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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/25/2009	.	
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The Committee on Health Regulation (Jones) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

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

409.9201 Medicaid fraud.—

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

(a) "Prescription drug" means any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined by, or described by s. 503(b) of the Federal



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12 Food, Drug, and Cosmetic Act or by s. 465.003(8), s. 499.003(46)
13 or (53) ~~s. 499.003(45) or (52)~~, or s. 499.007(13).

14
15 The value of individual items of the legend drugs or goods or
16 services involved in distinct transactions committed during a
17 single scheme or course of conduct, whether involving a single
18 person or several persons, may be aggregated when determining
19 the punishment for the offense.

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

22 465.0265 Centralized prescription filling.-

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

28 Section 3. Subsections (31) through (54) of section
29 499.003, Florida Statutes, are amended to read:

30 499.003 Definitions of terms used in this part.-As used in
31 this part, the term:

32 (31) "Manufacturer" means:

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

35 (b) The holder or holders of a New Drug Application (NDA),
36 an Abbreviated New Drug Application (ANDA), a Biologics License
37 Application (BLA), or a New Animal Drug Application (NADA),
38 provided such application has become effective or is otherwise
39 approved consistent with s. 499.023.†

40 (c) A private label distributor for whom the private label



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41 distributor's prescription drugs are originally manufactured and
42 labeled for the distributor and have not been repackaged; ~~or the~~
43 ~~distribution point for the manufacturer, contract manufacturer,~~
44 ~~or private label distributor whether the establishment is a~~
45 ~~member of the manufacturer's affiliated group or is a contract~~
46 ~~distribution site.~~

47 (d) A person registered under the federal act as a
48 manufacturer who has entered into a written agreement with
49 another manufacturer that authorizes either manufacturer to
50 distribute a prescription drug, which is identified in the
51 agreement, as the manufacturer of that drug consistent with the
52 federal act.

53
54 The term excludes pharmacies that are operating in compliance
55 with pharmacy practice standards as defined in chapter 465 and
56 rules adopted under that chapter.

57 (32) "Manufacturer's distributor" means a person permitted
58 under this part as a prescription drug manufacturer's
59 distributor.

60 (33) ~~(32)~~ "New drug" means:

61 (a) Any drug the composition of which is such that the drug
62 is not generally recognized, among experts qualified by
63 scientific training and experience to evaluate the safety and
64 effectiveness of drugs, as safe and effective for use under the
65 conditions prescribed, recommended, or suggested in the labeling
66 of that drug; or

67 (b) Any drug the composition of which is such that the
68 drug, as a result of investigations to determine its safety and
69 effectiveness for use under certain conditions, has been



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70 recognized for use under such conditions, but which drug has
71 not, other than in those investigations, been used to a material
72 extent or for a material time under such conditions.

73 (34)~~(33)~~ "Normal distribution chain" means a wholesale
74 distribution of a prescription drug in which the wholesale
75 distributor or its wholly owned subsidiary purchases ~~and~~
76 ~~receives~~ the specific unit of the prescription drug directly
77 from the manufacturer or manufacturer's distributor; receives
78 the specific unit of the prescription drug directly from the
79 manufacturer, manufacturer's distributor, or manufacturer's
80 third-party logistics provider; and distributes the prescription
81 drug directly, or through up to two intracompany transfers, to a
82 chain pharmacy warehouse or a person authorized by law to
83 purchase prescription drugs for the purpose of administering or
84 dispensing the drug, as defined in s. 465.003. For purposes of
85 this subsection, the term "intracompany" means any transaction
86 or transfer between any parent, division, or subsidiary wholly
87 owned by a corporate entity.

88 (35)~~(34)~~ "Nursing home" means a facility licensed under
89 part II of chapter 400.

90 (36)~~(35)~~ "Official compendium" means the current edition of
91 the official United States Pharmacopoeia and National Formulary,
92 or any supplement thereto.

93 (37)~~(36)~~ "Pedigree paper" means a document in written or
94 electronic form approved by the department which contains
95 information required by s. 499.01212 regarding the sale and
96 distribution of any given prescription drug.

97 (38)~~(37)~~ "Permittee" means any person holding a permit
98 issued pursuant to s. 499.012.



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99 ~~(39)~~~~(38)~~ "Person" means any individual, child, joint
100 venture, syndicate, fiduciary, partnership, corporation,
101 division of a corporation, firm, trust, business trust, company,
102 estate, public or private institution, association,
103 organization, group, city, county, city and county, political
104 subdivision of this state, other governmental agency within this
105 state, and any representative, agent, or agency of any of the
106 foregoing, or any other group or combination of the foregoing.

107 ~~(40)~~~~(39)~~ "Pharmacist" means a person licensed under chapter
108 465.

109 ~~(41)~~~~(40)~~ "Pharmacy" means an entity licensed under chapter
110 465.

111 ~~(42)~~~~(41)~~ "Prepackaged drug product" means a drug that
112 originally was in finished packaged form sealed by a
113 manufacturer and that is placed in a properly labeled container
114 by a pharmacy or practitioner authorized to dispense pursuant to
115 chapter 465 for the purpose of dispensing in the establishment
116 in which the prepackaging occurred.

117 ~~(43)~~~~(42)~~ "Prescription drug" means a prescription,
118 medicinal, or legend drug, including, but not limited to,
119 finished dosage forms or active ingredients subject to, defined
120 by, or described by s. 503(b) of the Federal Food, Drug, and
121 Cosmetic Act or s. 465.003(8), s. 499.007(13), or subsection
122 (11), subsection ~~(48)~~ ~~(47)~~, or subsection ~~(53)~~ ~~(52)~~.

123 ~~(44)~~~~(43)~~ "Prescription drug label" means any display of
124 written, printed, or graphic matter upon the immediate container
125 of any prescription drug prior to its dispensing to an
126 individual patient pursuant to a prescription of a practitioner
127 authorized by law to prescribe.



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128 ~~(45)-(44)~~ "Prescription label" means any display of written,
129 printed, or graphic matter upon the immediate container of any
130 prescription drug dispensed pursuant to a prescription of a
131 practitioner authorized by law to prescribe.

132 ~~(46)-(45)~~ "Prescription medical oxygen" means oxygen USP
133 which is a drug that can only be sold on the order or
134 prescription of a practitioner authorized by law to prescribe.
135 The label of prescription medical oxygen must comply with
136 current labeling requirements for oxygen under the Federal Food,
137 Drug, and Cosmetic Act.

138 ~~(47)-(46)~~ "Primary wholesale distributor" means any
139 wholesale distributor that:

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

143 (b)1. Directly purchased prescription drugs from not fewer
144 than 50 different prescription drug manufacturers in the
145 previous year; or

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

149 (c) For purposes of this subsection, "directly from
150 manufacturers" means:

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

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

156 a. The affiliated group purchases 90 percent or more of the



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157 total dollar volume of its purchases of prescription drugs from
158 the manufacturer in the previous year; and

159 b. The wholesale distributor discloses to the department
160 the names of all members of the affiliated group of which the
161 wholesale distributor is a member and the affiliated group
162 agrees in writing to provide records on prescription drug
163 purchases by the members of the affiliated group not later than
164 48 hours after the department requests access to such records,
165 regardless of the location where the records are stored.

