

By Senator Gruters

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1 A bill to be entitled
2 An act relating to prescription drug importation
3 programs; creating s. 381.02035, F.S.; establishing
4 the Canadian Prescription Drug Importation Program
5 within the Agency for Health Care Administration for a
6 specified purpose; defining terms; requiring the
7 agency to contract with a vendor to facilitate
8 wholesale prescription drug importation under the
9 program; providing responsibilities for the vendor;
10 providing eligibility criteria for prescription drugs,
11 for Canadian suppliers, and for importers under the
12 program; requiring participating Canadian suppliers
13 and importers to comply with specified federal
14 requirements in distributing prescription drugs
15 imported under the program; prohibiting Canadian
16 suppliers and importers from distributing, dispensing,
17 or selling prescription drugs imported under the
18 program outside of this state; requiring the agency to
19 request federal approval of the program; providing
20 requirements for such request; requiring the agency to
21 begin operating the program within a specified
22 timeframe after receiving federal approval; requiring
23 the agency, in consultation with the vendor, to submit
24 an annual report to the Governor and the Legislature
25 by a specified date; providing requirements for such
26 report; requiring the agency to adopt rules; creating
27 s. 499.0285, F.S.; requiring the Department of
28 Business and Professional Regulation to establish the
29 International Prescription Drug Importation Program

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30 for a specified purpose; defining terms; providing
31 eligibility criteria for prescription drugs,
32 exporters, and importers under the program; requiring
33 participating importers to submit certain
34 documentation to the department for prescription drugs
35 imported under the program; requiring the department
36 to immediately suspend the importation of a specific
37 prescription drug or the importation by a specific
38 importer if a violation has occurred under the
39 program; authorizing the department to revoke such
40 suspension under certain circumstances; requiring the
41 department to adopt rules; creating s. 465.0157, F.S.;
42 establishing an international export pharmacy permit
43 for participation in the International Prescription
44 Drug Importation Program; providing requirements for
45 permit application and renewal; amending s. 465.017,
46 F.S.; authorizing the department to inspect
47 international export pharmacy permittees; amending s.
48 499.01, F.S.; requiring nonresident prescription drug
49 manufacturers to register with the department to
50 participate in the program; providing an exception;
51 establishing an international prescription drug
52 wholesale distributor permit; providing requirements
53 for such permit; amending s. 499.012, F.S.; providing
54 permit application requirements for international
55 prescription drug wholesale distributors and
56 nonresident prescription drug manufacturers to
57 participate in the program; amending ss. 499.005,
58 499.0051, and 499.015, F.S.; conforming provisions to

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59 changes made by the act; amending s. 499.065, F.S.;

60 requiring the department to inspect international

61 prescription drug wholesale distributor establishments

62 and to require the immediate closure of such

63 establishments under certain circumstances; requiring

64 the Department of Business and Professional

65 Regulation, in collaboration with the Department of

66 Health, to negotiate a federal arrangement to operate

67 a pilot program for importing prescription drugs into

68 this state; providing that implementation of the act

69 is contingent upon such federal arrangement or

70 obtaining federal guidance; providing an effective

71 date.

72

73 Be It Enacted by the Legislature of the State of Florida:

74

75 Section 1. Section 381.02035, Florida Statutes, is created

76 to read:

77 381.02035 Canadian Prescription Drug Importation Program.-

78 (1) PROGRAM ESTABLISHED.-The agency shall establish a

79 program for the importation of safe and effective prescription

80 drugs from Canada which have the highest potential for cost

81 savings to the state.

82 (2) DEFINITIONS.-As used in this section, the term:

83 (a) "Agency" means the Agency for Health Care

84 Administration.

85 (b) "Canadian supplier" means a manufacturer, a wholesale

86 distributor, or a pharmacy appropriately licensed or permitted

87 under Canadian law to manufacture, distribute, or dispense

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88 prescription drugs.

89 (c) "County health department" means a health care facility
90 established under part I of chapter 154.

91 (d) "Department" means the Department of Health.

92 (e) "Free clinic" means a clinic that delivers medical
93 diagnostic services or nonsurgical medical treatment free of
94 charge to low-income recipients.

95 (f) "Medicaid pharmacy" means a pharmacy licensed under
96 chapter 465 which has a Medicaid provider agreement in effect
97 with the agency and is in good standing with the agency.

98 (g) "Pharmacist" means a person who holds an active and
99 unencumbered license to practice pharmacy pursuant to chapter
100 465.

101 (h) "Prescription drug" has the same meaning as in s.
102 499.003.

103 (i) "Program" means the Canadian Prescription Drug
104 Importation Program.

105 (3) IMPORTATION PROCESS.—

106 (a) The agency shall contract with a vendor to provide
107 services under the program.

108 (b) The vendor shall develop by December 1, 2019, and each
109 year thereafter revise, a Wholesale Prescription Drug
110 Importation List identifying the prescription drugs that have
111 the highest potential for cost savings to the state. In
112 developing the list, the vendor shall consider, at a minimum,
113 which prescription drugs will provide the greatest cost savings
114 to state programs, including prescription drugs for which there
115 are shortages, specialty prescription drugs, and high-volume
116 prescription drugs. The agency, in consultation with the

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117 department, shall review the Wholesale Prescription Drug
118 Importation List every 3 months to ensure that it continues to
119 meet the requirements of the program, and may direct the vendor
120 to revise the list, as necessary.

