

By the Committees on Health and Human Services Appropriations;
and Health Regulation; and Senator Peadar

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1 A bill to be entitled
2 An act relating to manufacturers and purchasers of
3 prescription drugs; amending ss. 409.9201 and
4 465.0265, F.S.; conforming cross-references; amending
5 s. 499.003, F.S.; defining new terms and redefining
6 terms related to the Florida Drug and Cosmetic Act;
7 amending s. 499.01, F.S.; authorizing a prescription
8 drug manufacturer's distributor permit and revising
9 the requirements related to certain other permits;
10 conforming a cross-reference; amending s. 499.012,
11 F.S.; restricting issuance of a permit for a
12 prescription drug manufacturer's distributor at
13 certain addresses; amending s. 499.0121, F.S.;
14 eliminating cross-references to defined terms and
15 clarifying a recordkeeping requirement related to
16 pedigree papers; amending s. 499.01211, F.S.;
17 eliminating cross-references for certain defined
18 terms; amending s. 499.01212, F.S.; revising
19 requirements for a pedigree paper; amending s. 499.03,
20 F.S.; eliminating cross-references for certain defined
21 terms; amending s. 499.041, F.S.; establishing a fee
22 for the prescription drug manufacturer's distributor
23 permit; authorizing the Department of Health to retain
24 a specified monetary amount as a fee if an application
25 submitted under the Florida Drug and Cosmetic Act is
26 withdrawn or becomes void; amending ss. 499.05 and
27 794.075, F.S.; conforming cross-references;
28 authorizing certain statements to be used on certain
29 pedigree papers until a specified date; providing an

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30 appropriation and authorizing additional positions;
31 providing an effective date.

32
33 Be It Enacted by the Legislature of the State of Florida:

34
35 Section 1. Paragraph (a) of subsection (1) of section
36 409.9201, Florida Statutes, is amended to read:

37 409.9201 Medicaid fraud.—

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

39 (a) "Prescription drug" means any drug, including, but not
40 limited to, finished dosage forms or active ingredients that are
41 subject to, defined by, or described by s. 503(b) of the Federal
42 Food, Drug, and Cosmetic Act or by s. 465.003(8), s. 499.003(46)
43 or (53) ~~s. 499.003(45) or (52)~~, or s. 499.007(13).

44
45 The value of individual items of the legend drugs or goods or
46 services involved in distinct transactions committed during a
47 single scheme or course of conduct, whether involving a single
48 person or several persons, may be aggregated when determining
49 the punishment for the offense.

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

52 465.0265 Centralized prescription filling.—

53 (3) The filling, delivery, and return of a prescription by
54 one pharmacy for another pursuant to this section shall not be
55 construed as the filling of a transferred prescription as set
56 forth in s. 465.026 or as a wholesale distribution as set forth
57 in s. 499.003(54) ~~s. 499.003(53)~~.

58 Section 3. Subsection (18) and subsections (31) through

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59 (54) of section 499.003, Florida Statutes, are amended to read:
60 499.003 Definitions of terms used in this part.—As used in
61 this part, the term:

62 (18) "Drop shipment" means the sale of a prescription drug
63 from a manufacturer or the manufacturer's distributor to a
64 wholesale distributor, where the wholesale distributor takes
65 title to, but not possession of, the prescription drug, and the
66 manufacturer of the prescription drug, the manufacturer's
67 distributor, or the manufacturer's third-party logistics
68 provider ships the prescription drug directly to a chain
69 pharmacy warehouse or a person authorized by law to purchase
70 prescription drugs for the purpose of administering or
71 dispensing the drug, as defined in s. 465.003.

72 (31) "Manufacturer" means:

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

75 (b) The holder or holders of a New Drug Application (NDA),
76 an Abbreviated New Drug Application (ANDA), a Biologics License
77 Application (BLA), or a New Animal Drug Application (NADA),
78 provided such application has become effective or is otherwise
79 approved consistent with s. 499.023.~~†~~

80 (c) A private label distributor for whom the private label
81 distributor's prescription drugs are originally manufactured and
82 labeled for the distributor and have not been repackaged; ~~or the~~
83 ~~distribution point for the manufacturer, contract manufacturer,~~
84 ~~or private label distributor whether the establishment is a~~
85 ~~member of the manufacturer's affiliated group or is a contract~~
86 ~~distribution site.~~

87 (d) A person registered under the federal act as a

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88 manufacturer who has entered into a written agreement with
89 another manufacturer that authorizes either manufacturer to
90 distribute a prescription drug, which is identified in the
91 agreement, as the manufacturer of that drug consistent with the
92 federal act.

93

94 The term excludes pharmacies that are operating in compliance
95 with pharmacy practice standards as defined in chapter 465 and
96 rules adopted under that chapter.

97 (32) "Manufacturer's distributor" means a person permitted
98 under this part as a prescription drug manufacturer's
99 distributor.

100 (33)~~(32)~~ "New drug" means:

101 (a) Any drug the composition of which is such that the drug
102 is not generally recognized, among experts qualified by
103 scientific training and experience to evaluate the safety and
104 effectiveness of drugs, as safe and effective for use under the
105 conditions prescribed, recommended, or suggested in the labeling
106 of that drug; or

107 (b) Any drug the composition of which is such that the
108 drug, as a result of investigations to determine its safety and
109 effectiveness for use under certain conditions, has been
110 recognized for use under such conditions, but which drug has
111 not, other than in those investigations, been used to a material
112 extent or for a material time under such conditions.

113 (34)~~(33)~~ "Normal distribution chain" means a wholesale
114 distribution of a prescription drug in which the wholesale
115 distributor or its wholly owned subsidiary purchases ~~and~~
116 ~~receives~~ the specific unit of the prescription drug directly

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117 from the manufacturer or manufacturer's distributor; receives
118 the specific unit of the prescription drug directly from the
119 manufacturer, manufacturer's distributor, or manufacturer's
120 third-party logistics provider; and distributes the prescription
121 drug directly, or through up to two intracompany transfers, to a
122 chain pharmacy warehouse or a person authorized by law to
123 purchase prescription drugs for the purpose of administering or
124 dispensing the drug, as defined in s. 465.003. For purposes of
125 this subsection, the term "intracompany" means any transaction
126 or transfer between any parent, division, or subsidiary wholly
127 owned by a corporate entity.

128 ~~(35)~~~~(34)~~ "Nursing home" means a facility licensed under
129 part II of chapter 400.

130 ~~(36)~~~~(35)~~ "Official compendium" means the current edition of
131 the official United States Pharmacopoeia and National Formulary,
132 or any supplement thereto.

133 ~~(37)~~~~(36)~~ "Pedigree paper" means a document in written or
134 electronic form approved by the department which contains
135 information required by s. 499.01212 regarding the sale and
136 distribution of any given prescription drug.

137 ~~(38)~~~~(37)~~ "Permittee" means any person holding a permit
138 issued pursuant to s. 499.012.

139 ~~(39)~~~~(38)~~ "Person" means any individual, child, joint
140 venture, syndicate, fiduciary, partnership, corporation,
141 division of a corporation, firm, trust, business trust, company,
142 estate, public or private institution, association,
143 organization, group, city, county, city and county, political
144 subdivision of this state, other governmental agency within this
145 state, and any representative, agent, or agency of any of the

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146 foregoing, or any other group or combination of the foregoing.

147 (40)~~(39)~~ "Pharmacist" means a person licensed under chapter
148 465.

149 (41)~~(40)~~ "Pharmacy" means an entity licensed under chapter
150 465.