166 ~~(48)~~~~(47)~~ "Proprietary drug," or "OTC drug," means a patent
167 or over-the-counter drug in its unbroken, original package,
168 which drug is sold to the public by, or under the authority of,
169 the manufacturer or primary distributor thereof, is not
170 misbranded under the provisions of this part, and can be
171 purchased without a prescription.

172 ~~(49)~~~~(48)~~ "Repackage" includes repacking or otherwise
173 changing the container, wrapper, or labeling to further the
174 distribution of the drug, device, or cosmetic.

175 ~~(50)~~~~(49)~~ "Repackager" means a person who repackages. The
176 term excludes pharmacies that are operating in compliance with
177 pharmacy practice standards as defined in chapter 465 and rules
178 adopted under that chapter.

179 ~~(51)~~~~(50)~~ "Retail pharmacy" means a community pharmacy
180 licensed under chapter 465 that purchases prescription drugs at
181 fair market prices and provides prescription services to the
182 public.

183 ~~(52)~~~~(51)~~ "Secondary wholesale distributor" means a
184 wholesale distributor that is not a primary wholesale
185 distributor.



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186 ~~(53)(52)~~ "Veterinary prescription drug" means a
187 prescription drug intended solely for veterinary use. The label
188 of the drug must bear the statement, "Caution: Federal law
189 restricts this drug to sale by or on the order of a licensed
190 veterinarian."

191 ~~(54)(53)~~ "Wholesale distribution" means distribution of
192 prescription drugs to persons other than a consumer or patient,
193 but does not include:

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

197 1. The purchase or other acquisition by a hospital or other
198 health care entity that is a member of a group purchasing
199 organization of a prescription drug for its own use from the
200 group purchasing organization or from other hospitals or health
201 care entities that are members of that organization.

202 2. The sale, purchase, or trade of a prescription drug or
203 an offer to sell, purchase, or trade a prescription drug by a
204 charitable organization described in s. 501(c)(3) of the
205 Internal Revenue Code of 1986, as amended and revised, to a
206 nonprofit affiliate of the organization to the extent otherwise
207 permitted by law.

208 3. The sale, purchase, or trade of a prescription drug or
209 an offer to sell, purchase, or trade a prescription drug among
210 hospitals or other health care entities that are under common
211 control. For purposes of this subparagraph, "common control"
212 means the power to direct or cause the direction of the
213 management and policies of a person or an organization, whether
214 by ownership of stock, by voting rights, by contract, or



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215 otherwise.

216 4. The sale, purchase, trade, or other transfer of a
217 prescription drug from or for any federal, state, or local
218 government agency or any entity eligible to purchase
219 prescription drugs at public health services prices pursuant to
220 Pub. L. No. 102-585, s. 602 to a contract provider or its
221 subcontractor for eligible patients of the agency or entity
222 under the following conditions:

223 a. The agency or entity must obtain written authorization
224 for the sale, purchase, trade, or other transfer of a
225 prescription drug under this subparagraph from the State Surgeon
226 General or his or her designee.

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

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

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

234 e. The contract provider and subcontractor must maintain
235 and produce immediately for inspection all records of movement
236 or transfer of all the prescription drugs belonging to the
237 agency or entity, including, but not limited to, the records of
238 receipt and disposition of prescription drugs. Each contractor
239 and subcontractor dispensing or administering these drugs must
240 maintain and produce records documenting the dispensing or
241 administration. Records that are required to be maintained
242 include, but are not limited to, a perpetual inventory itemizing
243 drugs received and drugs dispensed by prescription number or



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244 administered by patient identifier, which must be submitted to
245 the agency or entity quarterly.

246 f. The contract provider or subcontractor may administer or
247 dispense the prescription drugs only to the eligible patients of
248 the agency or entity or must return the prescription drugs for
249 or to the agency or entity. The contract provider or
250 subcontractor must require proof from each person seeking to
251 fill a prescription or obtain treatment that the person is an
252 eligible patient of the agency or entity and must, at a minimum,
253 maintain a copy of this proof as part of the records of the
254 contractor or subcontractor required under sub-subparagraph e.

255 g. In addition to the departmental inspection authority set
256 forth in s. 499.051, the establishment of the contract provider
257 and subcontractor and all records pertaining to prescription
258 drugs subject to this subparagraph shall be subject to
259 inspection by the agency or entity. All records relating to
260 prescription drugs of a manufacturer under this subparagraph
261 shall be subject to audit by the manufacturer of those drugs,
262 without identifying individual patient information.

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

266 1. The sale, purchase, or trade of a prescription drug
267 among federal, state, or local government health care entities
268 that are under common control and are authorized to purchase
269 such prescription drug.

270 2. The sale, purchase, or trade of a prescription drug or
271 an offer to sell, purchase, or trade a prescription drug for
272 emergency medical reasons. For purposes of this subparagraph,



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273 the term "emergency medical reasons" includes transfers of
274 prescription drugs by a retail pharmacy to another retail
275 pharmacy to alleviate a temporary shortage.

276 3. The transfer of a prescription drug acquired by a
277 medical director on behalf of a licensed emergency medical
278 services provider to that emergency medical services provider
279 and its transport vehicles for use in accordance with the
280 provider's license under chapter 401.

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

283 5. The donation of a prescription drug by a health care
284 entity to a charitable organization that has been granted an
285 exemption under s. 501(c)(3) of the Internal Revenue Code of
286 1986, as amended, and that is authorized to possess prescription
287 drugs.

288 6. The transfer of a prescription drug by a person
289 authorized to purchase or receive prescription drugs to a person
290 licensed or permitted to handle reverse distributions or
291 destruction under the laws of the jurisdiction in which the
292 person handling the reverse distribution or destruction receives
293 the drug.

294 7. The transfer of a prescription drug by a hospital or
295 other health care entity to a person licensed under this part to
296 repackage prescription drugs for the purpose of repackaging the
297 prescription drug for use by that hospital, or other health care
298 entity and other health care entities that are under common
299 control, if ownership of the prescription drugs remains with the
300 hospital or other health care entity at all times. In addition
301 to the recordkeeping requirements of s. 499.0121(6), the



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302 hospital or health care entity that transfers prescription drugs
303 pursuant to this subparagraph must reconcile all drugs
304 transferred and returned and resolve any discrepancies in a
305 timely manner.

306 (c) The distribution of prescription drug samples by
307 manufacturers' representatives or distributors' representatives
308 conducted in accordance with s. 499.028.

309 (d) The sale, purchase, or trade of blood and blood
310 components intended for transfusion. As used in this paragraph,
311 the term "blood" means whole blood collected from a single donor
312 and processed for transfusion or further manufacturing, and the
313 term "blood components" means that part of the blood separated
314 by physical or mechanical means.

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

317 (f) The sale, purchase, or trade of a prescription drug
318 between pharmacies as a result of a sale, transfer, merger, or
319 consolidation of all or part of the business of the pharmacies
320 from or with another pharmacy, whether accomplished as a
321 purchase and sale of stock or of business assets.

