

By the Committee on 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26 withdrawn or becomes void; amending ss. 499.05 and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 effective date.

31
32 Be It Enacted by the Legislature of the State of Florida:

33
34 Section 1. Paragraph (a) of subsection (1) of section
35 409.9201, Florida Statutes, is amended to read:

36 409.9201 Medicaid fraud.—

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

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

43
44 The value of individual items of the legend drugs or goods or
45 services involved in distinct transactions committed during a
46 single scheme or course of conduct, whether involving a single
47 person or several persons, may be aggregated when determining
48 the punishment for the offense.

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

51 465.0265 Centralized prescription filling.—

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

57 Section 3. Subsections (31) through (54) of section
58 499.003, Florida Statutes, are amended to read:

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59 499.003 Definitions of terms used in this part.—As used in
60 this part, the term:

61 (31) "Manufacturer" means:

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

64 (b) The holder or holders of a New Drug Application (NDA),
65 an Abbreviated New Drug Application (ANDA), a Biologics License
66 Application (BLA), or a New Animal Drug Application (NADA),
67 provided such application has become effective or is otherwise
68 approved consistent with s. 499.023.~~†~~

69 (c) A private label distributor for whom the private label
70 distributor's prescription drugs are originally manufactured and
71 labeled for the distributor and have not been repackaged;~~or the~~
72 ~~distribution point for the manufacturer, contract manufacturer,~~
73 ~~or private label distributor whether the establishment is a~~
74 ~~member of the manufacturer's affiliated group or is a contract~~
75 ~~distribution site.~~

76 (d) A person registered under the federal act as a
77 manufacturer who has entered into a written agreement with
78 another manufacturer that authorizes either manufacturer to
79 distribute a prescription drug, which is identified in the
80 agreement, as the manufacturer of that drug consistent with the
81 federal act.

82
83 The term excludes pharmacies that are operating in compliance
84 with pharmacy practice standards as defined in chapter 465 and
85 rules adopted under that chapter.

86 (32) "Manufacturer's distributor" means a person permitted
87 under this part as a prescription drug manufacturer's

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88 distributor.

89 (33)~~(32)~~ "New drug" means:

90 (a) Any drug the composition of which is such that the drug
91 is not generally recognized, among experts qualified by
92 scientific training and experience to evaluate the safety and
93 effectiveness of drugs, as safe and effective for use under the
94 conditions prescribed, recommended, or suggested in the labeling
95 of that drug; or

96 (b) Any drug the composition of which is such that the
97 drug, as a result of investigations to determine its safety and
98 effectiveness for use under certain conditions, has been
99 recognized for use under such conditions, but which drug has
100 not, other than in those investigations, been used to a material
101 extent or for a material time under such conditions.

102 (34)~~(33)~~ "Normal distribution chain" means a wholesale
103 distribution of a prescription drug in which the wholesale
104 distributor or its wholly owned subsidiary purchases ~~and~~
105 ~~receives~~ the specific unit of the prescription drug directly
106 from the manufacturer or manufacturer's distributor; receives
107 the specific unit of the prescription drug directly from the
108 manufacturer, manufacturer's distributor, or manufacturer's
109 third-party logistics provider; and distributes the prescription
110 drug directly, or through up to two intracompany transfers, to a
111 chain pharmacy warehouse or a person authorized by law to
112 purchase prescription drugs for the purpose of administering or
113 dispensing the drug, as defined in s. 465.003. For purposes of
114 this subsection, the term "intracompany" means any transaction
115 or transfer between any parent, division, or subsidiary wholly
116 owned by a corporate entity.

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117 (35)~~(34)~~ "Nursing home" means a facility licensed under
118 part II of chapter 400.

119 (36)~~(35)~~ "Official compendium" means the current edition of
120 the official United States Pharmacopoeia and National Formulary,
121 or any supplement thereto.

122 (37)~~(36)~~ "Pedigree paper" means a document in written or
123 electronic form approved by the department which contains
124 information required by s. 499.01212 regarding the sale and
125 distribution of any given prescription drug.

126 (38)~~(37)~~ "Permittee" means any person holding a permit
127 issued pursuant to s. 499.012.

128 (39)~~(38)~~ "Person" means any individual, child, joint
129 venture, syndicate, fiduciary, partnership, corporation,
130 division of a corporation, firm, trust, business trust, company,
131 estate, public or private institution, association,
132 organization, group, city, county, city and county, political
133 subdivision of this state, other governmental agency within this
134 state, and any representative, agent, or agency of any of the
135 foregoing, or any other group or combination of the foregoing.

136 (40)~~(39)~~ "Pharmacist" means a person licensed under chapter
137 465.

138 (41)~~(40)~~ "Pharmacy" means an entity licensed under chapter
139 465.

140 (42)~~(41)~~ "Prepackaged drug product" means a drug that
141 originally was in finished packaged form sealed by a
142 manufacturer and that is placed in a properly labeled container
143 by a pharmacy or practitioner authorized to dispense pursuant to
144 chapter 465 for the purpose of dispensing in the establishment
145 in which the prepackaging occurred.

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146 (43)~~(42)~~ "Prescription drug" means a prescription,
147 medicinal, or legend drug, including, but not limited to,
148 finished dosage forms or active ingredients subject to, defined
149 by, or described by s. 503(b) of the Federal Food, Drug, and
150 Cosmetic Act or s. 465.003(8), s. 499.007(13), or subsection
151 (11), subsection (48) ~~(47)~~, or subsection (53) ~~(52)~~.

152 (44)~~(43)~~ "Prescription drug label" means any display of
153 written, printed, or graphic matter upon the immediate container
154 of any prescription drug prior to its dispensing to an
155 individual patient pursuant to a prescription of a practitioner
156 authorized by law to prescribe.

157 (45)~~(44)~~ "Prescription label" means any display of written,
158 printed, or graphic matter upon the immediate container of any
159 prescription drug dispensed pursuant to a prescription of a
160 practitioner authorized by law to prescribe.

161 (46)~~(45)~~ "Prescription medical oxygen" means oxygen USP
162 which is a drug that can only be sold on the order or
163 prescription of a practitioner authorized by law to prescribe.
164 The label of prescription medical oxygen must comply with
165 current labeling requirements for oxygen under the Federal Food,
166 Drug, and Cosmetic Act.

167 (47)~~(46)~~ "Primary wholesale distributor" means any
168 wholesale distributor that:

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

172 (b)1. Directly purchased prescription drugs from not fewer
173 than 50 different prescription drug manufacturers in the
174 previous year; or

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

178 (c) For purposes of this subsection, "directly from
179 manufacturers" means:

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

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

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

188 b. The wholesale distributor discloses to the department
189 the names of all members of the affiliated group of which the
190 wholesale distributor is a member and the affiliated group
191 agrees in writing to provide records on prescription drug
192 purchases by the members of the affiliated group not later than
193 48 hours after the department requests access to such records,
194 regardless of the location where the records are stored.