121 (c) The vendor shall identify Canadian suppliers that are
122 in full compliance with relevant Canadian federal and provincial
123 laws and regulations and who have agreed to export prescription
124 drugs identified on the list. The vendor must verify that such
125 Canadian suppliers meet all of the requirements of the program
126 and will export prescription drugs at prices that will provide
127 cost savings to the state. The vendor shall contract with such
128 eligible Canadian suppliers, or facilitate contracts between
129 eligible importers and Canadian suppliers, to import
130 prescription drugs under the program.

131 (d) The vendor shall assist the agency with the annual
132 report required in subsection (9) and shall provide any
133 information requested by the agency for such report.

134 (4) ELIGIBLE PRESCRIPTION DRUGS.—Eligible importers may
135 import a prescription drug from an eligible Canadian supplier
136 if:

137 (a) The drug meets the United States Food and Drug
138 Administration's standards relating to safety, effectiveness,
139 misbranding, and adulteration;

140 (b) Importing the drug would not violate the patent laws of
141 the United States;

142 (c) Importing the drug is expected to generate cost
143 savings; and

144 (d) The drug is not:

145 1. A controlled substance as defined in 21 U.S.C. s. 802;

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146 2. A biological product as defined in 42 U.S.C. s. 262;

147 3. An infused drug;

148 4. An intravenously injected drug;

149 5. A drug that is inhaled during surgery; or

150 6. A drug that is a parenteral drug, the importation of
151 which is determined by the United States Secretary of Health and
152 Human Services to pose a threat to the public health.

153 (5) ELIGIBLE CANADIAN SUPPLIERS.—A Canadian supplier may
154 export prescription drugs into this state under the program if
155 the supplier is:

156 (a) In full compliance with relevant Canadian federal and
157 provincial laws and regulations; and

158 (b) Identified by the vendor as eligible to participate in
159 the program.

160 (6) ELIGIBLE IMPORTERS.—The following entities may import
161 prescription drugs from a Canadian supplier under the program:

162 (a) A pharmacist or wholesaler employed by or under
163 contract with the department's central pharmacy, for
164 distribution to a county health department or free clinic for
165 dispensing to clients treated in such department or such clinic.

166 (b) A pharmacist or wholesaler employed by or under
167 contract with a Medicaid pharmacy, for dispensing to the
168 pharmacy's Medicaid recipients.

169 (c) A pharmacist or wholesaler employed by or under
170 contract with the Department of Corrections, for dispensing to
171 inmates in the custody of the Department of Corrections.

172 (d) A pharmacist or wholesaler employed by or under
173 contract with a developmental disabilities center, as defined in
174 s. 393.063, for dispensing to clients treated in such center.

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175 (e) A pharmacist or wholesaler employed by or under
176 contract with a treatment facility, as defined in s. 394.455,
177 for dispensing to patients treated in such a facility.

178 (7) DISTRIBUTION REQUIREMENTS.—Eligible Canadian suppliers
179 and importers participating under the program:

180 (a) Must comply with the tracking and tracing requirements
181 of 21 U.S.C. ss. 360eee et seq.

182 (b) May not distribute, dispense, or sell prescription
183 drugs imported under the program outside of this state.

184 (8) FEDERAL APPROVAL.—By July 1, 2020, the agency shall
185 submit a request to the United States Secretary of Health and
186 Human Services for approval of the program under 21 U.S.C. s.
187 384(1). The agency shall begin operating the program within 6
188 months after receiving such approval. The request must, at a
189 minimum:

190 (a) Describe the agency's plan for operating the program;

191 (b) Demonstrate how the prescription drugs imported into
192 this state under the program will meet the applicable federal
193 and state standards for safety and effectiveness;

194 (c) Include a list of prescription drugs that have the
195 highest potential for cost savings to the state through
196 importation at the time that the request is submitted;

197 (d) Estimate the total cost savings attributable to the
198 program; and

199 (e) Include a list of potential Canadian suppliers from
200 which the state would import prescription drugs and demonstrate
201 that the suppliers are in full compliance with relevant Canadian
202 federal and provincial laws and regulations.

203 (9) ANNUAL REPORTING.—By December 1 of each year, the

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204 agency shall submit a report to the Governor, the President of
205 the Senate, and the Speaker of the House of Representatives on
206 the operation of the program during the previous fiscal year.

207 The report must include, at a minimum:

208 (a) A list of the prescription drugs that were imported
209 under the program;

210 (b) The number of participating entities;

211 (c) The number of prescriptions dispensed through the
212 program;

213 (d) The estimated cost savings during the previous fiscal
214 year and to date;

215 (e) A description of the methodology used to determine
216 which prescription drugs may be included on the Wholesale
217 Prescription Drug Importation List; and

218 (f) Documentation demonstrating how the program ensures
219 that:

220 1. Canadian suppliers participating in the program are of
221 high quality, of high performance, and in full compliance with
222 relevant Canadian federal and provincial laws and regulations;

223 2. Prescription drugs imported under the program are not
224 shipped, sold, or dispensed outside of this state once in the
225 possession of the importer;

226 3. Prescription drugs imported under the program are pure,
227 unadulterated, potent, and safe;

228 4. The program does not put consumers at a higher health
229 and safety risk than if the program did not exist; and

230 5. The program provides cost savings to the state on
231 imported prescription drugs.