322 ~~(55)-(54)~~ "Wholesale distributor" means any person engaged
323 in wholesale distribution of prescription drugs in or into this
324 state, including, but not limited to, manufacturers;
325 repackagers; own-label distributors; jobbers; private-label
326 distributors; brokers; warehouses, including manufacturers' and
327 distributors' warehouses, chain drug warehouses, and wholesale
328 drug warehouses; independent wholesale drug traders; exporters;
329 retail pharmacies; and the agents thereof that conduct wholesale
330 distributions.



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331 Section 4. Section 499.01, Florida Statutes, is amended to
332 read:

333 499.01 Permits.—

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

336 (a) A prescription drug manufacturer;

337 (b) A prescription drug repackager;

338 (c) A nonresident prescription drug manufacturer;

339 (d) A prescription drug wholesale distributor;

340 (e) An out-of-state prescription drug wholesale
341 distributor;

342 (f) A retail pharmacy drug wholesale distributor;

343 (g) A restricted prescription drug distributor;

344 (h) A complimentary drug distributor;

345 (i) A freight forwarder;

346 (j) A veterinary prescription drug retail establishment;

347 (k) A veterinary prescription drug wholesale distributor;

348 (l) A limited prescription drug veterinary wholesale
349 distributor;

350 (m) A medical oxygen retail establishment;

351 (n) A compressed medical gas wholesale distributor;

352 (o) A compressed medical gas manufacturer;

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

354 (q) A device manufacturer;

355 (r) A cosmetic manufacturer;

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

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

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

359 (2) The following permits are established:



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360 (a) *Prescription drug manufacturer permit.*—A prescription
361 drug manufacturer permit is required for any person or entity
362 that is a manufacturer of manufactures a prescription drug and
363 manufactures or distributes its prescription drugs at or from an
364 establishment in this state.

365 1. A person that operates an establishment permitted as a
366 prescription drug manufacturer may engage in wholesale
367 distribution of prescription drugs manufactured at that
368 establishment and must comply with all the provisions of this
369 part and the rules adopted under this part that apply to a
370 wholesale distributor, except the provisions in s. 499.01212.

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

373 (b) *Prescription drug repackager permit.*—A prescription
374 drug repackager permit is required for any person that
375 repackages a prescription drug in this state.

376 1. A person that operates an establishment permitted as a
377 prescription drug repackager may engage in wholesale
378 distribution of prescription drugs repackaged at that
379 establishment and must comply with all the provisions of this
380 part and the rules adopted under this part that apply to a
381 wholesale distributor.

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

384 (c) *Nonresident prescription drug manufacturer permit.*—A
385 nonresident prescription drug manufacturer permit is required
386 for any person that is a manufacturer of prescription drugs, ~~or~~
387 ~~the distribution point for a manufacturer of prescription drugs~~
388 ~~unless permitted as a third party logistics provider, and~~



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389 located outside of this state, ~~or that is an entity to whom an~~
390 ~~approved new drug application has been issued by the United~~
391 ~~States Food and Drug Administration, or the contracted~~
392 ~~manufacturer of the approved new drug application holder, and~~
393 ~~located outside the United States,~~ which engages in the
394 wholesale distribution in this state of the prescription drugs
395 it manufactures or is responsible for manufacturing. Each such
396 manufacturer ~~or entity~~ must be permitted by the department and
397 comply with all the provisions required of a wholesale
398 distributor under this part, except s. 499.01212.

399 1. A person that distributes prescription drugs for which
400 he or she is not the manufacturer ~~that it did not manufacture~~
401 must also obtain an out-of-state prescription drug wholesale
402 distributor permit, third-party logistics provider permit, or
403 prescription drug manufacturer's distributor permit, as
404 applicable, pursuant to this section to engage in the wholesale
405 distribution of the prescription drugs for which it is not the
406 manufacturer ~~manufactured by another person~~ and comply with the
407 requirements of that permit for the wholesale distribution of
408 those prescription drugs for which the person is not the
409 manufacturer ~~an out-of-state prescription drug wholesale~~
410 ~~distributor.~~

411 2. Any such person must comply with the licensing or
412 permitting requirements of the jurisdiction in which the
413 establishment is located and the federal act, and any product
414 wholesaled into this state must comply with this part. If a
415 person intends to import prescription drugs from a foreign
416 country into this state, the nonresident prescription drug
417 manufacturer must provide to the department a list identifying



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418 each prescription drug it intends to import and document
419 approval by the United States Food and Drug Administration for
420 such importation.

421 3. A nonresident prescription drug manufacturer permit,
422 prescription drug manufacturer's distributor permit, or third-
423 party logistics provider permit is not required for a
424 manufacturer to distribute, directly or through the
425 manufacturer's distributor or third-party logistics provider, a
426 prescription drug active pharmaceutical ingredient that it
427 manufactures to a prescription drug manufacturer permitted in
428 this state in limited quantities intended for research and
429 development and not for resale, or human use other than lawful
430 clinical trials and biostudies authorized and regulated by
431 federal law. A manufacturer, manufacturer's distributor, or
432 third-party logistics provider claiming to be exempt from the
433 permit requirements of this subparagraph and the prescription
434 drug manufacturer purchasing and receiving the active
435 pharmaceutical ingredient shall comply with the recordkeeping
436 requirements of s. 499.0121(6), but not the requirements of s.
437 499.01212. The prescription drug manufacturer purchasing and
438 receiving the active pharmaceutical ingredient shall maintain on
439 file a record of the FDA registration number; the out-of-state
440 license, permit, or registration number; and, if available, a
441 copy of the most current FDA inspection report, for all
442 manufacturers, manufacturer's distributors, or third-party
443 logistics providers from whom they purchase and receive active
444 pharmaceutical ingredients under this section. The department
445 shall specify by rule the allowable number of transactions
446 within a given period of time and the amount of active



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447 pharmaceutical ingredients that qualify as limited quantities
448 for purposes of this exemption. The failure to comply with the
449 requirements of this subparagraph, or rules adopted by the
450 department to administer this subparagraph, for the purchase of
451 prescription drug active pharmaceutical ingredients is a
452 violation of s. 499.005(14).

453 (d) *Prescription drug wholesale distributor permit.*—A
454 prescription drug wholesale distributor is a wholesale
455 distributor that may engage in the wholesale distribution of
456 prescription drugs. A prescription drug wholesale distributor
457 that applies to the department for a new permit or the renewal
458 of a permit must submit a bond of \$100,000, or other equivalent
459 means of security acceptable to the department, such as an
460 irrevocable letter of credit or a deposit in a trust account or
461 financial institution, payable to the Florida Drug, Device, and
462 Cosmetic Trust Fund. The purpose of the bond is to secure
463 payment of any administrative penalties imposed by the
464 department and any fees and costs incurred by the department
465 regarding that permit which are authorized under state law and
466 which the permittee fails to pay 30 days after the fine or costs
467 become final. The department may make a claim against such bond
468 or security until 1 year after the permittee's license ceases to
469 be valid or until 60 days after any administrative or legal
470 proceeding authorized in this part which involves the permittee
471 is concluded, including any appeal, whichever occurs later. The
472 department may adopt rules for issuing a prescription drug
473 wholesale distributor-broker permit to a person who engages in
474 the wholesale distribution of prescription drugs and does not
475 take physical possession of any prescription drugs.