151 (42)~~(41)~~ "Prepackaged drug product" means a drug that
152 originally was in finished packaged form sealed by a
153 manufacturer and that is placed in a properly labeled container
154 by a pharmacy or practitioner authorized to dispense pursuant to
155 chapter 465 for the purpose of dispensing in the establishment
156 in which the prepackaging occurred.

157 (43)~~(42)~~ "Prescription drug" means a prescription,
158 medicinal, or legend drug, including, but not limited to,
159 finished dosage forms or active ingredients subject to, defined
160 by, or described by s. 503(b) of the Federal Food, Drug, and
161 Cosmetic Act or s. 465.003(8), s. 499.007(13), or subsection
162 (11), subsection (48) ~~(47)~~, or subsection (53) ~~(52)~~.

163 (44)~~(43)~~ "Prescription drug label" means any display of
164 written, printed, or graphic matter upon the immediate container
165 of any prescription drug prior to its dispensing to an
166 individual patient pursuant to a prescription of a practitioner
167 authorized by law to prescribe.

168 (45)~~(44)~~ "Prescription label" means any display of written,
169 printed, or graphic matter upon the immediate container of any
170 prescription drug dispensed pursuant to a prescription of a
171 practitioner authorized by law to prescribe.

172 (46)~~(45)~~ "Prescription medical oxygen" means oxygen USP
173 which is a drug that can only be sold on the order or
174 prescription of a practitioner authorized by law to prescribe.

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175 The label of prescription medical oxygen must comply with
176 current labeling requirements for oxygen under the Federal Food,
177 Drug, and Cosmetic Act.

178 (47)~~(46)~~ "Primary wholesale distributor" means any
179 wholesale distributor that:

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

183 (b)1. Directly purchased prescription drugs from not fewer
184 than 50 different prescription drug manufacturers in the
185 previous year; or

186 2. Has, or the affiliated group, as defined in s. 1504 of
187 the Internal Revenue Code, of which the wholesale distributor is
188 a member has, not fewer than 250 employees.

189 (c) For purposes of this subsection, "directly from
190 manufacturers" means:

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

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

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

199 b. The wholesale distributor discloses to the department
200 the names of all members of the affiliated group of which the
201 wholesale distributor is a member and the affiliated group
202 agrees in writing to provide records on prescription drug
203 purchases by the members of the affiliated group not later than

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204 48 hours after the department requests access to such records,
205 regardless of the location where the records are stored.

206 (48)~~(47)~~ "Proprietary drug," or "OTC drug," means a patent
207 or over-the-counter drug in its unbroken, original package,
208 which drug is sold to the public by, or under the authority of,
209 the manufacturer or primary distributor thereof, is not
210 misbranded under the provisions of this part, and can be
211 purchased without a prescription.

212 (49)~~(48)~~ "Repackage" includes repacking or otherwise
213 changing the container, wrapper, or labeling to further the
214 distribution of the drug, device, or cosmetic.

215 (50)~~(49)~~ "Repackager" means a person who repackages. The
216 term excludes pharmacies that are operating in compliance with
217 pharmacy practice standards as defined in chapter 465 and rules
218 adopted under that chapter.

219 (51)~~(50)~~ "Retail pharmacy" means a community pharmacy
220 licensed under chapter 465 that purchases prescription drugs at
221 fair market prices and provides prescription services to the
222 public.

223 (52)~~(51)~~ "Secondary wholesale distributor" means a
224 wholesale distributor that is not a primary wholesale
225 distributor.

226 (53)~~(52)~~ "Veterinary prescription drug" means a
227 prescription drug intended solely for veterinary use. The label
228 of the drug must bear the statement, "Caution: Federal law
229 restricts this drug to sale by or on the order of a licensed
230 veterinarian."

231 (54)~~(53)~~ "Wholesale distribution" means distribution of
232 prescription drugs to persons other than a consumer or patient,

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233 but does not include:

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

237 1. The purchase or other acquisition by a hospital or other
238 health care entity that is a member of a group purchasing
239 organization of a prescription drug for its own use from the
240 group purchasing organization or from other hospitals or health
241 care entities that are members of that organization.

242 2. The sale, purchase, or trade of a prescription drug or
243 an offer to sell, purchase, or trade a prescription drug by a
244 charitable organization described in s. 501(c)(3) of the
245 Internal Revenue Code of 1986, as amended and revised, to a
246 nonprofit affiliate of the organization to the extent otherwise
247 permitted by law.

248 3. The sale, purchase, or trade of a prescription drug or
249 an offer to sell, purchase, or trade a prescription drug among
250 hospitals or other health care entities that are under common
251 control. For purposes of this subparagraph, "common control"
252 means the power to direct or cause the direction of the
253 management and policies of a person or an organization, whether
254 by ownership of stock, by voting rights, by contract, or
255 otherwise.

256 4. The sale, purchase, trade, or other transfer of a
257 prescription drug from or for any federal, state, or local
258 government agency or any entity eligible to purchase
259 prescription drugs at public health services prices pursuant to
260 Pub. L. No. 102-585, s. 602 to a contract provider or its
261 subcontractor for eligible patients of the agency or entity

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262 under the following conditions:

263 a. The agency or entity must obtain written authorization
264 for the sale, purchase, trade, or other transfer of a
265 prescription drug under this subparagraph from the State Surgeon
266 General or his or her designee.

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

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

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

274 e. The contract provider and subcontractor must maintain
275 and produce immediately for inspection all records of movement
276 or transfer of all the prescription drugs belonging to the
277 agency or entity, including, but not limited to, the records of
278 receipt and disposition of prescription drugs. Each contractor
279 and subcontractor dispensing or administering these drugs must
280 maintain and produce records documenting the dispensing or
281 administration. Records that are required to be maintained
282 include, but are not limited to, a perpetual inventory itemizing
283 drugs received and drugs dispensed by prescription number or
284 administered by patient identifier, which must be submitted to
285 the agency or entity quarterly.

286 f. The contract provider or subcontractor may administer or
287 dispense the prescription drugs only to the eligible patients of
288 the agency or entity or must return the prescription drugs for
289 or to the agency or entity. The contract provider or
290 subcontractor must require proof from each person seeking to

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291 fill a prescription or obtain treatment that the person is an
292 eligible patient of the agency or entity and must, at a minimum,
293 maintain a copy of this proof as part of the records of the
294 contractor or subcontractor required under sub-subparagraph e.

295 g. In addition to the departmental inspection authority set
296 forth in s. 499.051, the establishment of the contract provider
297 and subcontractor and all records pertaining to prescription
298 drugs subject to this subparagraph shall be subject to
299 inspection by the agency or entity. All records relating to
300 prescription drugs of a manufacturer under this subparagraph
301 shall be subject to audit by the manufacturer of those drugs,
302 without identifying individual patient information.

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

306 1. The sale, purchase, or trade of a prescription drug
307 among federal, state, or local government health care entities
308 that are under common control and are authorized to purchase
309 such prescription drug.

310 2. The sale, purchase, or trade of a prescription drug or
311 an offer to sell, purchase, or trade a prescription drug for
312 emergency medical reasons. For purposes of this subparagraph,
313 the term "emergency medical reasons" includes transfers of
314 prescription drugs by a retail pharmacy to another retail
315 pharmacy to alleviate a temporary shortage.

316 3. The transfer of a prescription drug acquired by a
317 medical director on behalf of a licensed emergency medical
318 services provider to that emergency medical services provider
319 and its transport vehicles for use in accordance with the

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320 provider's license under chapter 401.

