property at the time and place of the offense or, if such
633 cannot be satisfactorily ascertained, the cost of replacement of
634 the property within a reasonable time after the offense. Amounts
635 of value of separate contraband legend drugs involved in
636 distinct transactions for the distribution of the contraband
637 legend drugs committed pursuant to one scheme or course of



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638 conduct, whether involving the same person or several persons,
639 may be aggregated in determining the punishment of the offense.

640 Section 7. Section 499.00523, Florida Statutes, is created
641 to read:

642 499.00523 Sale or purchase of contraband legend drugs
643 resulting in great bodily harm.--A person who knowingly sells,
644 purchases, manufactures, delivers, or brings into this state, or
645 who is knowingly in actual or constructive possession of, any
646 amount of contraband legend drugs, and whose acts in violation
647 of this section result in great bodily harm to a person, commits
648 a felony of the first degree, punishable as provided in s.
649 775.082, s. 775.083, or s. 775.084.

650 Section 8. Section 499.00525, Florida Statutes, is created
651 to read:

652 499.00525 Sale or purchase of contraband legend drugs
653 resulting in death.--A person who knowingly manufactures, sells,
654 purchases, delivers, or brings into this state, or who is
655 knowingly in actual or constructive possession of, any amount of
656 contraband legend drugs, and whose acts in violation of this
657 section result in the death of a person, commits a felony of the
658 first degree, punishable by a term of years not exceeding life,
659 as provided in s. 775.082, s. 775.083, or s. 775.084.

660 Section 9. Section 499.006, Florida Statutes, is amended
661 to read:

662 499.006 Adulterated drug or device.--A drug or device is
663 adulterated:

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



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

669 (3) If it is a drug and the methods used in, or the
670 facilities or controls used for, its manufacture, processing,
671 packing, or holding do not conform to, or are not operated or
672 administered in conformity with, current good manufacturing
673 practices to assure that the drug meets the requirements of ss.
674 499.001-499.081 and that the drug has the identity and strength,
675 and meets the standard of quality and purity, which it purports
676 or is represented to possess;

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

680 (5) If it is a drug and it bears or contains, for the
681 purpose of coloring only, a color additive that is unsafe within
682 the meaning of the federal act; or, if it is a color additive,
683 the intended use of which in or on drugs is for the purpose of
684 coloring only, and it is unsafe within the meaning of the
685 federal act;

686 (6) If it purports to be, or is represented as, a drug the
687 name of which is recognized in the official compendium, and its
688 strength differs from, or its quality or purity falls below, the
689 standard set forth in such compendium. The determination as to
690 strength, quality, or purity must be made in accordance with the
691 tests or methods of assay set forth in such compendium, or, when
692 such tests or methods of assay are absent or inadequate, in
693 accordance with those tests or methods of assay prescribed under



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694 authority of the federal act. A drug defined in the official
695 compendium is not adulterated under this subsection merely
696 because it differs from the standard of strength, quality, or
697 purity set forth for that drug in such compendium if its
698 difference in strength, quality, or purity from such standard is
699 plainly stated on its label;

700 (7) If it is not subject to subsection (6) and its
701 strength differs from, or its purity or quality falls below the
702 standard of, that which it purports or is represented to
703 possess; ~~or~~

704 (8) If it is a drug:

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

707 (b) For which any substance has been substituted wholly or
708 in part; ~~or~~

709 (9) If it is a drug or device for which the expiration
710 date has passed; ~~or~~

711 (10) If it is a legend drug for which the required
712 pedigree paper is nonexistent, fraudulent, or incomplete under
713 the requirements of ss. 499.001-499.081 or applicable rules or
714 that has been purchased, held, sold, or distributed at any time
715 by a person not authorized under federal or state law to do so.

716 Section 10. Subsection (2) of section 499.007, Florida
717 Statutes, is amended to read:

718 499.007 Misbranded drug or device.--A drug or device is
719 misbranded:

720 (2) Unless, if in package form, it bears a label
721 containing:



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722 (a) The name and place of business of the manufacturer,
 723 repackager, or distributor; ~~in addition, for a medicinal drug,~~
 724 ~~as defined in s. 499.003, the label must contain the name and~~
 725 ~~place of business of the manufacturer~~ of the finished dosage
 726 form of the drug. For the purpose of this paragraph, the
 727 finished dosage form of a medicinal drug is that form of the
 728 drug which is, or is intended to be, dispensed or administered
 729 to the patient and requires no further manufacturing or
 730 processing other than packaging, reconstitution, and labeling;
 731 and

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

737 Section 11. Subsections (1) and (3) of section 499.01,
 738 Florida Statutes, are amended to read:

739 499.01 Permits; applications; renewal; general
 740 requirements.--

741 (1) Any person that is required under ss. 499.001-499.081
 742 to have a permit must apply to the department on forms furnished
 743 by the department.

744 (a) A permit issued pursuant to ss. 499.001-499.081 may be
 745 issued only to a natural person ~~an individual~~ who is at least 18
 746 years of age or to an applicant that is not a natural person if
 747 each person who, directly or indirectly, manages, controls, or
 748 oversees the operation of that applicant ~~a corporation that is~~



749 ~~registered pursuant to chapter 607 or chapter 617 and each~~
 750 ~~officer of which~~ is at least 18 years of age.

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

753 (c) A person that applies for or renews a permit to
 754 manufacture or distribute legend drugs may not use a name
 755 identical to the name used by any other establishment or
 756 licensed person authorized to purchase prescription drugs in
 757 this state, except that a restricted drug distributor permit
 758 issued to a health care entity will be issued in the name in
 759 which the institutional pharmacy permit is issued and a retail
 760 pharmacy drug wholesaler will be issued a permit in the name of
 761 its retail pharmacy permit.

762 (d) A permit is required for each establishment that
 763 operates as a:

- 764 1. Prescription drug manufacturer;
- 765 2. Over-the-counter drug manufacturer;
- 766 3. Compressed medical gas manufacturer;
- 767 4. Device manufacturer;
- 768 5. Cosmetic manufacturer;
- 769 6. Prescription drug wholesaler;
- 770 7. Compressed medical gas wholesaler;
- 771 8. Out-of-state prescription drug wholesaler;
- 772 9. Retail pharmacy drug wholesaler;
- 773 10. Veterinary legend drug retail establishment;
- 774 11. Medical oxygen retail establishment;
- 775 12. Complimentary drug distributor; or
- 776 13. Restricted prescription drug distributor.



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777 (e) A permit for a prescription drug manufacturer,
778 prescription drug wholesaler, or retail pharmacy wholesaler may
779 not be issued to the address of a health care entity or to a
780 pharmacy licensed under chapter 465, except as provided in this
781 paragraph. The department may issue a prescription drug
782 manufacturer's permit to an applicant at the same address as a
783 licensed nuclear pharmacy, which is a health care entity, for
784 the purpose of manufacturing prescription drugs used in positron
785 emission tomography or other radiopharmaceuticals, as listed in
786 a rule adopted by the department pursuant to this paragraph. The
787 purpose of this exemption is to ensure availability of state-of-
788 the-art pharmaceuticals that would pose a significant danger to
789 the public health if manufactured at a separate establishment
790 address from the nuclear pharmacy from which the prescription
791 drugs are dispensed. The department may also issue a retail
792 pharmacy wholesaler permit to the address of a community
793 pharmacy licensed under chapter 465 which does not meet the
794 definition of a closed pharmacy in s. 499.003.

795 (f) A county or municipality may not issue an occupational
796 license for any licensing period beginning on or after October
797 1, 2003, for any establishment that requires a permit pursuant
798 to ss. 499.001-499.081, unless the establishment exhibits a
799 current permit issued by the department for the establishment.
800 Upon presentation of the requisite permit issued by the
801 department, an occupational license may be issued by the
802 municipality or county in which application is made. The
803 department shall furnish to local agencies responsible for



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804 issuing occupational licenses a current list of all
805 establishments licensed pursuant to ss. 499.001-499.081.

806 (g)(f) Notwithstanding subsection (4), a permitted person
807 in good standing may change the type of permit issued to that
808 person by completing a new application for the requested permit,
809 paying the amount of the difference in the permit fees if the
810 fee for the new permit is more than the fee for the original
811 permit, and meeting the applicable permitting conditions for the
812 new permit type. The new permit expires on the expiration date
813 of the original permit being changed; however, a new permit for
814 a prescription drug wholesaler and an out-of-state prescription
815 drug wholesaler shall expire on the expiration date of the
816 original permit or 1 year after the date of issuance of the new
817 permit, whichever is earlier. A refund may not be issued if the
818 ~~biennial~~ fee for the new permit is less than the fee that was
819 paid for the original permit ~~for which a fee was paid.~~

820 (3) The department shall adopt rules for the biennial
821 renewal of permits.

822 (a) The department shall renew a permit upon receipt of
823 the renewal application and renewal fee if the applicant meets
824 the requirements established under ss. 499.001-499.081 and the
825 rules adopted under those sections.

826 (b) A permit, unless sooner suspended or revoked,
827 automatically expires 2 years after the last day of the
828 anniversary month in which the permit was originally issued;
829 except that a prescription drug wholesaler permit or an out-of-
830 state prescription drug wholesaler permit issued from July 1,
831 2003, through December 31, 2003, shall expire 1 year after the



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832 last day of the anniversary month in which the permit was
833 issued. Any valid prescription drug wholesaler or out-of-state
834 prescription drug wholesaler permit issued by the department on
835 or before June 30, 2003, with an expiration date between January
836 1, 2005, and June 30, 2005, shall automatically expire 1 year
837 prior to the expiration date stated on the permit. A permittee
838 that submits a renewal application for a permit with a stated
839 expiration date between January 1, 2005, and June 30, 2005,
840 shall receive a credit of one-half of the permit fee paid when
841 the application for the expiring permit was submitted. Any valid
842 prescription drug wholesaler or out-of-state prescription drug
843 wholesaler permit issued by the department on or before June 30,
844 2003, with an expiration date between July 1, 2004, and December
845 31, 2004, shall automatically expire 6 months prior to the
846 expiration date stated on the permit. A permittee that submits a
847 renewal application for a permit with a stated expiration date
848 between July 1, 2004, and December 31, 2004, shall receive a
849 credit of one-fourth of the permit fee paid when the application
850 for the expiring permit was submitted. A permittee whose permit
851 expiration date was accelerated in this paragraph may request a
852 pro rata refund equivalent to the credit available for
853 submission of a renewal application if the permittee does not
854 submit a renewal application. A permit issued under ss. 499.001-
855 499.081 ~~may~~ ~~must~~ be renewed by making application for renewal on
856 forms furnished by the department and paying the appropriate
857 fees. If a renewal application and fee are ~~not~~ submitted and
858 postmarked ~~after~~ ~~by~~ the expiration date of the permit, the
859 permit may be renewed ~~reinstated~~ only upon payment of a late



860 renewal delinquent fee of \$100, plus the required renewal fee,
 861 not later than ~~within~~ 60 days after the expiration date.

862 (c) Failure to renew a permit in accordance with this
 863 section precludes any future renewal of that permit. If a permit
 864 issued pursuant to this section has expired and cannot be
 865 renewed, before an establishment may engage in activities that
 866 require a permit under ss. 499.001-499.081, the establishment
 867 must submit an application for a new permit, pay the applicable
 868 application fee, the initial permit fee, and all applicable
 869 penalties, and be issued a new permit by the department.

870 ~~Continuing to engage in activities that require a permit under~~
 871 ~~ss. 499.001-499.081 requires a new permit application and~~
 872 ~~payment of an application fee, initial permit fee, and~~
 873 ~~applicable penalties.~~

874 Section 12. Effective January 1, 2004, section 499.01,
 875 Florida Statutes, as amended by this act, is amended to read:

876 499.01 Permits; applications; renewal; general
 877 requirements.--

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

- 880 (a) A prescription drug manufacturer;
- 881 (b) A prescription drug repackager;
- 882 (c) An over-the-counter drug manufacturer;
- 883 (d) A compressed medical gas manufacturer;
- 884 (e) A device manufacturer;
- 885 (f) A cosmetic manufacturer;
- 886 (g) A prescription drug wholesaler;
- 887 (h) A compressed medical gas wholesaler;



- 888 | (i) An out-of-state prescription drug wholesaler;
- 889 | (j) A nonresident prescription drug manufacturer;
- 890 | (k) A freight forwarder;
- 891 | (l) A retail pharmacy drug wholesaler;
- 892 | (m) A veterinary legend drug retail establishment;
- 893 | (n) A medical oxygen retail establishment;
- 894 | (o) A complimentary drug distributor; or
- 895 | (p) A restricted prescription drug distributor.
- 896 | ~~(1) Any person that is required under ss. 499.001-499.081~~
- 897 | ~~to have a permit must apply to the department on forms furnished~~
- 898 | ~~by the department.~~
- 899 | (2)(a) A permit issued pursuant to ss. 499.001-499.081 may
- 900 | be issued only to a natural person who is at least 18 years of
- 901 | age or to an applicant that is not a natural person if each
- 902 | person who, directly or indirectly, manages, controls, or
- 903 | oversees the operation of that applicant is at least 18 years of
- 904 | age.
- 905 | (b) An establishment that is a place of residence may not
- 906 | receive a permit and may not operate under ss. 499.001-499.081.
- 907 | (c) A person that applies for or renews a permit to
- 908 | manufacture or distribute legend drugs may not use a name
- 909 | identical to the name used by any other establishment or
- 910 | licensed person authorized to purchase prescription drugs in
- 911 | this state, except that a restricted drug distributor permit
- 912 | issued to a health care entity will be issued in the name in
- 913 | which the institutional pharmacy permit is issued and a retail
- 914 | pharmacy drug wholesaler will be issued a permit in the name of
- 915 | its retail pharmacy permit.



- 916 ~~(d) A permit is required for each establishment that~~
 917 ~~operates as a:~~
- 918 ~~1. Prescription drug manufacturer;~~
 - 919 ~~2. Over the counter drug manufacturer;~~
 - 920 ~~3. Compressed medical gas manufacturer;~~
 - 921 ~~4. Device manufacturer;~~
 - 922 ~~5. Cosmetic manufacturer;~~
 - 923 ~~6. Prescription drug wholesaler;~~
 - 924 ~~7. Compressed medical gas wholesaler;~~
 - 925 ~~8. Out of state prescription drug wholesaler;~~
 - 926 ~~9. Retail pharmacy drug wholesaler;~~
 - 927 ~~10. Veterinary legend drug retail establishment;~~
 - 928 ~~11. Medical oxygen retail establishment;~~
 - 929 ~~12. Complimentary drug distributor; or~~
 - 930 ~~13. Restricted prescription drug distributor.~~

931 (d)(e) A permit for a prescription drug manufacturer,
 932 prescription drug repackager, prescription drug wholesaler, or
 933 retail pharmacy wholesaler may not be issued to the address of a
 934 health care entity or to a pharmacy licensed under chapter 465,
 935 except as provided in this paragraph. The department may issue a
 936 prescription drug manufacturer's permit to an applicant at the
 937 same address as a licensed nuclear pharmacy, which is a health
 938 care entity, for the purpose of manufacturing prescription drugs
 939 used in positron emission tomography or other
 940 radiopharmaceuticals, as listed in a rule adopted by the
 941 department pursuant to this paragraph. The purpose of this
 942 exemption is to assure availability of state-of-the-art
 943 pharmaceuticals that would pose a significant danger to the



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944 public health if manufactured at a separate establishment
945 address from the nuclear pharmacy from which the prescription
946 drugs are dispensed. The department may also issue a retail
947 pharmacy wholesaler permit to the address of a community
948 pharmacy licensed under chapter 465 which does not meet the
949 definition of a closed pharmacy in s. 499.003.

950 (e)~~(f)~~ A county or municipality may not issue an
951 occupational license for any licensing period beginning on or
952 after October 1, 2003, for any establishment that requires a
953 permit pursuant to ss. 499.001-499.081, unless the establishment
954 exhibits a current permit issued by the department for the
955 establishment. Upon presentation of the requisite permit issued
956 by the department, an occupational license may be issued by the
957 municipality or county in which application is made. The
958 department shall furnish to local agencies responsible for
959 issuing occupational licenses a current list of all
960 establishments licensed pursuant to ss. 499.001-499.081.

961 (3)~~(g)~~ Notwithstanding subsection (7)~~(4)~~, a permitted
962 person in good standing may change the type of permit issued to
963 that person by completing a new application for the requested
964 permit, paying the amount of the difference in the permit fees
965 if the fee for the new permit is more than the fee for the
966 original permit, and meeting the applicable permitting
967 conditions for the new permit type. The new permit expires on
968 the expiration date of the original permit being changed;
969 however, a new permit for a prescription drug wholesaler, an
970 out-of-state prescription drug wholesaler, or a retail pharmacy
971 drug wholesaler shall expire on the expiration date of the



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972 original permit or 1 year after the date of issuance of the new
 973 permit, whichever is earlier. A refund may not be issued if the
 974 fee for the new permit is less than the fee that was paid for
 975 the original permit.

976 (4)(2) A written application for a permit or to renew a
 977 permit must be filed with the department on forms furnished by
 978 the department. The department shall establish, by rule, the
 979 form and content of the application to obtain or renew a permit.
 980 The applicant must submit to the department with the application
 981 a statement that swears or affirms that the information is true
 982 and correct.

983 (5)(a) Except for a permit for a prescription drug
 984 wholesaler or an out-of-state prescription drug wholesaler, an
 985 application for a permit must include ~~information that an~~
 986 ~~applicant must provide includes, but need not be limited to:~~

- 987 1. The name, full business address, and telephone number
 988 of the applicant;
- 989 2. All trade or business names used by the applicant;
- 990 3. The address, telephone numbers, and the names of
 991 contact persons for each facility used by the applicant for the
 992 storage, handling, and distribution of prescription drugs;
- 993 4. The type of ownership or operation, such as a
 994 partnership, corporation, or sole proprietorship; and
- 995 5. The names of the owner and the operator of the
 996 establishment, including:
 - 997 a. If an individual, the name of the individual;
 - 998 b. If a partnership, the name of each partner and the name
 999 of the partnership;



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1000 c. If a corporation, the name and title of each corporate
1001 officer and director, the corporate names, and the name of the
1002 state of incorporation;

1003 d. If a sole proprietorship, the full name of the sole
1004 proprietor and the name of the business entity; ~~and~~

1005 e. If a limited liability company, the name of each
1006 member, the name of each manager, the name of the limited
1007 liability company, and the name of the state in which the
1008 limited liability company was organized; and

1009 ~~f.e.~~ Any other relevant information that the department
1010 requires.

1011 (b) Upon approval of the application by the department and
1012 payment of the required fee, the department shall issue a permit
1013 to the applicant, if the applicant meets the requirements of ss.
1014 499.001-499.081 and rules adopted under those sections.

1015 (c) Any change in information required under paragraph (a)
1016 must be submitted to the department before the change occurs.

1017 (d) The department shall consider, at a minimum, the
1018 following factors in reviewing the qualifications of persons to
1019 be permitted under ss. 499.001-499.081:

1020 1. The applicant's having been found guilty, regardless of
1021 adjudication, in a court of this state or other jurisdiction, of
1022 a violation of a law that directly relates to a drug, device, or
1023 cosmetic. A plea of nolo contendere constitutes a finding of
1024 guilt for purposes of this subparagraph.

1025 2. The applicant's having been disciplined by a regulatory
1026 agency in any state for any offense that would constitute a
1027 violation of ss. 499.001-499.081.



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1028 3. Any felony conviction of the applicant under a federal,
1029 state, or local law;

1030 4. The applicant's past experience in manufacturing or
1031 distributing drugs, devices, or cosmetics;

1032 5. The furnishing by the applicant of false or fraudulent
1033 material in any application made in connection with
1034 manufacturing or distributing drugs, devices, or cosmetics;

1035 6. Suspension or revocation by a federal, state, or local
1036 government of any permit currently or previously held by the
1037 applicant for the manufacture or distribution of any drugs,
1038 devices, or cosmetics;

1039 7. Compliance with permitting requirements under any
1040 previously granted permits;

1041 8. Compliance with requirements to maintain or make
1042 available to the state permitting authority or to federal,
1043 state, or local law enforcement officials those records required
1044 under this section; and

1045 9. Any other factors or qualifications the department
1046 considers relevant to and consistent with the public health and
1047 safety.

1048 (6) Except for permits for prescription drug wholesalers
1049 or out-of-state prescription drug wholesalers:

1050 (a)~~(3)~~ The department shall adopt rules for the biennial
1051 renewal of permits.

1052 (b)~~(a)~~ The department shall renew a permit upon receipt of
1053 the renewal application and renewal fee if the applicant meets
1054 the requirements established under ss. 499.001-499.081 and the
1055 rules adopted under those sections.