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476 (e) *Out-of-state prescription drug wholesale distributor*
477 *permit.*—An out-of-state prescription drug wholesale distributor
478 is a wholesale distributor located outside this state which
479 engages in the wholesale distribution of prescription drugs into
480 this state and which must be permitted by the department and
481 comply with all the provisions required of a wholesale
482 distributor under this part. An out-of-state prescription drug
483 wholesale distributor that applies to the department for a new
484 permit or the renewal of a permit must submit a bond of
485 \$100,000, or other equivalent means of security acceptable to
486 the department, such as an irrevocable letter of credit or a
487 deposit in a trust account or financial institution, payable to
488 the Florida Drug, Device, and Cosmetic Trust Fund. The purpose
489 of the bond is to secure payment of any administrative penalties
490 imposed by the department and any fees and costs incurred by the
491 department regarding that permit which are authorized under
492 state law and which the permittee fails to pay 30 days after the
493 fine or costs become final. The department may make a claim
494 against such bond or security until 1 year after the permittee's
495 license ceases to be valid or until 60 days after any
496 administrative or legal proceeding authorized in this part which
497 involves the permittee is concluded, including any appeal,
498 whichever occurs later.

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

503 2. An out-of-state prescription drug wholesale distributor
504 permit is not required for an intracompany sale or transfer of a



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505 prescription drug from an out-of-state establishment that is
506 duly licensed as a prescription drug wholesale distributor, in
507 its state of residence, to a licensed prescription drug
508 wholesale distributor in this state, if both wholesale
509 distributors conduct wholesale distributions of prescription
510 drugs under the same business name. The recordkeeping
511 requirements of ss. 499.0121(6) and 499.01212 must be followed
512 for this transaction.

513 (f) *Retail pharmacy drug wholesale distributor permit.*—A
514 retail pharmacy drug wholesale distributor is a retail pharmacy
515 engaged in wholesale distribution of prescription drugs within
516 this state under the following conditions:

517 1. The pharmacy must obtain a retail pharmacy drug
518 wholesale distributor permit pursuant to this part and the rules
519 adopted under this part.

520 2. The wholesale distribution activity does not exceed 30
521 percent of the total annual purchases of prescription drugs. If
522 the wholesale distribution activity exceeds the 30-percent
523 maximum, the pharmacy must obtain a prescription drug wholesale
524 distributor permit.

525 3. The transfer of prescription drugs that appear in any
526 schedule contained in chapter 893 is subject to chapter 893 and
527 the federal Comprehensive Drug Abuse Prevention and Control Act
528 of 1970.

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

533 5. All records of sales of prescription drugs subject to



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534 this section must be maintained separate and distinct from other
535 records and comply with the recordkeeping requirements of this
536 part.

537 (g) *Restricted prescription drug distributor permit.*—A
538 restricted prescription drug distributor permit is required for
539 any person that engages in the distribution of a prescription
540 drug, which distribution is not considered “wholesale
541 distribution” under s. 499.003(54)(a) ~~s. 499.003(53)(a)~~.

542 1. A person who engages in the receipt or distribution of a
543 prescription drug in this state for the purpose of processing
544 its return or its destruction must obtain a permit as a
545 restricted prescription drug distributor if such person is not
546 the person initiating the return, the prescription drug
547 wholesale supplier of the person initiating the return, or the
548 manufacturer of the drug.

549 2. Storage, handling, and recordkeeping of these
550 distributions must comply with the requirements for wholesale
551 distributors under s. 499.0121, but not those set forth in s.
552 499.01212.

553 3. A person who applies for a permit as a restricted
554 prescription drug distributor, or for the renewal of such a
555 permit, must provide to the department the information required
556 under s. 499.012.

557 4. The department may adopt rules regarding the
558 distribution of prescription drugs by hospitals, health care
559 entities, charitable organizations, or other persons not
560 involved in wholesale distribution, which rules are necessary
561 for the protection of the public health, safety, and welfare.

562 (h) *Complimentary drug distributor permit.*—A complimentary



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563 drug distributor permit is required for any person that engages
564 in the distribution of a complimentary drug, subject to the
565 requirements of s. 499.028.

566 (i) *Freight forwarder permit.*—A freight forwarder permit is
567 required for any person that engages in the distribution of a
568 prescription drug as a freight forwarder unless the person is a
569 common carrier. The storage, handling, and recordkeeping of such
570 distributions must comply with the requirements for wholesale
571 distributors under s. 499.0121, but not those set forth in s.
572 499.01212. A freight forwarder must provide the source of the
573 prescription drugs with a validated airway bill, bill of lading,
574 or other appropriate documentation to evidence the exportation
575 of the product.

576 (j) *Veterinary prescription drug retail establishment*
577 *permit.*—A veterinary prescription drug retail establishment
578 permit is required for any person that sells veterinary
579 prescription drugs to the public but does not include a pharmacy
580 licensed under chapter 465.

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

584 2. Veterinary prescription drugs may not be sold in excess
585 of the amount clearly indicated on the order or beyond the date
586 indicated on the order.

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

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

591 5. A veterinary prescription drug retail establishment must



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592 sell a veterinary prescription drug in the original, sealed
593 manufacturer's container with all labeling intact and legible.
594 The department may adopt by rule additional labeling
595 requirements for the sale of a veterinary prescription drug.

596 6. A veterinary prescription drug retail establishment must
597 comply with all of the wholesale distribution requirements of s.
598 499.0121.

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

602 (k) *Veterinary prescription drug wholesale distributor*
603 *permit.*—A veterinary prescription drug wholesale distributor
604 permit is required for any person that engages in the
605 distribution of veterinary prescription drugs in or into this
606 state. A veterinary prescription drug wholesale distributor that
607 also distributes prescription drugs subject to, defined by, or
608 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
609 Act which it did not manufacture must obtain a permit as a
610 prescription drug wholesale distributor, an out-of-state
611 prescription drug wholesale distributor, or a limited
612 prescription drug veterinary wholesale distributor in lieu of
613 the veterinary prescription drug wholesale distributor permit. A
614 veterinary prescription drug wholesale distributor must comply
615 with the requirements for wholesale distributors under s.
616 499.0121, but not those set forth in s. 499.01212.

617 (l) *Limited prescription drug veterinary wholesale*
618 *distributor permit.*—Unless engaging in the activities of and
619 permitted as a prescription drug manufacturer, nonresident
620 prescription drug manufacturer, prescription drug wholesale



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621 distributor, or out-of-state prescription drug wholesale
622 distributor, a limited prescription drug veterinary wholesale
623 distributor permit is required for any person that engages in
624 the distribution in or into this state of veterinary
625 prescription drugs and prescription drugs subject to, defined
626 by, or described by s. 503(b) of the Federal Food, Drug, and
627 Cosmetic Act under the following conditions:

628 1. The person is engaged in the business of wholesaling
629 prescription and veterinary prescription drugs to persons:

630 a. Licensed as veterinarians practicing on a full-time
631 basis;

632 b. Regularly and lawfully engaged in instruction in
633 veterinary medicine;

634 c. Regularly and lawfully engaged in law enforcement
635 activities;

636 d. For use in research not involving clinical use; or
637 e. For use in chemical analysis or physical testing or for
638 purposes of instruction in law enforcement activities, research,
639 or testing.