232 (10) RULEMAKING AUTHORITY.—The agency shall adopt rules

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233 necessary to implement this section.

234 Section 2. Section 499.0285, Florida Statutes, is created
235 to read:

236 499.0285 International Prescription Drug Importation
237 Program.—

238 (1) PROGRAM ESTABLISHED.—The department shall establish a
239 program for the importation of safe and effective prescription
240 drugs from foreign nations with whom the United States has
241 current mutual recognition agreements, cooperation agreements,
242 memoranda of understanding, or other federal mechanisms
243 recognizing their adherence to current good manufacturing
244 practices for pharmaceutical products.

245 (2) DEFINITIONS.—As used in this section, the term:

246 (a) "Exporter" means an international prescription drug
247 wholesale distributor, a nonresident prescription drug
248 manufacturer registered to participate in the program, or an
249 international export pharmacy that exports prescription drugs
250 into this state under the program.

251 (b) "Foreign recipient" means an entity other than the
252 original prescription drug manufacturer which receives the
253 prescription drug before its importation into this state under
254 the program.

255 (c) "Good manufacturing practice" refers to the good
256 manufacturing practice regulations in 21 C.F.R. parts 210 and
257 211.

258 (d) "Importer" means a wholesale distributor, a pharmacy,
259 or a pharmacist importing prescription drugs into this state
260 under the program.

261 (e) "International export pharmacy" means a pharmacy

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262 located outside of the United States which holds an active and
263 unencumbered permit under chapter 465 to export prescription
264 drugs into this state under the program.

265 (f) "International prescription drug wholesale distributor"
266 means a prescription drug wholesale distributor located outside
267 of the United States which holds an active and unencumbered
268 permit under this part to export and distribute prescription
269 drugs into this state under the program.

270 (g) "Nonresident prescription drug manufacturer" means an
271 entity located outside of the United States which holds an
272 active and unencumbered permit under this part to manufacture
273 prescription drugs and has registered with the department to
274 export and distribute such prescription drugs into this state
275 under the program.

276 (h) "Pharmacist" means a person who holds an active and
277 unencumbered license to practice pharmacy under chapter 465.

278 (i) "Pharmacy" means an entity that holds an active and
279 unencumbered permit under chapter 465.

280 (j) "Program" means the International Prescription Drug
281 Importation Program established under this section.

282 (k) "Qualified laboratory" means a laboratory that has been
283 approved by the department for the purposes of this section.

284 (3) ELIGIBLE PRESCRIPTION DRUGS.—An eligible importer may
285 import a prescription drug from an eligible exporter if:

286 (a) The drug meets the United States Food and Drug
287 Administration's standards relating to safety, effectiveness,
288 misbranding, and adulteration;

289 (b) Importing the drug would not violate the patent laws of
290 the United States; and

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291 (c) The drug is not:
292 1. A controlled substance as defined in 21 U.S.C. s. 802;
293 2. A biological product as defined in 42 U.S.C. s. 262;
294 3. An infused drug;
295 4. An intravenously injected drug;
296 5. A drug that is inhaled during surgery; or
297 6. A drug that is a parenteral drug, the importation of
298 which is determined by the United States Secretary of Health and
299 Human Services to pose a threat to the public health.

300 (4) EXPORTERS.—

301 (a) The following entities may export prescription drugs
302 into this state under the program:

- 303 1. An international prescription drug wholesale
304 distributor.
305 2. A nonresident prescription drug manufacturer.
306 3. An international export pharmacy.

307 (b) An eligible exporter shall register with the department
308 before exporting prescription drugs into this state under the
309 program.

310 (c) An exporter may not distribute, sell, or dispense
311 prescription drugs imported under the program to any person
312 residing outside of this state.

313 (5) IMPORTERS.—

314 (a) The following entities may import prescription drugs
315 under the program:

- 316 1. A wholesale distributor.
317 2. A pharmacy.
318 3. A pharmacist.

319 (b) An eligible importer shall register with the department

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320 before importing prescription drugs into this state under the
321 program.

322 (c) An importer may not distribute, sell, or dispense
323 prescription drugs imported under the program to any person
324 residing outside of this state.

325 (6) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

326 (a) A participating importer must submit the following
327 information and documentation to the department:

328 1. The name and the quantity of the active ingredient of
329 the prescription drug.

330 2. A description of the dosage form of the prescription
331 drug.

332 3. The date on which the prescription drug is shipped.

333 4. The quantity of the prescription drug that is shipped.

334 5. The point of origin and destination of the prescription
335 drug.

336 6. The price paid by the importer for the prescription
337 drug.

338 7. Documentation from the exporter specifying:

339 a. The original source of the prescription drug; and

340 b. The quantity of each lot of the prescription drug

341 originally received by the seller from such source.

342 8. The lot or control number assigned to the prescription
343 drug by the manufacturer.

344 9. The name, address, telephone number, and professional
345 license or permit number of the importer.

346 10. In the case of a prescription drug that is shipped
347 directly by the first foreign recipient from the manufacturer:

348 a. Documentation demonstrating that the prescription drug

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349 was received by the recipient from the manufacturer and
350 subsequently shipped by the first foreign recipient to the
351 importer.

352 b. Documentation of the quantity of each lot of the
353 prescription drug received by the first foreign recipient
354 demonstrating that the quantity being imported into this state
355 is not more than the quantity that was received by the first
356 foreign recipient.