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1056 (c)~~(b)~~ A permit, unless sooner suspended or revoked,
1057 automatically expires 2 years after the last day of the
1058 anniversary month in which the permit was originally issued;
1059 ~~except that a prescription drug wholesaler permit and an out-of-~~
1060 ~~state prescription drug wholesaler permit, issued from July 1,~~
1061 ~~2003, through December 31, 2003, shall expire 1 year after the~~
1062 ~~last day of the anniversary month in which the permit was~~
1063 ~~issued. Any valid prescription drug wholesaler or out-of-state~~
1064 ~~prescription drug wholesaler permit issued by the department on~~
1065 ~~or before June 30, 2003, with an expiration date between January~~
1066 ~~1, 2005, and June 30, 2005, shall automatically expire 1 year~~
1067 ~~prior to the expiration date stated on the permit. A permittee~~
1068 ~~that submits a renewal application for a permit with a stated~~
1069 ~~expiration date between January 1, 2005, and June 30, 2005,~~
1070 ~~shall receive a credit of one-half of the permit fee paid when~~
1071 ~~the application for the expiring permit was submitted. Any valid~~
1072 ~~prescription drug wholesaler or out-of-state prescription drug~~
1073 ~~wholesaler permit issued by the department on or before June 30,~~
1074 ~~2003, with an expiration date between July 1, 2004, and December~~
1075 ~~31, 2004, shall automatically expire 6 months prior to the~~
1076 ~~expiration date stated on the permit. A permittee that submits a~~
1077 ~~renewal application for a permit with a stated expiration date~~
1078 ~~between July 1, 2004, and December 31, 2004, shall receive a~~
1079 ~~credit of one-fourth of the permit fee paid when the application~~
1080 ~~for the expiring permit was submitted. A permittee whose permit~~
1081 ~~expiration date was accelerated in this paragraph may request a~~
1082 ~~pro rata refund equivalent to the credit available for~~
1083 ~~submission of a renewal application if the permittee does not~~



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1084 ~~submit a renewal application.~~ A permit issued under ss. 499.001-
1085 499.081 may be renewed by making application for renewal on
1086 forms furnished by the department and paying the appropriate
1087 fees. If a renewal application and fee are submitted and
1088 postmarked after the expiration date of the permit, the permit
1089 may be renewed only upon payment of a late renewal delinquent
1090 fee of \$100, plus the required renewal fee, not later than 60
1091 days after the expiration date.

1092 (d)~~(e)~~ Failure to renew a permit in accordance with this
1093 section precludes any future renewal of that permit. If a permit
1094 issued pursuant to this section has expired and cannot be
1095 renewed, before an establishment may engage in activities that
1096 require a permit under ss. 499.001-499.081, the establishment
1097 must submit an application for a new permit, pay the applicable
1098 application fee, the initial permit fee, and all applicable
1099 penalties, and be issued a new permit by the department.

1100 (7)~~(4)~~ A permit issued by the department is
1101 nontransferable. Each permit is valid only for the person or
1102 governmental unit to which it is issued and is not subject to
1103 sale, assignment, or other transfer, voluntarily or
1104 involuntarily; nor is a permit valid for any establishment other
1105 than the establishment for which it was originally issued.

1106 (a) A person permitted under ss. 499.001-499.081 must
1107 notify the department before making a change of address. The
1108 department shall set a change of location fee not to exceed
1109 \$100.

1110 (b)1. An application for a new permit is required when a
1111 majority of the ownership or controlling interest of a permitted



1112 establishment is transferred or assigned or when a lessee agrees
 1113 to undertake or provide services to the extent that legal
 1114 liability for operation of the establishment will rest with the
 1115 lessee. The application for the new permit must be made before
 1116 the date of the sale, transfer, assignment, or lease.

1117 2. A permittee that is authorized to distribute legend
 1118 drugs may transfer such drugs to the new owner or lessee under
 1119 subparagraph 1. only after the new owner or lessee has been
 1120 approved for a permit to distribute legend drugs.

1121 ~~(c) The department shall deny, suspend, or revoke the~~
 1122 ~~permit of any person or establishment if the assignment, sale,~~
 1123 ~~transfer, or lease of an establishment permitted under ss.~~
 1124 ~~499.001-499.081 will avoid an administrative penalty, civil~~
 1125 ~~action, or criminal prosecution.~~

1126 (c)(d) If an establishment permitted under ss. 499.001-
 1127 499.081 closes, the owner must notify the department in writing
 1128 before the effective date of closure and must:

- 1129 1. Return the permit to the department;
- 1130 2. If the permittee is authorized to distribute legend
 1131 drugs, indicate the disposition of such drugs, including the
 1132 name, address, and inventory, and provide the name and address
 1133 of a person to contact regarding access to records that are
 1134 required to be maintained under ss. 499.001-499.081. Transfer
 1135 of ownership of legend drugs may be made only to persons
 1136 authorized to possess legend drugs under ss. 499.001-499.081.

1137
 1138 The department may revoke the permit of any person that fails to
 1139 comply with the requirements of this subsection.



1140 ~~(8)(5)~~ A permit must be posted in a conspicuous place on
1141 the licensed premise.

1142 Section 13. Section 499.012, Florida Statutes, is amended
1143 to read:

1144 499.012 Wholesale distribution; definitions; permits;
1145 applications; general requirements.--

1146 (1) As used in this section, the term:

1147 (a) "Wholesale distribution" means distribution of
1148 prescription drugs to persons other than a consumer or patient,
1149 but does not include:

1150 1. Any of the following activities, which is not a
1151 violation of s. 499.005(21) if such activity is conducted in
1152 accordance with s. 499.014:

1153 a. The purchase or other acquisition by a hospital or
1154 other health care entity that is a member of a group purchasing
1155 organization of a prescription drug for its own use from the
1156 group purchasing organization or from other hospitals or health
1157 care entities that are members of that organization.

1158 b. The sale, purchase, or trade of a prescription drug or
1159 an offer to sell, purchase, or trade a prescription drug by a
1160 charitable organization described in s. 501(c)(3) of the
1161 Internal Revenue Code of 1986, as amended and revised, to a
1162 nonprofit affiliate of the organization to the extent otherwise
1163 permitted by law.

1164 c. The sale, purchase, or trade of a prescription drug or
1165 an offer to sell, purchase, or trade a prescription drug among
1166 hospitals or other health care entities that are under common
1167 control. For purposes of this section, "common control" means



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1168 | the power to direct or cause the direction of the management and
 1169 | policies of a person or an organization, whether by ownership of
 1170 | stock, by voting rights, by contract, or otherwise.

1171 | d. The sale, purchase, trade, or other transfer of a
 1172 | prescription drug from or for any federal, state, or local
 1173 | government agency or any entity eligible to purchase
 1174 | prescription drugs at public health services prices pursuant to
 1175 | Pub. L. No. 102-585, s. 602 to a contract provider or its
 1176 | subcontractor for eligible patients of the agency or entity
 1177 | under the following conditions:

1178 | (I) The agency or entity must obtain written authorization
 1179 | for the sale, purchase, trade, or other transfer of a
 1180 | prescription drug under this sub-subparagraph from the Secretary
 1181 | of Health or his or her designee.

1182 | (II) The contract provider or subcontractor must be
 1183 | authorized by law to administer or dispense prescription drugs.

1184 | (III) In the case of a subcontractor, the agency or entity
 1185 | must be a party to and execute the subcontract.

1186 | (IV) A contract provider or subcontractor must maintain
 1187 | separate and apart from other prescription drug inventory any
 1188 | prescription drugs of the agency or entity in its possession.

1189 | (V) The contract provider and subcontractor must maintain
 1190 | and produce immediately for inspection all records of movement
 1191 | or transfer of all the prescription drugs belonging to the
 1192 | agency or entity, including, but not limited to, the records of
 1193 | receipt and disposition of prescription drugs. Each contractor
 1194 | and subcontractor dispensing or administering these drugs must
 1195 | maintain and produce records documenting the dispensing or



1196 administration. Records that are required to be maintained
 1197 include, but are not limited to, a perpetual inventory itemizing
 1198 drugs received and drugs dispensed by prescription number or
 1199 administered by patient identifier, which must be submitted to
 1200 the agency or entity quarterly.

1201 (VI) The contract provider or subcontractor may administer
 1202 or dispense the prescription drugs only to the eligible patients
 1203 of the agency or entity or must return the prescription drugs
 1204 for or to the agency or entity. The contract provider or
 1205 subcontractor must require proof from each person seeking to
 1206 fill a prescription or obtain treatment that the person is an
 1207 eligible patient of the agency or entity and must, at a minimum,
 1208 maintain a copy of this proof as part of the records of the
 1209 contractor or subcontractor required under sub-sub-subparagraph
 1210 (V).

1211 (VII) In addition to the departmental inspection authority
 1212 set forth in s. 499.051, the establishment of the contract
 1213 provider and subcontractor and all records pertaining to
 1214 prescription drugs subject to this sub-subparagraph shall be
 1215 subject to inspection by the agency or entity. All records
 1216 relating to prescription drugs of a manufacturer under this sub-
 1217 subparagraph shall be subject to audit by the manufacturer of
 1218 those drugs, without identifying individual patient information.

1219 2. Any of the following activities, which is not a
 1220 violation of s. 499.005(21) if such activity is conducted in
 1221 accordance with rules established by the department:

1222 a. The sale, purchase, or trade of a prescription drug
 1223 among federal, state, or local government health care entities



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1224 that are under common control and are authorized to purchase
1225 such prescription drug.

1226 b. The sale, purchase, or trade of a prescription drug or
1227 an offer to sell, purchase, or trade a prescription drug for
1228 emergency medical reasons. For purposes of this sub-
1229 subparagraph, the term "emergency medical reasons" includes
1230 transfers of prescription drugs by a retail pharmacy to another
1231 retail pharmacy to alleviate a temporary shortage.

1232 c. The transfer of a prescription drug acquired by a
1233 medical director on behalf of a licensed emergency medical
1234 services provider to that emergency medical services provider
1235 and its transport vehicles for use in accordance with the
1236 provider's license under chapter 401.

1237 d. The revocation of a sale or the return of a
1238 prescription drug to the person's prescription drug wholesale
1239 supplier.

1240 e. The donation of a prescription drug by a health care
1241 entity to a charitable organization that has been granted an
1242 exemption under s. 501(c)(3) of the Internal Revenue Code of
1243 1986, as amended, and that is authorized to possess prescription
1244 drugs.

1245 f. The transfer of a prescription drug by a person
1246 authorized to purchase or receive prescription drugs to a person
1247 licensed or permitted to handle reverse distributions or
1248 destruction under the laws of the jurisdiction in which the
1249 person handling the reverse distribution or destruction receives
1250 the drug.



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1251 g. The transfer of a prescription drug by a hospital or
1252 other health care entity to a person licensed under this chapter
1253 to repackage prescription drugs for the purpose of repackaging
1254 the prescription drug for use by that hospital, or other health
1255 care entity and other health care entities that are under common
1256 control, if ownership of the prescription drugs remains with the
1257 hospital or other health care entity at all times. In addition
1258 to the recordkeeping requirements of s. 499.0121(6), the
1259 hospital or health care entity that transfers prescription drugs
1260 pursuant to this sub-subparagraph must reconcile all drugs
1261 transferred and returned and resolve any discrepancies in a
1262 timely manner.

1263 3. The distribution of prescription drug samples by
1264 manufacturers' representatives or distributors' representatives
1265 conducted in accordance with s. 499.028.

1266 4. The sale, purchase, or trade of blood and blood
1267 components intended for transfusion. As used in this
1268 subparagraph, the term "blood" means whole blood collected from
1269 a single donor and processed either for transfusion or further
1270 manufacturing, and the term "blood components" means that part
1271 of the blood separated by physical or mechanical means.

1272 5. The lawful dispensing of a prescription drug in
1273 accordance with chapter 465.

1274 (b) "Wholesale distributor" means any person engaged in
1275 wholesale distribution of prescription drugs in or into this
1276 state, including, but not limited to, manufacturers; repackagers
1277 ~~repackers~~; own-label distributors; jobbers; private-label
1278 distributors; brokers; warehouses, including manufacturers' and



1279 distributors' warehouses, chain drug warehouses, and wholesale
 1280 drug warehouses; independent wholesale drug traders; exporters;
 1281 retail pharmacies; and the agents thereof that conduct wholesale
 1282 distributions.

1283 (c) "Retail pharmacy" means a community pharmacy licensed
 1284 under chapter 465 that purchases prescription drugs at fair
 1285 market prices and provides prescription services to the public.

1286 (d) "Primary wholesaler" means any wholesale distributor
 1287 that:

1288 1. Purchased 90 percent or more of the total dollar volume
 1289 of its purchases of prescription drugs directly from
 1290 manufacturers in the previous year; and

1291 2.a. Directly purchased prescription drugs from not fewer
 1292 than 50 different prescription drug manufacturers in the
 1293 previous year; or

1294 b. Has, or the affiliated group, as defined in s. 1504 of
 1295 the Internal Revenue Code, of which the wholesale distributor is
 1296 a member has, not fewer than 250 employees.

1297 (e) "Directly from a manufacturer" means:

1298 1. Purchases made by the wholesale distributor directly
 1299 from the manufacturer of prescription drugs; and

1300 2. Transfers from a member of an affiliated group, as
 1301 defined in s. 1504 of the Internal Revenue Code, of which the
 1302 wholesale distributor is a member, if:

1303 a. The affiliated group purchases 90 percent or more of
 1304 the total dollar volume of its purchases of prescription drugs
 1305 from manufacturers in the previous year; or



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1306 b. The wholesale distributor discloses to the department
1307 the names of all members of the affiliated group of which the
1308 wholesale distributor is a member and the affiliated group
1309 agrees in writing to provide records on prescription drug
1310 purchases by the members of the affiliated group not later than
1311 48 hours after the department requests access to such records,
1312 regardless of the location where the records are stored.

1313 (f) "Secondary wholesaler" means a wholesale distributor
1314 that is not a primary wholesaler.

1315 (2) The following types of wholesaler permits are
1316 established:

1317 (a) A prescription drug wholesaler's permit. A
1318 prescription drug wholesaler is a wholesale distributor that may
1319 engage in the wholesale distribution of prescription drugs. A
1320 prescription drug wholesaler that applies to the department for
1321 a new permit or the renewal of a permit after July 1, 2003
1322 January 1, 1993, must submit a bond of \$100,000, or other
1323 equivalent means of security acceptable to the department, such
1324 as an irrevocable letter of credit or a deposit in a trust
1325 account or financial institution \$200, payable to the Florida
1326 Drug, Device, and Cosmetic Trust Fund. The purpose of the bond
1327 is to secure payment of any administrative penalties imposed by
1328 the department and any fees and costs incurred by the department
1329 regarding that permit which are authorized under state law and
1330 which the permittee fails to pay 30 days after the fine or costs
1331 become final. The department may make a claim against such bond
1332 or security until 1 year after the permittee's license ceases to
1333 be valid or until 60 days after any administrative or legal



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1334 proceeding authorized in ss. 499.001-499.081 which involves the
1335 permittee is concluded, including any appeal, whichever occurs
1336 later. This bond will be refunded to the permittee when the
1337 permit is returned to the department and the permittee ceases to
1338 function as a business. A permittee that fails to notify the
1339 department before changing the address of the business, fails to
1340 notify the department before closing the business, or fails to
1341 notify the department before a change of ownership forfeits its
1342 bond. The department may adopt rules for issuing a prescription
1343 drug wholesaler-broker permit to a person who engages in the
1344 wholesale distribution of prescription drugs and does not take
1345 physical possession of any prescription drugs.

1346 (b) A compressed medical gas wholesaler's permit. A
1347 compressed medical gas wholesaler is a wholesale distributor
1348 that is limited to the wholesale distribution of compressed
1349 medical gases to other than the consumer or patient. The
1350 compressed medical gas must be in the original sealed container
1351 that was purchased by that wholesaler. A compressed medical gas
1352 wholesaler may not possess or engage in the wholesale
1353 distribution of any prescription drug other than compressed
1354 medical gases. The department shall adopt rules that govern the
1355 wholesale distribution of prescription medical oxygen for
1356 emergency use. With respect to the emergency use of prescription
1357 medical oxygen, those rules may not be inconsistent with rules
1358 and regulations of federal agencies unless the Legislature
1359 specifically directs otherwise.

1360 (c) An out-of-state prescription drug wholesaler's permit.
1361 An out-of-state prescription drug wholesaler is a wholesale



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1362 distributor located outside this state which engages in the
1363 wholesale distribution of prescription drugs into this state and
1364 which must be permitted by the department and comply with all
1365 the provisions required of a wholesale distributor under ss.
1366 499.001-499.081. An out-of-state prescription drug wholesaler
1367 that applies to the department for a new permit or the renewal
1368 of a permit after July 1, 2003, must submit a bond of \$100,000,
1369 or other equivalent means of security acceptable to the
1370 department, such as an irrevocable letter of credit or a deposit
1371 in a trust account or financial institution, payable to the
1372 Florida Drug, Device, and Cosmetic Trust Fund. The purpose of
1373 the bond is to secure payment of any administrative penalties
1374 imposed by the department and any fees and costs incurred by the
1375 department regarding that permit which are authorized under
1376 state law and which the permittee fails to pay 30 days after the
1377 fine or costs become final. The department may make a claim
1378 against such bond or security until 1 year after the permittee's
1379 license ceases to be valid or until 60 days after any
1380 administrative or legal proceeding authorized in ss. 499.001-
1381 499.081 which involves the permittee is concluded, including any
1382 appeal, whichever occurs later.

1383 1. The out-of-state drug wholesaler must maintain at all
1384 times a license or permit to engage in the wholesale
1385 distribution of prescription drugs in compliance with laws of
1386 the state in which it is a resident.

1387 2. An out-of-state prescription drug wholesaler's permit
1388 is not required for an intracompany sale or transfer of a
1389 prescription drug from an out-of-state establishment that is



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1390 duly licensed as a prescription drug wholesaler, in its state of
 1391 residence, to a licensed prescription drug wholesaler in this
 1392 state, if both wholesalers conduct wholesale distributions of
 1393 prescription drugs under the same business name ~~are under common~~
 1394 ~~control~~. The recordkeeping requirements of s. 499.0121(6) must
 1395 be followed for this transaction.

1396 ~~3. The department may adopt rules that allow out-of-state~~
 1397 ~~drug wholesalers to obtain a drug wholesale permit on the basis~~
 1398 ~~of reciprocity to the extent that an out-of-state drug~~
 1399 ~~wholesaler:~~

1400 ~~a. Possesses a valid permit granted by another state that~~
 1401 ~~has requirements comparable to those that a drug wholesaler in~~
 1402 ~~this state must meet as prerequisites to obtaining a permit~~
 1403 ~~under the laws of this state.~~

1404 ~~b. Can show that the other state from which the wholesaler~~
 1405 ~~holds a permit would extend reciprocal treatment under its own~~
 1406 ~~laws to a drug wholesaler of this state.~~

1407 (d) A retail pharmacy wholesaler's permit. A retail
 1408 pharmacy wholesaler is a retail pharmacy engaged in wholesale
 1409 distribution of prescription drugs within this state under the
 1410 following conditions:

1411 1. The pharmacy must obtain a retail pharmacy wholesaler's
 1412 permit pursuant to ss. 499.001-499.081 and the rules adopted
 1413 under those sections.

1414 2. The wholesale distribution activity does not exceed 30
 1415 percent of the total annual purchases of prescription drugs. If
 1416 the wholesale distribution activity exceeds the 30-percent



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1417 maximum, the pharmacy must obtain a prescription drug
1418 wholesaler's permit.

1419 3. The transfer of prescription drugs that appear in any
1420 schedule contained in chapter 893 is subject to chapter 893 and
1421 the federal Comprehensive Drug Abuse Prevention and Control Act
1422 of 1970.

1423 4. The transfer is between a retail pharmacy and another
1424 retail pharmacy, or a Modified Class II institutional pharmacy,
1425 or a health care practitioner licensed in this state and
1426 authorized by law to dispense or prescribe prescription drugs.

1427 5. All records of sales of prescription drugs subject to
1428 this section must be maintained separate and distinct from other
1429 records and comply with the recordkeeping requirements of ss.
1430 499.001-499.081.

1431 (3) A person that engages in wholesale distribution of
1432 prescription drugs in this state must have a wholesale
1433 distributor's permit issued by the department, except as noted
1434 in this section. Each establishment must be separately permitted
1435 except as noted in this subsection.

1436 (a) A separate establishment permit is not required when a
1437 permitted prescription drug wholesaler consigns a prescription
1438 drug to a pharmacy that is permitted under chapter 465 and
1439 located in this state, provided that:

1440 1. The consignor wholesaler notifies the department in
1441 writing of the contract to consign prescription drugs to a
1442 pharmacy along with the identity and location of each consignee
1443 pharmacy;

1444 2. The pharmacy maintains its permit under chapter 465;



1445 3. The consignor wholesaler, which has no legal authority
1446 to dispense prescription drugs, complies with all wholesale
1447 distribution requirements of s. 499.0121 with respect to the
1448 consigned drugs and maintains records documenting the transfer
1449 of title or other completion of the wholesale distribution of
1450 the consigned prescription drugs;

1451 4. The distribution of the prescription drug is otherwise
1452 lawful under this chapter and other applicable law;

1453 5. Open packages containing prescription drugs within a
1454 pharmacy are the responsibility of the pharmacy, regardless of
1455 how the drugs are titled; and

1456 6. The pharmacy dispenses the consigned prescription drug
1457 in accordance with the limitations of its permit under chapter
1458 465 or returns the consigned prescription drug to the consignor
1459 wholesaler. In addition, a person who holds title to
1460 prescription drugs may transfer the drugs to a person permitted
1461 or licensed to handle the reverse distribution or destruction of
1462 drugs. Any other distribution by and means of the consigned
1463 prescription drug by any person, not limited to the consignor
1464 wholesaler or consignee pharmacy, to any other person is
1465 prohibited.