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

644 3. The person does not distribute in any jurisdiction
645 prescription drugs subject to, defined by, or described by s.
646 503(b) of the Federal Food, Drug, and Cosmetic Act to any person
647 who is authorized to sell, distribute, purchase, trade, or use
648 these drugs on or for humans.

649 4. A limited prescription drug veterinary wholesale



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650 distributor that applies to the department for a new permit or
651 the renewal of a permit must submit a bond of \$20,000, or other
652 equivalent means of security acceptable to the department, such
653 as an irrevocable letter of credit or a deposit in a trust
654 account or financial institution, payable to the Florida Drug,
655 Device, and Cosmetic Trust Fund. The purpose of the bond is to
656 secure payment of any administrative penalties imposed by the
657 department and any fees and costs incurred by the department
658 regarding that permit which are authorized under state law and
659 which the permittee fails to pay 30 days after the fine or costs
660 become final. The department may make a claim against such bond
661 or security until 1 year after the permittee's license ceases to
662 be valid or until 60 days after any administrative or legal
663 proceeding authorized in this part which involves the permittee
664 is concluded, including any appeal, whichever occurs later.

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

669 6. A limited prescription drug veterinary wholesale
670 distributor must comply with the requirements for wholesale
671 distributors under ss. 499.0121 and 499.01212, except that a
672 limited prescription drug veterinary wholesale distributor is
673 not required to provide a pedigree paper as required by s.
674 499.01212 upon the wholesale distribution of a prescription drug
675 to a veterinarian.

676 7. A limited prescription drug veterinary wholesale
677 distributor may not return to inventory for subsequent wholesale
678 distribution any prescription drug subject to, defined by, or



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679 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
680 Act which has been returned by a veterinarian.

681 8. A limited prescription drug veterinary wholesale
682 distributor permit is not required for an intracompany sale or
683 transfer of a prescription drug from an out-of-state
684 establishment that is duly licensed to engage in the wholesale
685 distribution of prescription drugs in its state of residence to
686 a licensed limited prescription drug veterinary wholesale
687 distributor in this state if both wholesale distributors conduct
688 wholesale distributions of prescription drugs under the same
689 business name. The recordkeeping requirements of ss. 499.0121(6)
690 and 499.01212 must be followed for this transaction.

691 (m) *Medical oxygen retail establishment permit.*—A medical
692 oxygen retail establishment permit is required for any person
693 that sells medical oxygen to patients only. The sale must be
694 based on an order from a practitioner authorized by law to
695 prescribe. The term does not include a pharmacy licensed under
696 chapter 465.

697 1. A medical oxygen retail establishment may not possess,
698 purchase, sell, or trade any prescription drug other than
699 medical oxygen.

700 2. A medical oxygen retail establishment may refill medical
701 oxygen for an individual patient based on an order from a
702 practitioner authorized by law to prescribe. A medical oxygen
703 retail establishment that refills medical oxygen must comply
704 with all appropriate state and federal good manufacturing
705 practices.

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



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708 4. Prescription medical oxygen sold by a medical oxygen
709 retail establishment pursuant to a practitioner's order may not
710 be returned into the retail establishment's inventory.

711 (n) *Compressed medical gas wholesale distributor permit.*—A
712 compressed medical gas wholesale distributor is a wholesale
713 distributor that is limited to the wholesale distribution of
714 compressed medical gases to other than the consumer or patient.
715 The compressed medical gas must be in the original sealed
716 container that was purchased by that wholesale distributor. A
717 compressed medical gas wholesale distributor may not possess or
718 engage in the wholesale distribution of any prescription drug
719 other than compressed medical gases. The department shall adopt
720 rules that govern the wholesale distribution of prescription
721 medical oxygen for emergency use. With respect to the emergency
722 use of prescription medical oxygen, those rules may not be
723 inconsistent with rules and regulations of federal agencies
724 unless the Legislature specifically directs otherwise.

725 (o) *Compressed medical gas manufacturer permit.*—A
726 compressed medical gas manufacturer permit is required for any
727 person that engages in the manufacture of compressed medical
728 gases or repackages compressed medical gases from one container
729 to another.

730 1. A compressed medical gas manufacturer may not
731 manufacture or possess any prescription drug other than
732 compressed medical gases.

733 2. A compressed medical gas manufacturer may engage in
734 wholesale distribution of compressed medical gases manufactured
735 at that establishment and must comply with all the provisions of
736 this part and the rules adopted under this part that apply to a



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737 wholesale distributor.

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

740 (p) *Over-the-counter drug manufacturer permit.*—An over-the-
741 counter drug manufacturer permit is required for any person that
742 engages in the manufacture or repackaging of an over-the-counter
743 drug.

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

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

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

752 (q) *Device manufacturer permit.*—A device manufacturer
753 permit is required for any person that engages in the
754 manufacture, repackaging, or assembly of medical devices for
755 human use in this state, except that a permit is not required if
756 the person is engaged only in manufacturing, repackaging, or
757 assembling a medical device pursuant to a practitioner's order
758 for a specific patient.

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

762 2. The department shall adopt rules related to storage,
763 handling, and recordkeeping requirements for manufacturers of
764 medical devices for human use.

765 (r) *Cosmetic manufacturer permit.*—A cosmetic manufacturer



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766 permit is required for any person that manufactures or
767 repackages cosmetics in this state. A person that only labels or
768 changes the labeling of a cosmetic but does not open the
769 container sealed by the manufacturer of the product is exempt
770 from obtaining a permit under this paragraph.

771 (s) Third-party ~~Third-party~~ *logistics provider permit.*—A
772 third-party ~~third-party~~ logistics provider permit is required
773 for any person that contracts with a prescription drug wholesale
774 distributor or prescription drug manufacturer to provide
775 warehousing, distribution, or other logistics services on behalf
776 of a manufacturer or wholesale distributor, but who does not
777 take title to the prescription drug or have responsibility to
778 direct the sale or disposition of the prescription drug. Each
779 third-party ~~third-party~~ logistics provider permittee shall
780 comply with the requirements for wholesale distributors under
781 ss. 499.0121 and 499.01212, with the exception of those
782 wholesale distributions described in s. 499.01212(3)(a), and
783 other rules that the department requires.

784 (t) *Health care clinic establishment permit.*—Effective
785 January 1, 2009, a health care clinic establishment permit is
786 required for the purchase of a prescription drug by a place of
787 business at one general physical location owned and operated by
788 a legal business entity that has been issued a federal tax
789 identification number and through which qualified practitioners
790 practice their profession under state law ~~a professional~~
791 ~~corporation or professional limited liability company described~~
792 ~~in chapter 621, or a corporation that employs a veterinarian as~~
793 ~~a qualifying practitioner.~~ For the purpose of this paragraph,
794 the term "qualifying practitioner" means a licensed health care



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795 practitioner defined in s. 456.001 or a veterinarian licensed
796 under chapter 474, who is authorized under the appropriate
797 practice act to prescribe and administer a prescription drug.