195 (48)~~(47)~~ "Proprietary drug," or "OTC drug," means a patent
196 or over-the-counter drug in its unbroken, original package,
197 which drug is sold to the public by, or under the authority of,
198 the manufacturer or primary distributor thereof, is not
199 misbranded under the provisions of this part, and can be
200 purchased without a prescription.

201 (49)~~(48)~~ "Repackage" includes repacking or otherwise
202 changing the container, wrapper, or labeling to further the
203 distribution of the drug, device, or cosmetic.

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204 (50)~~(49)~~ "Repackager" means a person who repackages. The
205 term excludes pharmacies that are operating in compliance with
206 pharmacy practice standards as defined in chapter 465 and rules
207 adopted under that chapter.

208 (51)~~(50)~~ "Retail pharmacy" means a community pharmacy
209 licensed under chapter 465 that purchases prescription drugs at
210 fair market prices and provides prescription services to the
211 public.

212 (52)~~(51)~~ "Secondary wholesale distributor" means a
213 wholesale distributor that is not a primary wholesale
214 distributor.

215 (53)~~(52)~~ "Veterinary prescription drug" means a
216 prescription drug intended solely for veterinary use. The label
217 of the drug must bear the statement, "Caution: Federal law
218 restricts this drug to sale by or on the order of a licensed
219 veterinarian."

220 (54)~~(53)~~ "Wholesale distribution" means distribution of
221 prescription drugs to persons other than a consumer or patient,
222 but does not include:

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

226 1. The purchase or other acquisition by a hospital or other
227 health care entity that is a member of a group purchasing
228 organization of a prescription drug for its own use from the
229 group purchasing organization or from other hospitals or health
230 care entities that are members of that organization.

231 2. The sale, purchase, or trade of a prescription drug or
232 an offer to sell, purchase, or trade a prescription drug by a

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233 charitable organization described in s. 501(c)(3) of the
234 Internal Revenue Code of 1986, as amended and revised, to a
235 nonprofit affiliate of the organization to the extent otherwise
236 permitted by law.

237 3. The sale, purchase, or trade of a prescription drug or
238 an offer to sell, purchase, or trade a prescription drug among
239 hospitals or other health care entities that are under common
240 control. For purposes of this subparagraph, "common control"
241 means the power to direct or cause the direction of the
242 management and policies of a person or an organization, whether
243 by ownership of stock, by voting rights, by contract, or
244 otherwise.

245 4. The sale, purchase, trade, or other transfer of a
246 prescription drug from or for any federal, state, or local
247 government agency or any entity eligible to purchase
248 prescription drugs at public health services prices pursuant to
249 Pub. L. No. 102-585, s. 602 to a contract provider or its
250 subcontractor for eligible patients of the agency or entity
251 under the following conditions:

252 a. The agency or entity must obtain written authorization
253 for the sale, purchase, trade, or other transfer of a
254 prescription drug under this subparagraph from the State Surgeon
255 General or his or her designee.

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

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

260 d. A contract provider or subcontractor must maintain
261 separate and apart from other prescription drug inventory any

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262 prescription drugs of the agency or entity in its possession.

263 e. The contract provider and subcontractor must maintain
264 and produce immediately for inspection all records of movement
265 or transfer of all the prescription drugs belonging to the
266 agency or entity, including, but not limited to, the records of
267 receipt and disposition of prescription drugs. Each contractor
268 and subcontractor dispensing or administering these drugs must
269 maintain and produce records documenting the dispensing or
270 administration. Records that are required to be maintained
271 include, but are not limited to, a perpetual inventory itemizing
272 drugs received and drugs dispensed by prescription number or
273 administered by patient identifier, which must be submitted to
274 the agency or entity quarterly.

275 f. The contract provider or subcontractor may administer or
276 dispense the prescription drugs only to the eligible patients of
277 the agency or entity or must return the prescription drugs for
278 or to the agency or entity. The contract provider or
279 subcontractor must require proof from each person seeking to
280 fill a prescription or obtain treatment that the person is an
281 eligible patient of the agency or entity and must, at a minimum,
282 maintain a copy of this proof as part of the records of the
283 contractor or subcontractor required under sub-subparagraph e.

284 g. In addition to the departmental inspection authority set
285 forth in s. 499.051, the establishment of the contract provider
286 and subcontractor and all records pertaining to prescription
287 drugs subject to this subparagraph shall be subject to
288 inspection by the agency or entity. All records relating to
289 prescription drugs of a manufacturer under this subparagraph
290 shall be subject to audit by the manufacturer of those drugs,

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291 without identifying individual patient information.

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

295 1. The sale, purchase, or trade of a prescription drug
296 among federal, state, or local government health care entities
297 that are under common control and are authorized to purchase
298 such prescription drug.

299 2. The sale, purchase, or trade of a prescription drug or
300 an offer to sell, purchase, or trade a prescription drug for
301 emergency medical reasons. For purposes of this subparagraph,
302 the term "emergency medical reasons" includes transfers of
303 prescription drugs by a retail pharmacy to another retail
304 pharmacy to alleviate a temporary shortage.

305 3. The transfer of a prescription drug acquired by a
306 medical director on behalf of a licensed emergency medical
307 services provider to that emergency medical services provider
308 and its transport vehicles for use in accordance with the
309 provider's license under chapter 401.

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

312 5. The donation of a prescription drug by a health care
313 entity to a charitable organization that has been granted an
314 exemption under s. 501(c)(3) of the Internal Revenue Code of
315 1986, as amended, and that is authorized to possess prescription
316 drugs.

317 6. The transfer of a prescription drug by a person
318 authorized to purchase or receive prescription drugs to a person
319 licensed or permitted to handle reverse distributions or

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320 destruction under the laws of the jurisdiction in which the
321 person handling the reverse distribution or destruction receives
322 the drug.

323 7. The transfer of a prescription drug by a hospital or
324 other health care entity to a person licensed under this part to
325 repackage prescription drugs for the purpose of repackaging the
326 prescription drug for use by that hospital, or other health care
327 entity and other health care entities that are under common
328 control, if ownership of the prescription drugs remains with the
329 hospital or other health care entity at all times. In addition
330 to the recordkeeping requirements of s. 499.0121(6), the
331 hospital or health care entity that transfers prescription drugs
332 pursuant to this subparagraph must reconcile all drugs
333 transferred and returned and resolve any discrepancies in a
334 timely manner.

335 (c) The distribution of prescription drug samples by
336 manufacturers' representatives or distributors' representatives
337 conducted in accordance with s. 499.028.

338 (d) The sale, purchase, or trade of blood and blood
339 components intended for transfusion. As used in this paragraph,
340 the term "blood" means whole blood collected from a single donor
341 and processed for transfusion or further manufacturing, and the
342 term "blood components" means that part of the blood separated
343 by physical or mechanical means.