1466 (b) A wholesale distributor's permit is not required for
1467 the one-time transfer of title of a pharmacy's lawfully acquired
1468 prescription drug inventory by a pharmacy with a valid permit
1469 issued under chapter 465 to a consignor prescription drug
1470 wholesaler, permitted under this chapter, in accordance with a
1471 written consignment agreement between the pharmacy and that
1472 wholesaler if: the permitted pharmacy and the permitted



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1473 prescription drug wholesaler comply with all of the provisions
1474 of paragraph (a) and the prescription drugs continue to be
1475 within the permitted pharmacy's inventory for dispensing in
1476 accordance with the limitations of the pharmacy permit under
1477 chapter 465. A consignor drug wholesaler may not use the
1478 pharmacy as a wholesale distributor through which it distributes
1479 the legend drugs to other pharmacies. Nothing in this section is
1480 intended to prevent a wholesale drug distributor from obtaining
1481 this inventory in the event of nonpayment by the pharmacy.

1482 (c) The department shall require information from each
1483 wholesale distributor as part of the permit and renewal of such
1484 permit, as required under s. 499.01.

1485 (4) Personnel employed in wholesale distribution must have
1486 appropriate education and experience to enable them to perform
1487 their duties in compliance with state permitting requirements.

1488 (5) The department may adopt rules governing the
1489 recordkeeping, storage, and handling with respect to each of the
1490 distributions of prescription drugs specified in subparagraphs
1491 (1)(a)1.-4.

1492 Section 14. Effective January 1, 2004, section 499.012,
1493 Florida Statutes, as amended by this act, is amended to read:

1494 499.012 Wholesale distribution; definitions; permits;
1495 applications; general requirements.--

1496 (1) As used in this section, the term:

1497 (a) "Wholesale distribution" means distribution of
1498 prescription drugs to persons other than a consumer or patient,
1499 but does not include:



1500 1. Any of the following activities, which is not a
1501 violation of s. 499.005(21) if such activity is conducted in
1502 accordance with s. 499.014:

1503 a. The purchase or other acquisition by a hospital or
1504 other health care entity that is a member of a group purchasing
1505 organization of a prescription drug for its own use from the
1506 group purchasing organization or from other hospitals or health
1507 care entities that are members of that organization.

1508 b. The sale, purchase, or trade of a prescription drug or
1509 an offer to sell, purchase, or trade a prescription drug by a
1510 charitable organization described in s. 501(c)(3) of the
1511 Internal Revenue Code of 1986, as amended and revised, to a
1512 nonprofit affiliate of the organization to the extent otherwise
1513 permitted by law.

1514 c. The sale, purchase, or trade of a prescription drug or
1515 an offer to sell, purchase, or trade a prescription drug among
1516 hospitals or other health care entities that are under common
1517 control. For purposes of this section, "common control" means
1518 the power to direct or cause the direction of the management and
1519 policies of a person or an organization, whether by ownership of
1520 stock, by voting rights, by contract, or otherwise.

1521 d. The sale, purchase, trade, or other transfer of a
1522 prescription drug from or for any federal, state, or local
1523 government agency or any entity eligible to purchase
1524 prescription drugs at public health services prices pursuant to
1525 Pub. L. No. 102-585, s. 602 to a contract provider or its
1526 subcontractor for eligible patients of the agency or entity
1527 under the following conditions:



1528 (I) The agency or entity must obtain written authorization
 1529 for the sale, purchase, trade, or other transfer of a
 1530 prescription drug under this sub-subparagraph from the Secretary
 1531 of Health or his or her designee.

1532 (II) The contract provider or subcontractor must be
 1533 authorized by law to administer or dispense prescription drugs.

1534 (III) In the case of a subcontractor, the agency or entity
 1535 must be a party to and execute the subcontract.

1536 (IV) A contract provider or subcontractor must maintain
 1537 separate and apart from other prescription drug inventory any
 1538 prescription drugs of the agency or entity in its possession.

1539 (V) The contract provider and subcontractor must maintain
 1540 and produce immediately for inspection all records of movement
 1541 or transfer of all the prescription drugs belonging to the
 1542 agency or entity, including, but not limited to, the records of
 1543 receipt and disposition of prescription drugs. Each contractor
 1544 and subcontractor dispensing or administering these drugs must
 1545 maintain and produce records documenting the dispensing or
 1546 administration. Records that are required to be maintained
 1547 include, but are not limited to, a perpetual inventory itemizing
 1548 drugs received and drugs dispensed by prescription number or
 1549 administered by patient identifier, which must be submitted to
 1550 the agency or entity quarterly.

1551 (VI) The contract provider or subcontractor may administer
 1552 or dispense the prescription drugs only to the eligible patients
 1553 of the agency or entity or must return the prescription drugs
 1554 for or to the agency or entity. The contract provider or
 1555 subcontractor must require proof from each person seeking to



1556 fill a prescription or obtain treatment that the person is an
 1557 eligible patient of the agency or entity and must, at a minimum,
 1558 maintain a copy of this proof as part of the records of the
 1559 contractor or subcontractor required under sub-sub-subparagraph
 1560 (V).

1561 (VII) In addition to the departmental inspection authority
 1562 set forth in s. 499.051, the establishment of the contract
 1563 provider and subcontractor and all records pertaining to
 1564 prescription drugs subject to this sub-subparagraph shall be
 1565 subject to inspection by the agency or entity. All records
 1566 relating to prescription drugs of a manufacturer under this sub-
 1567 subparagraph shall be subject to audit by the manufacturer of
 1568 those drugs, without identifying individual patient information.

1569 2. Any of the following activities, which is not a
 1570 violation of s. 499.005(21) if such activity is conducted in
 1571 accordance with rules established by the department:

1572 a. The sale, purchase, or trade of a prescription drug
 1573 among federal, state, or local government health care entities
 1574 that are under common control and are authorized to purchase
 1575 such prescription drug.

1576 b. The sale, purchase, or trade of a prescription drug or
 1577 an offer to sell, purchase, or trade a prescription drug for
 1578 emergency medical reasons. For purposes of this sub-
 1579 subparagraph, the term "emergency medical reasons" includes
 1580 transfers of prescription drugs by a retail pharmacy to another
 1581 retail pharmacy to alleviate a temporary shortage.

1582 c. The transfer of a prescription drug acquired by a
 1583 medical director on behalf of a licensed emergency medical



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1584 services provider to that emergency medical services provider
1585 and its transport vehicles for use in accordance with the
1586 provider's license under chapter 401.

1587 d. The revocation of a sale or the return of a
1588 prescription drug to the person's prescription drug wholesale
1589 supplier.

1590 e. The donation of a prescription drug by a health care
1591 entity to a charitable organization that has been granted an
1592 exemption under s. 501(c)(3) of the Internal Revenue Code of
1593 1986, as amended, and that is authorized to possess prescription
1594 drugs.

1595 f. The transfer of a prescription drug by a person
1596 authorized to purchase or receive prescription drugs to a person
1597 licensed or permitted to handle reverse distributions or
1598 destruction under the laws of the jurisdiction in which the
1599 person handling the reverse distribution or destruction receives
1600 the drug.

1601 g. The transfer of a prescription drug by a hospital or
1602 other health care entity to a person licensed under this chapter
1603 to repackage prescription drugs for the purpose of repackaging
1604 the prescription drug for use by that hospital, or other health
1605 care entity and other health care entities that are under common
1606 control, if ownership of the prescription drugs remains with the
1607 hospital or other health care entity at all times. In addition
1608 to the recordkeeping requirements of s. 499.0121(6), the
1609 hospital or health care entity that transfers prescription drugs
1610 pursuant to this sub-subparagraph must reconcile all drugs



1611 transferred and returned and resolve any discrepancies in a
1612 timely manner.

1613 3. The distribution of prescription drug samples by
1614 manufacturers' representatives or distributors' representatives
1615 conducted in accordance with s. 499.028.

1616 4. The sale, purchase, or trade of blood and blood
1617 components intended for transfusion. As used in this
1618 subparagraph, the term "blood" means whole blood collected from
1619 a single donor and processed either for transfusion or further
1620 manufacturing, and the term "blood components" means that part
1621 of the blood separated by physical or mechanical means.

1622 5. The lawful dispensing of a prescription drug in
1623 accordance with chapter 465.

1624 (b) "Wholesale distributor" means any person engaged in
1625 wholesale distribution of prescription drugs in or into this
1626 state, including, but not limited to, manufacturers;
1627 repackagers; own-label distributors; jobbers; private-label
1628 distributors; brokers; warehouses, including manufacturers' and
1629 distributors' warehouses, chain drug warehouses, and wholesale
1630 drug warehouses; independent wholesale drug traders; exporters;
1631 retail pharmacies; and the agents thereof that conduct wholesale
1632 distributions.

1633 (c) "Retail pharmacy" means a community pharmacy licensed
1634 under chapter 465 that purchases prescription drugs at fair
1635 market prices and provides prescription services to the public.

1636 (d) "Primary wholesaler" means any wholesale distributor
1637 that:



1638 1. Purchased 90 percent or more of the total dollar volume
1639 of its purchases of prescription drugs directly from
1640 manufacturers in the previous year; and

1641 2.a. Directly purchased prescription drugs from not fewer
1642 than 50 different prescription drug manufacturers in the
1643 previous year; or

1644 b. Has, or the affiliated group, as defined in s. 1504 of
1645 the Internal Revenue Code, of which the wholesale distributor is
1646 a member has, not fewer than 250 employees.

1647 (e) "Directly from a manufacturer" means:

1648 1. Purchases made by the wholesale distributor directly
1649 from the manufacturer of prescription drugs; and

1650 2. Transfers from a member of an affiliated group, as
1651 defined in s. 1504 of the Internal Revenue Code, of which the
1652 wholesale distributor is a member, if:

1653 a. The affiliated group purchases 90 percent or more of
1654 the total dollar volume of its purchases of prescription drugs
1655 from manufacturers in the previous year; or

1656 b. The wholesale distributor discloses to the department
1657 the names of all members of the affiliated group of which the
1658 wholesale distributor is a member and the affiliated group
1659 agrees in writing to provide records on prescription drug
1660 purchases by the members of the affiliated group not later than
1661 48 hours after the department requests access to such records,
1662 regardless of the location where the records are stored.

1663 (f) "Secondary wholesaler" means a wholesale distributor
1664 that is not a primary wholesaler.



1665 (2) The following types of wholesaler permits are
1666 established:

1667 (a) A prescription drug wholesaler's permit. A
1668 prescription drug wholesaler is a wholesale distributor that may
1669 engage in the wholesale distribution of prescription drugs. A
1670 prescription drug wholesaler that applies to the department for
1671 a new permit or the renewal of a permit ~~after July 1, 2003~~, must
1672 submit a bond of \$100,000, or other equivalent means of security
1673 acceptable to the department, such as an irrevocable letter of
1674 credit or a deposit in a trust account or financial institution,
1675 payable to the Florida Drug, Device, and Cosmetic Trust Fund.
1676 The purpose of the bond is to secure payment of any
1677 administrative penalties imposed by the department and any fees
1678 and costs incurred by the department regarding that permit which
1679 are authorized under state law and which the permittee fails to
1680 pay 30 days after the fine or costs become final. The department
1681 may make a claim against such bond or security until 1 year
1682 after the permittee's license ceases to be valid or until 60
1683 days after any administrative or legal proceeding authorized in
1684 ss. 499.001-499.081 which involves the permittee is concluded,
1685 including any appeal, whichever occurs later. The department may
1686 adopt rules for issuing a prescription drug wholesaler-broker
1687 permit to a person who engages in the wholesale distribution of
1688 prescription drugs and does not take physical possession of any
1689 prescription drugs.

1690 (b) A compressed medical gas wholesaler's permit. A
1691 compressed medical gas wholesaler is a wholesale distributor
1692 that is limited to the wholesale distribution of compressed



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1693 | medical gases to other than the consumer or patient. The
1694 | compressed medical gas must be in the original sealed container
1695 | that was purchased by that wholesaler. A compressed medical gas
1696 | wholesaler may not possess or engage in the wholesale
1697 | distribution of any prescription drug other than compressed
1698 | medical gases. The department shall adopt rules that govern the
1699 | wholesale distribution of prescription medical oxygen for
1700 | emergency use. With respect to the emergency use of prescription
1701 | medical oxygen, those rules may not be inconsistent with rules
1702 | and regulations of federal agencies unless the Legislature
1703 | specifically directs otherwise.

1704 | (c) An out-of-state prescription drug wholesaler's permit.
1705 | An out-of-state prescription drug wholesaler is a wholesale
1706 | distributor located outside this state which engages in the
1707 | wholesale distribution of prescription drugs into this state and
1708 | which must be permitted by the department and comply with all
1709 | the provisions required of a wholesale distributor under ss.
1710 | 499.001-499.081. An out-of-state prescription drug wholesaler
1711 | that applies to the department for a new permit or the renewal
1712 | of a permit ~~after July 1, 2003~~, must submit a bond of \$100,000,
1713 | or other equivalent means of security acceptable to the
1714 | department, such as an irrevocable letter of credit or a deposit
1715 | in a trust account or financial institution, payable to the
1716 | Florida Drug, Device, and Cosmetic Trust Fund. The purpose of
1717 | the bond is to secure payment of any administrative penalties
1718 | imposed by the department and any fees and costs incurred by the
1719 | department regarding that permit which are authorized under
1720 | state law and which the permittee fails to pay 30 days after the



1721 fine or costs become final. The department may make a claim
 1722 against such bond or security until 1 year after the permittee's
 1723 license ceases to be valid or until 60 days after any
 1724 administrative or legal proceeding authorized in ss. 499.001-
 1725 499.081 which involves the permittee is concluded, including any
 1726 appeal, whichever occurs later.

1727 1. The out-of-state drug wholesaler must maintain at all
 1728 times a license or permit to engage in the wholesale
 1729 distribution of prescription drugs in compliance with laws of
 1730 the state in which it is a resident.

1731 2. An out-of-state prescription drug wholesaler's permit
 1732 is not required for an intracompany sale or transfer of a
 1733 prescription drug from an out-of-state establishment that is
 1734 duly licensed as a prescription drug wholesaler, in its state of
 1735 residence, to a licensed prescription drug wholesaler in this
 1736 state, if both wholesalers conduct wholesale distributions of
 1737 prescription drugs under the same business name. The
 1738 recordkeeping requirements of s. 499.0121(6) must be followed
 1739 for this transaction.

1740 (d) A retail pharmacy wholesaler's permit. A retail
 1741 pharmacy wholesaler is a retail pharmacy engaged in wholesale
 1742 distribution of prescription drugs within this state under the
 1743 following conditions:

1744 1. The pharmacy must obtain a retail pharmacy wholesaler's
 1745 permit pursuant to ss. 499.001-499.081 and the rules adopted
 1746 under those sections.

1747 2. The wholesale distribution activity does not exceed 30
 1748 percent of the total annual purchases of prescription drugs. If



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1749 the wholesale distribution activity exceeds the 30-percent
1750 maximum, the pharmacy must obtain a prescription drug
1751 wholesaler's permit.

1752 3. The transfer of prescription drugs that appear in any
1753 schedule contained in chapter 893 is subject to chapter 893 and
1754 the federal Comprehensive Drug Abuse Prevention and Control Act
1755 of 1970.

1756 4. The transfer is between a retail pharmacy and another
1757 retail pharmacy, or a Modified Class II institutional pharmacy,
1758 or a health care practitioner licensed in this state and
1759 authorized by law to dispense or prescribe prescription drugs.

1760 5. All records of sales of prescription drugs subject to
1761 this section must be maintained separate and distinct from other
1762 records and comply with the recordkeeping requirements of ss.
1763 499.001-499.081.

1764 (e) A nonresident prescription drug manufacturer's permit.
1765 A nonresident prescription drug manufacturer's permit is
1766 required for any person that is a manufacturer of prescription
1767 drugs, or the distribution point for a manufacturer of
1768 prescription drugs, and located outside of this state, or that
1769 is an entity to whom an approved new drug application has been
1770 issued by the United States Food and Drug Administration, or the
1771 contracted manufacturer of the approved new drug application
1772 holder, and located outside the United States, which engages in
1773 the wholesale distribution in this state of the prescription
1774 drugs it manufactures or is responsible for manufacturing. Each
1775 such manufacturer or entity must be permitted by the department



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1776 and comply with all the provisions required of a wholesale
1777 distributor under ss. 499.001-499.081, except s. 499.0121(6)(d).

1778 1. A person that distributes prescription drugs that it
1779 did not manufacture must also obtain an out-of-state
1780 prescription drug wholesaler permit pursuant this section to
1781 engage in the wholesale distribution of the prescription drugs
1782 manufactured by another person and comply with the requirements
1783 of an out-of-state prescription drug wholesaler.

1784 2. Any such person must comply with the licensing or
1785 permitting requirements of the jurisdiction in which the
1786 establishment is located and the federal act, and any product
1787 wholesaled into this state must comply with ss. 499.001-499.081.
1788 If a person intends to import prescription drugs from a foreign
1789 country into this state, the nonresident prescription drug
1790 manufacturer must provide to the department a list identifying
1791 each prescription drug it intends to import and document
1792 approval by the United States Food and Drug Administration for
1793 such importation.

1794 (f) A freight forwarder's permit. A freight forwarder's
1795 permit is required for any person that engages in the
1796 distribution of a legend drug as a freight forwarder unless the
1797 person is a common carrier. The storage, handling, and
1798 recordkeeping of such distributions must comply with the
1799 requirements for wholesale distributors under s. 499.0121,
1800 except those set forth in s. 499.0121(6)(d), (e), or (f). A
1801 freight forwarder must provide the source of the legend drugs
1802 with a validated airway bill, bill of lading, or other



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1803 appropriate documentation to evidence the exportation of the
1804 product.

1805 (3) An application for a permit or to renew a permit for a
1806 prescription drug wholesaler or an out-of-state prescription
1807 drug wholesaler submitted to the department must include:

1808 (a) The name, full business address, and telephone number
1809 of the applicant.

1810 (b) All trade or business names used by the applicant.

1811 (c) The address, telephone numbers, and names of contact
1812 persons for each facility used by the applicant for the storage,
1813 handling, and distribution of prescription drugs.

1814 (d) The type of ownership or operation, such as a
1815 partnership, corporation, or sole proprietorship.

1816 (e) The names of the owner and the operator of the
1817 establishment, including:

1818 1. If an individual, the name of the individual.

1819 2. If a partnership, the name of each partner and the name
1820 of the partnership.

1821 3. If a corporation:

1822 a. The name, address, and title of each corporate officer
1823 and director.

1824 b. The name and address of the corporation, resident agent
1825 of the corporation, the resident agent's address, and the
1826 corporation's state of incorporation.

1827 c. The name and address of each shareholder of the
1828 corporation that owns 5 percent or more of the outstanding stock
1829 of the corporation.



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1830 4. If a sole proprietorship, the full name of the sole
1831 proprietor and the name of the business entity.

1832 5. If a limited liability company:

1833 a. The name and address of each member.

1834 b. The name and address of each manager.

1835 c. The name and address of the limited liability company,
1836 the resident agent of the limited liability company, and the
1837 name of the state in which the limited liability company was
1838 organized.

1839 (f) If applicable, the name and address of each member of
1840 the affiliated group, as defined in s. 1504 of the Internal
1841 Revenue Code, of which the applicant is a member.

1842 (g)1. For an application for a new permit, the estimated
1843 annual dollar volume of prescription drug sales of the
1844 applicant, the estimated annual percentage of the applicant's
1845 total company sales that are prescription drugs, the applicant's
1846 estimated annual total dollar volume of purchases of
1847 prescription drugs, and the applicant's estimated annual total
1848 dollar volume of prescription drug purchases directly from
1849 manufacturers.

1850 2. For an application to renew a permit, the total dollar
1851 volume of prescription drug sales in the previous year, the
1852 total dollar volume of prescription drug sales made in the
1853 previous 6 months, the percentage of total company sales that
1854 were prescription drugs in the previous year, the total dollar
1855 volume of purchases of prescription drugs in the previous year,
1856 and the total dollar volume of prescription drug purchases
1857 directly from manufacturers in the previous year.



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1858
1859 Such portions of the information required pursuant to this
1860 paragraph which are a trade secret, as defined in s. 812.081,
1861 shall be maintained by the department as trade secret
1862 information is required to be maintained under s. 499.051.

1863 (h) The tax year of the applicant.

1864 (i) A copy of the deed for the property on which
1865 applicant's establishment is located, if the establishment is
1866 owned by the applicant, or a copy of the applicant's lease for
1867 the property on which applicant's establishment is located that
1868 has an original term of not less than 1 calendar year, if the
1869 establishment is not owned by the applicant.

1870 (j) A list of all licenses and permits issued to the
1871 applicant by any other state which authorize the applicant to
1872 purchase or possess prescription drugs.

1873 (k) The name of the manager of the establishment that is
1874 applying for the permit or to renew the permit, the next four
1875 highest ranking employees responsible for prescription drug
1876 wholesale operations for the establishment, and the name of all
1877 affiliated parties for the establishment, together with the
1878 personal information statement and fingerprints required
1879 pursuant to subsection (4) for each such person.

1880 (l) The name of each of the applicant's designated
1881 representatives as required by subsection (11), together with
1882 the personal information statement and fingerprints required
1883 pursuant to subsection (4) for each such person.

1884 (m) For an applicant that is a secondary wholesaler, each
1885 of the following:



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1886 1. A personal background information statement containing
1887 the background information and fingerprints required pursuant to
1888 subsection (4) for each person named in the applicant's response
1889 to paragraphs (k) and (l) and for each affiliated party of the
1890 applicant.

1891 2. If any of the five largest shareholders of the
1892 corporation seeking the permit is a corporation, the name,
1893 address, and title of each corporate officer and director of
1894 each such corporation; the name and address of such corporation;
1895 the name of such corporation's resident agent, such
1896 corporation's resident agent's address, and such corporation's
1897 state of its incorporation; and the name and address of each
1898 shareholder of such corporation that owns 5 percent or more of
1899 the stock of such corporation.