357 c. For an initial imported shipment, documentation
358 demonstrating that each batch of the prescription drug in the
359 shipment was statistically sampled and tested for authenticity
360 and degradation.

361 d. For any subsequent imported shipment, documentation
362 demonstrating that a statistically valid sample of the shipment
363 was tested for authenticity and degradation.

364 11. In the case of a prescription drug that is not shipped
365 directly from the first foreign recipient, documentation
366 demonstrating that each batch in each shipment offered for
367 importation into the state was statistically sampled and tested
368 for authenticity and degradation.

369 12. Certification from the importer or manufacturer that
370 the prescription drug:

371 a. Is approved for marketing in the United States and is
372 not adulterated or misbranded; and

373 b. Meets all of the labeling requirements under 21 U.S.C.
374 s. 352.

375 13. Qualified laboratory records, including complete data
376 derived from all tests necessary to ensure that the prescription
377 drug is in compliance with the requirements of this section.

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378 14. Documentation demonstrating that the testing required
379 by this section was conducted at a qualified laboratory.

380 15. Any other information the department determines is
381 necessary to ensure the protection of the public health.

382 (b) All testing required by this section must be conducted
383 in a qualified laboratory.

384 (c) The department shall maintain information and
385 documentation submitted under this section for a period of at
386 least 4 years.

387 (7) IMMEDIATE SUSPENSION.—The department shall immediately
388 suspend the importation of a specific prescription drug or the
389 importation of prescription drugs by a specific importer if the
390 department discovers that any prescription drug or any activity
391 is in violation of this section. The department may revoke the
392 suspension if, after conducting an investigation, it determines
393 that the public is adequately protected from counterfeit or
394 unsafe prescription drugs being imported into this state.

395 (8) RULEMAKING AUTHORITY.—The department shall adopt rules
396 necessary to implement this section.

397 Section 3. Section 465.0157, Florida Statutes, is created
398 to read:

399 465.0157 International export pharmacy permit.—

400 (1) To participate as an exporter of prescription drugs
401 into this state under the International Prescription Drug
402 Importation Program established in s. 499.0285, a pharmacy
403 located outside of the United States must hold an international
404 export pharmacy permit.

405 (2) An international export pharmacy must maintain at all
406 times an active and unencumbered license or a permit to operate

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407 the pharmacy in compliance with the laws of the jurisdiction in
408 which the dispensing facility is located and from which the
409 prescription drugs must be exported. Such jurisdiction must be
410 in a country with whom the United States has a current mutual
411 recognition agreement, cooperation agreement, memorandum of
412 understanding, or other federal mechanism recognizing the
413 country's adherence to current good manufacturing practices for
414 pharmaceutical products.

415 (3) An application for an international export pharmacy
416 permit must be submitted on a form developed and provided by the
417 board. The board may require an applicant to provide any
418 information it deems reasonably necessary to carry out the
419 purposes of this section.

420 (4) An applicant must submit the following to the board to
421 obtain an initial permit, or to the department to renew a
422 permit:

423 (a) Proof of an active and unencumbered license or permit
424 to operate the pharmacy in compliance with the laws of the
425 jurisdiction in which the dispensing facility is located and
426 from which the prescription drugs must be exported.

427 (b) Documentation demonstrating that the country in which
428 the pharmacy operates has a current mutual recognition
429 agreement, cooperation agreement, memorandum of understanding,
430 or other federal mechanism recognizing the country's adherence
431 to current good manufacturing practices for pharmaceutical
432 products.

433 (c) The locations, names, and titles of all principal
434 corporate officers and of the pharmacist who serves as the
435 prescription department manager for prescription drugs exported

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436 into this state under the International Prescription Drug
437 Importation Program.

438 (d) Written attestation by an owner or an officer of the
439 applicant, and by the applicant's prescription department
440 manager, that:

441 1. The attestor has read and understands the laws and rules
442 governing the manufacturing, distributing, and dispensing of
443 prescription drugs in this state.

444 2. A prescription drug shipped, mailed, or delivered into
445 this state meets or exceeds this state's standards for safety
446 and efficacy.

447 3. A prescription drug product shipped, mailed, or
448 delivered into this state may not have been, and may not be,
449 manufactured or distributed in violation of the laws and rules
450 of the jurisdiction in which the applicant is located and from
451 which the prescription drugs must be exported.

452 (e) A current inspection report from an inspection
453 conducted by the regulatory agency or the licensing agency of
454 the jurisdiction in which the applicant is located. The
455 inspection report must reflect compliance with this section. An
456 inspection report is current if the inspection was conducted
457 within 6 months before the date of submitting the application
458 for the initial permit or within 1 year before the date of
459 submitting an application for the permit renewal. If the
460 applicant is unable to submit a current inspection report
461 conducted by the regulatory agency or the licensing agency of
462 the jurisdiction in which the applicant is located and from
463 which the prescription drugs must be exported, due to acceptable
464 circumstances, as established by rule, or if an inspection has

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465 not been performed, the department shall:

466 1. Conduct, or contract with an entity to conduct, an
467 onsite inspection for which all costs must be borne by the
468 applicant;

469 2. Accept a current and satisfactory inspection report, as
470 determined by rule, from an entity approved by the board; or

471 3. Accept a current inspection report from the United
472 States Food and Drug Administration conducted pursuant to the
473 federal Drug Quality and Security Act, Pub. L. No. 113-54.