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

323 5. The donation of a prescription drug by a health care
324 entity to a charitable organization that has been granted an
325 exemption under s. 501(c)(3) of the Internal Revenue Code of
326 1986, as amended, and that is authorized to possess prescription
327 drugs.

328 6. The transfer of a prescription drug by a person
329 authorized to purchase or receive prescription drugs to a person
330 licensed or permitted to handle reverse distributions or
331 destruction under the laws of the jurisdiction in which the
332 person handling the reverse distribution or destruction receives
333 the drug.

334 7. The transfer of a prescription drug by a hospital or
335 other health care entity to a person licensed under this part to
336 repackage prescription drugs for the purpose of repackaging the
337 prescription drug for use by that hospital, or other health care
338 entity and other health care entities that are under common
339 control, if ownership of the prescription drugs remains with the
340 hospital or other health care entity at all times. In addition
341 to the recordkeeping requirements of s. 499.0121(6), the
342 hospital or health care entity that transfers prescription drugs
343 pursuant to this subparagraph must reconcile all drugs
344 transferred and returned and resolve any discrepancies in a
345 timely manner.

346 (c) The distribution of prescription drug samples by
347 manufacturers' representatives or distributors' representatives
348 conducted in accordance with s. 499.028.

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349 (d) The sale, purchase, or trade of blood and blood
350 components intended for transfusion. As used in this paragraph,
351 the term "blood" means whole blood collected from a single donor
352 and processed for transfusion or further manufacturing, and the
353 term "blood components" means that part of the blood separated
354 by physical or mechanical means.

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

357 (f) The sale, purchase, or trade of a prescription drug
358 between pharmacies as a result of a sale, transfer, merger, or
359 consolidation of all or part of the business of the pharmacies
360 from or with another pharmacy, whether accomplished as a
361 purchase and sale of stock or of business assets.

362 (55)~~(54)~~ "Wholesale distributor" means any person engaged
363 in wholesale distribution of prescription drugs in or into this
364 state, including, but not limited to, manufacturers;
365 repackagers; own-label distributors; jobbers; private-label
366 distributors; brokers; warehouses, including manufacturers' and
367 distributors' warehouses, chain drug warehouses, and wholesale
368 drug warehouses; independent wholesale drug traders; exporters;
369 retail pharmacies; and the agents thereof that conduct wholesale
370 distributions.

371 Section 4. Section 499.01, Florida Statutes, is amended to
372 read:

373 499.01 Permits.—

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

376 (a) A prescription drug manufacturer;

377 (b) A prescription drug repackager;

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- 378 (c) A nonresident prescription drug manufacturer;
- 379 (d) A prescription drug wholesale distributor;
- 380 (e) An out-of-state prescription drug wholesale
- 381 distributor;
- 382 (f) A retail pharmacy drug wholesale distributor;
- 383 (g) A restricted prescription drug distributor;
- 384 (h) A complimentary drug distributor;
- 385 (i) A freight forwarder;
- 386 (j) A veterinary prescription drug retail establishment;
- 387 (k) A veterinary prescription drug wholesale distributor;
- 388 (l) A limited prescription drug veterinary wholesale
- 389 distributor;
- 390 (m) A medical oxygen retail establishment;
- 391 (n) A compressed medical gas wholesale distributor;
- 392 (o) A compressed medical gas manufacturer;
- 393 (p) An over-the-counter drug manufacturer;
- 394 (q) A device manufacturer;
- 395 (r) A cosmetic manufacturer;
- 396 (s) A third-party ~~third party~~ logistics provider; ~~or~~
- 397 (t) A health care clinic establishment; or-
- 398 (u) A prescription drug manufacturer's distributor.
- 399 (2) The following permits are established:
- 400 (a) *Prescription drug manufacturer permit.*—A prescription
- 401 drug manufacturer permit is required for any person or entity
- 402 that is a manufacturer of ~~manufactures~~ a prescription drug and
- 403 manufactures or distributes its prescription drugs at or from an
- 404 establishment in this state.
- 405 1. A person that operates an establishment permitted as a
- 406 prescription drug manufacturer may engage in wholesale

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407 distribution of prescription drugs manufactured at that
408 establishment and must comply with all the provisions of this
409 part and the rules adopted under this part that apply to a
410 wholesale distributor, except the provisions in s. 499.01212.

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

413 (b) *Prescription drug repackager permit.*—A prescription
414 drug repackager permit is required for any person that
415 repackages a prescription drug in this state.

416 1. A person that operates an establishment permitted as a
417 prescription drug repackager may engage in wholesale
418 distribution of prescription drugs repackaged at that
419 establishment and must comply with all the provisions of this
420 part and the rules adopted under this part that apply to a
421 wholesale distributor.

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

424 (c) *Nonresident prescription drug manufacturer permit.*—A
425 nonresident prescription drug manufacturer permit is required
426 for any person that is a manufacturer of prescription drugs, ~~or~~
427 ~~the distribution point for a manufacturer of prescription drugs~~
428 ~~unless permitted as a third party logistics provider, and~~
429 ~~located outside of this state, or that is an entity to whom an~~
430 ~~approved new drug application has been issued by the United~~
431 ~~States Food and Drug Administration, or the contracted~~
432 ~~manufacturer of the approved new drug application holder, and~~
433 ~~located outside the United States,~~ which engages in the
434 wholesale distribution in this state of the prescription drugs
435 it manufactures or is responsible for manufacturing. Each such

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436 manufacturer ~~or entity~~ must be permitted by the department and
437 comply with all the provisions required of a wholesale
438 distributor under this part, except s. 499.01212.

439 1. A person that distributes prescription drugs for which
440 he or she is not the manufacturer ~~that it did not manufacture~~
441 must also obtain an out-of-state prescription drug wholesale
442 distributor permit, third-party logistics provider permit, or
443 prescription drug manufacturer's distributor permit, as
444 applicable, pursuant to this section to engage in the wholesale
445 distribution of the prescription drugs for which it is not the
446 manufacturer ~~manufactured by another person~~ and comply with the
447 requirements of that permit for the wholesale distribution of
448 those prescription drugs for which the person is not the
449 manufacturer ~~an out-of-state prescription drug wholesale~~
450 ~~distributor~~.

451 2. Any such person must comply with the licensing or
452 permitting requirements of the jurisdiction in which the
453 establishment is located and the federal act, and any product
454 wholesaled into this state must comply with this part. If a
455 person intends to import prescription drugs from a foreign
456 country into this state, the nonresident prescription drug
457 manufacturer must provide to the department a list identifying
458 each prescription drug it intends to import and document
459 approval by the United States Food and Drug Administration for
460 such importation.

461 3. A nonresident prescription drug manufacturer permit,
462 prescription drug manufacturer's distributor permit, or third-
463 party logistics provider permit is not required for a
464 manufacturer to distribute, directly or through the

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465 manufacturer's distributor or third-party logistics provider, a
466 prescription drug active pharmaceutical ingredient that it
467 manufactures to a prescription drug manufacturer permitted in
468 this state in limited quantities intended for research and
469 development and not for resale, or human use other than lawful
470 clinical trials and biostudies authorized and regulated by
471 federal law. A manufacturer, manufacturer's distributor, or
472 third-party logistics provider claiming to be exempt from the
473 permit requirements of this subparagraph and the prescription
474 drug manufacturer purchasing and receiving the active
475 pharmaceutical ingredient shall comply with the recordkeeping
476 requirements of s. 499.0121(6), but not the requirements of s.
477 499.01212. The prescription drug manufacturer purchasing and
478 receiving the active pharmaceutical ingredient shall maintain on
479 file a record of the FDA registration number; the out-of-state
480 license, permit, or registration number; and, if available, a
481 copy of the most current FDA inspection report, for all
482 manufacturers, manufacturer's distributors, or third-party
483 logistics providers from whom they purchase and receive active
484 pharmaceutical ingredients under this section. The department
485 shall specify by rule the allowable number of transactions
486 within a given period of time and the amount of active
487 pharmaceutical ingredients that qualify as limited quantities
488 for purposes of this exemption. The failure to comply with the
489 requirements of this subparagraph, or rules adopted by the
490 department to administer this subparagraph, for the purchase of
491 prescription drug active pharmaceutical ingredients is a
492 violation of s. 499.005(14).