1900 3. The name and address of all financial institutions in
1901 which the applicant has an account which is used to pay for the
1902 operation of the establishment or to pay for drugs purchased for
1903 the establishment, together with the names of all persons that
1904 are authorized signatories on such accounts. Any portions of the
1905 information required pursuant to this subparagraph which are a
1906 trade secret, as defined in s. 812.081, shall be maintained by
1907 the department as trade secret information is required to be
1908 maintained under s. 499.051.

1909 4. The sources of all funds and the amounts of such funds
1910 used to purchase or finance purchases of prescription drugs or
1911 to finance the premises on which the establishment is to be
1912 located.



1913 5. If any of the funds identified in subparagraph 4. were
 1914 borrowed, copies of all promissory notes or loans used to obtain
 1915 such funds.

1916 (n) Any other relevant information that the department
 1917 requires, including, but not limited to, any information related
 1918 to whether the applicant satisfies the definition of a primary
 1919 wholesaler or a secondary wholesaler.

1920 (4)(a) Each person required under subsection (3) to
 1921 provide a personal information statement and fingerprints
 1922 pursuant to this subsection shall provide the following
 1923 information to the department on forms prescribed by the
 1924 department:

1925 1. The person's places of residence for the past 7 years.

1926 2. The person's date and place of birth.

1927 3. The person's occupations, positions of employment, and
 1928 offices held during the past 7 years.

1929 4. The principal business and address of any business,
 1930 corporation, or other organization in which each such office of
 1931 the person was held or in which each such occupation or position
 1932 of employment was carried on.

1933 5. Whether the person has been, during the past 7 years,
 1934 the subject of any proceeding for the revocation of any license
 1935 and, if so, the nature of the proceeding and the disposition of
 1936 the proceeding.

1937 6. Whether, during the past 7 years, the person has been
 1938 enjoined, either temporarily or permanently, by a court of
 1939 competent jurisdiction from violating any federal or state law
 1940 regulating the possession, control, or distribution of



1941 prescription drugs, together with details concerning any such
 1942 event.

1943 7. A description of any involvement by the person with any
 1944 business, including any investments, other than the ownership of
 1945 stock in a publicly traded company or mutual fund, during the
 1946 past 7 years, which manufactured, administered, prescribed,
 1947 distributed, or stored pharmaceutical products and any lawsuits
 1948 in which such businesses were named as a party.

1949 8. A description of any felony criminal offense of which
 1950 the person, as an adult, was found guilty, regardless of whether
 1951 adjudication of guilt was withheld or whether the person pled
 1952 guilty or nolo contendere. A criminal offense committed in
 1953 another jurisdiction which would have been a felony in this
 1954 state must be reported. If the person indicates that a criminal
 1955 conviction is under appeal and submits a copy of the notice of
 1956 appeal of that criminal offense, the applicant must, within 15
 1957 days after the disposition of the appeal, submit to the
 1958 department a copy of the final written order of disposition.

1959 9. A photograph of the person taken in the previous 30
 1960 days.

1961 10. A set of fingerprints of the person on a form and
 1962 under procedures specified by the department, together with
 1963 payment of an amount equal to the costs incurred by the
 1964 department for the criminal record check of the person.

1965 11. The name, address, occupation, and date and place of
 1966 birth for each member of the person's immediate family who is 18
 1967 years of age or older. As used in this subparagraph, the term
 1968 "member of the person's immediate family" includes the person's



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1969 spouse, children, parents, siblings, the spouses of the person's
1970 children, and the spouses of the person's siblings.

1971 12. Any other relevant information that the department
1972 requires.

1973 (b) The information required pursuant to paragraph (a)
1974 shall be provided under oath.

1975 (c) The department shall submit the fingerprints provided
1976 by a person for initial licensure to the Department of Law
1977 Enforcement for a statewide criminal record check and for
1978 forwarding to the Federal Bureau of Investigation for a national
1979 criminal record check of the person. The department shall submit
1980 the fingerprints provided by a person as a part of a renewal
1981 application to the Department of Law Enforcement for a statewide
1982 criminal record check, and for forwarding to the Federal Bureau
1983 of Investigation for a national criminal record check, for the
1984 initial renewal of a permit after January 1, 2004; for any
1985 subsequent renewal of a permit, the department shall submit the
1986 required information for a statewide and national criminal
1987 record check of the person. Any person who, as a part of an
1988 initial permit application or initial permit renewal after
1989 January 1, 2004, submits to the department a set of fingerprints
1990 required for the criminal record check required in this
1991 paragraph shall not be required to provide a subsequent set of
1992 fingerprints for a criminal record check to the department, if
1993 the person has undergone a criminal record check as a condition
1994 of the issuance of an initial permit or the initial renewal of a
1995 permit of an applicant after January 1, 2004.



1996 (5) The department may deny an application for a permit or
 1997 refuse to renew a permit for a prescription drug wholesaler or
 1998 an out-of-state prescription drug wholesaler if:

1999 (a) The applicant has not met the requirements for the
 2000 permit.

2001 (b) The management, officers, or directors of the
 2002 applicant or any affiliated party are found by the department to
 2003 be incompetent or untrustworthy.

2004 (c) The applicant is so lacking in experience in managing
 2005 a wholesale distributor as to make the issuance of the proposed
 2006 permit hazardous to the public health.

2007 (d) The applicant is so lacking in experience in managing
 2008 a wholesale distributor as to jeopardize the reasonable promise
 2009 of successful operation of the wholesale distributor.

2010 (e) The applicant is lacking in experience in the
 2011 distribution of prescription drugs.

2012 (f) The applicant's past experience in manufacturing or
 2013 distributing prescription drugs indicates that the applicant
 2014 poses a public health risk.

2015 (g) The applicant is affiliated directly or indirectly
 2016 through ownership, control, or other business relations, with
 2017 any person or persons whose business operations are or have been
 2018 detrimental to the public health.

2019 (h) The applicant, or any affiliated party, has been found
 2020 guilty of or has pleaded guilty or nolo contendere to any felony
 2021 or crime punishable by imprisonment for 1 year or more under the
 2022 laws of the United States, any state, or any other country,
 2023 regardless of whether adjudication of guilt was withheld.



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2024 (i) The applicant or any affiliated party has been charged
2025 with a felony in a state or federal court and the disposition of
2026 that charge is pending during the application review or renewal
2027 review period.

2028 (j) The applicant has furnished false or fraudulent
2029 information or material in any application made in this state or
2030 any other state in connection with obtaining a permit or license
2031 to manufacture or distribute drugs, devices, or cosmetics.

2032 (k) That a federal, state, or local government permit
2033 currently or previously held by the applicant, or any affiliated
2034 party, for the manufacture or distribution of any drugs,
2035 devices, or cosmetics has been disciplined, suspended, or
2036 revoked and has not been reinstated.

2037 (l) The applicant does not possess the financial or
2038 physical resources to operate in compliance with the permit
2039 being sought, this chapter, and the rules adopted under this
2040 chapter.

2041 (m) The applicant or any affiliated party receives,
2042 directly or indirectly, financial support and assistance from a
2043 person who was an affiliated party of a permittee whose permit
2044 was subject to discipline or was suspended or revoked, other
2045 than through the ownership of stock in a publicly traded company
2046 or a mutual fund.

2047 (n) The applicant or any affiliated party receives,
2048 directly or indirectly, financial support and assistance from a
2049 person who has been found guilty of any violation of ss.
2050 499.001-499.081 or chapter 465, chapter 501, or chapter 893, any
2051 rules adopted under any of those sections or chapters, any



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2052 federal or state drug law, or any felony where the underlying
2053 facts related to drugs, regardless of whether the person has
2054 been pardoned, had her or his civil rights restored, or had
2055 adjudication withheld, other than through the ownership of stock
2056 in a publicly traded company or a mutual fund.

2057 (o) The applicant for renewal of a permit under paragraph
2058 (2)(a) or paragraph (2)(c) has not actively engaged in the
2059 wholesale distribution of prescription drugs, as demonstrated by
2060 the regular and systematic distribution of prescription drugs
2061 throughout the year as evidenced by not fewer than 12 wholesale
2062 distributions in the previous year and not fewer than three
2063 wholesale distributions in the previous 6 months.

2064 (p) Information obtained in response to subsection (3) or
2065 subsection (4) demonstrates it would not be in the best interest
2066 of the public health, safety, and welfare to issue a permit.

2067 (q) The applicant does not possess the financial standing
2068 and business experience for the successful operation of the
2069 applicant's business.

2070 (r) The applicant or any affiliated party has failed to
2071 comply with the requirements for manufacturing or distributing
2072 prescription drugs under ss. 499.001-499.081, similar federal
2073 laws, similar laws in other states, or the rules adopted under
2074 such laws.

2075 (6) Upon approval of the application by the department and
2076 payment of the required fee, the department shall issue or renew
2077 a prescription drug wholesaler or an out-of-state prescription
2078 drug wholesaler permit to the applicant.



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2079 (7) For permits for prescription drug wholesalers or out-
2080 of-state prescription drug wholesalers:

2081 (a) The department shall adopt rules for the annual
2082 renewal of permits. At least 90 days before the expiration of a
2083 permit, the department shall forward a permit renewal
2084 notification and renewal application to the prescription drug
2085 wholesaler or out-of-state prescription drug wholesaler at the
2086 mailing address of the permitted establishment on file with the
2087 department. The permit renewal notification must state
2088 conspicuously the date on which the permit for the establishment
2089 will expire and that the establishment may not operate unless
2090 the permit for the establishment is renewed timely.

2091 (b) A permit, unless sooner suspended or revoked,
2092 automatically expires 1 year after the last day of the
2093 anniversary month in which the permit was originally issued. A
2094 permit may be renewed by making application for renewal on forms
2095 furnished by the department and paying the appropriate fees. If
2096 a renewal application and fee are submitted and postmarked after
2097 the 45th day prior to the expiration date of the permit, the
2098 permit may be renewed only upon payment of a late renewal fee of
2099 \$100, plus the required renewal fee. A permittee that has
2100 submitted a renewal application in accordance with this
2101 paragraph may continue to operate under its permit, unless the
2102 permit is suspended or revoked, until final disposition of the
2103 renewal application.

2104 (c) Failure to renew a permit in accordance with this
2105 section precludes any future renewal of that permit. If a permit
2106 issued pursuant to this section has expired and cannot be



2107 renewed, before an establishment may engage in activities that
 2108 require a permit under ss. 499.001-499.081, the establishment
 2109 must submit an application for a new permit; pay the applicable
 2110 application fee, initial permit fee, and all applicable
 2111 penalties; and be issued a new permit by the department.

2112 (8)(3) A person that engages in wholesale distribution of
 2113 prescription drugs in this state must have a wholesale
 2114 distributor's permit issued by the department, except as noted
 2115 in this section. Each establishment must be separately permitted
 2116 except as noted in this subsection.

2117 (a) A separate establishment permit is not required when a
 2118 permitted prescription drug wholesaler consigns a prescription
 2119 drug to a pharmacy that is permitted under chapter 465 and
 2120 located in this state, provided that:

2121 1. The consignor wholesaler notifies the department in
 2122 writing of the contract to consign prescription drugs to a
 2123 pharmacy along with the identity and location of each consignee
 2124 pharmacy;

2125 2. The pharmacy maintains its permit under chapter 465;

2126 3. The consignor wholesaler, which has no legal authority
 2127 to dispense prescription drugs, complies with all wholesale
 2128 distribution requirements of s. 499.0121 with respect to the
 2129 consigned drugs and maintains records documenting the transfer
 2130 of title or other completion of the wholesale distribution of
 2131 the consigned prescription drugs;

2132 4. The distribution of the prescription drug is otherwise
 2133 lawful under this chapter and other applicable law;



2134 5. Open packages containing prescription drugs within a
2135 pharmacy are the responsibility of the pharmacy, regardless of
2136 how the drugs are titled; and

2137 6. The pharmacy dispenses the consigned prescription drug
2138 in accordance with the limitations of its permit under chapter
2139 465 or returns the consigned prescription drug to the consignor
2140 wholesaler. In addition, a person who holds title to
2141 prescription drugs may transfer the drugs to a person permitted
2142 or licensed to handle the reverse distribution or destruction of
2143 drugs. Any other distribution by and means of the consigned
2144 prescription drug by any person, not limited to the consignor
2145 wholesaler or consignee pharmacy, to any other person is
2146 prohibited.

2147 (b) A wholesale distributor's permit is not required for
2148 the one-time transfer of title of a pharmacy's lawfully acquired
2149 prescription drug inventory by a pharmacy with a valid permit
2150 issued under chapter 465 to a consignor prescription drug
2151 wholesaler, permitted under this chapter, in accordance with a
2152 written consignment agreement between the pharmacy and that
2153 wholesaler if: the permitted pharmacy and the permitted
2154 prescription drug wholesaler comply with all of the provisions
2155 of paragraph (a) and the prescription drugs continue to be
2156 within the permitted pharmacy's inventory for dispensing in
2157 accordance with the limitations of the pharmacy permit under
2158 chapter 465. A consignor drug wholesaler may not use the
2159 pharmacy as a wholesale distributor through which it distributes
2160 the legend drugs to other pharmacies. Nothing in this section is



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2161 intended to prevent a wholesale drug distributor from obtaining
2162 this inventory in the event of nonpayment by the pharmacy.

2163 (c) The department shall require information from each
2164 wholesale distributor as part of the permit and renewal of such
2165 permit, as required under s. 499.01 or s. 499.012.

2166 (9)(4) Personnel employed in wholesale distribution must
2167 have appropriate education and experience to enable them to
2168 perform their duties in compliance with state permitting
2169 requirements.

2170 (10) The name of a permittee or establishment on a
2171 prescription drug wholesaler permit or an out-of-state
2172 prescription drug wholesaler permit may not include any indicia
2173 of attainment of any educational degree, any indicia that the
2174 permittee or establishment possesses a professional license, or
2175 any name or abbreviation that the department determines is
2176 likely to cause confusion or mistake or that the department
2177 determines is deceptive, including that of any other entity
2178 authorized to purchase prescription drugs.

2179 (11)(a) Each establishment that is issued an initial or
2180 renewal permit as a prescription drug wholesaler or an out-of-
2181 state prescription drug wholesaler must designate in writing to
2182 the department at least one natural person to serve as the
2183 designated representative of the wholesaler. Such person must
2184 have an active certification as a designated representative from
2185 the department.

2186 (b) To be certified as a designated representative, a
2187 natural person must:



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- 2188 1. Submit an application on a form furnished by the
 2189 department and pay the appropriate fees;
- 2190 2. Be at least 18 years of age;
- 2191 3. Have not less than 2 years of verifiable full-time work
 2192 experience in a pharmacy licensed in this state or another
 2193 state, where the person's responsibilities included, but were
 2194 not limited to, recordkeeping for prescription drugs, or have
 2195 not less than 2 years of verifiable full-time managerial
 2196 experience with a prescription drug wholesaler licensed in this
 2197 state or in another state;
- 2198 4. Receive a passing score of at least 75 percent on an
 2199 examination given by the department regarding federal laws
 2200 governing distribution of prescription drugs and ss. 499.001-
 2201 499.081 and the rules adopted by the department governing the
 2202 wholesale distribution of prescription drugs. This requirement
 2203 shall be effective 1 year after the results of the initial
 2204 examination are mailed to the persons that took the examination.
 2205 The department shall offer such examinations at least four times
 2206 each calendar year; and
- 2207 5. Provide the department with a personal information
 2208 statement and fingerprints pursuant to subsection (4).
- 2209 (c) The department may deny an application for
 2210 certification as a designated representative or may suspend or
 2211 revoke a certification of a designated representative pursuant
 2212 to s. 499.067.
- 2213 (d) A designated representative:
- 2214 1. Must be actively involved in and aware of the actual
 2215 daily operation of the wholesale distributor.



2216 2. Must be employed full time in a managerial position by
2217 the wholesale distributor.

2218 3. Must be physically present at the establishment during
2219 normal business hours, except for time periods when absent due
2220 to illness, family illness or death, scheduled vacation, or
2221 other authorized absence.

2222 4. May serve as a designated representative for only one
2223 wholesale distributor at any one time.

2224 (e) A wholesale distributor must notify the department
2225 when a designated representative leaves the employ of the
2226 wholesale distributor. Such notice must be provided to the
2227 department within 10 business days after the last day of
2228 designated representative's employment with the wholesale
2229 distributor.

2230 (f) A wholesale distributor may not operate under a
2231 prescription drug wholesaler permit or an out-of-state
2232 prescription drug wholesaler permit for more than 10 business
2233 days after the designated representative leaves the employ of
2234 the wholesale distributor, unless the wholesale distributor
2235 employs another designated representative and notifies the
2236 department within 10 business days of the identity of the new
2237 designated representative.

2238 (12)(5) The department may adopt rules governing the
2239 recordkeeping, storage, and handling with respect to each of the
2240 distributions of prescription drugs specified in subparagraphs
2241 (1)(a)1.-4.



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2242 Section 15. Subsections (4), (6), (7), and (8) of section
2243 499.0121, Florida Statutes, are amended, and subsection (11) is
2244 added to said section, to read:

2245 499.0121 Storage and handling of prescription drugs;
2246 recordkeeping.--The department shall adopt rules to implement
2247 this section as necessary to protect the public health, safety,
2248 and welfare. Such rules shall include, but not be limited to,
2249 requirements for the storage and handling of prescription drugs
2250 and for the establishment and maintenance of prescription drug
2251 distribution records.

2252 (4) EXAMINATION OF MATERIALS AND RECORDS.--

2253 (a) Upon receipt, each outside shipping container must be
2254 visually examined for identity and to prevent the acceptance of
2255 contaminated prescription drugs that are otherwise unfit for
2256 distribution. This examination must be adequate to reveal
2257 container damage that would suggest possible contamination or
2258 other damage to the contents.

2259 (b) Each outgoing shipment must be carefully inspected for
2260 identity of the prescription drug products and to ensure that
2261 there is no delivery of prescription drugs that have expired or
2262 been damaged in storage or held under improper conditions.

2263 (c) The recordkeeping requirements in subsection (6) must
2264 be followed for all incoming and outgoing prescription drugs.

2265 (d) Upon receipt, a wholesaler must review records
2266 required under this section for the acquisition of prescription
2267 drugs for accuracy and completeness, considering the total facts
2268 and circumstances surrounding the transactions and the wholesale
2269 distributors involved. This includes authenticating each



2270 transaction listed on a pedigree paper, as defined in s.
 2271 499.003(31).

2272 (6) RECORDKEEPING.--The department shall adopt rules that
 2273 require keeping such records of prescription drugs as are
 2274 necessary for the protection of the public health.

2275 (a) Wholesale drug distributors must establish and
 2276 maintain inventories and records of all transactions regarding
 2277 the receipt and distribution or other disposition of
 2278 prescription drugs. These records must provide a complete audit
 2279 trail from receipt to sale or other disposition, be readily
 2280 retrievable for inspection, and include, at a minimum, the
 2281 following information:

2282 1. The source of the drugs, including the name and
 2283 principal address of the seller or transferor, and the address
 2284 of the location from which the drugs were shipped.+

2285 2. The name, principal address, and state license permit
 2286 or registration number of the person authorized to purchase
 2287 prescription drugs.+

2288 3. The name, strength, dosage form, and quantity of the
 2289 drugs received and distributed or disposed of.+~~and~~

2290 4. The dates of receipt and distribution or other
 2291 disposition of the drugs.

2292 5. Any financial documentation supporting the transaction.

2293 (b) Inventories and records must be made available for
 2294 inspection and photocopying by authorized federal, state, or
 2295 local officials for a period of 2 years following disposition of
 2296 the drugs or 3 years after the creation of the records,
 2297 whichever period is longer.



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2298 (c) Records described in this section that are kept at the
2299 inspection site or that can be immediately retrieved by computer
2300 or other electronic means must be readily available for
2301 authorized inspection during the retention period. Records that
2302 are kept at a central location outside of this state and that
2303 are not electronically retrievable must be made available for
2304 inspection within 2 working days after a request by an
2305 authorized official of a federal, state, or local law
2306 enforcement agency. Records that are maintained at a central
2307 location within this state must be maintained at an
2308 establishment that is permitted pursuant to ss. 499.001-499.081
2309 and must be readily available.

2310 (d)1. Each person who is engaged in the wholesale
2311 distribution of a prescription drug, and who is not an
2312 authorized distributor of record for the drug manufacturer's
2313 products of such drug, must provide to each wholesale
2314 distributor of such drug, before the sale is made to such
2315 wholesale distributor, a written statement under oath
2316 identifying each previous sale of the drug back to the last
2317 authorized distributor of record, the lot number of the drug,
2318 and the sales invoice number of the invoice evidencing the sale
2319 of the drug. The written statement ~~identifying all sales of~~
2320 ~~such drug~~ must accompany the drug ~~for each subsequent wholesale~~
2321 ~~distribution of the drug~~ to the next a wholesale distributor.
2322 The department shall adopt rules relating to the requirements of
2323 this written statement. This subparagraph does not apply to a
2324 manufacturer unless the manufacturer is performing the
2325 manufacturing operation of repackaging prescription drugs.



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2326 2. Each wholesale distributor of prescription drugs must
2327 maintain separate and distinct from other required records all
2328 statements that are required under subparagraph 1. and paragraph
2329 (e).

2330 3. Each manufacturer of a prescription drug sold in this
2331 state must maintain at its corporate offices a current list of
2332 authorized distributors of record and must make such list
2333 available to the department upon request.