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

346 (f) The sale, purchase, or trade of a prescription drug
347 between pharmacies as a result of a sale, transfer, merger, or
348 consolidation of all or part of the business of the pharmacies

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349 from or with another pharmacy, whether accomplished as a
350 purchase and sale of stock or of business assets.

351 (55)~~(54)~~ "Wholesale distributor" means any person engaged
352 in wholesale distribution of prescription drugs in or into this
353 state, including, but not limited to, manufacturers;
354 repackagers; own-label distributors; jobbers; private-label
355 distributors; brokers; warehouses, including manufacturers' and
356 distributors' warehouses, chain drug warehouses, and wholesale
357 drug warehouses; independent wholesale drug traders; exporters;
358 retail pharmacies; and the agents thereof that conduct wholesale
359 distributions.

360 Section 4. Section 499.01, Florida Statutes, is amended to
361 read:

362 499.01 Permits.—

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

- 365 (a) A prescription drug manufacturer;
366 (b) A prescription drug repackager;
367 (c) A nonresident prescription drug manufacturer;
368 (d) A prescription drug wholesale distributor;
369 (e) An out-of-state prescription drug wholesale
370 distributor;
371 (f) A retail pharmacy drug wholesale distributor;
372 (g) A restricted prescription drug distributor;
373 (h) A complimentary drug distributor;
374 (i) A freight forwarder;
375 (j) A veterinary prescription drug retail establishment;
376 (k) A veterinary prescription drug wholesale distributor;
377 (l) A limited prescription drug veterinary wholesale

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378 distributor;

379 (m) A medical oxygen retail establishment;

380 (n) A compressed medical gas wholesale distributor;

381 (o) A compressed medical gas manufacturer;

382 (p) An over-the-counter drug manufacturer;

383 (q) A device manufacturer;

384 (r) A cosmetic manufacturer;

385 (s) A third-party ~~third party~~ logistics provider; ~~or~~

386 (t) A health care clinic establishment; or-

387 (u) A prescription drug manufacturer's distributor.

388 (2) The following permits are established:

389 (a) *Prescription drug manufacturer permit.*—A prescription
390 drug manufacturer permit is required for any person or entity
391 that is a manufacturer of ~~manufactures~~ a prescription drug and
392 manufactures or distributes its prescription drugs at or from an
393 establishment in this state.

394 1. A person that operates an establishment permitted as a
395 prescription drug manufacturer may engage in wholesale
396 distribution of prescription drugs manufactured at that
397 establishment and must comply with all the provisions of this
398 part and the rules adopted under this part that apply to a
399 wholesale distributor, except the provisions in s. 499.01212.

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

402 (b) *Prescription drug repackager permit.*—A prescription
403 drug repackager permit is required for any person that
404 repackages a prescription drug in this state.

405 1. A person that operates an establishment permitted as a
406 prescription drug repackager may engage in wholesale

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407 distribution of prescription drugs repackaged 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.

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

413 (c) *Nonresident prescription drug manufacturer permit.*—A
414 nonresident prescription drug manufacturer permit is required
415 for any person that is a manufacturer of prescription drugs, ~~or~~
416 ~~the distribution point for a manufacturer of prescription drugs~~
417 ~~unless permitted as a third party logistics provider, and~~
418 ~~located outside of this state, or that is an entity to whom an~~
419 ~~approved new drug application has been issued by the United~~
420 ~~States Food and Drug Administration, or the contracted~~
421 ~~manufacturer of the approved new drug application holder, and~~
422 ~~located outside the United States,~~ which engages in the
423 wholesale distribution in this state of the prescription drugs
424 it manufactures or is responsible for manufacturing. Each such
425 manufacturer ~~or entity~~ must be permitted by the department and
426 comply with all the provisions required of a wholesale
427 distributor under this part, except s. 499.01212.

428 1. A person that distributes prescription drugs for which
429 he or she is not the manufacturer ~~that it did not manufacture~~
430 must also obtain an out-of-state prescription drug wholesale
431 distributor permit, third-party logistics provider permit, or
432 prescription drug manufacturer's distributor permit, as
433 applicable, pursuant to this section to engage in the wholesale
434 distribution of the prescription drugs for which it is not the
435 manufacturer ~~manufactured by another person~~ and comply with the

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436 requirements of that permit for the wholesale distribution of
437 those prescription drugs for which the person is not the
438 manufacturer ~~an out-of-state prescription drug wholesale~~
439 ~~distributor.~~

440 2. Any such person must comply with the licensing or
441 permitting requirements of the jurisdiction in which the
442 establishment is located and the federal act, and any product
443 wholesaled into this state must comply with this part. If a
444 person intends to import prescription drugs from a foreign
445 country into this state, the nonresident prescription drug
446 manufacturer must provide to the department a list identifying
447 each prescription drug it intends to import and document
448 approval by the United States Food and Drug Administration for
449 such importation.

450 3. A nonresident prescription drug manufacturer permit,
451 prescription drug manufacturer's distributor permit, or third-
452 party logistics provider permit is not required for a
453 manufacturer to distribute, directly or through the
454 manufacturer's distributor or third-party logistics provider, a
455 prescription drug active pharmaceutical ingredient that it
456 manufactures to a prescription drug manufacturer permitted in
457 this state in limited quantities intended for research and
458 development and not for resale, or human use other than lawful
459 clinical trials and biostudies authorized and regulated by
460 federal law. A manufacturer, manufacturer's distributor, or
461 third-party logistics provider claiming to be exempt from the
462 permit requirements of this subparagraph and the prescription
463 drug manufacturer purchasing and receiving the active
464 pharmaceutical ingredient shall comply with the recordkeeping

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465 requirements of s. 499.0121(6), but not the requirements of s.
466 499.01212. The prescription drug manufacturer purchasing and
467 receiving the active pharmaceutical ingredient shall maintain on
468 file a record of the FDA registration number; the out-of-state
469 license, permit, or registration number; and, if available, a
470 copy of the most current FDA inspection report, for all
471 manufacturers, manufacturer's distributors, or third-party
472 logistics providers from whom they purchase and receive active
473 pharmaceutical ingredients under this section. The department
474 shall specify by rule the allowable number of transactions
475 within a given period of time and the amount of active
476 pharmaceutical ingredients that qualify as limited quantities
477 for purposes of this exemption. The failure to comply with the
478 requirements of this subparagraph, or rules adopted by the
479 department to administer this subparagraph, for the purchase of
480 prescription drug active pharmaceutical ingredients is a
481 violation of s. 499.005(14).