798 1. An establishment must provide, as part of the
799 application required under s. 499.012, designation of a
800 qualifying practitioner who will be responsible for complying
801 with all legal and regulatory requirements related to the
802 purchase, recordkeeping, storage, and handling of the
803 prescription drugs. In addition, the designated qualifying
804 practitioner shall be the practitioner whose name, establishment
805 address, and license number is used on all distribution
806 documents for prescription drugs purchased or returned by the
807 health care clinic establishment. Upon initial appointment of a
808 qualifying practitioner, the qualifying practitioner and the
809 health care clinic establishment shall notify the department on
810 a form furnished by the department within 10 days after such
811 employment. In addition, the qualifying practitioner and health
812 care clinic establishment shall notify the department within 10
813 days after any subsequent change.

814 2. The health care clinic establishment must employ a
815 qualifying practitioner at each establishment.

816 3. In addition to the remedies and penalties provided in
817 this part, a violation of this chapter by the health care clinic
818 establishment or qualifying practitioner constitutes grounds for
819 discipline of the qualifying practitioner by the appropriate
820 regulatory board.

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



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824 5. A health care clinic establishment permit is not a
825 pharmacy permit or otherwise subject to chapter 465. A health
826 care clinic establishment that meets the criteria of a modified
827 Class II institutional pharmacy under s. 465.019 is not eligible
828 to be permitted under this paragraph.

829 6. This paragraph does not prohibit a licensed ~~qualifying~~
830 practitioner whose professional license authorizes the
831 practitioner to prescribe prescription drugs from purchasing
832 prescription drugs under his or her practice license.

833 7. This paragraph does not authorize the holder of this
834 permit to purchase or possess controlled substances listed in s.
835 893.03 or federal law.

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

839 (u) Prescription drug manufacturer's distributor permit.—A
840 prescription drug manufacturer's distributor permit is required
841 for any person who engages in the wholesale distribution of
842 prescription drugs in or into this state of which a member of
843 the person's affiliated group is the manufacturer of the
844 prescription drug, unless the person is permitted as a
845 prescription drug wholesale distributor, an out-of-state
846 prescription drug wholesale distributor, or a third-party
847 logistics provider. A person permitted as a prescription drug
848 wholesale distributor, out-of-state prescription drug wholesale
849 distributor, or a third-party logistics provider may change to a
850 prescription drug manufacturer's distributor permit as provided
851 in s. 499.012(2). A prescription drug manufacturer's distributor
852 permitee shall distribute only prescription drugs manufactured



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853 by members of its affiliated group and shall acquire title to
854 the prescription drugs before distributing them. Each
855 prescription drug manufacturer's distributor permittee or
856 applicant shall:

857 1. Identify, by name, address, and federal tax
858 identification number, all affiliated group members on a
859 document that is signed by a state-licensed certified public
860 accountant who certifies that the applicant is a member of the
861 affiliated group and each member has been identified on the
862 document. This document must be submitted as a part of the
863 application for a prescription drug manufacturer's distributor
864 permit and within 30 days after any change in the membership of
865 the affiliated group; and

866 2. Comply with the requirements for wholesale distributors
867 under s. 499.0121

868
869 As used in this paragraph, the term "affiliated group" means an
870 affiliated group as defined in 26 U.S.C. s. 1504, as amended.

871 Section 5. Paragraph (d) of subsection (1) of section
872 499.012, Florida Statutes, is amended to read:

873 499.012 Permit application requirements.—

874 (1)

875 (d) A permit for a prescription drug manufacturer,
876 prescription drug repackager, prescription drug wholesale
877 distributor, limited prescription drug veterinary wholesale
878 distributor, ~~or~~ retail pharmacy drug wholesale distributor, or
879 prescription drug manufacturer's distributor may not be issued
880 to the address of a health care entity or to a pharmacy licensed
881 under chapter 465, except as provided in this paragraph. The



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882 department may issue a prescription drug manufacturer permit to
883 an applicant at the same address as a licensed nuclear pharmacy,
884 which is a health care entity, for the purpose of manufacturing
885 prescription drugs used in positron emission tomography or other
886 radiopharmaceuticals, as listed in a rule adopted by the
887 department pursuant to this paragraph. The purpose of this
888 exemption is to assure availability of state-of-the-art
889 pharmaceuticals that would pose a significant danger to the
890 public health if manufactured at a separate establishment
891 address from the nuclear pharmacy from which the prescription
892 drugs are dispensed. The department may also issue a retail
893 pharmacy drug wholesale distributor permit to the address of a
894 community pharmacy licensed under chapter 465 which does not
895 meet the definition of a closed pharmacy in s. 499.003.

896 Section 6. Paragraph (d) of subsection (4) and paragraph
897 (e) of subsection (6) of section 499.0121, Florida Statutes, are
898 amended to read:

899 499.0121 Storage and handling of prescription drugs;
900 recordkeeping.—The department shall adopt rules to implement
901 this section as necessary to protect the public health, safety,
902 and welfare. Such rules shall include, but not be limited to,
903 requirements for the storage and handling of prescription drugs
904 and for the establishment and maintenance of prescription drug
905 distribution records.

906 (4) EXAMINATION OF MATERIALS AND RECORDS.—

907 (d) Upon receipt, a wholesale distributor must review
908 records required under this section for the acquisition of
909 prescription drugs for accuracy and completeness, considering
910 the total facts and circumstances surrounding the transactions



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911 and the wholesale distributors involved. This includes
912 authenticating each transaction listed on a pedigree paper,~~as~~
913 ~~defined in s. 499.003(36).~~

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

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

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

922 499.01211 Drug Wholesale Distributor Advisory Council.—

923 (2) The State Surgeon General, or his or her designee, and
924 the Secretary of Health Care Administration, or her or his
925 designee, shall be members of the council. The State Surgeon
926 General shall appoint nine additional members to the council who
927 shall be appointed to a term of 4 years each, as follows:

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

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

935 Section 8. Section 499.01212, Florida Statutes, is amended
936 to read:

937 499.01212 Pedigree paper.—

938 (1) APPLICATION.—Each person who is engaged in the
939 wholesale distribution of a prescription drug must, prior to or



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940 simultaneous with each wholesale distribution, provide a
941 pedigree paper to the person who receives the drug.

942 (2) FORMAT.—A pedigree paper must contain the following
943 information:

944 (a) For the wholesale distribution of a prescription drug
945 within the normal distribution chain:

946 1. The following statement: "This wholesale distributor
947 purchased the specific unit of the prescription drug directly
948 from the manufacturer or manufacturer's distributor."

949 2. The manufacturer's national drug code identifier and the
950 name and address of the wholesale distributor and the purchaser
951 of the prescription drug.

952 3. The name of the prescription drug as it appears on the
953 label.

954 4. The quantity, dosage form, and strength of the
955 prescription drug.

956

957 The wholesale distributor must also maintain and make available
958 to the department, upon request, the point of origin of the
959 prescription drugs, including intracompany transfers, the date
960 of the shipment from the manufacturer, manufacturer's
961 distributor, or manufacturer's third-party logistics provider to
962 the wholesale distributor, the lot numbers of such drugs, and
963 the invoice numbers from the manufacturer or manufacturer's
964 distributor.