2334 4. Each manufacturer shall file a written list of all of
2335 the manufacturer's authorized distributors of record with the
2336 department. A manufacturer shall notify the department not later
2337 than 10 days after any change to the list. The department shall
2338 publish a list of all authorized distributors of record on its
2339 website.

2340 5. For the purposes of this subsection, the term
2341 "authorized distributors of record" means a wholesale
2342 distributor ~~these distributors~~ with whom a manufacturer has
2343 established an ongoing relationship to distribute the
2344 manufacturer's products. Effective March 1, 2004, an ongoing
2345 relationship is deemed to exist when a wholesale distributor,
2346 including any affiliated group, as defined in s. 1504 of the
2347 Internal Revenue Code, of which the wholesale distributor is a
2348 member:

2349 a. Is listed on the manufacturer's current list of
2350 authorized distributors of record.

2351 b. Annually purchases not less than 90 percent of all of
2352 its purchases of a manufacturer's prescription drug products,



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2353 based on dollar volume, directly from the manufacturer and has
2354 total annual prescription drug sales of \$100 million or more.
2355 c. Has reported to the department pursuant to s.
2356 499.012(3)(g)2. that the wholesale distributor has total annual
2357 prescription drug sales of \$100 million or more, and has a
2358 verifiable account number issued by the manufacturer authorizing
2359 the wholesale distributor to purchase the manufacturer's drug
2360 products directly from that manufacturer and that wholesale
2361 distributor makes not fewer than 12 purchases of that
2362 manufacturer's drug products directly from the manufacturer
2363 using said verifiable account number in 12 months. The
2364 provisions of this sub-subparagraph apply with respect to a
2365 manufacturer that fails to file a copy of the manufacturer's
2366 list of authorized distributors of record with the department by
2367 July 1, 2003, that files a list of authorized distributors of
2368 record that contains fewer than five wholesale distributors
2369 permitted in this state, excluding the wholesale distributors
2370 described in sub-subparagraph b., or that, as a result of
2371 changes to the list of authorized distributors of record filed
2372 with the department, has fewer than five wholesale distributors
2373 permitted in this state as authorized distributors of record,
2374 excluding the wholesale distributors described in sub-
2375 subparagraph b.
2376
2377 A wholesale distributor that satisfies the requirements of sub-
2378 subparagraph b. or sub-subparagraph c. shall submit to the
2379 department documentation substantiating its qualification
2380 pursuant to sub-subparagraph b. or sub-subparagraph c. The



2381 department shall add those wholesale distributors that the
 2382 department has determined have met the requirements of sub-
 2383 subparagraph b. or sub-subparagraph c. to the list of authorized
 2384 distributors of record on the department's website.

2385 6. This paragraph expires July 1, 2006.

2386 (e)1. Notwithstanding paragraph (d), each person who is
 2387 engaged in the wholesale distribution of a specified drug must
 2388 provide to each wholesale distributor of such specified drug:

2389 a. Upon any sale, a written statement that:

2390 (I) If the establishment is not a member of an affiliated
 2391 group, as defined in s. 1504 of the Internal Revenue Code: "This
 2392 establishment purchased the specific unit of the specified drug
 2393 directly from the manufacturer"; or

2394 (II) If the establishment is a member of an affiliated
 2395 group, as defined in s. 1504 of the Internal Revenue Code: "This
 2396 establishment or a member of my affiliated group purchased the
 2397 specific unit of the specified drug directly from the
 2398 manufacturer"; or

2399 b. Before the wholesale distribution, a written statement,
 2400 under oath, that identifies each previous sale of the specific
 2401 unit of the specified drug back to the manufacturer of the
 2402 specified drug, the lot number of the specific unit of the
 2403 specified prescription drug, and the sales invoice number of the
 2404 invoice evidencing each previous sale of the specific unit of
 2405 the specified drug. The written statement identifying all sales
 2406 of such specific unit of the specified drug must accompany the
 2407 specific unit of the specified drug for each subsequent



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2408 wholesale distribution of the specific unit of the specified
 2409 drug to a wholesale distributor.

2410
 2411 The department shall adopt rules to administer the requirements
 2412 of these written statements.

2413 2. As used in this paragraph, the term "specified drug"
 2414 means a specific prescription drug on the list of drugs adopted
 2415 by the department by rule.

2416 3.a. A drug may be placed on the list of specified drugs
 2417 if the department has seized or issued a stop sale notice on the
 2418 prescription drug because of the adulteration, counterfeiting,
 2419 or diversion of the prescription drug from the legal channels of
 2420 distribution for prescription drugs, or the United States Food
 2421 and Drug Administration, a manufacturer, a wholesale
 2422 distributor, a law enforcement agency, or a government agency
 2423 responsible for regulating the sale or distribution of
 2424 prescription drugs in another state has notified the department
 2425 in writing or through a website operated by one of said entities
 2426 that the prescription drug has been adulterated, counterfeit or
 2427 diverted from the legal channels of distribution for
 2428 prescription drugs; and the prescription drug satisfies one of
 2429 the following criteria:

2430 (I) The prescription drug is included among the top 150
 2431 prescription drugs for which the state has incurred the highest
 2432 amount of Medicaid claims in the most recently ended state
 2433 fiscal year;



2434 (II) The prescription drug is available for normal
 2435 prescription use in dosages or strengths that have a wholesale
 2436 cost \$200 or more;

2437 (III) The prescription drug is used extensively for
 2438 patients with human immunodeficiency virus, acquired immune
 2439 deficiency syndrome, cancer, or other serious, life threatening
 2440 conditions, where drug nonresponsiveness would not be considered
 2441 to be medically unusual;

2442 (IV) The prescription drug is an injectable drug;

2443 (V) The prescription drug is subject to a special, limited
 2444 distribution process and is not generally sold to wholesale
 2445 distributors by the manufacturer of the prescription drug;

2446 (VI) The department has found not less than five instances
 2447 where statements required pursuant to paragraph (d) for the
 2448 prescription drug were not passed on other than because of
 2449 unintentional oversight, or have been passed on by or to a
 2450 wholesale distributor and such statements were fraudulent; or

2451 (VII) A shipment of a prescription drug has been reported
 2452 to a law enforcement agency as having been stolen or as missing.

2453 b. A prescription drug may be placed on the list of
 2454 specified drugs if the prescription drug satisfies any three of
 2455 the seven criteria set forth in sub-sub-paragraphs (I)-(VII).
 2456 However, a prescription drug may not be included on the list of
 2457 specified drugs if the prescription drug is unlikely to be
 2458 counterfeited or diverted from the legal channels of
 2459 distribution for prescription drugs.

2460 c. Before the department begins the rulemaking process to
 2461 place a drug on the list of specified drugs, except when the



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2462 department files a rule under the procedure specified in sub-
2463 subparagraph e., the Drug Wholesaler Advisory Council created in
2464 s. 499.01211 shall consider whether a prescription drug should
2465 be included on or added to the list of specified drugs using the
2466 criteria enumerated in sub-subparagraph a. or sub-subparagraph
2467 b. and provide a written recommendation adopted by majority vote
2468 to the secretary of the department concerning each such drug.
2469 This paragraph does not apply to any list of prescription drugs
2470 on which the department has begun rulemaking prior to this
2471 paragraph becoming law.

2472 d. When a prescription drug is added to the list of
2473 specified drugs, the requirements of this paragraph shall be
2474 effective as to the prescription drug beginning 60 days after
2475 the effective date of the rule adding the prescription drug to
2476 the list, except when the department files a rule under the
2477 procedure specified in sub-subparagraph e.

2478 e.(I) Notwithstanding chapter 120, if the Attorney General
2479 or Statewide Prosecutor certifies to the secretary of the
2480 department that a prescription drug should be added to the list
2481 of specified drugs by emergency rule, the department may proceed
2482 to add such drug to the list of specified drugs and the
2483 emergency rule shall be effective for a period of one year from
2484 the date on which the emergency rule is filed, if the department
2485 begins the rulemaking process to adopt a permanent rule to place
2486 the drug on the list of specified drugs not later than 90 days
2487 after the date on which the emergency rule was filed. An
2488 emergency rule adding a drug to the list of specified drugs may
2489 not be renewed.



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2490 (II) A prescription drug may be placed on the list of
2491 specified drugs through the procedure provided in this sub-
2492 subparagraph when:

2493 (A) The prescription drug satisfies any two of the
2494 criteria specified in sub-subparagraph a. or sub-subparagraph
2495 b.; or

2496 (B) The prescription drug satisfies any one of the
2497 criteria specified in sub-subparagraph a. or sub-subparagraph b.
2498 if the prescription drug has not yet become available for
2499 wholesale distribution or has been available for wholesale
2500 distribution for not more than 60 days.

2501 (III) Notwithstanding chapter 120, any emergency rule that
2502 places a prescription drug on the list of specified drugs may be
2503 challenged as being an invalid exercise of the delegated
2504 legislative authority only if the department lacks any
2505 substantial competent evidence that the prescription drug
2506 satisfied the criteria required pursuant to sub-sub-subparagraph
2507 (I) or sub-sub-subparagraph (II). Not later than 7 days after
2508 any request by any person, the department shall provide such
2509 person with the substantial competent evidence that justifies
2510 the department's adoption of an emergency rule placing a
2511 prescription drug on the list of specified drugs.

2512 (IV) The department shall notify all prescription drug
2513 wholesalers and out-of-state-prescription drug wholesalers by
2514 electronic means, facsimile, or United States mail and on the
2515 bureau's website when any emergency rule is adopted which places
2516 a prescription drug on the list of specified drugs. Not later
2517 than 7 days after the department adopts an emergency rule



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2518 placing a prescription drug on the list of specified drugs,
2519 wholesalers shall provide the department with the lot numbers
2520 and quantities of such prescription drug which the wholesaler
2521 owns or has in transit on the date that the department adopted
2522 the emergency rule placing the prescription drug on the list of
2523 specified drugs.

2524 (V) The requirements of subparagraph 1. do not apply to
2525 those lot numbers and quantities of a prescription drug which
2526 are included on a report filed pursuant to sub-sub-subparagraph
2527 (IV), and paragraph (6)(d) shall apply to those lot numbers and
2528 quantities of the prescription drug. In addition to the
2529 requirements of paragraph (6)(d), any wholesale distributor
2530 selling a prescription drug included on a report filed pursuant
2531 to sub-sub-subparagraph (IV) shall provide any wholesaler
2532 purchasing the prescription drugs with a statement under oath
2533 that the prescription drugs are among those included on a report
2534 filed pursuant to sub-sub-subparagraph (IV) and with a copy of
2535 the report filed by the wholesale distributor with the
2536 department for those prescription drugs.

2537 f. Not less than annually, the council and department
2538 shall evaluate whether each prescription drug included on the
2539 list of specified drugs should remain on the list. In
2540 determining whether a prescription drug should remain on the
2541 list of specified drugs, the council and department shall
2542 consider:

2543 (I) The availability of generic forms of the drug.

2544 (II) Changes in the price of the drug since the
2545 prescription drug was placed on the list.



2546 (III) The current status of the drug that caused the
 2547 department to place the prescription drug on the list of
 2548 specified drugs.

2549
 2550 The council shall provide a written recommendation adopted by
 2551 majority vote to the secretary of the department concerning each
 2552 drug that the council recommends be removed from the list of
 2553 specified drugs.

2554 4. This paragraph does not apply to a manufacturer;
 2555 however, a repackager must comply with this paragraph.

2556 5. This paragraph expires July 1, 2006.

2557 (f)1. Effective July 1, 2006, each person who is engaged
 2558 in the wholesale distribution of a prescription drug and who is
 2559 not the manufacturer of that drug must, before each wholesale
 2560 distribution of such drug, provide to the person who receives
 2561 the drug a pedigree paper as defined in s. 499.003(31).

2562 2. A repackager must comply with this paragraph.

2563 3. The department may by rule exempt compressed medical
 2564 gases and veterinary prescription drugs from the pedigree paper
 2565 requirements in this paragraph.

2566 4. Each wholesale distributor of prescription drugs must
 2567 maintain separate and distinct from other required records all
 2568 statements that are required under subparagraph 1.

2569 5. In order to verify compliance with subparagraph (d)1.,
 2570 each manufacturer of a prescription drug sold in this state must
 2571 make available upon request distribution documentation related
 2572 to its sales of prescription drugs, regardless of whether the



2573 prescription drug was sold directly by the manufacturer to a
 2574 person in Florida.

2575 (g) Each wholesale distributor, except for a manufacturer,
 2576 shall annually provide the department with a written list of all
 2577 wholesale distributors and manufacturers from whom the wholesale
 2578 distributor purchases prescription drugs. A wholesale
 2579 distributor, except a manufacturer, shall notify the department
 2580 not later than 10 days after any change to either list. Such
 2581 portions of the information required pursuant to this paragraph
 2582 which are a trade secret, as defined in s. 812.081, shall be
 2583 maintained by the department as trade secret information is
 2584 required to be maintained under s. 499.051.

2585 (7) WRITTEN POLICIES AND PROCEDURES.--Wholesale drug
 2586 distributors must establish, maintain, and adhere to written
 2587 policies and procedures, which must be followed for the receipt,
 2588 security, storage, inventory, and distribution of prescription
 2589 drugs, including policies and procedures for identifying,
 2590 recording, and reporting losses or thefts, and for correcting
 2591 all errors and inaccuracies in inventories. Wholesale drug
 2592 distributors must include in their written policies and
 2593 procedures:

2594 (a) A procedure whereby the oldest approved stock of a
 2595 prescription drug product is distributed first. The procedure
 2596 may permit deviation from this requirement, if the deviation is
 2597 temporary and appropriate.

2598 (b) A procedure to be followed for handling recalls and
 2599 withdrawals of prescription drugs. Such procedure must be
 2600 adequate to deal with recalls and withdrawals due to:



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2601 1. Any action initiated at the request of the Food and
2602 Drug Administration or any other federal, state, or local law
2603 enforcement or other government agency, including the
2604 department.

2605 2. Any voluntary action by the manufacturer or repackager
2606 to remove defective or potentially defective drugs from the
2607 market; or

2608 3. Any action undertaken to promote public health and
2609 safety by replacing existing merchandise with an improved
2610 product or new package design.

2611 (c) A procedure to ensure that wholesale drug distributors
2612 prepare for, protect against, and handle any crisis that affects
2613 security or operation of any facility if a strike, fire, flood,
2614 or other natural disaster, or a local, state, or national
2615 emergency, occurs.

2616 (d) A procedure to ensure that any outdated prescription
2617 drugs are segregated from other drugs and either returned to the
2618 manufacturer or repackager or destroyed. This procedure must
2619 provide for written documentation of the disposition of outdated
2620 prescription drugs. This documentation must be maintained for 2
2621 years after disposition of the outdated drugs.

2622 (8) RESPONSIBLE PERSONS.--Wholesale drug distributors must
2623 establish and maintain lists of officers, directors, managers,
2624 designated representatives, and other persons in charge of
2625 wholesale drug distribution, storage, and handling, including a
2626 description of their duties and a summary of their
2627 qualifications.



2628 (11) SHIPPING AND TRANSPORTATION.--The person responsible
 2629 for shipment and transportation of a prescription drug in a
 2630 wholesale distribution may use a common carrier; its own vehicle
 2631 or employee acting within the scope of employment if authorized
 2632 under s. 499.03 for the possession of prescription drugs in this
 2633 state; or, in the case of a prescription drug intended for
 2634 domestic distribution, an independent contractor who must be the
 2635 agent of the authorized seller or recipient responsible for
 2636 shipping and transportation as set forth in a written contract
 2637 between the parties. A person selling a prescription drug for
 2638 export must obtain documentation, such as a validated airway
 2639 bill, bill of lading, or other appropriate documentation that
 2640 the prescription drug was exported. A person responsible for
 2641 shipping or transporting prescription drugs is not required to
 2642 maintain documentation from a common carrier that the designated
 2643 recipient received the prescription drugs; however, the person
 2644 must obtain such documentation from the common carrier and make
 2645 it available to the department upon request of the department.

2646 Section 16. Effective January 1, 2004, subsection (12) is
 2647 added to section 499.0121, Florida Statutes, to read:

2648 499.0121 Storage and handling of prescription drugs;
 2649 recordkeeping.--The department shall adopt rules to implement
 2650 this section as necessary to protect the public health, safety,
 2651 and welfare. Such rules shall include, but not be limited to,
 2652 requirements for the storage and handling of prescription drugs
 2653 and for the establishment and maintenance of prescription drug
 2654 distribution records.



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2655 (12) DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing any
2656 prescription drugs from another wholesale drug distributor, a
2657 wholesale drug distributor must:

2658 (a) Enter an agreement with the selling wholesale drug
2659 distributor by which the selling wholesale drug distributor will
2660 indemnify the purchasing wholesale drug distributor for any loss
2661 caused to the purchasing wholesale drug distributor related to
2662 the purchase of drugs from the selling wholesale drug
2663 distributor which are determined to be counterfeit or to have
2664 been distributed in violation of any federal or state law
2665 governing the distribution of drugs.

2666 (b) Determine that the selling wholesale drug distributor
2667 has insurance coverage of not less than the greater of 1 percent
2668 of the amount of total dollar volume of the prescription drug
2669 sales reported to the department pursuant to s. 499.012(3)(g) or
2670 \$500,000; however the coverage need not exceed \$2 million.

2671 (c) Obtain information from the selling wholesale drug
2672 distributor, including the length of time the selling wholesale
2673 drug distributor has been licensed in this state, a copy of the
2674 selling wholesale drug distributor's licenses or permits, and
2675 background information concerning the ownership of the selling
2676 wholesale drug distributor, including the experience of the
2677 wholesale distributor in the wholesale distribution of
2678 prescription drugs.

2679 (d) Verify that the selling wholesale drug distributor's
2680 Florida permit is valid.

2681 (e) Inspect the selling wholesale drug distributor's
2682 licensed establishment to document that it has a policies and



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2683 procedures manual relating to the distribution of drugs, the
2684 appropriate temperature controlled environment for drugs
2685 requiring temperature control, an alarm system, appropriate
2686 access restrictions, and procedures to ensure that records
2687 related to the wholesale distribution of prescription drugs are
2688 maintained as required by law:

2689 1. Before purchasing any drug from the wholesale drug
2690 distributor, and at least once each subsequent year; or

2691 2. Before purchasing any drug from the wholesale drug
2692 distributor, and each subsequent year obtain a complete copy of
2693 the most recent inspection report for the establishment which
2694 was prepared by the department or the regulatory authority
2695 responsible for wholesale drug distributors in the state in
2696 which the establishment is located.

2697 Section 17. Section 499.01211, Florida Statutes, is
2698 created to read:

2699 499.01211 Drug Wholesaler Advisory Council.--

2700 (1) There is created the Drug Wholesaler Advisory Council
2701 within the department. The council shall meet at least once each
2702 calendar quarter. Staff for the council shall be provided by the
2703 department. The council shall consist of 11 members who shall
2704 serve without compensation. The council shall elect a
2705 chairperson and a vice chairperson annually.

2706 (2) The secretary of the department, or his or her
2707 designee, and the Secretary of Health Care Administration, or
2708 her or his designee, shall be members of the council. The
2709 Secretary of Health shall appoint nine additional members to the



2710 council who shall be appointed to a term of 4 years each, as
 2711 follows:

2712 (a) Three different persons each of whom is employed by a
 2713 different prescription drug wholesaler licensed under this
 2714 chapter which operates nationally and is a primary wholesaler,
 2715 as defined in s. 499.012 (1)(d).

2716 (b) One person employed by a prescription drug wholesaler
 2717 licensed under this chapter which is a secondary wholesaler, as
 2718 defined in s. 499.012(1)(f).

2719 (c) One person employed by a retail pharmacy chain located
 2720 in this state.

2721 (d) One person who is a member of the Board of Pharmacy
 2722 and is a pharmacist licensed under chapter 465.

2723 (e) One person who is a physician licensed pursuant to
 2724 chapter 458 or 459.

2725 (f) One person who is an employee of a hospital licensed
 2726 pursuant to chapter 395 and is a pharmacist licensed pursuant to
 2727 chapter 465.

2728 (g) One person who is an employee of a pharmaceutical
 2729 manufacturer.

2730 (3) The council shall review ss. 499.001-499.081 and the
 2731 rules adopted to administer ss. 499.001-499.081 annually,
 2732 provide input to the department regarding all proposed rules to
 2733 administer ss. 499.001-499.081, make written recommendation to
 2734 the secretary of the department regarding the listing of all
 2735 specified drugs pursuant to s. 499.0121(6)(e), make
 2736 recommendations to the department to improve the protection of
 2737 the prescription drugs and public health, make recommendations



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2738 to improve coordination with other states' regulatory agencies
2739 and the federal government concerning the wholesale distribution
2740 of drugs, and make recommendations to minimize the impact of
2741 regulation of the wholesale distribution industry while ensuring
2742 protection of the public health.

2743 Section 18. Effective January 1, 2004, paragraph (b) of
2744 subsection (2) of section 499.0122, Florida Statutes, is amended
2745 to read:

2746 499.0122 Medical oxygen and veterinary legend drug retail
2747 establishments; definitions, permits, general requirements.--
2748 (2)

2749 (b) The department shall adopt rules relating to
2750 information required from each retail establishment pursuant to
2751 s. 499.01(4) and (5)~~(2)~~, including requirements for
2752 prescriptions or orders.