482 (d) *Prescription drug wholesale distributor permit.*—A
483 prescription drug wholesale distributor is a wholesale
484 distributor that may engage in the wholesale distribution of
485 prescription drugs. A prescription drug wholesale distributor
486 that applies to the department for a new permit or the renewal
487 of a permit must submit a bond of \$100,000, or other equivalent
488 means of security acceptable to the department, such as an
489 irrevocable letter of credit or a deposit in a trust account or
490 financial institution, payable to the Florida Drug, Device, and
491 Cosmetic Trust Fund. The purpose of the bond is to secure
492 payment of any administrative penalties imposed by the
493 department and any fees and costs incurred by the department

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494 regarding that permit which are authorized under state law and
495 which the permittee fails to pay 30 days after the fine or costs
496 become final. The department may make a claim against such bond
497 or security until 1 year after the permittee's license ceases to
498 be valid or until 60 days after any administrative or legal
499 proceeding authorized in this part which involves the permittee
500 is concluded, including any appeal, whichever occurs later. The
501 department may adopt rules for issuing a prescription drug
502 wholesale distributor-broker permit to a person who engages in
503 the wholesale distribution of prescription drugs and does not
504 take physical possession of any prescription drugs.

505 (e) *Out-of-state prescription drug wholesale distributor*
506 *permit.*—An out-of-state prescription drug wholesale distributor
507 is a wholesale distributor located outside this state which
508 engages in the wholesale distribution of prescription drugs into
509 this state and which must be permitted by the department and
510 comply with all the provisions required of a wholesale
511 distributor under this part. An out-of-state prescription drug
512 wholesale distributor that applies to the department for a new
513 permit or the renewal of a permit must submit a bond of
514 \$100,000, or other equivalent means of security acceptable to
515 the department, such as an irrevocable letter of credit or a
516 deposit in a trust account or financial institution, payable to
517 the Florida Drug, Device, and Cosmetic Trust Fund. The purpose
518 of the bond is to secure payment of any administrative penalties
519 imposed by the department and any fees and costs incurred by the
520 department regarding that permit which are authorized under
521 state law and which the permittee fails to pay 30 days after the
522 fine or costs become final. The department may make a claim

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523 against such bond or security until 1 year after the permittee's
524 license ceases to be valid or until 60 days after any
525 administrative or legal proceeding authorized in this part which
526 involves the permittee is concluded, including any appeal,
527 whichever occurs later.

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

532 2. An out-of-state prescription drug wholesale distributor
533 permit is not required for an intracompany sale or transfer of a
534 prescription drug from an out-of-state establishment that is
535 duly licensed as a prescription drug wholesale distributor, in
536 its state of residence, to a licensed prescription drug
537 wholesale distributor in this state, if both wholesale
538 distributors conduct wholesale distributions of prescription
539 drugs under the same business name. The recordkeeping
540 requirements of ss. 499.0121(6) and 499.01212 must be followed
541 for this transaction.

542 (f) *Retail pharmacy drug wholesale distributor permit.*—A
543 retail pharmacy drug wholesale distributor is a retail pharmacy
544 engaged in wholesale distribution of prescription drugs within
545 this state under the following conditions:

546 1. The pharmacy must obtain a retail pharmacy drug
547 wholesale distributor permit pursuant to this part and the rules
548 adopted under this part.

549 2. The wholesale distribution activity does not exceed 30
550 percent of the total annual purchases of prescription drugs. If
551 the wholesale distribution activity exceeds the 30-percent

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552 maximum, the pharmacy must obtain a prescription drug wholesale
553 distributor permit.

554 3. The transfer of prescription drugs that appear in any
555 schedule contained in chapter 893 is subject to chapter 893 and
556 the federal Comprehensive Drug Abuse Prevention and Control Act
557 of 1970.

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

562 5. All records of sales of prescription drugs subject to
563 this section must be maintained separate and distinct from other
564 records and comply with the recordkeeping requirements of this
565 part.

566 (g) *Restricted prescription drug distributor permit.*—A
567 restricted prescription drug distributor permit is required for
568 any person that engages in the distribution of a prescription
569 drug, which distribution is not considered "wholesale
570 distribution" under s. 499.003(54)(a) ~~s. 499.003(53)(a)~~.

571 1. A person who engages in the receipt or distribution of a
572 prescription drug in this state for the purpose of processing
573 its return or its destruction must obtain a permit as a
574 restricted prescription drug distributor if such person is not
575 the person initiating the return, the prescription drug
576 wholesale supplier of the person initiating the return, or the
577 manufacturer of the drug.

578 2. Storage, handling, and recordkeeping of these
579 distributions must comply with the requirements for wholesale
580 distributors under s. 499.0121, but not those set forth in s.

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581 499.01212.

582 3. A person who applies for a permit as a restricted
583 prescription drug distributor, or for the renewal of such a
584 permit, must provide to the department the information required
585 under s. 499.012.

586 4. The department may adopt rules regarding the
587 distribution of prescription drugs by hospitals, health care
588 entities, charitable organizations, or other persons not
589 involved in wholesale distribution, which rules are necessary
590 for the protection of the public health, safety, and welfare.

591 (h) *Complimentary drug distributor permit.*—A complimentary
592 drug distributor permit is required for any person that engages
593 in the distribution of a complimentary drug, subject to the
594 requirements of s. 499.028.

595 (i) *Freight forwarder permit.*—A freight forwarder permit is
596 required for any person that engages in the distribution of a
597 prescription drug as a freight forwarder unless the person is a
598 common carrier. The storage, handling, and recordkeeping of such
599 distributions must comply with the requirements for wholesale
600 distributors under s. 499.0121, but not those set forth in s.
601 499.01212. A freight forwarder must provide the source of the
602 prescription drugs with a validated airway bill, bill of lading,
603 or other appropriate documentation to evidence the exportation
604 of the product.

605 (j) *Veterinary prescription drug retail establishment*
606 *permit.*—A veterinary prescription drug retail establishment
607 permit is required for any person that sells veterinary
608 prescription drugs to the public but does not include a pharmacy
609 licensed under chapter 465.

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

613 2. Veterinary prescription drugs may not be sold in excess
614 of the amount clearly indicated on the order or beyond the date
615 indicated on the order.

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

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

620 5. A veterinary prescription drug retail establishment must
621 sell a veterinary prescription drug in the original, sealed
622 manufacturer's container with all labeling intact and legible.
623 The department may adopt by rule additional labeling
624 requirements for the sale of a veterinary prescription drug.

625 6. A veterinary prescription drug retail establishment must
626 comply with all of the wholesale distribution requirements of s.
627 499.0121.

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

631 (k) *Veterinary prescription drug wholesale distributor*
632 *permit.*—A veterinary prescription drug wholesale distributor
633 permit is required for any person that engages in the
634 distribution of veterinary prescription drugs in or into this
635 state. A veterinary prescription drug wholesale distributor that
636 also distributes prescription drugs subject to, defined by, or
637 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
638 Act which it did not manufacture must obtain a permit as a

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639 prescription drug wholesale distributor, an out-of-state
640 prescription drug wholesale distributor, or a limited
641 prescription drug veterinary wholesale distributor in lieu of
642 the veterinary prescription drug wholesale distributor permit. A
643 veterinary prescription drug wholesale distributor must comply
644 with the requirements for wholesale distributors under s.
645 499.0121, but not those set forth in s. 499.01212.