493 (d) *Prescription drug wholesale distributor permit.*—A

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494 prescription drug wholesale distributor is a wholesale
495 distributor that may engage in the wholesale distribution of
496 prescription drugs. A prescription drug wholesale distributor
497 that applies to the department for a new permit or the renewal
498 of a permit must submit a bond of \$100,000, or other equivalent
499 means of security acceptable to the department, such as an
500 irrevocable letter of credit or a deposit in a trust account or
501 financial institution, payable to the Florida Drug, Device, and
502 Cosmetic Trust Fund. The purpose of the bond is to secure
503 payment of any administrative penalties imposed by the
504 department and any fees and costs incurred by the department
505 regarding that permit which are authorized under state law and
506 which the permittee fails to pay 30 days after the fine or costs
507 become final. The department may make a claim against such bond
508 or security until 1 year after the permittee's license ceases to
509 be valid or until 60 days after any administrative or legal
510 proceeding authorized in this part which involves the permittee
511 is concluded, including any appeal, whichever occurs later. The
512 department may adopt rules for issuing a prescription drug
513 wholesale distributor-broker permit to a person who engages in
514 the wholesale distribution of prescription drugs and does not
515 take physical possession of any prescription drugs.

516 (e) *Out-of-state prescription drug wholesale distributor*
517 *permit.*—An out-of-state prescription drug wholesale distributor
518 is a wholesale distributor located outside this state which
519 engages in the wholesale distribution of prescription drugs into
520 this state and which must be permitted by the department and
521 comply with all the provisions required of a wholesale
522 distributor under this part. An out-of-state prescription drug

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523 wholesale distributor that applies to the department for a new
524 permit or the renewal of a permit must submit a bond of
525 \$100,000, or other equivalent means of security acceptable to
526 the department, such as an irrevocable letter of credit or a
527 deposit in a trust account or financial institution, payable to
528 the Florida Drug, Device, and Cosmetic Trust Fund. The purpose
529 of the bond is to secure payment of any administrative penalties
530 imposed by the department and any fees and costs incurred by the
531 department regarding that permit which are authorized under
532 state law and which the permittee fails to pay 30 days after the
533 fine or costs become final. The department may make a claim
534 against such bond or security until 1 year after the permittee's
535 license ceases to be valid or until 60 days after any
536 administrative or legal proceeding authorized in this part which
537 involves the permittee is concluded, including any appeal,
538 whichever occurs later.

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

543 2. An out-of-state prescription drug wholesale distributor
544 permit is not required for an intracompany sale or transfer of a
545 prescription drug from an out-of-state establishment that is
546 duly licensed as a prescription drug wholesale distributor, in
547 its state of residence, to a licensed prescription drug
548 wholesale distributor in this state, if both wholesale
549 distributors conduct wholesale distributions of prescription
550 drugs under the same business name. The recordkeeping
551 requirements of ss. 499.0121(6) and 499.01212 must be followed

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552 for this transaction.

553 (f) *Retail pharmacy drug wholesale distributor permit.*—A
554 retail pharmacy drug wholesale distributor is a retail pharmacy
555 engaged in wholesale distribution of prescription drugs within
556 this state under the following conditions:

557 1. The pharmacy must obtain a retail pharmacy drug
558 wholesale distributor permit pursuant to this part and the rules
559 adopted under this part.

560 2. The wholesale distribution activity does not exceed 30
561 percent of the total annual purchases of prescription drugs. If
562 the wholesale distribution activity exceeds the 30-percent
563 maximum, the pharmacy must obtain a prescription drug wholesale
564 distributor permit.

565 3. The transfer of prescription drugs that appear in any
566 schedule contained in chapter 893 is subject to chapter 893 and
567 the federal Comprehensive Drug Abuse Prevention and Control Act
568 of 1970.

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

573 5. All records of sales of prescription drugs subject to
574 this section must be maintained separate and distinct from other
575 records and comply with the recordkeeping requirements of this
576 part.

577 (g) *Restricted prescription drug distributor permit.*—A
578 restricted prescription drug distributor permit is required for
579 any person that engages in the distribution of a prescription
580 drug, which distribution is not considered "wholesale

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581 distribution" under s. 499.003(54)(a) ~~s. 499.003(53)(a)~~.

582 1. A person who engages in the receipt or distribution of a
583 prescription drug in this state for the purpose of processing
584 its return or its destruction must obtain a permit as a
585 restricted prescription drug distributor if such person is not
586 the person initiating the return, the prescription drug
587 wholesale supplier of the person initiating the return, or the
588 manufacturer of the drug.

589 2. Storage, handling, and recordkeeping of these
590 distributions must comply with the requirements for wholesale
591 distributors under s. 499.0121, but not those set forth in s.
592 499.01212.

593 3. A person who applies for a permit as a restricted
594 prescription drug distributor, or for the renewal of such a
595 permit, must provide to the department the information required
596 under s. 499.012.

597 4. The department may adopt rules regarding the
598 distribution of prescription drugs by hospitals, health care
599 entities, charitable organizations, or other persons not
600 involved in wholesale distribution, which rules are necessary
601 for the protection of the public health, safety, and welfare.

602 (h) *Complimentary drug distributor permit.*—A complimentary
603 drug distributor permit is required for any person that engages
604 in the distribution of a complimentary drug, subject to the
605 requirements of s. 499.028.

606 (i) *Freight forwarder permit.*—A freight forwarder permit is
607 required for any person that engages in the distribution of a
608 prescription drug as a freight forwarder unless the person is a
609 common carrier. The storage, handling, and recordkeeping of such

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610 distributions must comply with the requirements for wholesale
611 distributors under s. 499.0121, but not those set forth in s.
612 499.01212. A freight forwarder must provide the source of the
613 prescription drugs with a validated airway bill, bill of lading,
614 or other appropriate documentation to evidence the exportation
615 of the product.

616 (j) *Veterinary prescription drug retail establishment*
617 *permit.*—A veterinary prescription drug retail establishment
618 permit is required for any person that sells veterinary
619 prescription drugs to the public but does not include a pharmacy
620 licensed under chapter 465.

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

624 2. Veterinary prescription drugs may not be sold in excess
625 of the amount clearly indicated on the order or beyond the date
626 indicated on the order.

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

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

631 5. A veterinary prescription drug retail establishment must
632 sell a veterinary prescription drug in the original, sealed
633 manufacturer's container with all labeling intact and legible.
634 The department may adopt by rule additional labeling
635 requirements for the sale of a veterinary prescription drug.

636 6. A veterinary prescription drug retail establishment must
637 comply with all of the wholesale distribution requirements of s.
638 499.0121.