2753 Section 19. Paragraph (c) of subsection (2) of section
2754 499.0122, Florida Statutes, is amended to read:

2755 499.0122 Medical oxygen and veterinary legend drug retail
2756 establishments; definitions, permits, general requirements.--
2757 (2)

2758 (c) A retail establishment must comply with all of the
2759 wholesale distribution requirements of s. 499.0121 except those
2760 set forth in s. 499.0121(6)(d), (e), and (f).

2761 Section 20. Effective January 1, 2004, section 499.013,
2762 Florida Statutes, is amended to read:

2763 499.013 Manufacturers and repackagers of drugs, devices,
2764 and cosmetics; definitions, permits, and general requirements.--



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2765 (1) As used in this section, the terms ~~term~~ "manufacture"
2766 and "repackage" have ~~has~~ the meaning as in assigned to it under
2767 s. 499.003. A pharmacy is exempt from these definitions ~~this~~
2768 ~~definition~~ if it is operating in compliance with pharmacy
2769 practice standards as defined in chapter 465 and the rules
2770 adopted under that chapter.

2771 (2) Any person that engages in the manufacture or
2772 repackaging of drugs, devices, or cosmetics in this state must
2773 first obtain one of the following permits and may engage only in
2774 the activity allowed under that permit:

2775 (a) A prescription drug manufacturer's permit is required
2776 for any person that manufactures a prescription drug in this
2777 state. A prescription drug repackager's permit is required for
2778 any person that repackages a prescription drug in this state.

2779 1. A person that operates an establishment permitted as a
2780 prescription drug manufacturer or prescription drug repackager
2781 may engage in wholesale distribution of prescription drugs
2782 manufactured or repackaged at that establishment and must comply
2783 with all the provisions of ss. 499.001-499.081 and the rules
2784 adopted under those sections that apply to a wholesale
2785 distributor.

2786 2. A prescription drug manufacturer permittee or
2787 prescription drug repackager must comply with all appropriate
2788 state and federal good manufacturing practices.

2789 (b) An over-the-counter drug manufacturer's permit is
2790 required for any person that engages in the manufacture or
2791 repackaging of an over-the-counter drug.



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2792 | 1. An over-the-counter drug manufacturer permittee may not
2793 | possess or purchase prescription drugs.

2794 | 2. A pharmacy is exempt from obtaining an over-the-counter
2795 | drug manufacturer's permit if it is operating in compliance with
2796 | pharmacy practice standards as defined in chapter 465 and the
2797 | rules adopted under that chapter.

2798 | 3. An over-the-counter drug manufacturer permittee must
2799 | comply with all appropriate state and federal good manufacturing
2800 | practices.

2801 | (c) A compressed medical gas manufacturer's permit is
2802 | required for any person that engages in the manufacture of
2803 | compressed medical gases or repackages compressed medical gases
2804 | from one container to another.

2805 | 1. A compressed medical gas manufacturer permittee may not
2806 | manufacture or possess any prescription drug other than
2807 | compressed medical gases.

2808 | 2. A compressed medical gas manufacturer permittee may
2809 | engage in wholesale distribution of compressed medical gases
2810 | manufactured at that establishment and must comply with all the
2811 | provisions of ss. 499.001-499.081 and the rules adopted under
2812 | those sections that apply to a wholesale distributor.

2813 | 3. A compressed medical gas manufacturer permittee must
2814 | comply with all appropriate state and federal good manufacturing
2815 | practices.

2816 | (d) A device manufacturer's permit is required for any
2817 | person that engages in the manufacture, repackaging, or assembly
2818 | of medical devices for human use in this state, except that a
2819 | permit is not required if the person is engaged only in



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2820 manufacturing, repackaging, or assembling a medical device
2821 pursuant to a practitioner's order for a specific patient.

2822 1. A manufacturer or repackager of medical devices in this
2823 state must comply with all appropriate state and federal good
2824 manufacturing practices and quality system rules.

2825 2. The department shall adopt rules related to storage,
2826 handling, and recordkeeping requirements for manufacturers of
2827 medical devices for human use.

2828 (e) A cosmetic manufacturer's permit is required for any
2829 person that manufactures or repackages cosmetics in this state.
2830 A person that only labels or changes the labeling of a cosmetic
2831 but does not open the container sealed by the manufacturer of
2832 the product is exempt from obtaining a permit under this
2833 paragraph.

2834 (3) The department may adopt such rules as are necessary
2835 for the protection of the public health, safety, and welfare
2836 regarding good manufacturing practices that manufacturers and
2837 repackagers must follow to ensure the safety of the products.

2838 (4) Each manufacturer or repackager of medical devices,
2839 over-the-counter drugs, or cosmetics must maintain records that
2840 include the name and principal address of the seller or
2841 transferor of the product, the address of the location from
2842 which the product was shipped, the date of the transaction, the
2843 name and quantity of the product involved, and the name and
2844 principal address of the person who purchased the product.

2845 Section 21. Subsection (3) of section 499.014, Florida
2846 Statutes, is amended to read:



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2847 499.014 Distribution of legend drugs by hospitals, health
2848 care entities, charitable organizations, and return or
2849 destruction companies; permits, general requirements.--

2850 (3) Storage, ~~and~~ handling, and recordkeeping of these
2851 distributions must comply with the requirements for wholesale
2852 distributors under s. 499.0121, except those set forth in s.
2853 499.0121(6)(d), (e), and (f).

2854 Section 22. Paragraph (a) of subsection (1) and subsection
2855 (3) of section 499.015, Florida Statutes, are amended to read:

2856 499.015 Registration of drugs, devices, and cosmetics;
2857 issuance of certificates of free sale.--

2858 (1)(a) Except for those persons exempted from the
2859 definition in s. 499.003(~~28~~)(~~21~~), any person who manufactures,
2860 packages, repackages, labels, or relabels a drug, device, or
2861 cosmetic in this state must register such drug, device, or
2862 cosmetic biennially with the department; pay a fee in accordance
2863 with the fee schedule provided by s. 499.041; and comply with
2864 this section. The registrant must list each separate and
2865 distinct drug, device, or cosmetic at the time of registration.

2866 (3) Except for those persons exempted from the definition
2867 in s. 499.003(~~28~~)(~~21~~), a person may not sell any product that he
2868 or she has failed to register in conformity with this section.
2869 Such failure to register subjects such drug, device, or cosmetic
2870 product to seizure and condemnation as provided in ss. 499.062-
2871 499.064, and subjects such person to the penalties and remedies
2872 provided in ss. 499.001-499.081.

2873 Section 23. Subsection (3) of section 499.024, Florida
2874 Statutes, is amended to read:



2875 499.024 Drug product classification.--The secretary shall
2876 adopt rules to classify drug products intended for use by humans
2877 which the United States Food and Drug Administration has not
2878 classified in the federal act or the Code of Federal
2879 Regulations.

2880 (3) Any product that falls under the drug definition, s.
2881 499.003(17)~~(12)~~, may be classified under the authority of this
2882 section. This section does not subject portable emergency oxygen
2883 inhalators to classification; however, this section does not
2884 exempt any person from ss. 499.01 and 499.015.

2885 Section 24. Subsection (1) of section 499.03, Florida
2886 Statutes, is amended to read:

2887 499.03 Possession of new drugs or legend drugs without
2888 prescriptions unlawful; exemptions and exceptions.--

2889 (1) A person may not possess, or possess with intent to
2890 sell, dispense, or deliver, any habit-forming, toxic, harmful,
2891 or new drug subject to s. 499.003(29)~~(22)~~, or legend drug as
2892 defined in s. 499.003(25)~~(19)~~, unless the possession of the drug
2893 has been obtained by a valid prescription of a practitioner
2894 licensed by law to prescribe the drug. However, this section
2895 does not apply to the delivery of such drugs to persons included
2896 in any of the classes named in this subsection, or to the agents
2897 or employees of such persons, for use in the usual course of
2898 their businesses or practices or in the performance of their
2899 official duties, as the case may be; nor does this section apply
2900 to the possession of such drugs by those persons or their agents
2901 or employees for such use:



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2902 (a) A licensed pharmacist or any person under the licensed
2903 pharmacist's supervision while acting within the scope of the
2904 licensed pharmacist's practice;

2905 (b) A licensed practitioner authorized by law to prescribe
2906 legend drugs or any person under the licensed practitioner's
2907 supervision while acting within the scope of the licensed
2908 practitioner's practice;

2909 (c) A qualified person who uses legend drugs for lawful
2910 research, teaching, or testing, and not for resale;

2911 (d) A licensed hospital or other institution that procures
2912 such drugs for lawful administration or dispensing by
2913 practitioners;

2914 (e) An officer or employee of a federal, state, or local
2915 government; or

2916 (f) A person that holds a valid permit issued by the
2917 department pursuant to ss. 499.001-499.081 which authorizes that
2918 person to possess prescription drugs.

2919 Section 25. Section 499.041, Florida Statutes, is amended
2920 to read:

2921 499.041 Schedule of fees for drug, device, and cosmetic
2922 applications and permits, product registrations, and free-sale
2923 certificates.--

2924 (1) The department shall assess applicants requiring a
2925 manufacturing permit an annual fee within the ranges established
2926 in this section for the specific type of manufacturer.

2927 (a) The fee for a prescription drug manufacturer's permit
2928 may not be less than \$500 or more than \$750 ~~\$600~~ annually.



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2929 (b) The fee for a device manufacturer's permit may not be
2930 less than \$500 or more than \$600 annually.

2931 (c) The fee for a cosmetic manufacturer's permit may not
2932 be less than \$250 or more than \$400 annually.

2933 (d) The fee for an over-the-counter drug manufacturer's
2934 permit may not be less than \$300 or more than \$400 annually.

2935 (e) The fee for a compressed medical gas manufacturer's
2936 permit may not be less than \$400 or more than \$500 annually.

2937 (f) The fee for a prescription drug repackager's permit
2938 may not be less than \$500 or more than \$750 annually.

2939 (g)~~(f)~~ A manufacturer may not be required to pay more than
2940 one fee per establishment to obtain an additional manufacturing
2941 permit, but each manufacturer must pay the highest fee
2942 applicable to his or her operation in each establishment.

2943 (2) The department shall assess an applicant that is
2944 required to have a wholesaling permit an annual fee within the
2945 ranges established in this section for the specific type of
2946 wholesaling.

2947 (a) The fee for a prescription drug wholesaler's permit
2948 may not be less than \$300 or more than \$800 ~~\$400~~ annually.†

2949 (b) The fee for a compressed medical gas wholesaler's
2950 permit may not be less than \$200 or more than \$300 annually.†

2951 (c) The fee for an out-of-state prescription drug
2952 wholesaler's permit may not be less than \$300 ~~\$200~~ or more than
2953 \$800 ~~\$300~~ annually.†

2954 (d) The fee for a nonresident prescription drug
2955 manufacturer's permit may not be less than \$300 or more than
2956 \$500 annually.



2957 (e)~~(d)~~ The fee for a retail pharmacy wholesaler's permit
 2958 may not be less than \$35 or more than \$50 annually.

2959 (f) The fee for a freight forwarder's permit may not be
 2960 less than \$200 or more than \$300 annually.

2961 (3) The department shall assess an applicant that is
 2962 required to have a retail establishment permit an annual fee
 2963 within the ranges established in this section for the specific
 2964 type of retail establishment.

2965 (a) The fee for a veterinary legend drug retail
 2966 establishment permit may not be less than \$200 or more than \$300
 2967 annually.†

2968 (b) The fee for a medical oxygen retail establishment
 2969 permit may not be less than \$200 or more than \$300 annually.

2970 (4) The department shall assess an applicant that is
 2971 required to have a restricted prescription drug distributor's
 2972 permit an annual fee of not less than \$200 or more than \$300.

2973 (5) In addition to the fee charged for a permit required
 2974 by ss. 499.001-499.081, ~~beginning January 1, 1993,~~ the
 2975 department shall assess applicants an initial application fee of
 2976 \$150 for each new permit issued by the department which requires
 2977 an onsite inspection.

2978 (6) A person that is required to register drugs, devices,
 2979 or cosmetic products under s. 499.015 shall pay an annual
 2980 product registration fee of not less than \$5 or more than \$15
 2981 for each separate and distinct product in package form. The
 2982 registration fee is in addition to the fee charged for a free-
 2983 sale certificate.



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2984 (7) The department shall assess an applicant that requests
2985 a free-sale certificate a fee of \$25. A fee of \$2 will be
2986 charged for each signature copy of a free-sale certificate that
2987 is obtained at the same time the free-sale certificate is
2988 issued.

2989 (8) The department shall assess an out-of-state
2990 prescription drug wholesaler applicant or permittee an on-site
2991 inspection fee of not less than \$1,000 or more than \$3,000
2992 annually, to be based on the actual cost of the inspection if an
2993 on-site inspection is performed by agents of the department.

2994 (9) The department shall assess each person applying for
2995 certification as a designated representative a fee of \$150, plus
2996 the cost of processing the criminal history record check.

2997 (10)~~(8)~~ The department shall assess other fees as provided
2998 in ss. 499.001-499.081.

2999 Section 26. Paragraph (g) of subsection (1) of section
3000 499.05, Florida Statutes, is amended to read:

3001 499.05 Rules.--

3002 (1) The department shall adopt rules to implement and
3003 enforce ss. 499.001-499.081 with respect to:

3004 (g) Inspections and investigations conducted under s.
3005 499.051, and the identification of information claimed to be a
3006 trade secret and exempt from the public records law as provided
3007 in s. 499.051~~(7)~~~~(5)~~.

3008 Section 27. Subsection (2) and present subsection (5) of
3009 section 499.051, Florida Statutes, are amended, present
3010 subsections (4) and (5) of said section are redesignated as



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3011 subsections (6) and (7), respectively, and new subsections (4)
3012 and (5) are added to said section, to read:

3013 499.051 Inspections and investigations.--

3014 (2) In addition to the authority set forth in subsection
3015 (1), the department and any duly designated officer or employee
3016 of the department may enter and inspect any other establishment
3017 for the purpose of determining compliance with ss. 499.001-
3018 499.081 and rules adopted under those sections regarding any
3019 drug, device, or cosmetic product. ~~The authority to enter and~~
3020 ~~inspect does not extend to the practice of the profession of~~
3021 ~~pharmacy, as defined in chapter 465 and the rules adopted under~~
3022 ~~that chapter, in a pharmacy permitted under chapter 465. The~~
3023 ~~Department of Business and Professional Regulation shall conduct~~
3024 ~~routine inspections of retail pharmacy wholesalers at the time~~
3025 ~~of the regular pharmacy permit inspection and shall send the~~
3026 ~~inspection report regarding drug wholesale activity to the~~
3027 ~~Department of Health.~~

3028 (4) Any application for a permit made pursuant to ss.
3029 499.01 and 499.012 and rules adopted under those sections
3030 constitutes permission for agents of the Department of Health
3031 and the Department of Law Enforcement, after presenting proper
3032 identification, to inspect, review, and copy any financial
3033 document or record related to the manufacture, repackaging, or
3034 distribution of a drug as is necessary to verify compliance with
3035 ss. 499.001-499.081 and the rules adopted by the department to
3036 administer those sections, in order to discover, investigate,
3037 and determine the existence of compliance or to elicit, receive,
3038 respond to, and resolve complaints and violations.



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3039 (5) The authority to inspect under this section includes
3040 the authority to access, review, and copy any and all financial
3041 documents related to the activity of manufacturing, repackaging,
3042 or distributing prescription drugs.

3043 (7)~~(5)~~ The complaint and all information obtained pursuant
3044 to the investigation by the department are confidential and
3045 exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I
3046 of the State Constitution until the investigation and the
3047 enforcement action are completed. However, trade secret
3048 information contained therein as defined by s. 812.081(1)(c)
3049 shall remain confidential and exempt from the provisions of s.
3050 119.07(1) and s. 24(a), Art. I of the State Constitution, as
3051 long as the information is retained by the department. This
3052 subsection does not prohibit the department from using such
3053 information for regulatory or enforcement proceedings under this
3054 chapter or from providing such information to any law
3055 enforcement agency or any other regulatory agency. However, the
3056 receiving agency shall keep such records confidential and exempt
3057 as provided in this subsection. In addition, this subsection is
3058 not intended to prevent compliance with the provisions of s.
3059 499.0121(6)(d), (e), and (f), and the pedigree papers required
3060 in those paragraphs ~~that subsection~~ shall not be deemed a trade
3061 secret.

3062 Section 28. Subsection (4) is added to section 499.055,
3063 Florida Statutes, to read:

3064 499.055 Reports and dissemination of information by
3065 department.--



3066 (4) The department shall publish on the department's
 3067 website and update at least monthly:

3068 (a) A list of the prescription drug wholesalers, out-of-
 3069 state prescription drug wholesalers, and retail pharmacy drug
 3070 wholesalers against whom the department has initiated
 3071 enforcement action pursuant to 499.001-499.081 to suspend or
 3072 revoke a permit, seek an injunction, or otherwise file an
 3073 administrative complaint and the permit number of each such
 3074 wholesaler.

3075 (b) A list of the prescription drug wholesalers, out-of-
 3076 state prescription drug wholesalers, and retail pharmacy drug
 3077 wholesalers to which the department has issued a permit,
 3078 including the date on which each permit will expire.

3079 (c) A list of the prescription drug wholesalers, out-of-
 3080 state prescription drug wholesalers, and retail pharmacy drug
 3081 wholesalers' permits that have been returned to the department,
 3082 were suspended, were revoked, have expired, or were not renewed
 3083 in the previous year.

3084 Section 29. Section 499.065, Florida Statutes, is created
 3085 to read:

3086 499.065 Imminent danger.--

3087 (1) Notwithstanding s. 499.051, the department shall
 3088 inspect each prescription drug wholesale establishment,
 3089 prescription drug repackager establishment, and retail pharmacy
 3090 drug wholesaler establishment that is required to be permitted
 3091 under this chapter as often as necessary to ensure compliance
 3092 with applicable laws and rules. The department shall have the



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3093 right of entry and access to these facilities at any reasonable
3094 time.

3095 (2) To protect the public from prescription drugs that are
3096 adulterated or otherwise unfit for human consumption, the
3097 department may examine, sample, seize, and stop the sale or use
3098 of prescription drugs to determine the condition of those drugs.
3099 The department may immediately seize and remove any prescription
3100 drugs if the Secretary of Health or his or her designee
3101 determines that such prescription drugs represent a threat to
3102 the public health. The owner of any property seized under this
3103 section may, within 10 days after the seizure, apply to a court
3104 of competent jurisdiction for whatever relief is appropriate. At
3105 any time after 10 days, the department may destroy the drugs as
3106 contraband.

3107 (3) The department may determine that a prescription drug
3108 wholesale establishment, prescription drug repackager
3109 establishment, or retail pharmacy drug wholesaler establishment
3110 that is required to be permitted under this chapter is an
3111 imminent danger to the public health and require its immediate
3112 closure if such establishment fails to comply with applicable
3113 laws and rules and, because of such failure, presents an
3114 imminent threat to the public's health, safety, or welfare. Any
3115 establishment so deemed and closed shall remain closed until
3116 allowed by the department or by judicial order to reopen.

3117
3118 For purposes of this section, a refusal to allow entry to the
3119 department for inspection at reasonable times or a failure or
3120 refusal to provide the department with required documentation



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3121 for purposes of inspection constitutes an imminent danger to the
 3122 public health.

3123 Section 30. Subsection (1) of section 499.066, Florida
 3124 Statutes, is amended, and subsection (7) is added to said
 3125 section, to read:

3126 499.066 Penalties; remedies.--In addition to other
 3127 penalties and other enforcement provisions:

3128 (1) The department may institute such suits or other legal
 3129 proceedings as are required to enforce any provision of ss.
 3130 499.001-499.081. If it appears that a person has violated any
 3131 provision of ss. 499.001-499.081 for which criminal prosecution
 3132 is provided, the department may provide the appropriate state
 3133 attorney or other prosecuting agency having jurisdiction with
 3134 respect to such prosecution with the relevant information in the
 3135 department's possession. ~~When the department believes that any~~
 3136 ~~person has violated ss. 499.001-499.081 or any rules adopted~~
 3137 ~~pursuant to those sections, it may issue and deliver an order to~~
 3138 ~~cease and desist from such violation.~~

3139 (7) Resignation or termination of an affiliated party does
 3140 not affect the department's jurisdiction or discretion to
 3141 proceed with action to suspend or revoke a permit or to impose
 3142 other penalties or enforcement actions authorized by law.

3143 Section 31. Section 499.0661, Florida Statutes, is created
 3144 to read:

3145 499.0661 Cease and desist orders; removal of certain
 3146 persons.--



3147 (1) DEFINITION.--As used in this section, the term
 3148 "permittee" means any person holding a permit issued pursuant to
 3149 s. 499.012.

3150 (2) CEASE AND DESIST ORDERS.--

3151 (a) In addition to any authority otherwise provided in
 3152 this chapter, the department may issue and serve a complaint
 3153 stating charges upon any permittee or upon any affiliated party,
 3154 whenever the department has reasonable cause to believe that the
 3155 person or individual named therein is engaging in or has engaged
 3156 in conduct that is:

3157 1. An act that demonstrates a lack of fitness or
 3158 trustworthiness to engage in the business authorized under the
 3159 permit issued pursuant to ss. 499.001-499.081, is hazardous to
 3160 the public health, or constitutes business operations that are a
 3161 detriment to the public health;

3162 2. A violation of any provision of ss. 499.001-499.081;

3163 3. A violation of any rule of the department;

3164 4. A violation of any order of the department; or

3165 5. A breach of any written agreement with the department.