474 Section 4. Subsection (2) of section 465.017, Florida
475 Statutes, is amended to read:

476 465.017 Authority to inspect; disposal.—

477 (2) Duly authorized agents and employees of the department
478 may inspect a nonresident pharmacy registered under s. 465.0156,
479 an international export pharmacy permittee under s. 465.0157, or
480 a nonresident sterile compounding permittee under s. 465.0158
481 pursuant to this section. The costs of such inspections shall be
482 borne by such pharmacy or permittee.

483 Section 5. Subsection (1) and paragraph (c) of subsection
484 (2) of section 499.01, Florida Statutes, are amended, and
485 paragraph (s) is added to subsection (2) of that section, to
486 read:

487 499.01 Permits.—

488 (1) Before operating, a permit is required for each person
489 and establishment that intends to operate as:

- 490 (a) A prescription drug manufacturer;
491 (b) A prescription drug repackager;
492 (c) A nonresident prescription drug manufacturer;
493 (d) A nonresident prescription drug repackager;

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- 494 (e) A prescription drug wholesale distributor;
- 495 (f) An out-of-state prescription drug wholesale
496 distributor;
- 497 (g) A retail pharmacy drug wholesale distributor;
- 498 (h) A restricted prescription drug distributor;
- 499 (i) A complimentary drug distributor;
- 500 (j) A freight forwarder;
- 501 (k) A veterinary prescription drug retail establishment;
- 502 (l) A veterinary prescription drug wholesale distributor;
- 503 (m) A limited prescription drug veterinary wholesale
504 distributor;
- 505 (n) An over-the-counter drug manufacturer;
- 506 (o) A device manufacturer;
- 507 (p) A cosmetic manufacturer;
- 508 (q) A third party logistics provider; ~~or~~
- 509 (r) A health care clinic establishment; or
- 510 (s) An international prescription drug wholesale
511 distributor.
- 512 (2) The following permits are established:
- 513 (c) *Nonresident prescription drug manufacturer permit.*—A
514 nonresident prescription drug manufacturer permit is required
515 for any person that is a manufacturer of prescription drugs,
516 unless permitted as a third party logistics provider, located
517 outside of this state or outside the United States and that
518 engages in the distribution in this state of such prescription
519 drugs. Each such manufacturer must be permitted by the
520 department and comply with all of the provisions required of a
521 prescription drug manufacturer under this part. To participate
522 as an exporter of prescription drugs into this state under the

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523 International Prescription Drug Importation Program established
524 in s. 499.0285, a nonresident prescription drug manufacturer
525 located outside of the United States must register with the
526 department before engaging in any activities under that section.
527 Such manufacturer must be licensed or permitted in a country
528 with whom the United States has a current mutual recognition
529 agreement, cooperation agreement, memorandum of understanding,
530 or other federal mechanism recognizing the country's adherence
531 to current good manufacturing practices for pharmaceutical
532 products. The department shall adopt rules for issuing a virtual
533 nonresident prescription drug manufacturer permit to a person
534 who engages in the manufacture of prescription drugs but does
535 not make or take physical possession of any prescription drugs.
536 The rules adopted by the department under this section may
537 exempt virtual nonresident manufacturers from certain
538 establishment, security, and storage requirements set forth in
539 s. 499.0121.

540 1. A person that distributes prescription drugs for which
541 the person is not the manufacturer must also obtain an out-of-
542 state prescription drug wholesale distributor permit,
543 international prescription drug wholesale distributor permit, or
544 third party logistics provider permit pursuant to this section
545 to engage in the distribution of such prescription drugs when
546 required by this part. This subparagraph does not apply to a
547 manufacturer that distributes prescription drugs only for the
548 manufacturer of the prescription drugs where both manufacturers
549 are affiliates.

550 2. Any such person must comply with the licensing or
551 permitting requirements of the jurisdiction in which the

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552 establishment is located and the federal act, and any
553 prescription drug distributed into this state must comply with
554 this part. If a person intends to import prescription drugs from
555 a foreign country into this state, the nonresident prescription
556 drug manufacturer must provide to the department a list
557 identifying each prescription drug it intends to import and
558 document approval by the United States Food and Drug
559 Administration for such importation. A nonresident prescription
560 drug manufacturer that has registered to participate in the
561 International Prescription Drug Importation Program pursuant to
562 this section is not required to provide such documentation for
563 prescription drugs imported under that program.

564 (s) International prescription drug wholesale distributor.—
565 A wholesale distributor located outside of the United States
566 must obtain an international prescription drug wholesale
567 distributor permit to engage in the wholesale exportation and
568 the distribution of prescription drugs in this state under the
569 International Prescription Drug Importation Program established
570 in s. 499.0285. The wholesale distributor must be licensed or
571 permitted to operate in a country with whom the United States
572 has a mutual recognition agreement, cooperation agreement,
573 memorandum of understanding, or other federal mechanism
574 recognizing the country's adherence to current good
575 manufacturing practices for pharmaceutical products. The
576 wholesale distributor must maintain at all times a license or
577 permit to engage in the wholesale distribution of prescription
578 drugs in compliance with the laws of the jurisdiction in which
579 it operates. An international prescription drug wholesale
580 distributor permit may not be issued to a wholesale distributor

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581 if the jurisdiction in which the wholesale distributor operates
582 does not require a license to engage in the wholesale
583 distribution of prescription drugs.