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

642 (k) *Veterinary prescription drug wholesale distributor*
643 *permit.*—A veterinary prescription drug wholesale distributor
644 permit is required for any person that engages in the
645 distribution of veterinary prescription drugs in or into this
646 state. A veterinary prescription drug wholesale distributor that
647 also distributes prescription drugs subject to, defined by, or
648 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
649 Act which it did not manufacture must obtain a permit as a
650 prescription drug wholesale distributor, an out-of-state
651 prescription drug wholesale distributor, or a limited
652 prescription drug veterinary wholesale distributor in lieu of
653 the veterinary prescription drug wholesale distributor permit. A
654 veterinary prescription drug wholesale distributor must comply
655 with the requirements for wholesale distributors under s.
656 499.0121, but not those set forth in s. 499.01212.

657 (l) *Limited prescription drug veterinary wholesale*
658 *distributor permit.*—Unless engaging in the activities of and
659 permitted as a prescription drug manufacturer, nonresident
660 prescription drug manufacturer, prescription drug wholesale
661 distributor, or out-of-state prescription drug wholesale
662 distributor, a limited prescription drug veterinary wholesale
663 distributor permit is required for any person that engages in
664 the distribution in or into this state of veterinary
665 prescription drugs and prescription drugs subject to, defined
666 by, or described by s. 503(b) of the Federal Food, Drug, and
667 Cosmetic Act under the following conditions:

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- 668 1. The person is engaged in the business of wholesaling
669 prescription and veterinary prescription drugs to persons:
- 670 a. Licensed as veterinarians practicing on a full-time
671 basis;
- 672 b. Regularly and lawfully engaged in instruction in
673 veterinary medicine;
- 674 c. Regularly and lawfully engaged in law enforcement
675 activities;
- 676 d. For use in research not involving clinical use; or
677 e. For use in chemical analysis or physical testing or for
678 purposes of instruction in law enforcement activities, research,
679 or testing.
- 680 2. No more than 30 percent of total annual prescription
681 drug sales may be prescription drugs approved for human use
682 which are subject to, defined by, or described by s. 503(b) of
683 the Federal Food, Drug, and Cosmetic Act.
- 684 3. The person does not distribute in any jurisdiction
685 prescription drugs subject to, defined by, or described by s.
686 503(b) of the Federal Food, Drug, and Cosmetic Act to any person
687 who is authorized to sell, distribute, purchase, trade, or use
688 these drugs on or for humans.
- 689 4. A limited prescription drug veterinary wholesale
690 distributor that applies to the department for a new permit or
691 the renewal of a permit must submit a bond of \$20,000, or other
692 equivalent means of security acceptable to the department, such
693 as an irrevocable letter of credit or a deposit in a trust
694 account or financial institution, payable to the Florida Drug,
695 Device, and Cosmetic Trust Fund. The purpose of the bond is to
696 secure payment of any administrative penalties imposed by the

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697 department and any fees and costs incurred by the department
698 regarding that permit which are authorized under state law and
699 which the permittee fails to pay 30 days after the fine or costs
700 become final. The department may make a claim against such bond
701 or security until 1 year after the permittee's license ceases to
702 be valid or until 60 days after any administrative or legal
703 proceeding authorized in this part which involves the permittee
704 is concluded, including any appeal, whichever occurs later.

705 5. A limited prescription drug veterinary wholesale
706 distributor must maintain at all times a license or permit to
707 engage in the wholesale distribution of prescription drugs in
708 compliance with laws of the state in which it is a resident.

709 6. A limited prescription drug veterinary wholesale
710 distributor must comply with the requirements for wholesale
711 distributors under ss. 499.0121 and 499.01212, except that a
712 limited prescription drug veterinary wholesale distributor is
713 not required to provide a pedigree paper as required by s.
714 499.01212 upon the wholesale distribution of a prescription drug
715 to a veterinarian.

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

721 8. A limited prescription drug veterinary wholesale
722 distributor permit is not required for an intracompany sale or
723 transfer of a prescription drug from an out-of-state
724 establishment that is duly licensed to engage in the wholesale
725 distribution of prescription drugs in its state of residence to

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726 a licensed limited prescription drug veterinary wholesale
727 distributor in this state if both wholesale distributors conduct
728 wholesale distributions of prescription drugs under the same
729 business name. The recordkeeping requirements of ss. 499.0121(6)
730 and 499.01212 must be followed for this transaction.

731 (m) *Medical oxygen retail establishment permit.*—A medical
732 oxygen retail establishment permit is required for any person
733 that sells medical oxygen to patients only. The sale must be
734 based on an order from a practitioner authorized by law to
735 prescribe. The term does not include a pharmacy licensed under
736 chapter 465.

737 1. A medical oxygen retail establishment may not possess,
738 purchase, sell, or trade any prescription drug other than
739 medical oxygen.

740 2. A medical oxygen retail establishment may refill medical
741 oxygen for an individual patient based on an order from a
742 practitioner authorized by law to prescribe. A medical oxygen
743 retail establishment that refills medical oxygen must comply
744 with all appropriate state and federal good manufacturing
745 practices.

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

748 4. Prescription medical oxygen sold by a medical oxygen
749 retail establishment pursuant to a practitioner's order may not
750 be returned into the retail establishment's inventory.

751 (n) *Compressed medical gas wholesale distributor permit.*—A
752 compressed medical gas wholesale distributor is a wholesale
753 distributor that is limited to the wholesale distribution of
754 compressed medical gases to other than the consumer or patient.

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755 The compressed medical gas must be in the original sealed
756 container that was purchased by that wholesale distributor. A
757 compressed medical gas wholesale distributor may not possess or
758 engage in the wholesale distribution of any prescription drug
759 other than compressed medical gases. The department shall adopt
760 rules that govern the wholesale distribution of prescription
761 medical oxygen for emergency use. With respect to the emergency
762 use of prescription medical oxygen, those rules may not be
763 inconsistent with rules and regulations of federal agencies
764 unless the Legislature specifically directs otherwise.

765 (o) *Compressed medical gas manufacturer permit.*—A
766 compressed medical gas manufacturer permit is required for any
767 person that engages in the manufacture of compressed medical
768 gases or repackages compressed medical gases from one container
769 to another.

770 1. A compressed medical gas manufacturer may not
771 manufacture or possess any prescription drug other than
772 compressed medical gases.

773 2. A compressed medical gas manufacturer may engage in
774 wholesale distribution of compressed medical gases manufactured
775 at that establishment and must comply with all the provisions of
776 this part and the rules adopted under this part that apply to a
777 wholesale distributor.

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

780 (p) *Over-the-counter drug manufacturer permit.*—An over-the-
781 counter drug manufacturer permit is required for any person that
782 engages in the manufacture or repackaging of an over-the-counter
783 drug.

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

786 2. A pharmacy is exempt from obtaining an over-the-counter
787 drug manufacturer permit if it is operating in compliance with
788 pharmacy practice standards as defined in chapter 465 and the
789 rules adopted under that chapter.

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

792 (q) *Device manufacturer permit.*—A device manufacturer
793 permit is required for any person that engages in the
794 manufacture, repackaging, or assembly of medical devices for
795 human use in this state, except that a permit is not required if
796 the person is engaged only in manufacturing, repackaging, or
797 assembling a medical device pursuant to a practitioner's order
798 for a specific patient.

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

802 2. The department shall adopt rules related to storage,
803 handling, and recordkeeping requirements for manufacturers of
804 medical devices for human use.

805 (r) *Cosmetic manufacturer permit.*—A cosmetic manufacturer
806 permit is required for any person that manufactures or
807 repackages cosmetics in this state. A person that only labels or
808 changes the labeling of a cosmetic but does not open the
809 container sealed by the manufacturer of the product is exempt
810 from obtaining a permit under this paragraph.