646 (1) *Limited prescription drug veterinary wholesale*
647 *distributor permit.*—Unless engaging in the activities of and
648 permitted as a prescription drug manufacturer, nonresident
649 prescription drug manufacturer, prescription drug wholesale
650 distributor, or out-of-state prescription drug wholesale
651 distributor, a limited prescription drug veterinary wholesale
652 distributor permit is required for any person that engages in
653 the distribution in or into this state of veterinary
654 prescription drugs and prescription drugs subject to, defined
655 by, or described by s. 503(b) of the Federal Food, Drug, and
656 Cosmetic Act under the following conditions:

- 657 1. The person is engaged in the business of wholesaling
658 prescription and veterinary prescription drugs to persons:
- 659 a. Licensed as veterinarians practicing on a full-time
660 basis;
 - 661 b. Regularly and lawfully engaged in instruction in
662 veterinary medicine;
 - 663 c. Regularly and lawfully engaged in law enforcement
664 activities;
 - 665 d. For use in research not involving clinical use; or
 - 666 e. For use in chemical analysis or physical testing or for
667 purposes of instruction in law enforcement activities, research,

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668 or testing.

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

673 3. The person does not distribute in any jurisdiction
674 prescription drugs subject to, defined by, or described by s.
675 503(b) of the Federal Food, Drug, and Cosmetic Act to any person
676 who is authorized to sell, distribute, purchase, trade, or use
677 these drugs on or for humans.

678 4. A limited prescription drug veterinary wholesale
679 distributor that applies to the department for a new permit or
680 the renewal of a permit must submit a bond of \$20,000, or other
681 equivalent means of security acceptable to the department, such
682 as an irrevocable letter of credit or a deposit in a trust
683 account or financial institution, payable to the Florida Drug,
684 Device, and Cosmetic Trust Fund. The purpose of the bond is to
685 secure payment of any administrative penalties imposed by the
686 department and any fees and costs incurred by the department
687 regarding that permit which are authorized under state law and
688 which the permittee fails to pay 30 days after the fine or costs
689 become final. The department may make a claim against such bond
690 or security until 1 year after the permittee's license ceases to
691 be valid or until 60 days after any administrative or legal
692 proceeding authorized in this part which involves the permittee
693 is concluded, including any appeal, whichever occurs later.

694 5. A limited prescription drug veterinary wholesale
695 distributor must maintain at all times a license or permit to
696 engage in the wholesale distribution of prescription drugs in

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697 compliance with laws of the state in which it is a resident.

698 6. A limited prescription drug veterinary wholesale
699 distributor must comply with the requirements for wholesale
700 distributors under ss. 499.0121 and 499.01212, except that a
701 limited prescription drug veterinary wholesale distributor is
702 not required to provide a pedigree paper as required by s.
703 499.01212 upon the wholesale distribution of a prescription drug
704 to a veterinarian.

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

710 8. A limited prescription drug veterinary wholesale
711 distributor permit is not required for an intracompany sale or
712 transfer of a prescription drug from an out-of-state
713 establishment that is duly licensed to engage in the wholesale
714 distribution of prescription drugs in its state of residence to
715 a licensed limited prescription drug veterinary wholesale
716 distributor in this state if both wholesale distributors conduct
717 wholesale distributions of prescription drugs under the same
718 business name. The recordkeeping requirements of ss. 499.0121(6)
719 and 499.01212 must be followed for this transaction.

720 (m) *Medical oxygen retail establishment permit.*—A medical
721 oxygen retail establishment permit is required for any person
722 that sells medical oxygen to patients only. The sale must be
723 based on an order from a practitioner authorized by law to
724 prescribe. The term does not include a pharmacy licensed under
725 chapter 465.

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726 1. A medical oxygen retail establishment may not possess,
727 purchase, sell, or trade any prescription drug other than
728 medical oxygen.

729 2. A medical oxygen retail establishment may refill medical
730 oxygen for an individual patient based on an order from a
731 practitioner authorized by law to prescribe. A medical oxygen
732 retail establishment that refills medical oxygen must comply
733 with all appropriate state and federal good manufacturing
734 practices.

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

737 4. Prescription medical oxygen sold by a medical oxygen
738 retail establishment pursuant to a practitioner's order may not
739 be returned into the retail establishment's inventory.

740 (n) *Compressed medical gas wholesale distributor permit.*—A
741 compressed medical gas wholesale distributor is a wholesale
742 distributor that is limited to the wholesale distribution of
743 compressed medical gases to other than the consumer or patient.
744 The compressed medical gas must be in the original sealed
745 container that was purchased by that wholesale distributor. A
746 compressed medical gas wholesale distributor may not possess or
747 engage in the wholesale distribution of any prescription drug
748 other than compressed medical gases. The department shall adopt
749 rules that govern the wholesale distribution of prescription
750 medical oxygen for emergency use. With respect to the emergency
751 use of prescription medical oxygen, those rules may not be
752 inconsistent with rules and regulations of federal agencies
753 unless the Legislature specifically directs otherwise.

754 (o) *Compressed medical gas manufacturer permit.*—A

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755 compressed medical gas manufacturer permit is required for any
756 person that engages in the manufacture of compressed medical
757 gases or repackages compressed medical gases from one container
758 to another.

759 1. A compressed medical gas manufacturer may not
760 manufacture or possess any prescription drug other than
761 compressed medical gases.

762 2. A compressed medical gas manufacturer may engage in
763 wholesale distribution of compressed medical gases manufactured
764 at that establishment and must comply with all the provisions of
765 this part and the rules adopted under this part that apply to a
766 wholesale distributor.

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

769 (p) *Over-the-counter drug manufacturer permit.*—An over-the-
770 counter drug manufacturer permit is required for any person that
771 engages in the manufacture or repackaging of an over-the-counter
772 drug.

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

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

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

781 (q) *Device manufacturer permit.*—A device manufacturer
782 permit is required for any person that engages in the
783 manufacture, repackaging, or assembly of medical devices for

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784 human use in this state, except that a permit is not required if
785 the person is engaged only in manufacturing, repackaging, or
786 assembling a medical device pursuant to a practitioner's order
787 for a specific patient.

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

791 2. The department shall adopt rules related to storage,
792 handling, and recordkeeping requirements for manufacturers of
793 medical devices for human use.

794 (r) *Cosmetic manufacturer permit.*—A cosmetic manufacturer
795 permit is required for any person that manufactures or
796 repackages cosmetics in this state. A person that only labels or
797 changes the labeling of a cosmetic but does not open the
798 container sealed by the manufacturer of the product is exempt
799 from obtaining a permit under this paragraph.