584 Section 6. Subsection (2), paragraph (a) of subsection (4),
585 subsections (8), (10), (11), and (14), and paragraphs (a), (b),
586 and (f) of subsection (15) of section 499.012, Florida Statutes,
587 are amended to read:

588 499.012 Permit application requirements.—

589 (2) Notwithstanding subsection (6), a permitted person in
590 good standing may change the type of permit issued to that
591 person by completing a new application for the requested permit,
592 paying the amount of the difference in the permit fees if the
593 fee for the new permit is more than the fee for the original
594 permit, and meeting the applicable permitting conditions for the
595 new permit type. The new permit expires on the expiration date
596 of the original permit being changed; however, a new permit for
597 a prescription drug wholesale distributor, an out-of-state
598 prescription drug wholesale distributor, an international
599 prescription drug wholesale distributor, or a retail pharmacy
600 drug wholesale distributor shall expire on the expiration date
601 of the original permit or 1 year after the date of issuance of
602 the new permit, whichever is earlier. A refund may not be issued
603 if the fee for the new permit is less than the fee that was paid
604 for the original permit.

605 (4) (a) Except for a permit for a prescription drug
606 wholesale distributor, an international prescription drug
607 wholesale distributor, or an out-of-state prescription drug
608 wholesale distributor, an application for a permit must include:

609 1. The name, full business address, and telephone number of

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610 the applicant;

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

612 3. The address, telephone numbers, and the names of contact
613 persons for each facility used by the applicant for the storage,
614 handling, and distribution of prescription drugs;

615 4. The type of ownership or operation, such as a
616 partnership, corporation, or sole proprietorship; and

617 5. The names of the owner and the operator of the
618 establishment, including:

619 a. If an individual, the name of the individual;

620 b. If a partnership, the name of each partner and the name
621 of the partnership;

622 c. If a corporation, the name and title of each corporate
623 officer and director, the corporate names, and the name of the
624 state of incorporation;

625 d. If a sole proprietorship, the full name of the sole
626 proprietor and the name of the business entity;

627 e. If a limited liability company, the name of each member,
628 the name of each manager, the name of the limited liability
629 company, and the name of the state in which the limited
630 liability company was organized; and

631 f. Any other relevant information that the department
632 requires.

633 (8) An application for a permit or to renew a permit for a
634 prescription drug wholesale distributor, an international
635 prescription drug wholesale distributor, or an out-of-state
636 prescription drug wholesale distributor submitted to the
637 department must include:

638 (a) The name, full business address, and telephone number

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639 of the applicant.

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

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

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

646 (e) The names of the owner and the operator of the
647 establishment, including:

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

649 2. If a partnership, the name of each partner and the name
650 of the partnership.

651 3. If a corporation:

652 a. The name, address, and title of each corporate officer
653 and director.

654 b. The name and address of the corporation, resident agent
655 of the corporation, the resident agent's address, and the
656 corporation's state of incorporation.

657 c. The name and address of each shareholder of the
658 corporation that owns 5 percent or more of the outstanding stock
659 of the corporation.

660 4. If a sole proprietorship, the full name of the sole
661 proprietor and the name of the business entity.

662 5. If a limited liability company:

663 a. The name and address of each member.

664 b. The name and address of each manager.

665 c. The name and address of the limited liability company,
666 the resident agent of the limited liability company, and the
667 name of the state in which the limited liability company was

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668 organized.

669 (f) If applicable, the name and address of each affiliate
670 of the applicant.

671 (g) The applicant's gross annual receipts attributable to
672 prescription drug wholesale distribution activities for the
673 previous tax year.

674 (h) The tax year of the applicant.

675 (i) A copy of the deed for the property on which
676 applicant's establishment is located, if the establishment is
677 owned by the applicant, or a copy of the applicant's lease for
678 the property on which applicant's establishment is located that
679 has an original term of not less than 1 calendar year, if the
680 establishment is not owned by the applicant.

681 (j) A list of all licenses and permits issued to the
682 applicant by any other state or other jurisdiction which
683 authorize the applicant to purchase or possess prescription
684 drugs.

685 (k) The name of the manager of the establishment that is
686 applying for the permit or to renew the permit, the next four
687 highest ranking employees responsible for prescription drug
688 wholesale operations for the establishment, and the name of all
689 affiliated parties for the establishment, together with the
690 personal information statement and fingerprints required
691 pursuant to subsection (9) for each of such persons.

692 (l) The name of each of the applicant's designated
693 representatives as required by subsection (15), together with
694 the personal information statement and fingerprints required
695 pursuant to subsection (9) for each such person.

696 (m) Evidence of a surety bond in this state or any other

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697 state in the United States in the amount of \$100,000. If the
698 annual gross receipts of the applicant's previous tax year are
699 \$10 million or less, evidence of a surety bond in the amount of
700 \$25,000. The specific language of the surety bond must include
701 the State of Florida as a beneficiary, payable to the
702 Professional Regulation Trust Fund. In lieu of the surety bond,
703 the applicant may provide other equivalent security such as an
704 irrevocable letter of credit, or a deposit in a trust account or
705 financial institution, which includes the State of Florida as a
706 beneficiary, payable to the Professional Regulation Trust Fund.
707 The purpose of the bond or other security is to secure payment
708 of any administrative penalties imposed by the department and
709 any fees and costs incurred by the department regarding that
710 permit which are authorized under state law and which the
711 permittee fails to pay 30 days after the fine or costs become
712 final. The department may make a claim against such bond or
713 security until 1 year after the permittee's license ceases to be
714 valid or until 60 days after any administrative or legal
715 proceeding authorized in this part which involves the permittee
716 is concluded, including any appeal, whichever occurs later.