811 (s) Third-party ~~Third party~~ *logistics provider permit.*—A
812 third-party ~~third party~~ logistics provider permit is required

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813 for any person that contracts with a prescription drug wholesale
814 distributor or prescription drug manufacturer to provide
815 warehousing, distribution, or other logistics services on behalf
816 of a manufacturer or wholesale distributor, but who does not
817 take title to the prescription drug or have responsibility to
818 direct the sale or disposition of the prescription drug. Each
819 third-party ~~third party~~ logistics provider permittee shall
820 comply with the requirements for wholesale distributors under
821 ss. 499.0121 and 499.01212, with the exception of those
822 wholesale distributions described in s. 499.01212(3)(a), and
823 other rules that the department requires.

824 (t) *Health care clinic establishment permit.*—Effective
825 January 1, 2009, a health care clinic establishment permit is
826 required for the purchase of a prescription drug by a place of
827 business at one general physical location owned and operated by
828 a legal business entity that has been issued a federal tax
829 identification number and through which qualified practitioners
830 practice their profession under state law ~~a professional~~
831 ~~corporation or professional limited liability company described~~
832 ~~in chapter 621, or a corporation that employs a veterinarian as~~
833 ~~a qualifying practitioner.~~ For the purpose of this paragraph,
834 the term "qualifying practitioner" means a licensed health care
835 practitioner defined in s. 456.001 or a veterinarian licensed
836 under chapter 474, who is authorized under the appropriate
837 practice act to prescribe and administer a prescription drug.

838 1. An establishment must provide, as part of the
839 application required under s. 499.012, designation of a
840 qualifying practitioner who will be responsible for complying
841 with all legal and regulatory requirements related to the

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842 purchase, recordkeeping, storage, and handling of the
843 prescription drugs. In addition, the designated qualifying
844 practitioner shall be the practitioner whose name, establishment
845 address, and license number is used on all distribution
846 documents for prescription drugs purchased or returned by the
847 health care clinic establishment. Upon initial appointment of a
848 qualifying practitioner, the qualifying practitioner and the
849 health care clinic establishment shall notify the department on
850 a form furnished by the department within 10 days after such
851 employment. In addition, the qualifying practitioner and health
852 care clinic establishment shall notify the department within 10
853 days after any subsequent change.

854 2. The health care clinic establishment must employ a
855 qualifying practitioner at each establishment.

856 3. In addition to the remedies and penalties provided in
857 this part, a violation of this chapter by the health care clinic
858 establishment or qualifying practitioner constitutes grounds for
859 discipline of the qualifying practitioner by the appropriate
860 regulatory board.

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

864 5. A health care clinic establishment permit is not a
865 pharmacy permit or otherwise subject to chapter 465. A health
866 care clinic establishment that meets the criteria of a modified
867 Class II institutional pharmacy under s. 465.019 is not eligible
868 to be permitted under this paragraph.

869 6. This paragraph does not prohibit a licensed ~~qualifying~~
870 practitioner whose professional license authorizes the

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871 practitioner to prescribe prescription drugs from purchasing
872 prescription drugs under his or her practice license.

873 7. This paragraph does not authorize the holder of this
874 permit to purchase or possess controlled substances listed in s.
875 893.03 or federal law.

876 8. Prescription drugs that may be distributed to the holder
877 of this permit are limited to those prescription drugs that can
878 be lawfully prescribed by the qualifying practitioner.

879 (u) Prescription drug manufacturer's distributor permit.—A
880 prescription drug manufacturer's distributor permit is required
881 for any person who engages in the wholesale distribution of
882 prescription drugs in or into this state of which a member of
883 the person's affiliated group is the manufacturer of the
884 prescription drug, unless the person is permitted as a
885 prescription drug wholesale distributor, an out-of-state
886 prescription drug wholesale distributor, or a third-party
887 logistics provider. A person permitted as a prescription drug
888 wholesale distributor, out-of-state prescription drug wholesale
889 distributor, or a third-party logistics provider may change to a
890 prescription drug manufacturer's distributor permit as provided
891 in s. 499.012(2). A prescription drug manufacturer's distributor
892 permittee shall distribute only prescription drugs manufactured
893 by members of its affiliated group and shall acquire title to
894 the prescription drugs before distributing them. Each
895 prescription drug manufacturer's distributor permittee or
896 applicant shall:

897 1. Identify, by name, address, and federal tax
898 identification number, all affiliated group members on a
899 document that is signed by a state-licensed certified public

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900 accountant who certifies that the applicant is a member of the
901 affiliated group and each member has been identified on the
902 document. This document must be submitted as a part of the
903 application for a prescription drug manufacturer's distributor
904 permit and within 30 days after any change in the membership of
905 the affiliated group; and

906 2. Comply with the requirements for wholesale distributors
907 under s. 499.0121

908
909 As used in this paragraph, the term "affiliated group" means an
910 affiliated group as defined in 26 U.S.C. s. 1504, as amended.

911 Section 5. Paragraph (d) of subsection (1) of section
912 499.012, Florida Statutes, is amended to read:

913 499.012 Permit application requirements.—

914 (1)

915 (d) A permit for a prescription drug manufacturer,
916 prescription drug repackager, prescription drug wholesale
917 distributor, limited prescription drug veterinary wholesale
918 distributor, ~~or~~ retail pharmacy drug wholesale distributor, or
919 prescription drug manufacturer's distributor may not be issued
920 to the address of a health care entity or to a pharmacy licensed
921 under chapter 465, except as provided in this paragraph. The
922 department may issue a prescription drug manufacturer permit to
923 an applicant at the same address as a licensed nuclear pharmacy,
924 which is a health care entity, for the purpose of manufacturing
925 prescription drugs used in positron emission tomography or other
926 radiopharmaceuticals, as listed in a rule adopted by the
927 department pursuant to this paragraph. The purpose of this
928 exemption is to assure availability of state-of-the-art

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929 pharmaceuticals that would pose a significant danger to the
930 public health if manufactured at a separate establishment
931 address from the nuclear pharmacy from which the prescription
932 drugs are dispensed. The department may also issue a retail
933 pharmacy drug wholesale distributor permit to the address of a
934 community pharmacy licensed under chapter 465 which does not
935 meet the definition of a closed pharmacy in s. 499.003.

936 Section 6. Paragraph (d) of subsection (4) and paragraph
937 (e) of subsection (6) of section 499.0121, Florida Statutes, are
938 amended to read:

939 499.0121 Storage and handling of prescription drugs;
940 recordkeeping.—The department shall adopt rules to implement
941 this section as necessary to protect the public health, safety,
942 and welfare. Such rules shall include, but not be limited to,
943 requirements for the storage and handling of prescription drugs
944 and for the establishment and maintenance of prescription drug
945 distribution records.

946 (4) EXAMINATION OF MATERIALS AND RECORDS.—

947 (d) Upon receipt, a wholesale distributor must review
948 records required under this section for the acquisition of
949 prescription drugs for accuracy and completeness, considering
950 the total facts and circumstances surrounding the transactions
951 and the wholesale distributors involved. This includes
952 authenticating each transaction listed on a pedigree paper,~~as~~
953 ~~defined in s. 499.003(36).~~

954 (6) RECORDKEEPING.—The department shall adopt rules that
955 require keeping such records of prescription drugs as are
956 necessary for the protection of the public health.

957 (e) When a pedigree paper is required by this part, a

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958 wholesale distributor must maintain pedigree papers separate and
959 distinct from other records required under this part ~~chapter~~.