3166 (b) The complaint must contain a statement of facts and
 3167 notice of opportunity for a hearing pursuant to ss. 120.569 and
 3168 120.57.

3169 (c) If a hearing is not requested within the time allowed
 3170 by ss. 120.569 and 120.57, or if a hearing is held and the
 3171 department finds that any of the charges are proven, the
 3172 department may enter an order directing the permittee or the
 3173 affiliated party named in the complaint to cease and desist from
 3174 engaging in the conduct complained of and take corrective action



3175 to remedy the effects of past improper conduct and ensure future
 3176 compliance.

3177 (d) A contested or default cease and desist order is
 3178 effective when reduced to writing and served upon the permittee
 3179 or affiliated party named therein. An uncontested cease and
 3180 desist order is effective as agreed.

3181 (e) Whenever the department finds that conduct described
 3182 in paragraph (a) is likely to cause an immediate threat to the
 3183 public health, it may issue an emergency cease and desist order
 3184 requiring the permittee or any affiliated party to immediately
 3185 cease and desist from engaging in the conduct complained of and
 3186 to take corrective and remedial action. The emergency order is
 3187 effective immediately upon service of a copy of the order upon
 3188 the permittee or affiliated party named therein and remains
 3189 effective for 90 days. If the department begins nonemergency
 3190 cease and desist proceedings under this subsection, the
 3191 emergency order remains effective until the conclusion of the
 3192 proceedings under ss. 120.569 and 120.57.

3193 (3) REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.--

3194 (a) The department may issue and serve a complaint stating
 3195 charges upon any affiliated party and upon the permittee
 3196 involved whenever the department has reason to believe that an
 3197 affiliated party is engaging in or has engaged in conduct that
 3198 constitutes:

- 3199 1. An act that demonstrates a lack of fitness or
- 3200 trustworthiness to engage in the business authorized under the
- 3201 permit issued pursuant to ss. 499.001-499.081, is hazardous to



3202 the public health, or constitutes business operations that are a
 3203 detriment to the public health;

3204 2. A willful violation of ss. 499.001-499.081; however, if
 3205 the violation constitutes a misdemeanor, a complaint may not be
 3206 served as provided in this section until the affiliated party is
 3207 notified in writing of the matter of the violation and has been
 3208 afforded a reasonable period of time, as set forth in the
 3209 notice, to correct the violation and has failed to do so;

3210 3. A violation of any other law involving fraud or moral
 3211 turpitude which constitutes a felony;

3212 4. A willful violation of any rule of the department;

3213 5. A willful violation of any order of the department; or

3214 6. A material misrepresentation of fact, made knowingly
 3215 and willfully or made with reckless disregard for the truth of
 3216 the matter.

3217 (b) The complaint must contain a statement of facts and
 3218 notice of opportunity for a hearing pursuant to ss. 120.569 and
 3219 120.57.

3220 (c) If a hearing is not requested within the time allotted
 3221 by ss. 120.569 and 120.57, or if a hearing is held and the
 3222 department finds that any of the charges in the complaint are
 3223 proven true, the department may enter an order removing the
 3224 affiliated party or restricting or prohibiting participation by
 3225 the person in the affairs of that permittee or of any other
 3226 permittee.

3227 (d) A contested or default order of removal, restriction,
 3228 or prohibition is effective when reduced to writing and served



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3229 on the permittee and the affiliated party. An uncontested order
3230 of removal, restriction, or prohibition is effective as agreed.

3231 (e)1. The chief executive officer, designated
3232 representative, or the person holding the equivalent office, of
3233 a permittee shall promptly notify the department if she or he
3234 has actual knowledge that any affiliated party is charged with a
3235 felony in a state or federal court.

3236 2. Whenever any affiliated party is charged with a felony
3237 in a state or federal court or with the equivalent of a felony
3238 in the courts of any foreign country with which the United
3239 States maintains diplomatic relations, and the charge alleges
3240 violation of any law involving prescription drugs,
3241 pharmaceuticals, fraud, theft, or moral turpitude, the
3242 department may enter an emergency order suspending the
3243 affiliated party or restricting or prohibiting participation by
3244 the affiliated party in the affairs of the particular permittee
3245 or of any other permittee upon service of the order upon the
3246 permittee and the affiliated party charged. The order must
3247 contain notice of opportunity for a hearing pursuant to ss.
3248 120.569 and 120.57, where the affiliated party may request a
3249 postsuspension hearing to show that continued service to or
3250 participation in the affairs of the permittee does not pose a
3251 threat to the public health or the interests of the permittee
3252 and does not threaten to impair public confidence in the
3253 permittee. In accordance with applicable departmental rules, the
3254 department shall notify the affiliated party whether the order
3255 suspending or prohibiting the person from participation in the
3256 affairs of a permittee will be rescinded or otherwise modified.



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3257 The emergency order remains in effect, unless otherwise modified
3258 by the department, until the criminal charge is disposed of. The
3259 acquittal of the person charged, or the final, unappealed
3260 dismissal of all charges against the person, dissolves the
3261 emergency order, but does not prohibit the department from
3262 instituting proceedings under paragraph (a). If the person
3263 charged is convicted or pleads guilty or nolo contendere,
3264 whether or not an adjudication of guilt is entered by the court,
3265 the emergency order shall become final.

3266 (f) Any affiliated party removed pursuant to this section
3267 is not eligible for reemployment by the permittee or to be an
3268 affiliated party of any permittee except upon the written
3269 consent of the department. Any affiliated party who is removed,
3270 restricted, or prohibited from participating in the affairs of a
3271 permittee pursuant to this section may petition the department
3272 for modification or termination of the removal, restriction, or
3273 prohibition.

3274 Section 32. Effective January 1, 2004, subsection (1) of
3275 section 499.067, Florida Statutes, is amended, and subsections
3276 (6) and (7) are added to said section, to read:

3277 499.067 Denial, suspension, or revocation of permit,
3278 certification, or registration.--

3279 (1)(a) The department may deny, suspend, or revoke a
3280 permit if it finds that there has been a substantial failure to
3281 comply with ss. 499.001-499.081 or chapter 465, chapter 501, or
3282 chapter 893, the rules adopted under any of those sections or
3283 chapters, any final order of the department, or applicable



3284 federal laws or regulations or other state laws or rules
3285 governing drugs, devices, or cosmetics.

3286 (b) The department may deny an application for a permit or
3287 certification, or suspend or revoke a permit or certification,
3288 if the department finds it is shown that:

3289 1. The applicant is not of good moral character or that it
3290 would be a danger or not in the best interest of the public
3291 health, safety, and welfare if the applicant were issued a
3292 permit or certification.

3293 2. The applicant has not met the requirements for the
3294 permit or certification.

3295 3. The applicant is not eligible for a permit or
3296 certification for any of the reasons enumerated in s. 499.01 or
3297 s. 499.012(5).

3298 4. The applicant, permittee, or person certified under s.
3299 499.012(11) demonstrates any of the conditions enumerated in s.
3300 499.01 or s. 499.012(5).

3301 5. The applicant, permittee, or person certified under s.
3302 499.012(11) has committed any violation of ss. 499.005-
3303 499.00525.

3304 (6) The department shall deny, suspend, or revoke the
3305 permit of any person or establishment if the assignment, sale,
3306 transfer, or lease of an establishment permitted under ss.
3307 499.001-499.081 will avoid an administrative penalty, civil
3308 action, or criminal prosecution.

3309 (7) Notwithstanding s. 120.60(5), if a permittee fails to
3310 comply with s. 499.01(7), the department may revoke the permit
3311 of the permittee and shall provide notice of the intended agency



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3312 action by posting a notice at the department's headquarters and
 3313 by mailing a copy of the notice of intended agency action by
 3314 certified mail to the most recent mailing address on record with
 3315 the department and, if the permittee is not a natural person, to
 3316 the permittee's registered agent on file with the Department of
 3317 State.

3318 Section 33. Section 499.069, Florida Statutes, is amended
 3319 to read:

3320 499.069 Criminal punishment for violations of s. 499.005
 3321 related to devices and cosmetics; dissemination of false
 3322 advertisement.--

3323 (1) Any person who violates any of the provisions of s.
 3324 499.005 with respect to a device or cosmetic commits ~~is guilty~~
 3325 ~~of~~ a misdemeanor of the second degree, punishable as provided in
 3326 s. 775.082 or s. 775.083; but, if the violation is committed
 3327 after a conviction of such person under this section has become
 3328 final, such person is guilty of a misdemeanor of the first
 3329 degree, punishable as provided in s. 775.082 or s. 775.083 or as
 3330 otherwise provided in ss. 499.001-499.081, except that any
 3331 person who violates subsection (8) ~~or~~ subsection (10)~~,~~
 3332 ~~subsection (14), subsection (15), or subsection (17)~~ of s.
 3333 499.005 with respect to a device or cosmetic commits ~~is guilty~~
 3334 ~~of~~ a felony of the third degree, punishable as provided in s.
 3335 775.082, s. 775.083, or s. 775.084, or as otherwise provided in
 3336 ss. 499.001-499.081.

3337 ~~(2) A person is not subject to the penalties of subsection~~
 3338 ~~(1) for having violated any of the provisions of s. 499.005 if~~
 3339 ~~he or she establishes a guaranty or undertaking, which guaranty~~



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3340 ~~or undertaking is signed by and contains the name and address of~~
 3341 ~~the person residing in the state, or the manufacturer, from whom~~
 3342 ~~he or she received the article in good faith, to the effect that~~
 3343 ~~such article is not adulterated or misbranded within the meaning~~
 3344 ~~of ss. 499.001-499.081, citing such sections.~~

3345 (2)(3) A publisher, radio broadcast licensee, or agency or
 3346 medium for the dissemination of an advertisement, except the
 3347 manufacturer, wholesaler, or seller of the article to which a
 3348 false advertisement relates, is not liable under this section by
 3349 reason of the dissemination by him or her of such false
 3350 advertisement, unless he or she has refused, on the request of
 3351 the department, to furnish to the department the name and post
 3352 office address of the manufacturer, wholesaler, seller, or
 3353 advertising agency that asked him or her to disseminate such
 3354 advertisement.

3355 Section 34. Section 499.0691, Florida Statutes, is created
 3356 to read:

3357 499.0691 Criminal punishment for violations related to
 3358 drugs; dissemination of false advertisement.--

3359 (1) Any person who violates any of the following
 3360 provisions commits a misdemeanor of the second degree,
 3361 punishable as provided in s. 775.082 or s. 775.083; but, if the
 3362 violation is committed after a conviction of such person under
 3363 this section has become final, such person commits a misdemeanor
 3364 of the first degree, punishable as provided in s. 775.082 or s.
 3365 775.083, or as otherwise provided in ss. 499.001-499.081:

3366 (a) The manufacture, repackaging, sale, delivery, or
 3367 holding or offering for sale of any drug that is adulterated or



3368 misbranded or has otherwise been rendered unfit for human or
 3369 animal use.

3370 (b) The adulteration or misbranding of any drug intended
 3371 for further distribution.

3372 (c) The receipt of any drug that is adulterated or
 3373 misbranded, and the delivery or proffered delivery of such drug,
 3374 for pay or otherwise.

3375 (d) The dissemination of any false or misleading
 3376 advertisement of a drug.

3377 (e) The use, on the labeling of any drug or in any
 3378 advertisement relating to such drug, of any representation or
 3379 suggestion that an application of the drug is effective when it
 3380 is not or that the drug complies with ss. 499.001-499.081 when
 3381 it does not.

3382 (f) The purchase or receipt of a compressed medical gas
 3383 from a person that is not authorized under this chapter to
 3384 distribute compressed medical gases.

3385 (g) Charging a dispensing fee for dispensing,
 3386 administering, or distributing a prescription drug sample.

3387 (h) The failure to maintain records related to a drug as
 3388 required by ss. 499.001-499.081 and rules adopted under those
 3389 sections, except for pedigree papers, invoices, or shipping
 3390 documents related to legend drugs.

3391 (i) The possession of any drug in violation of ss.
 3392 499.001-499.081, except if the violation relates to a deficiency
 3393 in pedigree papers.

3394 (2) Any person who violates any of the following
 3395 provisions commits a felony of the third degree, punishable as



3396 provided in s. 775.082, s. 775.083, or s. 775.084, or as
 3397 otherwise provided in ss. 499.001-499.081:
 3398 (a) The refusal or constructive refusal to allow:
 3399 1. The department to enter or inspect an establishment in
 3400 which drugs are manufactured, processed, repackaged, sold,
 3401 brokered, or held;
 3402 2. Inspection of any record of that establishment;
 3403 3. The department to enter and inspect any vehicle that is
 3404 being used to transport drugs; or
 3405 4. The department to take samples of any drug.
 3406 (b) The sale, purchase, or trade, or the offer to sell,
 3407 purchase, or trade, a drug sample as defined in s. 499.028; the
 3408 distribution of a drug sample in violation of s. 499.028; or the
 3409 failure to otherwise comply with s. 499.028.
 3410 (c) Providing the department with false or fraudulent
 3411 records, or making false or fraudulent statements, regarding any
 3412 matter within the provisions of this chapter related to a drug.
 3413 (d) The failure to receive, maintain, or provide invoices
 3414 and shipping documents, other than pedigree papers, if
 3415 applicable, related to the distribution of a legend drug.
 3416 (e) The importation of a legend drug for wholesale
 3417 distribution, except as provided by s. 801(d) of the Federal
 3418 Food, Drug, and Cosmetic Act.
 3419 (f) The wholesale distribution of any prescription drug
 3420 that was:
 3421 1. Purchased by a public or private hospital or other
 3422 health care entity; or



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3423 2. Donated or supplied at a reduced price to a charitable
3424 organization.

3425 (g) The failure to obtain a permit as a prescription drug
3426 wholesaler when a permit is required by ss. 499.001-499.081 for
3427 that activity.

3428 (h) Knowingly possessing any adulterated or misbranded
3429 legend drug outside of a designated quarantine area.

3430 (i) The purchase or sale of prescription drugs for
3431 wholesale distribution in exchange for currency, as defined in
3432 s. 560.103(6).

3433 (3) Any person who violates any of the following
3434 provisions commits a felony of the second degree, punishable as
3435 provided in s. 775.082, s. 775.083, or s. 775.084, or as
3436 otherwise provided in ss. 499.001-499.081:

3437 (a) Knowingly manufacturing, repackaging, selling,
3438 delivering, or holding or offering for sale any drug that is
3439 adulterated or misbranded or has otherwise been rendered unfit
3440 for human or animal use.

3441 (b) Knowingly adulterating a drug that is intended for
3442 further distribution.

3443 (c) Knowingly receiving a drug that is adulterated and
3444 delivering or proffering delivery of such drug for pay or
3445 otherwise.

3446 (d) Committing any act that causes a drug to be a
3447 counterfeit drug, or selling, dispensing, or knowingly holding
3448 for sale a counterfeit drug.

3449 (e) Forging, counterfeiting, simulating, or falsely
3450 representing any drug, or, without the authority of the



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3451 manufacturer, using any mark, stamp, tag, label, or other
3452 identification device authorized or required by rules adopted
3453 under ss. 499.001-499.081.

3454 (f) Knowingly obtaining or attempting to obtain a
3455 prescription drug for wholesale distribution by fraud, deceit,
3456 misrepresentation, or subterfuge, or engaging in
3457 misrepresentation or fraud in the distribution of a drug.

3458 (g) Removing a pharmacy's dispensing label from a
3459 dispensed prescription drug with the intent to further
3460 distribute the prescription drug.

3461 (h) Knowingly distributing a prescription drug that was
3462 previously dispensed by a licensed pharmacy, unless such
3463 distribution was authorized in chapter 465 or the rules adopted
3464 under chapter 465.

3465 (4) A publisher, radio broadcast licensee, or agency or
3466 medium for the dissemination of an advertisement, except the
3467 manufacturer, repackager, wholesaler, or seller of the article
3468 to which a false advertisement relates, is not liable under this
3469 section by reason of the dissemination by him or her of such
3470 false advertisement, unless he or she has refused, on the
3471 request of the department, to furnish to the department the name
3472 and post office address of the manufacturer, repackager,
3473 wholesaler, seller, or advertising agency that asked him or her
3474 to disseminate such advertisement.

3475 Section 35. Paragraphs (d), (f), (h), (i), and (j) of
3476 subsection (3) of section 921.0022, Florida Statutes, are
3477 amended to read:



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3478	921.0022	Criminal Punishment Code; offense severity
3479		ranking chart.--
3480	(3)	OFFENSE SEVERITY RANKING CHART
	Florida	Felony
3481	Statute	Degree Description
3482		(d) LEVEL 4
3483	316.1935(3)	2nd Driving at high speed or with wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a marked patrol vehicle with siren and lights activated.
3484	<u>499.0051(1)</u>	<u>3rd Failure to maintain or deliver pedigree papers.</u>
3485	<u>499.0051(2)</u>	<u>3rd Failure to authenticate pedigree papers.</u>
3486	<u>499.0051(6)</u>	<u>2nd Sale or delivery, or possession with intent to sell, contraband legend drugs.</u>
3487	784.07(2)(b)	3rd Battery of law enforcement officer, firefighter, intake



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			officer, etc.
3488	784.074(1)(c)	3rd	Battery of sexually violent predators facility staff.
3489	784.075	3rd	Battery on detention or commitment facility staff.
3490	784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
3491	784.08(2)(c)	3rd	Battery on a person 65 years of age or older.
3492	784.081(3)	3rd	Battery on specified official or employee.
3493	784.082(3)	3rd	Battery by detained person on visitor or other detainee.
3494	784.083(3)	3rd	Battery on code inspector.
3495	784.085	3rd	Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.
3496	787.03(1)	3rd	Interference with custody; wrongly takes child from



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3497	787.04(2)	3rd	appointed guardian. Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
3498	787.04(3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
3499	790.115(1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
3500	790.115(2)(b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school property.
3501	790.115(2)(c)	3rd	Possessing firearm on school property.
3502	800.04(7)(d)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
3503	810.02(4)(a)	3rd	Burglary, or attempted



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			burglary, of an unoccupied structure; unarmed; no assault or battery.
3504	810.02(4)(b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
3505	810.06	3rd	Burglary; possession of tools.
3506	810.08(2)(c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
3507	812.014(2)(c)3.	3rd	Grand theft, 3rd degree \$10,000 or more but less than \$20,000.
3508	812.014 (2)(c)4.-10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
3509	812.0195(2)	3rd	Dealing in stolen property by use of the Internet; property stolen \$300 or more.
3510	817.563(1)	3rd	Sell or deliver substance other than controlled



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			substance agreed upon, excluding s. 893.03(5) drugs.
3511	817.568(2)(a)	3rd	Fraudulent use of personal identification information.
3512	817.625(2)(a)	3rd	Fraudulent use of scanning device or reencoder.
3513	828.125(1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
3514	837.02(1)	3rd	Perjury in official proceedings.
3515	837.021(1)	3rd	Make contradictory statements in official proceedings.
3516	839.13(2)(a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
3517	839.13(2)(c)	3rd	Falsifying records of the Department of Children and Family Services.
3518	843.021	3rd	Possession of a concealed handcuff key by a person in



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3519	843.025	3rd	custody. Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
3520	843.15(1)(a)	3rd	Failure to appear while on bail for felony (bond estreature or bond jumping).
3521	874.05(1)	3rd	Encouraging or recruiting another to join a criminal street gang.
3522	893.13(2)(a)1.	2nd	Purchase of cocaine (or other s. 893.03(1)(a), (b), or (d), (2)(a), (2)(b), or (2)(c)4. drugs).
3523	914.14(2)	3rd	Witnesses accepting bribes.
3524	914.22(1)	3rd	Force, threaten, etc., witness, victim, or informant.
3525	914.23(2)	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
3526			



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3527	918.12	3rd	Tampering with jurors.
3528	934.215	3rd	Use of two-way communications device to facilitate commission of a crime.
3529			(f) LEVEL 6
3530	316.027(1)(b)	2nd	Accident involving death, failure to stop; leaving scene.
3531	316.193(2)(b)	3rd	Felony DUI, 4th or subsequent conviction.
3532	<u>499.0051(3)</u>	<u>2nd</u>	<u>Forgery of pedigree papers.</u>
3533	<u>499.0051(4)</u>	<u>2nd</u>	<u>Purchase or receipt of legend drug from unauthorized person.</u>
3534	<u>499.0051(5)</u>	<u>2nd</u>	<u>Sale of legend drug to unauthorized person.</u>
3535	775.0875(1)	3rd	Taking firearm from law enforcement officer.
	775.21(10)	3rd	Sexual predators; failure to register; failure to renew driver's license or identification card.



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3536	784.021(1)(a)	3rd	Aggravated assault; deadly weapon without intent to kill.
3537	784.021(1)(b)	3rd	Aggravated assault; intent to commit felony.
3538	784.041	3rd	Felony battery.
3539	784.048(3)	3rd	Aggravated stalking; credible threat.
3540	784.048(5)	3rd	Aggravated stalking of person under 16.
3541	784.07(2)(c)	2nd	Aggravated assault on law enforcement officer.
3542	784.074(1)(b)	2nd	Aggravated assault on sexually violent predators facility staff.
3543	784.08(2)(b)	2nd	Aggravated assault on a person 65 years of age or older.
3544	784.081(2)	2nd	Aggravated assault on specified official or employee.
3545			



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3546	784.082(2)	2nd	Aggravated assault by detained person on visitor or other detainee.
3547	784.083(2)	2nd	Aggravated assault on code inspector.
3548	787.02(2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.
3549	790.115(2)(d)	2nd	Discharging firearm or weapon on school property.
3550	790.161(2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.
3551	790.164(1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
3552	790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.