717 (n) For establishments used in wholesale distribution,
718 proof of an inspection conducted by the department, the United
719 States Food and Drug Administration, or another governmental
720 entity charged with the regulation of good manufacturing
721 practices related to wholesale distribution of prescription
722 drugs, within timeframes set forth by the department in
723 departmental rules, which demonstrates substantial compliance
724 with current good manufacturing practices applicable to
725 wholesale distribution of prescription drugs. The department may

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726 recognize another state's or jurisdiction's inspection of a
727 wholesale distributor located in that state or jurisdiction if
728 such state's or jurisdiction's laws are deemed to be
729 substantially equivalent to the law of this state by the
730 department. The department may accept an inspection by a third-
731 party accreditation or inspection service which meets the
732 criteria set forth in department rule.

733 (o) Any other relevant information that the department
734 requires.

735 (p) Documentation of the credentialing policies and
736 procedures required by s. 499.0121(15).

737 (q) For international prescription drug wholesale
738 distributors and nonresident prescription drug manufacturers to
739 participate in the International Prescription Drug Importation
740 Program established under s. 499.0285, documentation
741 demonstrating that the applicant is appropriately licensed or
742 permitted by a country with whom the United States has a mutual
743 recognition agreement, cooperation agreement, memorandum of
744 understanding, or other mechanism recognizing the country's
745 adherence to current good manufacturing practices for
746 pharmaceutical products.

747 (10) The department may deny an application for a permit or
748 refuse to renew a permit for a prescription drug wholesale
749 distributor, an international prescription drug wholesale
750 distributor, or an out-of-state prescription drug wholesale
751 distributor if:

752 (a) The applicant has not met the requirements for the
753 permit.

754 (b) The management, officers, or directors of the applicant

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755 or any affiliated party are found by the department to be
756 incompetent or untrustworthy.

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

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

763 (e) The applicant is lacking in experience in the
764 distribution of prescription drugs.

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

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

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

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

781 (j) The applicant has furnished false or fraudulent
782 information or material in any application made in this state or
783 any other state in connection with obtaining a permit or license

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784 to manufacture or distribute drugs, devices, or cosmetics.

785 (k) That a federal, state, or local government permit
786 currently or previously held by the applicant, or any affiliated
787 party, for the manufacture or distribution of any drugs,
788 devices, or cosmetics has been disciplined, suspended, or
789 revoked and has not been reinstated.

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

794 (m) The applicant or any affiliated party receives,
795 directly or indirectly, financial support and assistance from a
796 person who was an affiliated party of a permittee whose permit
797 was subject to discipline or was suspended or revoked, other
798 than through the ownership of stock in a publicly traded company
799 or a mutual fund.

800 (n) The applicant or any affiliated party receives,
801 directly or indirectly, financial support and assistance from a
802 person who has been found guilty of any violation of this part
803 or chapter 465, chapter 501, or chapter 893, any rules adopted
804 under this part or those chapters, any federal or state drug
805 law, or any felony where the underlying facts related to drugs,
806 regardless of whether the person has been pardoned, had her or
807 his civil rights restored, or had adjudication withheld, other
808 than through the ownership of stock in a publicly traded company
809 or a mutual fund.

810 (o) The applicant for renewal of a permit under s.
811 499.01(2)(e) or (f) has not actively engaged in the wholesale
812 distribution of prescription drugs, as demonstrated by the

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813 regular and systematic distribution of prescription drugs
814 throughout the year as evidenced by not fewer than 12 wholesale
815 distributions in the previous year and not fewer than three
816 wholesale distributions in the previous 6 months.

817 (p) Information obtained in response to s. 499.01(2)(e) or
818 (f) demonstrates it would not be in the best interest of the
819 public health, safety, and welfare to issue a permit.

820 (q) The applicant does not possess the financial standing
821 and business experience for the successful operation of the
822 applicant.

823 (r) The applicant or any affiliated party has failed to
824 comply with the requirements for manufacturing or distributing
825 prescription drugs under this part, similar federal laws,
826 similar laws in other states, or the rules adopted under such
827 laws.

828 (11) Upon approval of the application by the department and
829 payment of the required fee, the department shall issue or renew
830 a prescription drug wholesale distributor, an international
831 prescription drug wholesale distributor, or an out-of-state
832 prescription drug wholesale distributor permit to the applicant.

833 (14) The name of a permittee or establishment on a
834 prescription drug wholesale distributor permit, an international
835 prescription drug wholesale distributor permit, or an out-of-
836 state prescription drug wholesale distributor permit may not
837 include any indicia of attainment of any educational degree, any
838 indicia that the permittee or establishment possesses a
839 professional license, or any name or abbreviation that the
840 department determines is likely to cause confusion or mistake or
841 that the department determines is deceptive, including that of

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842 any other entity authorized to purchase prescription drugs.

843 (15) (a) Each establishment that is issued an initial or
844 renewal permit as a prescription drug wholesale distributor, an
845 international prescription drug wholesale distributor, or an
846 out-of-state prescription drug wholesale distributor must
847 designate in writing to the department at least one natural
848 person to serve as the designated representative of the
849 wholesale distributor. Such person must have an active
850 certification as a designated representative from the
851 department.