965 (b) For all other wholesale distributions of prescription
966 drugs:

967 1. The quantity, dosage form, and strength of the
968 prescription drugs.



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- 969 2. The lot numbers of the prescription drugs.
- 970 3. The name and address of each owner of the prescription
971 drug and his or her signature.
- 972 4. Shipping information, including the name and address of
973 each person certifying delivery or receipt of the prescription
974 drug.
- 975 5. An invoice number, a shipping document number, or
976 another number uniquely identifying the transaction. When a
977 manufacturer uses a manufacturer's distributor to sell the
978 manufacturer's prescription drugs, the invoice number, shipping
979 document number, or other number uniquely identifying the
980 transaction between the manufacturer and manufacturer's
981 distributor may be omitted from the pedigree paper.
- 982 6. A certification that the recipient wholesale distributor
983 has authenticated the pedigree papers.
- 984 7. The unique serialization of the prescription drug, if
985 the manufacturer or repackager has uniquely serialized the
986 individual prescription drug unit.
- 987 8. The name, address, telephone number, and, if available,
988 e-mail contact information of each wholesale distributor,
989 including each third-party logistics provider and manufacturer's
990 distributor involved in the chain of the prescription drug's
991 custody.
- 992 (3) EXCEPTIONS.—A pedigree paper is not required for:
- 993 (a) The wholesale distribution of a prescription drug by
994 the manufacturer, by the manufacturer's distributor, or by a
995 third-party ~~third party~~ logistics provider performing a
996 wholesale distribution of a prescription drug for a
997 manufacturer.



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998 (b) The wholesale distribution of a prescription drug by a
999 freight forwarder within the authority of a freight forwarder
1000 permit.

1001 (c) The wholesale distribution of a prescription drug by a
1002 limited prescription drug veterinary wholesale distributor to a
1003 veterinarian.

1004 (d) The wholesale distribution of a compressed medical gas.

1005 (e) The wholesale distribution of a veterinary prescription
1006 drug.

1007 (f) A drop shipment, provided:

1008 1. The wholesale distributor delivers to the recipient of
1009 the prescription drug, within 14 days after the shipment
1010 notification from the manufacturer or manufacturer's
1011 distributor, an invoice and the following sworn statement: "This
1012 wholesale distributor purchased the specific unit of the
1013 prescription drug listed on the invoice directly from the
1014 manufacturer or manufacturer's distributor, and the specific
1015 unit of prescription drug was shipped by the manufacturer,
1016 manufacturer's distributor, or manufacturer's third-party
1017 logistics provider directly to a person authorized by law to
1018 administer or dispense the legend drug, as defined in s.
1019 465.003, Florida Statutes, or a member of an affiliated group,
1020 with the exception of a repackager." The invoice must contain a
1021 unique cross-reference to the shipping document sent by the
1022 manufacturer, manufacturer's distributor, or manufacturer's
1023 third-party logistics provider to the recipient of the
1024 prescription drug.

1025 2. The manufacturer or manufacturer's distributor of the
1026 prescription drug shipped directly to the recipient provides and



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1027 the recipient of the prescription drug acquires, within 14 days
1028 after receipt of the prescription drug, a shipping document from
1029 the manufacturer, manufacturer's distributor, or manufacturer's
1030 third-party logistics provider which ~~that~~ contains, at a
1031 minimum:

1032 a. The name and address of the manufacturer or
1033 manufacturer's distributor, including the point of origin of the
1034 shipment, and the names and addresses of the wholesale
1035 distributor and the purchaser.

1036 b. The name of the prescription drug as it appears on the
1037 label.

1038 c. The quantity, dosage form, and strength of the
1039 prescription drug.

1040 d. The date of the shipment from the manufacturer,
1041 manufacturer's distributor, or manufacturer's third-party
1042 logistics provider.

1043 3. The wholesale distributor maintains and makes available
1044 to the department, upon request, the lot number of such drug if
1045 not contained in the shipping document acquired by the
1046 recipient.

1047 4. The wholesale distributor that takes title to, but not
1048 possession of, the prescription drug is not a member of the
1049 affiliated group that receives the prescription drug directly
1050 from the manufacturer.

1051
1052 Failure of the manufacturer, manufacturer's distributor, or
1053 manufacturer's third-party logistics provider to provide, the
1054 recipient to acquire, or the wholesale distributor to deliver
1055 the documentation required under this paragraph shall constitute



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1056 failure to acquire or deliver a pedigree paper under ss.
1057 499.005(28) and 499.0051. Forgery by the manufacturer,
1058 manufacturer's distributor, or manufacturer's third-party
1059 logistics provider, the recipient, or the wholesale distributor
1060 of the documentation required to be acquired or delivered under
1061 this paragraph shall constitute forgery of a pedigree paper
1062 under s. 499.0051.

1063 (g) The wholesale distribution of a prescription drug by a
1064 warehouse within an affiliated group to a warehouse or retail
1065 pharmacy within its affiliated group, provided:

1066 1. Any affiliated group member that purchases or receives a
1067 prescription drug from outside the affiliated group must receive
1068 a pedigree paper if the prescription drug is distributed in or
1069 into this state and a pedigree paper is required under this
1070 section and must authenticate the documentation as required in
1071 s. 499.0121(4), regardless of whether the affiliated group
1072 member is directly subject to regulation under this part; and

1073 2. The affiliated group makes available, within 48 hours,
1074 to the department on request to one or more of its members all
1075 records related to the purchase or acquisition of prescription
1076 drugs by members of the affiliated group, regardless of the
1077 location where the records are stored, if the prescription drugs
1078 were distributed in or into this state.

1079 (h) The repackaging of prescription drugs by a repackager
1080 solely for distribution to its affiliated group members for the
1081 exclusive distribution to and among retail pharmacies that are
1082 members of the affiliated group to which the repackager is a
1083 member.

1084 1. The repackager must:



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1085 a. For all repackaged prescription drugs distributed in or
1086 into this state, state in writing under oath with each
1087 distribution of a repackaged prescription drug to an affiliated
1088 group member warehouse or repackager: "All repackaged
1089 prescription drugs are purchased by the affiliated group
1090 directly from the manufacturer, manufacturer's distributor, or
1091 from a prescription drug wholesale distributor that purchased
1092 the prescription drugs directly from the manufacturer or
1093 manufacturer's distributor."

1094 b. Purchase all prescription drugs it repackages:

1095 (I) Directly from the manufacturer or manufacturer's
1096 distributor; or

1097 (II) From a prescription drug wholesale distributor that
1098 purchased the prescription drugs directly from the manufacturer
1099 or manufacturer's distributor.

1100 c. Maintain records in accordance with this section to
1101 document that it purchased the prescription drugs directly from
1102 the manufacturer, manufacturer's distributor, or that its
1103 prescription drug wholesale supplier purchased the prescription
1104 drugs directly from the manufacturer or manufacturer's
1105 distributor.

1106 2. All members of the affiliated group must provide, within
1107 48 hours, to agents of the department on request to one or more
1108 of its members records of purchases by all members of the
1109 affiliated group of prescription drugs that have been
1110 repackaged, regardless of the location at which the records are
1111 stored or at which the repackager is located.