960 Section 7. Paragraphs (a) and (b) of subsection (2) of
961 section 499.01211, Florida Statutes, are amended to read:

962 499.01211 Drug Wholesale Distributor Advisory Council.—

963 (2) The State Surgeon General, or his or her designee, and
964 the Secretary of Health Care Administration, or her or his
965 designee, shall be members of the council. The State Surgeon
966 General shall appoint nine additional members to the council who
967 shall be appointed to a term of 4 years each, as follows:

968 (a) Three different persons each of whom is employed by a
969 different prescription drug wholesale distributor licensed under
970 this part which operates nationally and is a primary wholesale
971 distributor, ~~as defined in s. 499.003(46)~~.

972 (b) One person employed by a prescription drug wholesale
973 distributor licensed under this part which is a secondary
974 wholesale distributor, ~~as defined in s. 499.003(51)~~.

975 Section 8. Section 499.01212, Florida Statutes, is amended
976 to read:

977 499.01212 Pedigree paper.—

978 (1) APPLICATION.—Each person who is engaged in the
979 wholesale distribution of a prescription drug must, prior to or
980 simultaneous with each wholesale distribution, provide a
981 pedigree paper to the person who receives the drug.

982 (2) FORMAT.—A pedigree paper must contain the following
983 information:

984 (a) For the wholesale distribution of a prescription drug
985 within the normal distribution chain:

986 1. The following statement: "This wholesale distributor

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987 purchased the specific unit of the prescription drug directly
988 from the manufacturer or manufacturer's distributor."

989 2. The manufacturer's national drug code identifier and the
990 name and address of the wholesale distributor and the purchaser
991 of the prescription drug.

992 3. The name of the prescription drug as it appears on the
993 label.

994 4. The quantity, dosage form, and strength of the
995 prescription drug.

996
997 The wholesale distributor must also maintain and make available
998 to the department, upon request, the point of origin of the
999 prescription drugs, including intracompany transfers, the date
1000 of the shipment from the manufacturer, manufacturer's
1001 distributor, or manufacturer's third-party logistics provider to
1002 the wholesale distributor, the lot numbers of such drugs, and
1003 the invoice numbers from the manufacturer or manufacturer's
1004 distributor.

1005 (b) For all other wholesale distributions of prescription
1006 drugs:

1007 1. The quantity, dosage form, and strength of the
1008 prescription drugs.

1009 2. The lot numbers of the prescription drugs.

1010 3. The name and address of each owner of the prescription
1011 drug and his or her signature.

1012 4. Shipping information, including the name and address of
1013 each person certifying delivery or receipt of the prescription
1014 drug.

1015 5. An invoice number, a shipping document number, or

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1016 another number uniquely identifying the transaction. When a
1017 manufacturer uses a manufacturer's distributor to sell the
1018 manufacturer's prescription drugs, the invoice number, shipping
1019 document number, or other number uniquely identifying the
1020 transaction between the manufacturer and manufacturer's
1021 distributor may be omitted from the pedigree paper.

1022 6. A certification that the recipient wholesale distributor
1023 has authenticated the pedigree papers.

1024 7. The unique serialization of the prescription drug, if
1025 the manufacturer or repackager has uniquely serialized the
1026 individual prescription drug unit.

1027 8. The name, address, telephone number, and, if available,
1028 e-mail contact information of each wholesale distributor,
1029 including each third-party logistics provider and manufacturer's
1030 distributor involved in the chain of the prescription drug's
1031 custody.

1032 (3) EXCEPTIONS.—A pedigree paper is not required for:

1033 (a) The wholesale distribution of a prescription drug by
1034 the manufacturer, by the manufacturer's distributor, or by a
1035 third-party ~~third-party~~ logistics provider performing a
1036 wholesale distribution of a prescription drug for a
1037 manufacturer.

1038 (b) The wholesale distribution of a prescription drug by a
1039 freight forwarder within the authority of a freight forwarder
1040 permit.

1041 (c) The wholesale distribution of a prescription drug by a
1042 limited prescription drug veterinary wholesale distributor to a
1043 veterinarian.

1044 (d) The wholesale distribution of a compressed medical gas.

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1045 (e) The wholesale distribution of a veterinary prescription
1046 drug.

1047 (f) A drop shipment, provided:

1048 1. The wholesale distributor delivers to the recipient of
1049 the prescription drug, within 14 days after the shipment
1050 notification from the manufacturer or manufacturer's
1051 distributor, an invoice and the following sworn statement: "This
1052 wholesale distributor purchased the specific unit of the
1053 prescription drug listed on the invoice directly from the
1054 manufacturer or manufacturer's distributor, and the specific
1055 unit of prescription drug was shipped by the manufacturer,
1056 manufacturer's distributor, or manufacturer's third-party
1057 logistics provider directly to a person authorized by law to
1058 administer or dispense the legend drug, as defined in s.
1059 465.003, Florida Statutes, or a member of an affiliated group,
1060 with the exception of a repackager." The invoice must contain a
1061 unique cross-reference to the shipping document sent by the
1062 manufacturer, manufacturer's distributor, or manufacturer's
1063 third-party logistics provider to the recipient of the
1064 prescription drug.

1065 2. The manufacturer or manufacturer's distributor of the
1066 prescription drug shipped directly to the recipient provides and
1067 the recipient of the prescription drug acquires, within 14 days
1068 after receipt of the prescription drug, a shipping document from
1069 the manufacturer, manufacturer's distributor, or manufacturer's
1070 third-party logistics provider which ~~that~~ contains, at a
1071 minimum:

1072 a. The name and address of the manufacturer or
1073 manufacturer's distributor, including the point of origin of the

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1074 shipment, and the names and addresses of the wholesale
1075 distributor and the purchaser.

1076 b. The name of the prescription drug as it appears on the
1077 label.

1078 c. The quantity, dosage form, and strength of the
1079 prescription drug.

1080 d. The date of the shipment from the manufacturer,
1081 manufacturer's distributor, or manufacturer's third-party
1082 logistics provider.

1083 3. The wholesale distributor maintains and makes available
1084 to the department, upon request, the lot number of such drug if
1085 not contained in the shipping document acquired by the
1086 recipient.

1087 4. The wholesale distributor that takes title to, but not
1088 possession of, the prescription drug is not a member of the
1089 affiliated group that receives the prescription drug directly
1090 from the manufacturer.

1091
1092 Failure of the manufacturer, manufacturer's distributor, or
1093 manufacturer's third-party logistics provider to provide, the
1094 recipient to acquire, or the wholesale distributor to deliver
1095 the documentation required under this paragraph shall constitute
1096 failure to acquire or deliver a pedigree paper under ss.

1097 499.005(28) and 499.0051. Forgery by the manufacturer,
1098 manufacturer's distributor, or manufacturer's third-party
1099 logistics provider, the recipient, or the wholesale distributor
1100 of the documentation required to be acquired or delivered under
1101 this paragraph shall constitute forgery of a pedigree paper
1102 under s. 499.0051.

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1103 (g) The wholesale distribution of a prescription drug by a
1104 warehouse within an affiliated group to a warehouse or retail
1105 pharmacy within its affiliated group, provided:

1106 1. Any affiliated group member that purchases or receives a
1107 prescription drug from outside the affiliated group must receive
1108 a pedigree paper if the prescription drug is distributed in or
1109 into this state and a pedigree paper is required under this
1110 section and must authenticate the documentation as required in
1111 s. 499.0121(4), regardless of whether the affiliated group
1112 member is directly subject to regulation under this part; and

1113 2. The affiliated group makes available, within 48 hours,
1114 to the department on request to one or more of its members all
1115 records related to the purchase or acquisition of prescription
1116 drugs by members of the affiliated group, regardless of the
1117 location where the records are stored, if the prescription drugs
1118 were distributed in or into this state.