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3553	794.011(8)(a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
3554	794.05(1)	2nd	Unlawful sexual activity with specified minor.
3555	800.04(5)(d)	3rd	Lewd or lascivious molestation; victim 12 years of age or older but less than 16 years; offender less than 18 years.
3556	800.04(6)(b)	2nd	Lewd or lascivious conduct; offender 18 years of age or older.
3557	806.031(2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
3558	810.02(3)(c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
3559	812.014(2)(b)1.	2nd	Property stolen \$20,000 or more, but less than \$100,000, grand theft in 2nd degree.
	812.014(2)(b)2.	2nd	Property stolen; cargo valued



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			at less than \$50,000, grand theft in 2nd degree.
3560	812.015(9)	2nd	Retail theft; property stolen \$300 or more; second or subsequent conviction.
3561	812.13(2)(c)	2nd	Robbery, no firearm or other weapon (strong-arm robbery).
3562	817.034(4)(a)1.	1st	Communications fraud, value greater than \$50,000.
3563	817.4821(5)	2nd	Possess cloning paraphernalia with intent to create cloned cellular telephones.
3564	825.102(1)	3rd	Abuse of an elderly person or disabled adult.
3565	825.102(3)(c)	3rd	Neglect of an elderly person or disabled adult.
3566	825.1025(3)	3rd	Lewd or lascivious molestation of an elderly person or disabled adult.
3567	825.103(2)(c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less



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			than \$20,000.
3568	827.03(1)	3rd	Abuse of a child.
3569	827.03(3)(c)	3rd	Neglect of a child.
3570	827.071(2)&(3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
3571	836.05	2nd	Threats; extortion.
3572	836.10	2nd	Written threats to kill or do bodily injury.
3573	843.12	3rd	Aids or assists person to escape.
3574	847.0135(3)	3rd	Solicitation of a child, via a computer service, to commit an unlawful sex act.
3575	914.23	2nd	Retaliation against a witness, victim, or informant, with bodily injury.
3576	943.0435(9)	3rd	Sex offenders; failure to comply with reporting requirements.



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3577	944.35(3)(a)2.	3rd	Committing malicious battery upon or inflicting cruel or inhuman treatment on an inmate or offender on community supervision, resulting in great bodily harm.
3578	944.40	2nd	Escapes.
3579	944.46	3rd	Harboring, concealing, aiding escaped prisoners.
3580	944.47(1)(a)5.	2nd	Introduction of contraband (firearm, weapon, or explosive) into correctional facility.
3581	951.22(1)	3rd	Intoxicating drug, firearm, or weapon introduced into county facility.
3582			(h) LEVEL 8
3583	316.193 (3)(c)3.a.	2nd	DUI manslaughter.
3584	327.35(3)(c)3.	2nd	Vessel BUI manslaughter.
3585	<u>499.0051(7)</u>	<u>1st</u>	<u>Forgery of prescription or</u>



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			<u>legend drug labels.</u>
3586	<u>499.0052</u>	<u>1st</u>	<u>Trafficking in contraband</u> <u>legend drugs.</u>
3587	560.123(8)(b)2.	2nd	Failure to report currency or payment instruments totaling or exceeding \$20,000, but less than \$100,000 by money transmitter.
3588	560.125(5)(b)	2nd	Money transmitter business by unauthorized person, currency or payment instruments totaling or exceeding \$20,000, but less than \$100,000.
3589	655.50(10)(b)2.	2nd	Failure to report financial transactions totaling or exceeding \$20,000, but less than \$100,000 by financial institutions.
3590	777.03(2)(a)	1st	Accessory after the fact, capital felony.
3591	782.04(4)	2nd	Killing of human without design when engaged in act or attempt of any felony other



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			than arson, sexual battery, robbery, burglary, kidnapping, aircraft piracy, or unlawfully discharging bomb.
3592	782.051(2)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony not enumerated in s. 782.04(3).
3593	782.071(1)(b)	1st	Committing vehicular homicide and failing to render aid or give information.
3594	782.072(2)	1st	Committing vessel homicide and failing to render aid or give information.
3595	790.161(3)	1st	Discharging a destructive device which results in bodily harm or property damage.
3596	794.011(5)	2nd	Sexual battery, victim 12 years or over, offender does not use physical force likely to cause serious injury.
3597	800.04(4)	2nd	Lewd or lascivious battery.



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3598	806.01(1)	1st	Maliciously damage dwelling or structure by fire or explosive, believing person in structure.
3599	810.02(2)(a)	1st,PBL	Burglary with assault or battery.
3600	810.02(2)(b)	1st,PBL	Burglary; armed with explosives or dangerous weapon.
3601	810.02(2)(c)	1st	Burglary of a dwelling or structure causing structural damage or \$1,000 or more property damage.
3602	812.13(2)(b)	1st	Robbery with a weapon.
3603	812.135(2)	1st	Home-invasion robbery.
3604	825.102(2)	2nd	Aggravated abuse of an elderly person or disabled adult.
3605	825.1025(2)	2nd	Lewd or lascivious battery upon an elderly person or disabled adult.
3606	825.103(2)(a)	1st	Exploiting an elderly person



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			or disabled adult and property is valued at \$100,000 or more.
3607	837.02(2)	2nd	Perjury in official proceedings relating to prosecution of a capital felony.
3608	837.021(2)	2nd	Making contradictory statements in official proceedings relating to prosecution of a capital felony.
3609	860.121(2)(c)	1st	Shooting at or throwing any object in path of railroad vehicle resulting in great bodily harm.
3610	860.16	1st	Aircraft piracy.
3611	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).
3612	893.13(2)(b)	1st	Purchase in excess of 10 grams of any substance specified in s. 893.03(1)(a)



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			or (b).
3613	893.13(6)(c)	1st	Possess in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
3614	893.135(1)(a)2.	1st	Trafficking in cannabis, more than 2,000 lbs., less than 10,000 lbs.
3615	893.135(1)(b)1.b.	1st	Trafficking in cocaine, more than 200 grams, less than 400 grams.
3616	893.135(1)(c)1.b.	1st	Trafficking in illegal drugs, more than 14 grams, less than 28 grams.
3617	893.135(1)(d)1.b.	1st	Trafficking in phencyclidine, more than 200 grams, less than 400 grams.
3618	893.135(1)(e)1.b.	1st	Trafficking in methaqualone, more than 5 kilograms, less than 25 kilograms.
3619	893.135(1)(f)1.b.	1st	Trafficking in amphetamine, more than 28 grams, less than 200 grams.
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3621	893.135(1)(g)1.b.	1st	Trafficking in flunitrazepam, 14 grams or more, less than 28 grams.
3622	893.135(1)(h)1.b.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 5 kilograms or more, less than 10 kilograms.
3623	893.135(1)(j)1.b.	1st	Trafficking in 1,4-Butanediol, 5 kilograms or more, less than 10 kilograms.
3624	893.135(1)(k)2.b.	1st	Trafficking in Phenethylamines, 200 grams or more, less than 400 grams.
3625	895.03(1)	1st	Use or invest proceeds derived from pattern of racketeering activity.
3626	895.03(2)	1st	Acquire or maintain through racketeering activity any interest in or control of any enterprise or real property.
3627	895.03(3)	1st	Conduct or participate in any enterprise through pattern of racketeering activity.



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3628	896.101(5)(b)	2nd	Money laundering, financial transactions totaling or exceeding \$20,000, but less than \$100,000.
3629	896.104(4)(a)2.	2nd	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding \$20,000 but less than \$100,000.
3630	316.193(3)(c)3.b.	1st	(i) LEVEL 9 DUI manslaughter; failing to render aid or give information.
3631	327.35(3)(c)3.b.	1st	BUI manslaughter; failing to render aid or give information.
3632	<u>499.00523</u>	<u>1st</u>	<u>Sale or purchase of contraband legend drugs resulting in great bodily harm.</u>
3633	560.123(8)(b)3.	1st	Failure to report currency or payment instruments totaling or exceeding \$100,000 by



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3634	560.125(5)(c)	1st	money transmitter. Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding \$100,000.
3635	655.50(10)(b)3.	1st	Failure to report financial transactions totaling or exceeding \$100,000 by financial institution.
3636	775.0844	1st	Aggravated white collar crime.
3637	782.04(1)	1st	Attempt, conspire, or solicit to commit premeditated murder.
3638	782.04(3)	1st,PBL	Accomplice to murder in connection with arson, sexual battery, robbery, burglary, and other specified felonies.
3639	782.051(1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04(3).
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3641	782.07(2)	1st	Aggravated manslaughter of an elderly person or disabled adult.
3642	787.01(1)(a)1.	1st,PBL	Kidnapping; hold for ransom or reward or as a shield or hostage.
3643	787.01(1)(a)2.	1st,PBL	Kidnapping with intent to commit or facilitate commission of any felony.
3644	787.01(1)(a)4.	1st,PBL	Kidnapping with intent to interfere with performance of any governmental or political function.
3645	787.02(3)(a)	1st	False imprisonment; child under age 13; perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
3646	790.161	1st	Attempted capital destructive device offense.
	790.166(2)	1st,PBL	Possessing, selling, using, or attempting to use a weapon



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			of mass destruction.
3647	794.011(2)	1st	Attempted sexual battery; victim less than 12 years of age.
3648	794.011(2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.
3649	794.011(4)	1st	Sexual battery; victim 12 years or older, certain circumstances.
3650	794.011(8)(b)	1st	Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial authority.
3651	800.04(5)(b)	1st	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
3652	812.13(2)(a)	1st,PBL	Robbery with firearm or other deadly weapon.
3653	812.133(2)(a)	1st,PBL	Carjacking; firearm or other



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			deadly weapon.
3654	827.03(2)	1st	Aggravated child abuse.
3655	847.0145(1)	1st	Selling, or otherwise transferring custody or control, of a minor.
3656	847.0145(2)	1st	Purchasing, or otherwise obtaining custody or control, of a minor.
3657	859.01	1st	Poisoning or introducing bacteria, radioactive materials, viruses, or chemical compounds into food, drink, medicine, or water with intent to kill or injure another person.
3658	893.135	1st	Attempted capital trafficking offense.
3659	893.135(1)(a)3.	1st	Trafficking in cannabis, more than 10,000 lbs.
3660	893.135 (1)(b)1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.
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3662	893.135(1)(c)1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
3663	893.135(1)(d)1.c.	1st	Trafficking in phencyclidine, more than 400 grams.
3664	893.135(1)(e)1.c.	1st	Trafficking in methaqualone, more than 25 kilograms.
3665	893.135(1)(f)1.c.	1st	Trafficking in amphetamine, more than 200 grams.
3666	893.135(1)(h)1.c.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 10 kilograms or more.
3667	893.135(1)(j)1.c.	1st	Trafficking in 1,4-Butanediol, 10 kilograms or more.
3668	893.135(1)(k)2.c.	1st	Trafficking in Phenethylamines, 400 grams or more.
3669	896.101(5)(c)	1st	Money laundering, financial instruments totaling or exceeding \$100,000.
	896.104(4)(a)3.	1st	Structuring transactions to



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3670			evade reporting or registration requirements, financial transactions totaling or exceeding \$100,000.
3671			(j) LEVEL 10
3672	<u>499.00525</u>	<u>1st</u>	<u>Sale or purchase of contraband legend drugs resulting in death.</u>
3673	782.04(2)	1st,PBL	Unlawful killing of human; act is homicide, unpremeditated.
3674	787.01(1)(a)3.	1st,PBL	Kidnapping; inflict bodily harm upon or terrorize victim.
3675	787.01(3)(a)	Life	Kidnapping; child under age 13, perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
3675	782.07(3)	1st	Aggravated manslaughter of a child.



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794.011(3) Life Sexual battery; victim 12 years or older, offender uses or threatens to use deadly weapon or physical force to cause serious injury.

876.32 1st Treason against the state.

Section 36. Paragraph (a) of subsection (1) of section 16.56, Florida Statutes, is amended to read:

16.56 Office of Statewide Prosecution.--

(1) There is created in the Department of Legal Affairs an Office of Statewide Prosecution. The office shall be a separate "budget entity" as that term is defined in chapter 216. The office may:

(a) Investigate and prosecute the offenses of:

1. Bribery, burglary, criminal usury, extortion, gambling, kidnapping, larceny, murder, prostitution, perjury, robbery, carjacking, and home-invasion robbery;

2. Any crime involving narcotic or other dangerous drugs;

3. Any violation of the provisions of the Florida RICO (Racketeer Influenced and Corrupt Organization) Act, including any offense listed in the definition of racketeering activity in s. 895.02(1)(a), providing such listed offense is investigated in connection with a violation of s. 895.03 and is charged in a separate count of an information or indictment containing a count charging a violation of s. 895.03, the prosecution of which listed offense may continue independently if the



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3699 prosecution of the violation of s. 895.03 is terminated for any
3700 reason;

3701 4. Any violation of the provisions of the Florida Anti-
3702 Fencing Act;

3703 5. Any violation of the provisions of the Florida
3704 Antitrust Act of 1980, as amended;

3705 6. Any crime involving, or resulting in, fraud or deceit
3706 upon any person;

3707 7. Any violation of s. 847.0135, relating to computer
3708 pornography and child exploitation prevention, or any offense
3709 related to a violation of s. 847.0135; ~~or~~

3710 8. Any violation of the provisions of chapter 815; or

3711 9. Any criminal violation of part I of chapter 499.

3712

3713 or any attempt, solicitation, or conspiracy to commit any of the
3714 crimes specifically enumerated above. The office shall have
3715 such power only when any such offense is occurring, or has
3716 occurred, in two or more judicial circuits as part of a related
3717 transaction, or when any such offense is connected with an
3718 organized criminal conspiracy affecting two or more judicial
3719 circuits.

3720 Section 37. Paragraph (a) of subsection (1) of section
3721 895.02, Florida Statutes, is amended to read:

3722 895.02 Definitions.--As used in ss. 895.01-895.08, the
3723 term:

3724 (1) "Racketeering activity" means to commit, to attempt to
3725 commit, to conspire to commit, or to solicit, coerce, or
3726 intimidate another person to commit:



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3727 (a) Any crime which is chargeable by indictment or
 3728 information under the following provisions of the Florida
 3729 Statutes:

3730 1. Section 210.18, relating to evasion of payment of
 3731 cigarette taxes.

3732 2. Section 403.727(3)(b), relating to environmental
 3733 control.

3734 3. Section 414.39, relating to public assistance fraud.

3735 4. Section 409.920, relating to Medicaid provider fraud.

3736 5. Section 440.105 or s. 440.106, relating to workers'
 3737 compensation.

3738 6. Sections 499.0051, 499.0052, 499.00523, 499.00525, and
 3739 499.0691, relating to crimes involving contraband and
 3740 adulterated drugs.

3741 ~~7.6.~~ Part IV of chapter 501, relating to telemarketing.

3742 ~~8.7.~~ Chapter 517, relating to sale of securities and
 3743 investor protection.

3744 ~~9.8.~~ Section 550.235, s. 550.3551, or s. 550.3605,
 3745 relating to dogracing and horseracing.

3746 ~~10.9.~~ Chapter 550, relating to jai alai frontons.

3747 ~~11.10.~~ Chapter 552, relating to the manufacture,
 3748 distribution, and use of explosives.

3749 ~~12.11.~~ Chapter 560, relating to money transmitters, if the
 3750 violation is punishable as a felony.

3751 ~~13.12.~~ Chapter 562, relating to beverage law enforcement.

3752 ~~14.13.~~ Section 624.401, relating to transacting insurance
 3753 without a certificate of authority, s. 624.437(4)(c)1., relating
 3754 to operating an unauthorized multiple-employer welfare



3755 arrangement, or s. 626.902(1)(b), relating to representing or
3756 aiding an unauthorized insurer.

3757 ~~15.14.~~ Section 655.50, relating to reports of currency
3758 transactions, when such violation is punishable as a felony.

3759 ~~16.15.~~ Chapter 687, relating to interest and usurious
3760 practices.

3761 ~~17.16.~~ Section 721.08, s. 721.09, or s. 721.13, relating
3762 to real estate timeshare plans.

3763 ~~18.17.~~ Chapter 782, relating to homicide.

3764 ~~19.18.~~ Chapter 784, relating to assault and battery.

3765 ~~20.19.~~ Chapter 787, relating to kidnapping.

3766 ~~21.20.~~ Chapter 790, relating to weapons and firearms.

3767 ~~22.21.~~ Section 796.03, s. 796.04, s. 796.05, or s.
3768 796.07, relating to prostitution.

3769 ~~23.22.~~ Chapter 806, relating to arson.

3770 ~~24.23.~~ Section 810.02(2)(c), relating to specified
3771 burglary of a dwelling or structure.

3772 ~~25.24.~~ Chapter 812, relating to theft, robbery, and
3773 related crimes.

3774 ~~26.25.~~ Chapter 815, relating to computer-related crimes.

3775 ~~27.26.~~ Chapter 817, relating to fraudulent practices,
3776 false pretenses, fraud generally, and credit card crimes.

3777 ~~28.27.~~ Chapter 825, relating to abuse, neglect, or
3778 exploitation of an elderly person or disabled adult.

3779 ~~29.28.~~ Section 827.071, relating to commercial sexual
3780 exploitation of children.

3781 ~~30.29.~~ Chapter 831, relating to forgery and
3782 counterfeiting.



3783 ~~31.30.~~ Chapter 832, relating to issuance of worthless
 3784 checks and drafts.

3785 ~~32.31.~~ Section 836.05, relating to extortion.

3786 ~~33.32.~~ Chapter 837, relating to perjury.

3787 ~~34.33.~~ Chapter 838, relating to bribery and misuse of
 3788 public office.

3789 ~~35.34.~~ Chapter 843, relating to obstruction of justice.

3790 ~~36.35.~~ Section 847.011, s. 847.012, s. 847.013, s. 847.06,
 3791 or s. 847.07, relating to obscene literature and profanity.

3792 ~~37.36.~~ Section 849.09, s. 849.14, s. 849.15, s. 849.23, or
 3793 s. 849.25, relating to gambling.

3794 ~~38.37.~~ Chapter 874, relating to criminal street gangs.

3795 ~~39.38.~~ Chapter 893, relating to drug abuse prevention and
 3796 control.

3797 ~~40.39.~~ Chapter 896, relating to offenses related to
 3798 financial transactions.

3799 ~~41.40.~~ Sections 914.22 and 914.23, relating to tampering
 3800 with a witness, victim, or informant, and retaliation against a
 3801 witness, victim, or informant.

3802 ~~42.41.~~ Sections 918.12 and 918.13, relating to tampering
 3803 with jurors and evidence.

3804 Section 38. Section 905.34, Florida Statutes, is amended
 3805 to read:

3806 905.34 Powers and duties; law applicable.--The
 3807 jurisdiction of a statewide grand jury impaneled under this
 3808 chapter shall extend throughout the state. The subject matter
 3809 jurisdiction of the statewide grand jury shall be limited to the
 3810 offenses of:



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- 3811 (1) Bribery, burglary, carjacking, home-invasion robbery,
3812 criminal usury, extortion, gambling, kidnapping, larceny,
3813 murder, prostitution, perjury, and robbery;
- 3814 (2) Crimes involving narcotic or other dangerous drugs;
- 3815 (3) Any violation of the provisions of the Florida RICO
3816 (Racketeer Influenced and Corrupt Organization) Act, including
3817 any offense listed in the definition of racketeering activity in
3818 s. 895.02(1)(a), providing such listed offense is investigated
3819 in connection with a violation of s. 895.03 and is charged in a
3820 separate count of an information or indictment containing a
3821 count charging a violation of s. 895.03, the prosecution of
3822 which listed offense may continue independently if the
3823 prosecution of the violation of s. 895.03 is terminated for any
3824 reason;
- 3825 (4) Any violation of the provisions of the Florida Anti-
3826 Fencing Act;
- 3827 (5) Any violation of the provisions of the Florida
3828 Antitrust Act of 1980, as amended;
- 3829 (6) Any violation of the provisions of chapter 815;
- 3830 (7) Any crime involving, or resulting in, fraud or deceit
3831 upon any person;
- 3832 (8) Any violation of s. 847.0135, s. 847.0137, or s.
3833 847.0138 relating to computer pornography and child exploitation
3834 prevention, or any offense related to a violation of s.
3835 847.0135, s. 847.0137, or s. 847.0138;
- 3836 (9) Any criminal violation of part I of chapter 499;
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3838 or any attempt, solicitation, or conspiracy to commit any
3839 violation of the crimes specifically enumerated above, when any
3840 such offense is occurring, or has occurred, in two or more
3841 judicial circuits as part of a related transaction or when any
3842 such offense is connected with an organized criminal conspiracy
3843 affecting two or more judicial circuits. The statewide grand
3844 jury may return indictments and presentments irrespective of the
3845 county or judicial circuit where the offense is committed or
3846 triable. If an indictment is returned, it shall be certified
3847 and transferred for trial to the county where the offense was
3848 committed. The powers and duties of, and law applicable to,
3849 county grand juries shall apply to a statewide grand jury except
3850 when such powers, duties, and law are inconsistent with the
3851 provisions of ss. 905.31-905.40.

3852 Section 39. If any provision of this act or its
3853 application to any person or circumstance is held invalid, the
3854 invalidity does not affect other provisions or applications of
3855 the act which can be given effect without the invalid provision
3856 or application, and to this end the provisions of this act are
3857 severable.

3858 Section 40. Except as otherwise expressly provided in this
3859 act, this act shall take effect July 1, 2003.