1112 Section 9. Subsection (1) of section 499.03, Florida
1113 Statutes, is amended to read:



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1114 499.03 Possession of certain drugs without prescriptions
1115 unlawful; exemptions and exceptions.—

1116 (1) A person may not possess, or possess with intent to
1117 sell, dispense, or deliver, any habit-forming, toxic, harmful,
1118 or new drug ~~subject to s. 499.003(32),~~ or prescription drug ~~as~~
1119 ~~defined in s. 499.003(42),~~ unless the possession of the drug has
1120 been obtained by a valid prescription of a practitioner licensed
1121 by law to prescribe the drug. However, this section does not
1122 apply to the delivery of such drugs to persons included in any
1123 of the classes named in this subsection, or to the agents or
1124 employees of such persons, for use in the usual course of their
1125 businesses or practices or in the performance of their official
1126 duties, as the case may be; nor does this section apply to the
1127 possession of such drugs by those persons or their agents or
1128 employees for such use:

1129 (a) A licensed pharmacist or any person under the licensed
1130 pharmacist's supervision while acting within the scope of the
1131 licensed pharmacist's practice;

1132 (b) A licensed practitioner authorized by law to prescribe
1133 prescription drugs or any person under the licensed
1134 practitioner's supervision while acting within the scope of the
1135 licensed practitioner's practice;

1136 (c) A qualified person who uses prescription drugs for
1137 lawful research, teaching, or testing, and not for resale;

1138 (d) A licensed hospital or other institution that procures
1139 such drugs for lawful administration or dispensing by
1140 practitioners;

1141 (e) An officer or employee of a federal, state, or local
1142 government; or



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1143 (f) A person that holds a valid permit issued by the
1144 department pursuant to this part which authorizes that person to
1145 possess prescription drugs.

1146 Section 10. Subsection (2) of section 499.041, Florida
1147 Statutes, is amended, and subsection (11) is added to that
1148 section, to read:

1149 499.041 Schedule of fees for drug, device, and cosmetic
1150 applications and permits, product registrations, and free-sale
1151 certificates.—

1152 (2) The department shall assess an applicant that is
1153 required to have a wholesaling permit an annual fee within the
1154 ranges established in this section for the specific type of
1155 wholesaling.

1156 (a) The fee for a prescription drug wholesale distributor
1157 permit may not be less than \$300 or more than \$800 annually.

1158 (b) The fee for a compressed medical gas wholesale
1159 distributor permit may not be less than \$200 or more than \$300
1160 annually.

1161 (c) The fee for an out-of-state prescription drug wholesale
1162 distributor permit may not be less than \$300 or more than \$800
1163 annually.

1164 (d) The fee for a nonresident prescription drug
1165 manufacturer permit may not be less than \$300 or more than \$500
1166 annually.

1167 (e) The fee for a retail pharmacy drug wholesale
1168 distributor permit may not be less than \$35 or more than \$50
1169 annually.

1170 (f) The fee for a freight forwarder permit may not be less
1171 than \$200 or more than \$300 annually.



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1172 (g) The fee for a veterinary prescription drug wholesale
1173 distributor permit may not be less than \$300 or more than \$500
1174 annually.

1175 (h) The fee for a limited prescription drug veterinary
1176 wholesale distributor permit may not be less than \$300 or more
1177 than \$500 annually.

1178 (i) The fee for a third-party ~~third party~~ logistics
1179 provider permit may not be less than \$200 or more than \$300
1180 annually.

1181 (j) The fee for a prescription drug manufacturer's
1182 distributor permit may not be less than \$500 or more than \$750
1183 annually.

1184 (11) The department shall retain a fee of \$150 or 50
1185 percent of the permit or certification fee, whichever is less,
1186 from each person applying for a permit or certification if the
1187 application is withdrawn or becomes void.

1188 Section 11. Paragraph (m) of subsection (1) of section
1189 499.05, Florida Statutes, is amended to read:

1190 499.05 Rules.—

1191 (1) The department shall adopt rules to implement and
1192 enforce this part with respect to:

1193 (m) The recordkeeping, storage, and handling with respect
1194 to each of the distributions of prescription drugs specified in
1195 s. 499.003(54) (a) - (d) ~~s. 499.003(53) (a) - (d)~~.

1196 Section 12. Subsection (1) of section 794.075, Florida
1197 Statutes, is amended to read:

1198 794.075 Sexual predators; erectile dysfunction drugs.—

1199 (1) A person may not possess a prescription drug, as
1200 defined in s. 499.003(43) ~~s. 499.003(42)~~, for the purpose of



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1201 treating erectile dysfunction if the person is designated as a
1202 sexual predator under s. 775.21.

1203 Section 13. (1) Notwithstanding the purchase of a
1204 prescription drug from the manufacturer's distributor, a person
1205 who is required to comply with the pedigree paper provisions
1206 under s. 499.01212, Florida Statutes, may continue to use the
1207 statement provided in s. 499.01212, Florida Statutes (2008),
1208 until September 30, 2010, for the wholesale distribution of a
1209 prescription drug that:

1210 (a) Is within the normal distribution chain as provided in
1211 s. 499.01212(2) (a), Florida Statutes;

1212 (b) Qualifies as a drop shipment as provided in s.
1213 499.01212(3) (f), Florida Statutes; or

1214 (c) Is a repackaged prescription drug as provided in s.
1215 499.01212(3) (h), Florida Statutes.

1216 (2) This section is repealed October 1, 2010.

1217 Section 14. This act shall take effect October 1, 2009.

1218
1219 ===== T I T L E A M E N D M E N T =====

1220 And the title is amended as follows:

1221 Delete everything before the enacting clause
1222 and insert:

1223 A bill to be entitled

1224 An act relating to manufacturers and purchasers of
1225 prescription drugs; amending ss. 409.9201 and
1226 465.0265, F.S.; conforming cross-references; amending
1227 s. 499.003, F.S.; defining new terms and redefining
1228 terms related to the Florida Drug and Cosmetic Act;
1229 amending s. 499.01, F.S.; authorizing a prescription



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1230 drug manufacturer's distributor permit and revising
1231 the requirements related to certain other permits;
1232 conforming a cross-reference; amending s. 499.012,
1233 F.S.; restricting issuance of a permit for a
1234 prescription drug manufacturer's distributor at
1235 certain addresses; amending s. 499.0121, F.S.;
1236 eliminating cross-references to defined terms and
1237 clarifying a recordkeeping requirement related to
1238 pedigree papers; amending s. 499.01211, F.S.;
1239 eliminating cross-references for certain defined
1240 terms; amending s. 499.01212, F.S.; revising
1241 requirements for a pedigree paper; amending s. 499.03,
1242 F.S.; eliminating cross-references for certain defined
1243 terms; amending s. 499.041, F.S.; establishing a fee
1244 for the prescription drug manufacturer's distributor
1245 permit; authorizing the Department of Health to retain
1246 a specified monetary amount as a fee if an application
1247 submitted under the Florida Drug and Cosmetic Act is
1248 withdrawn or becomes void; amending ss. 499.05 and
1249 794.075, F.S.; conforming cross-references;
1250 authorizing certain statements to be used on certain
1251 pedigree papers until a specified date; providing an
1252 effective date.