1119 (h) The repackaging of prescription drugs by a repackager
1120 solely for distribution to its affiliated group members for the
1121 exclusive distribution to and among retail pharmacies that are
1122 members of the affiliated group to which the repackager is a
1123 member.

1124 1. The repackager must:

1125 a. For all repackaged prescription drugs distributed in or
1126 into this state, state in writing under oath with each
1127 distribution of a repackaged prescription drug to an affiliated
1128 group member warehouse or repackager: "All repackaged
1129 prescription drugs are purchased by the affiliated group
1130 directly from the manufacturer, manufacturer's distributor, or
1131 from a prescription drug wholesale distributor that purchased

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1132 the prescription drugs directly from the manufacturer or
1133 manufacturer's distributor."

1134 b. Purchase all prescription drugs it repackages:

1135 (I) Directly from the manufacturer or manufacturer's
1136 distributor; or

1137 (II) From a prescription drug wholesale distributor that
1138 purchased the prescription drugs directly from the manufacturer
1139 or manufacturer's distributor.

1140 c. Maintain records in accordance with this section to
1141 document that it purchased the prescription drugs directly from
1142 the manufacturer, manufacturer's distributor, or that its
1143 prescription drug wholesale supplier purchased the prescription
1144 drugs directly from the manufacturer or manufacturer's
1145 distributor.

1146 2. All members of the affiliated group must provide, within
1147 48 hours, to agents of the department on request to one or more
1148 of its members records of purchases by all members of the
1149 affiliated group of prescription drugs that have been
1150 repackaged, regardless of the location at which the records are
1151 stored or at which the repackager is located.

1152 Section 9. Subsection (1) of section 499.03, Florida
1153 Statutes, is amended to read:

1154 499.03 Possession of certain drugs without prescriptions
1155 unlawful; exemptions and exceptions.—

1156 (1) A person may not possess, or possess with intent to
1157 sell, dispense, or deliver, any habit-forming, toxic, harmful,
1158 or new drug ~~subject to s. 499.003(32),~~ or prescription drug ~~as~~
1159 ~~defined in s. 499.003(42),~~ unless the possession of the drug has
1160 been obtained by a valid prescription of a practitioner licensed

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1161 by law to prescribe the drug. However, this section does not
1162 apply to the delivery of such drugs to persons included in any
1163 of the classes named in this subsection, or to the agents or
1164 employees of such persons, for use in the usual course of their
1165 businesses or practices or in the performance of their official
1166 duties, as the case may be; nor does this section apply to the
1167 possession of such drugs by those persons or their agents or
1168 employees for such use:

1169 (a) A licensed pharmacist or any person under the licensed
1170 pharmacist's supervision while acting within the scope of the
1171 licensed pharmacist's practice;

1172 (b) A licensed practitioner authorized by law to prescribe
1173 prescription drugs or any person under the licensed
1174 practitioner's supervision while acting within the scope of the
1175 licensed practitioner's practice;

1176 (c) A qualified person who uses prescription drugs for
1177 lawful research, teaching, or testing, and not for resale;

1178 (d) A licensed hospital or other institution that procures
1179 such drugs for lawful administration or dispensing by
1180 practitioners;

1181 (e) An officer or employee of a federal, state, or local
1182 government; or

1183 (f) A person that holds a valid permit issued by the
1184 department pursuant to this part which authorizes that person to
1185 possess prescription drugs.

1186 Section 10. Subsection (2) of section 499.041, Florida
1187 Statutes, is amended, and subsection (11) is added to that
1188 section, to read:

1189 499.041 Schedule of fees for drug, device, and cosmetic

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1190 applications and permits, product registrations, and free-sale
1191 certificates.-

1192 (2) The department shall assess an applicant that is
1193 required to have a wholesaling permit an annual fee within the
1194 ranges established in this section for the specific type of
1195 wholesaling.

1196 (a) The fee for a prescription drug wholesale distributor
1197 permit may not be less than \$300 or more than \$800 annually.

1198 (b) The fee for a compressed medical gas wholesale
1199 distributor permit may not be less than \$200 or more than \$300
1200 annually.

1201 (c) The fee for an out-of-state prescription drug wholesale
1202 distributor permit may not be less than \$300 or more than \$800
1203 annually.

1204 (d) The fee for a nonresident prescription drug
1205 manufacturer permit may not be less than \$300 or more than \$500
1206 annually.

1207 (e) The fee for a retail pharmacy drug wholesale
1208 distributor permit may not be less than \$35 or more than \$50
1209 annually.

1210 (f) The fee for a freight forwarder permit may not be less
1211 than \$200 or more than \$300 annually.

1212 (g) The fee for a veterinary prescription drug wholesale
1213 distributor permit may not be less than \$300 or more than \$500
1214 annually.

1215 (h) The fee for a limited prescription drug veterinary
1216 wholesale distributor permit may not be less than \$300 or more
1217 than \$500 annually.

1218 (i) The fee for a third-party ~~third party~~ logistics

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1219 provider permit may not be less than \$200 or more than \$300
1220 annually.

1221 (j) The fee for a prescription drug manufacturer's
1222 distributor permit may not be less than \$500 or more than \$750
1223 annually.

1224 (11) The department shall retain a fee of \$150 or 50
1225 percent of the permit or certification fee, whichever is less,
1226 from each person applying for a permit or certification if the
1227 application is withdrawn or becomes void.

1228 Section 11. Paragraph (m) of subsection (1) of section
1229 499.05, Florida Statutes, is amended to read:

1230 499.05 Rules.—

1231 (1) The department shall adopt rules to implement and
1232 enforce this part with respect to:

1233 (m) The recordkeeping, storage, and handling with respect
1234 to each of the distributions of prescription drugs specified in
1235 s. 499.003(54) (a) - (d) ~~s. 499.003(53) (a) - (d)~~.

1236 Section 12. Subsection (1) of section 794.075, Florida
1237 Statutes, is amended to read:

1238 794.075 Sexual predators; erectile dysfunction drugs.—

1239 (1) A person may not possess a prescription drug, as
1240 defined in s. 499.003(43) ~~s. 499.003(42)~~, for the purpose of
1241 treating erectile dysfunction if the person is designated as a
1242 sexual predator under s. 775.21.

1243 Section 13. (1) Notwithstanding the purchase of a
1244 prescription drug from the manufacturer's distributor, a person
1245 who is required to comply with the pedigree paper provisions
1246 under s. 499.01212, Florida Statutes, may continue to use the
1247 statement provided in s. 499.01212, Florida Statutes (2008),

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1248 until September 30, 2010, for the wholesale distribution of a
1249 prescription drug that:

1250 (a) Is within the normal distribution chain as provided in
1251 s. 499.01212(2)(a), Florida Statutes;

1252 (b) Qualifies as a drop shipment as provided in s.
1253 499.01212(3)(f), Florida Statutes; or

1254 (c) Is a repackaged prescription drug as provided in s.
1255 499.01212(3)(h), Florida Statutes.

1256 (2) This section expires October 1, 2010.

1257 Section 14. The sum of \$111,477 is appropriated to the
1258 Department of Health from the Drugs, Devices, and Cosmetics
1259 Trust Fund for the 2009-2010 fiscal year, and 2.0 full-time
1260 equivalent positions along with an associated salary rate of
1261 61,674 are authorized for the purpose of implementing the
1262 provisions of this act.

1263 Section 15. This act shall take effect October 1, 2009.