800 (s) Third-party ~~Third-party~~ *logistics provider permit.*—A
801 third-party ~~third-party~~ logistics provider permit is required
802 for any person that contracts with a prescription drug wholesale
803 distributor or prescription drug manufacturer to provide
804 warehousing, distribution, or other logistics services on behalf
805 of a manufacturer or wholesale distributor, but who does not
806 take title to the prescription drug or have responsibility to
807 direct the sale or disposition of the prescription drug. Each
808 third-party ~~third-party~~ logistics provider permittee shall
809 comply with the requirements for wholesale distributors under
810 ss. 499.0121 and 499.01212, with the exception of those
811 wholesale distributions described in s. 499.01212(3)(a), and
812 other rules that the department requires.

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

827 1. An establishment must provide, as part of the
828 application required under s. 499.012, designation of a
829 qualifying practitioner who will be responsible for complying
830 with all legal and regulatory requirements related to the
831 purchase, recordkeeping, storage, and handling of the
832 prescription drugs. In addition, the designated qualifying
833 practitioner shall be the practitioner whose name, establishment
834 address, and license number is used on all distribution
835 documents for prescription drugs purchased or returned by the
836 health care clinic establishment. Upon initial appointment of a
837 qualifying practitioner, the qualifying practitioner and the
838 health care clinic establishment shall notify the department on
839 a form furnished by the department within 10 days after such
840 employment. In addition, the qualifying practitioner and health
841 care clinic establishment shall notify the department within 10

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842 days after any subsequent change.

843 2. The health care clinic establishment must employ a
844 qualifying practitioner at each establishment.

845 3. In addition to the remedies and penalties provided in
846 this part, a violation of this chapter by the health care clinic
847 establishment or qualifying practitioner constitutes grounds for
848 discipline of the qualifying practitioner by the appropriate
849 regulatory board.

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

853 5. A health care clinic establishment permit is not a
854 pharmacy permit or otherwise subject to chapter 465. A health
855 care clinic establishment that meets the criteria of a modified
856 Class II institutional pharmacy under s. 465.019 is not eligible
857 to be permitted under this paragraph.

858 6. This paragraph does not prohibit a licensed ~~qualifying~~
859 practitioner whose professional license authorizes the
860 practitioner to prescribe prescription drugs from purchasing
861 prescription drugs under his or her practice license.

862 7. This paragraph does not authorize the holder of this
863 permit to purchase or possess controlled substances listed in s.
864 893.03 or federal law.

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

868 (u) Prescription drug manufacturer's distributor permit.—A
869 prescription drug manufacturer's distributor permit is required
870 for any person who engages in the wholesale distribution of

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871 prescription drugs in or into this state of which a member of
872 the person's affiliated group is the manufacturer of the
873 prescription drug, unless the person is permitted as a
874 prescription drug wholesale distributor, an out-of-state
875 prescription drug wholesale distributor, or a third-party
876 logistics provider. A person permitted as a prescription drug
877 wholesale distributor, out-of-state prescription drug wholesale
878 distributor, or a third-party logistics provider may change to a
879 prescription drug manufacturer's distributor permit as provided
880 in s. 499.012(2). A prescription drug manufacturer's distributor
881 permittee shall distribute only prescription drugs manufactured
882 by members of its affiliated group and shall acquire title to
883 the prescription drugs before distributing them. Each
884 prescription drug manufacturer's distributor permittee or
885 applicant shall:

886 1. Identify, by name, address, and federal tax
887 identification number, all affiliated group members on a
888 document that is signed by a state-licensed certified public
889 accountant who certifies that the applicant is a member of the
890 affiliated group and each member has been identified on the
891 document. This document must be submitted as a part of the
892 application for a prescription drug manufacturer's distributor
893 permit and within 30 days after any change in the membership of
894 the affiliated group; and

895 2. Comply with the requirements for wholesale distributors
896 under s. 499.0121

897
898 As used in this paragraph, the term "affiliated group" means an
899 affiliated group as defined in 26 U.S.C. s. 1504, as amended.

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900 Section 5. Paragraph (d) of subsection (1) of section
901 499.012, Florida Statutes, is amended to read:

902 499.012 Permit application requirements.—

903 (1)

904 (d) A permit for a prescription drug manufacturer,
905 prescription drug repackager, prescription drug wholesale
906 distributor, limited prescription drug veterinary wholesale
907 distributor, ~~or~~ retail pharmacy drug wholesale distributor, or
908 prescription drug manufacturer's distributor may not be issued
909 to the address of a health care entity or to a pharmacy licensed
910 under chapter 465, except as provided in this paragraph. The
911 department may issue a prescription drug manufacturer permit to
912 an applicant at the same address as a licensed nuclear pharmacy,
913 which is a health care entity, for the purpose of manufacturing
914 prescription drugs used in positron emission tomography or other
915 radiopharmaceuticals, as listed in a rule adopted by the
916 department pursuant to this paragraph. The purpose of this
917 exemption is to assure availability of state-of-the-art
918 pharmaceuticals that would pose a significant danger to the
919 public health if manufactured at a separate establishment
920 address from the nuclear pharmacy from which the prescription
921 drugs are dispensed. The department may also issue a retail
922 pharmacy drug wholesale distributor permit to the address of a
923 community pharmacy licensed under chapter 465 which does not
924 meet the definition of a closed pharmacy in s. 499.003.

925 Section 6. Paragraph (d) of subsection (4) and paragraph
926 (e) of subsection (6) of section 499.0121, Florida Statutes, are
927 amended to read:

928 499.0121 Storage and handling of prescription drugs;

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929 recordkeeping.—The department shall adopt rules to implement
930 this section as necessary to protect the public health, safety,
931 and welfare. Such rules shall include, but not be limited to,
932 requirements for the storage and handling of prescription drugs
933 and for the establishment and maintenance of prescription drug
934 distribution records.

935 (4) EXAMINATION OF MATERIALS AND RECORDS.—

936 (d) Upon receipt, a wholesale distributor must review
937 records required under this section for the acquisition of
938 prescription drugs for accuracy and completeness, considering
939 the total facts and circumstances surrounding the transactions
940 and the wholesale distributors involved. This includes
941 authenticating each transaction listed on a pedigree paper,~~as~~
942 ~~defined in s. 499.003(36).~~

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

946 (e) When a pedigree paper is required by this part, a
947 wholesale distributor must maintain pedigree papers separate and
948 distinct from other records required under this part ~~chapter~~.

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

951 499.01211 Drug Wholesale Distributor Advisory Council.—

952 (2) The State Surgeon General, or his or her designee, and
953 the Secretary of Health Care Administration, or her or his
954 designee, shall be members of the council. The State Surgeon
955 General shall appoint nine additional members to the council who
956 shall be appointed to a term of 4 years each, as follows:

957 (a) Three different persons each of whom is employed by a

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958 different prescription drug wholesale distributor licensed under
959 this part which operates nationally and is a primary wholesale
960 distributor, ~~as defined in s. 499.003(46)~~.

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

964 Section 8. Section 499.01212, Florida Statutes, is amended
965 to read:

966 499.01212 Pedigree paper.—

967 (1) APPLICATION.—Each person who is engaged in the
968 wholesale distribution of a prescription drug must, prior to or
969 simultaneous with each wholesale distribution, provide a
970 pedigree paper to the person who receives the drug.