852 (b) To be certified as a designated representative, a
853 natural person must:

854 1. Submit an application on a form furnished by the
855 department and pay the appropriate fees.

856 2. Be at least 18 years of age.

857 3. Have at least 2 years of verifiable full-time:

858 a. Work experience in a pharmacy licensed in this state or
859 another state or jurisdiction, where the person's
860 responsibilities included, but were not limited to,
861 recordkeeping for prescription drugs;

862 b. Managerial experience with a prescription drug wholesale
863 distributor licensed in this state or in another state or
864 another jurisdiction; or

865 c. Managerial experience with the United States Armed
866 Forces, where the person's responsibilities included, but were
867 not limited to, recordkeeping, warehousing, distributing, or
868 other logistics services pertaining to prescription drugs.

869 4. Receive a passing score of at least 75 percent on an
870 examination given by the department regarding federal laws

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871 governing distribution of prescription drugs and this part and
872 the rules adopted by the department governing the wholesale
873 distribution of prescription drugs. This requirement shall be
874 effective 1 year after the results of the initial examination
875 are mailed to the persons that took the examination. The
876 department shall offer such examinations at least four times
877 each calendar year.

878 5. Provide the department with a personal information
879 statement and fingerprints pursuant to subsection (9).

880 (f) A wholesale distributor may not operate under a
881 prescription drug wholesale distributor permit, an international
882 prescription drug wholesale distributor permit, or an out-of-
883 state prescription drug wholesale distributor permit for more
884 than 10 business days after the designated representative leaves
885 the employ of the wholesale distributor, unless the wholesale
886 distributor employs another designated representative and
887 notifies the department within 10 business days after ~~of~~ the
888 identity of the new designated representative.

889 Section 7. Subsection (20) of section 499.005, Florida
890 Statutes, is amended to read:

891 499.005 Prohibited acts.—It is unlawful for a person to
892 perform or cause the performance of any of the following acts in
893 this state:

894 (20) The importation of a prescription drug except as
895 provided by s. 801(d) of the Federal Food, Drug, and Cosmetic
896 Act or s. 499.0285.

897 Section 8. Paragraph (e) of subsection (12) of section
898 499.0051, Florida Statutes, is amended to read:

899 499.0051 Criminal acts.—

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900 (12) REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR
 901 TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO
 902 PRESCRIPTION DRUGS.—Any person who violates any of the following
 903 provisions commits a felony of the third degree, punishable as
 904 provided in s. 775.082, s. 775.083, or s. 775.084, or as
 905 otherwise provided in this part:

906 (e) The importation of a prescription drug for wholesale
 907 distribution, except as provided by s. 801(d) of the Federal
 908 Food, Drug, and Cosmetic Act or s. 499.0285.

909 Section 9. Paragraph (c) is added to subsection (1) of
 910 section 499.015, Florida Statutes, to read:

911 499.015 Registration of drugs and devices; issuance of
 912 certificates of free sale.—

913 (1)

914 (c) Registration under this section is not required for
 915 prescription drugs imported under the International Prescription
 916 Drug Importation Program established in s. 499.0285.

917 Section 10. Subsections (1) and (3) of section 499.065,
 918 Florida Statutes, are amended to read:

919 499.065 Inspections; imminent danger.—

920 (1) Notwithstanding s. 499.051, the department shall
 921 inspect each prescription drug wholesale distributor
 922 establishment, international prescription drug wholesale
 923 distributor establishment, prescription drug repackager
 924 establishment, veterinary prescription drug wholesale
 925 distributor establishment, limited prescription drug veterinary
 926 wholesale distributor establishment, and retail pharmacy drug
 927 wholesale distributor establishment that is required to be
 928 permitted under this part as often as necessary to ensure

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929 compliance with applicable laws and rules. The department shall
930 have the right of entry and access to these facilities at any
931 reasonable time.

932 (3) The department may determine that a prescription drug
933 wholesale distributor establishment, international prescription
934 drug wholesale distributor establishment, prescription drug
935 repackager establishment, veterinary prescription drug wholesale
936 distributor establishment, limited prescription drug veterinary
937 wholesale distributor establishment, or retail pharmacy drug
938 wholesale distributor establishment that is required to be
939 permitted under this part is an imminent danger to the public
940 health and shall require its immediate closure if the
941 establishment fails to comply with applicable laws and rules
942 and, because of the failure, presents an imminent threat to the
943 public's health, safety, or welfare. Any establishment so deemed
944 and closed shall remain closed until allowed by the department
945 or by judicial order to reopen.

946 Section 11. Notwithstanding the Federal Food, Drug, and
947 Cosmetic Act, the Department of Business and Professional
948 Regulation, in collaboration with the Department of Health,
949 shall negotiate a federal arrangement to operate a pilot program
950 for importing prescription drugs into this state. The proposal
951 to operate such a pilot program must demonstrate that the
952 program sets safety standards consistent with the current
953 federal requirements for the manufacturing and distributing of
954 prescription drugs; limits the importation of prescription drugs
955 to entities licensed or permitted by the state to manufacture,
956 distribute, or dispense prescription drugs; and includes
957 inspection and enforcement authority. Implementation of sections

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958 2 through 11 of this act is contingent upon such federal
959 arrangement or upon obtaining federal guidance.

960 Section 12. This act shall take effect July 1, 2019.