971 (2) FORMAT.—A pedigree paper must contain the following
972 information:

973 (a) For the wholesale distribution of a prescription drug
974 within the normal distribution chain:

975 1. The following statement: "This wholesale distributor
976 purchased the specific unit of the prescription drug directly
977 from the manufacturer or manufacturer's distributor."

978 2. The manufacturer's national drug code identifier and the
979 name and address of the wholesale distributor and the purchaser
980 of the prescription drug.

981 3. The name of the prescription drug as it appears on the
982 label.

983 4. The quantity, dosage form, and strength of the
984 prescription drug.

985

986 The wholesale distributor must also maintain and make available

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987 to the department, upon request, the point of origin of the
988 prescription drugs, including intracompany transfers, the date
989 of the shipment from the manufacturer, manufacturer's
990 distributor, or manufacturer's third-party logistics provider to
991 the wholesale distributor, the lot numbers of such drugs, and
992 the invoice numbers from the manufacturer or manufacturer's
993 distributor.

994 (b) For all other wholesale distributions of prescription
995 drugs:

996 1. The quantity, dosage form, and strength of the
997 prescription drugs.

998 2. The lot numbers of the prescription drugs.

999 3. The name and address of each owner of the prescription
1000 drug and his or her signature.

1001 4. Shipping information, including the name and address of
1002 each person certifying delivery or receipt of the prescription
1003 drug.

1004 5. An invoice number, a shipping document number, or
1005 another number uniquely identifying the transaction. When a
1006 manufacturer uses a manufacturer's distributor to sell the
1007 manufacturer's prescription drugs, the invoice number, shipping
1008 document number, or other number uniquely identifying the
1009 transaction between the manufacturer and manufacturer's
1010 distributor may be omitted from the pedigree paper.

1011 6. A certification that the recipient wholesale distributor
1012 has authenticated the pedigree papers.

1013 7. The unique serialization of the prescription drug, if
1014 the manufacturer or repackager has uniquely serialized the
1015 individual prescription drug unit.

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1016 8. The name, address, telephone number, and, if available,
1017 e-mail contact information of each wholesale distributor,
1018 including each third-party logistics provider and manufacturer's
1019 distributor involved in the chain of the prescription drug's
1020 custody.

1021 (3) EXCEPTIONS.—A pedigree paper is not required for:

1022 (a) The wholesale distribution of a prescription drug by
1023 the manufacturer, by the manufacturer's distributor, or by a
1024 third-party ~~third-party~~ logistics provider performing a
1025 wholesale distribution of a prescription drug for a
1026 manufacturer.

1027 (b) The wholesale distribution of a prescription drug by a
1028 freight forwarder within the authority of a freight forwarder
1029 permit.

1030 (c) The wholesale distribution of a prescription drug by a
1031 limited prescription drug veterinary wholesale distributor to a
1032 veterinarian.

1033 (d) The wholesale distribution of a compressed medical gas.

1034 (e) The wholesale distribution of a veterinary prescription
1035 drug.

1036 (f) A drop shipment, provided:

1037 1. The wholesale distributor delivers to the recipient of
1038 the prescription drug, within 14 days after the shipment
1039 notification from the manufacturer or manufacturer's
1040 distributor, an invoice and the following sworn statement: "This
1041 wholesale distributor purchased the specific unit of the
1042 prescription drug listed on the invoice directly from the
1043 manufacturer or manufacturer's distributor, and the specific
1044 unit of prescription drug was shipped by the manufacturer,

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1045 manufacturer's distributor, or manufacturer's third-party
1046 logistics provider directly to a person authorized by law to
1047 administer or dispense the legend drug, as defined in s.
1048 465.003, Florida Statutes, or a member of an affiliated group,
1049 with the exception of a repackager." The invoice must contain a
1050 unique cross-reference to the shipping document sent by the
1051 manufacturer, manufacturer's distributor, or manufacturer's
1052 third-party logistics provider to the recipient of the
1053 prescription drug.

1054 2. The manufacturer or manufacturer's distributor of the
1055 prescription drug shipped directly to the recipient provides and
1056 the recipient of the prescription drug acquires, within 14 days
1057 after receipt of the prescription drug, a shipping document from
1058 the manufacturer, manufacturer's distributor, or manufacturer's
1059 third-party logistics provider which ~~that~~ contains, at a
1060 minimum:

1061 a. The name and address of the manufacturer or
1062 manufacturer's distributor, including the point of origin of the
1063 shipment, and the names and addresses of the wholesale
1064 distributor and the purchaser.

1065 b. The name of the prescription drug as it appears on the
1066 label.

1067 c. The quantity, dosage form, and strength of the
1068 prescription drug.

1069 d. The date of the shipment from the manufacturer,
1070 manufacturer's distributor, or manufacturer's third-party
1071 logistics provider.

1072 3. The wholesale distributor maintains and makes available
1073 to the department, upon request, the lot number of such drug if

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1074 not contained in the shipping document acquired by the
1075 recipient.

1076 4. The wholesale distributor that takes title to, but not
1077 possession of, the prescription drug is not a member of the
1078 affiliated group that receives the prescription drug directly
1079 from the manufacturer.

1080
1081 Failure of the manufacturer, manufacturer's distributor, or
1082 manufacturer's third-party logistics provider to provide, the
1083 recipient to acquire, or the wholesale distributor to deliver
1084 the documentation required under this paragraph shall constitute
1085 failure to acquire or deliver a pedigree paper under ss.
1086 499.005(28) and 499.0051. Forgery by the manufacturer,
1087 manufacturer's distributor, or manufacturer's third-party
1088 logistics provider, the recipient, or the wholesale distributor
1089 of the documentation required to be acquired or delivered under
1090 this paragraph shall constitute forgery of a pedigree paper
1091 under s. 499.0051.

1092 (g) The wholesale distribution of a prescription drug by a
1093 warehouse within an affiliated group to a warehouse or retail
1094 pharmacy within its affiliated group, provided:

1095 1. Any affiliated group member that purchases or receives a
1096 prescription drug from outside the affiliated group must receive
1097 a pedigree paper if the prescription drug is distributed in or
1098 into this state and a pedigree paper is required under this
1099 section and must authenticate the documentation as required in
1100 s. 499.0121(4), regardless of whether the affiliated group
1101 member is directly subject to regulation under this part; and

1102 2. The affiliated group makes available, within 48 hours,

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1103 to the department on request to one or more of its members all
1104 records related to the purchase or acquisition of prescription
1105 drugs by members of the affiliated group, regardless of the
1106 location where the records are stored, if the prescription drugs
1107 were distributed in or into this state.

1108 (h) The repackaging of prescription drugs by a repackager
1109 solely for distribution to its affiliated group members for the
1110 exclusive distribution to and among retail pharmacies that are
1111 members of the affiliated group to which the repackager is a
1112 member.

1113 1. The repackager must:

1114 a. For all repackaged prescription drugs distributed in or
1115 into this state, state in writing under oath with each
1116 distribution of a repackaged prescription drug to an affiliated
1117 group member warehouse or repackager: "All repackaged
1118 prescription drugs are purchased by the affiliated group
1119 directly from the manufacturer, manufacturer's distributor, or
1120 from a prescription drug wholesale distributor that purchased
1121 the prescription drugs directly from the manufacturer or
1122 manufacturer's distributor."

1123 b. Purchase all prescription drugs it repackages:

1124 (I) Directly from the manufacturer or manufacturer's
1125 distributor; or

1126 (II) From a prescription drug wholesale distributor that
1127 purchased the prescription drugs directly from the manufacturer
1128 or manufacturer's distributor.

1129 c. Maintain records in accordance with this section to
1130 document that it purchased the prescription drugs directly from
1131 the manufacturer, manufacturer's distributor, or that its

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1132 prescription drug wholesale supplier purchased the prescription
1133 drugs directly from the manufacturer or manufacturer's
1134 distributor.

1135 2. All members of the affiliated group must provide, within
1136 48 hours, to agents of the department on request to one or more
1137 of its members records of purchases by all members of the
1138 affiliated group of prescription drugs that have been
1139 repackaged, regardless of the location at which the records are
1140 stored or at which the repackager is located.

1141 Section 9. Subsection (1) of section 499.03, Florida
1142 Statutes, is amended to read:

1143 499.03 Possession of certain drugs without prescriptions
1144 unlawful; exemptions and exceptions.—

1145 (1) A person may not possess, or possess with intent to
1146 sell, dispense, or deliver, any habit-forming, toxic, harmful,
1147 or new drug ~~subject to s. 499.003(32),~~ or prescription drug ~~as~~
1148 ~~defined in s. 499.003(42),~~ unless the possession of the drug has
1149 been obtained by a valid prescription of a practitioner licensed
1150 by law to prescribe the drug. However, this section does not
1151 apply to the delivery of such drugs to persons included in any
1152 of the classes named in this subsection, or to the agents or
1153 employees of such persons, for use in the usual course of their
1154 businesses or practices or in the performance of their official
1155 duties, as the case may be; nor does this section apply to the
1156 possession of such drugs by those persons or their agents or
1157 employees for such use:

1158 (a) A licensed pharmacist or any person under the licensed
1159 pharmacist's supervision while acting within the scope of the
1160 licensed pharmacist's practice;

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1161 (b) A licensed practitioner authorized by law to prescribe
1162 prescription drugs or any person under the licensed
1163 practitioner's supervision while acting within the scope of the
1164 licensed practitioner's practice;

1165 (c) A qualified person who uses prescription drugs for
1166 lawful research, teaching, or testing, and not for resale;

1167 (d) A licensed hospital or other institution that procures
1168 such drugs for lawful administration or dispensing by
1169 practitioners;

1170 (e) An officer or employee of a federal, state, or local
1171 government; or

1172 (f) A person that holds a valid permit issued by the
1173 department pursuant to this part which authorizes that person to
1174 possess prescription drugs.

1175 Section 10. Subsection (2) of section 499.041, Florida
1176 Statutes, is amended, and subsection (11) is added to that
1177 section, to read:

1178 499.041 Schedule of fees for drug, device, and cosmetic
1179 applications and permits, product registrations, and free-sale
1180 certificates.—

1181 (2) The department shall assess an applicant that is
1182 required to have a wholesaling permit an annual fee within the
1183 ranges established in this section for the specific type of
1184 wholesaling.

1185 (a) The fee for a prescription drug wholesale distributor
1186 permit may not be less than \$300 or more than \$800 annually.

1187 (b) The fee for a compressed medical gas wholesale
1188 distributor permit may not be less than \$200 or more than \$300
1189 annually.

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1190 (c) The fee for an out-of-state prescription drug wholesale
1191 distributor permit may not be less than \$300 or more than \$800
1192 annually.

1193 (d) The fee for a nonresident prescription drug
1194 manufacturer permit may not be less than \$300 or more than \$500
1195 annually.

1196 (e) The fee for a retail pharmacy drug wholesale
1197 distributor permit may not be less than \$35 or more than \$50
1198 annually.

1199 (f) The fee for a freight forwarder permit may not be less
1200 than \$200 or more than \$300 annually.

1201 (g) The fee for a veterinary prescription drug wholesale
1202 distributor permit may not be less than \$300 or more than \$500
1203 annually.

1204 (h) The fee for a limited prescription drug veterinary
1205 wholesale distributor permit may not be less than \$300 or more
1206 than \$500 annually.

1207 (i) The fee for a third-party ~~third-party~~ logistics
1208 provider permit may not be less than \$200 or more than \$300
1209 annually.

1210 (j) The fee for a prescription drug manufacturer's
1211 distributor permit may not be less than \$500 or more than \$750
1212 annually.

1213 (11) The department shall retain a fee of \$150 or 50
1214 percent of the permit or certification fee, whichever is less,
1215 from each person applying for a permit or certification if the
1216 application is withdrawn or becomes void.

1217 Section 11. Paragraph (m) of subsection (1) of section
1218 499.05, Florida Statutes, is amended to read:

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1219 499.05 Rules.—

1220 (1) The department shall adopt rules to implement and
1221 enforce this part with respect to:

1222 (m) The recordkeeping, storage, and handling with respect
1223 to each of the distributions of prescription drugs specified in
1224 s. 499.003(54)(a)-(d) ~~s. 499.003(53)(a)-(d)~~.

1225 Section 12. Subsection (1) of section 794.075, Florida
1226 Statutes, is amended to read:

1227 794.075 Sexual predators; erectile dysfunction drugs.—

1228 (1) A person may not possess a prescription drug, as
1229 defined in s. 499.003(43) ~~s. 499.003(42)~~, for the purpose of
1230 treating erectile dysfunction if the person is designated as a
1231 sexual predator under s. 775.21.

1232 Section 13. (1) Notwithstanding the purchase of a
1233 prescription drug from the manufacturer's distributor, a person
1234 who is required to comply with the pedigree paper provisions
1235 under s. 499.01212, Florida Statutes, may continue to use the
1236 statement provided in s. 499.01212, Florida Statutes (2008),
1237 until September 30, 2010, for the wholesale distribution of a
1238 prescription drug that:

1239 (a) Is within the normal distribution chain as provided in
1240 s. 499.01212(2)(a), Florida Statutes;

1241 (b) Qualifies as a drop shipment as provided in s.
1242 499.01212(3)(f), Florida Statutes; or

1243 (c) Is a repackaged prescription drug as provided in s.
1244 499.01212(3)(h), Florida Statutes.

1245 (2) This section expires October 1, 2010.

1246 Section 14. This act shall take effect October 1, 2009.