

By the Committees on Appropriations; and Health Policy; and
Senators Bean and 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.; requiring the
4 Agency for Health Care Administration to establish the
5 Canadian Prescription Drug Importation Program;
6 defining terms; requiring the agency to contract with
7 a vendor to facilitate wholesale prescription drug
8 importation under the program; providing
9 responsibilities for the vendor; providing eligibility
10 criteria for prescription drugs, Canadian suppliers,
11 and importers under the program; authorizing a
12 Canadian supplier to export drugs into this state
13 under the program under certain circumstances;
14 providing eligibility criteria and requirements for
15 drug importers; requiring participating Canadian
16 suppliers and importers to comply with specified
17 federal requirements for distributing prescription
18 drugs imported under the program; prohibiting Canadian
19 suppliers and importers from distributing, dispensing,
20 or selling prescription drugs imported under the
21 program outside of this state; requiring the agency to
22 request federal approval of the program; requiring the
23 request to include certain information; requiring the
24 agency to begin operating the program within a
25 specified timeframe after receiving federal approval;
26 providing certain documentation requirements;
27 requiring the agency to suspend the importation of
28 drugs in violation of this section or any federal or
29 state law or regulation; authorizing the agency to

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30 revoke the suspension under certain circumstances;
31 requiring the agency to submit an annual report to the
32 Governor and the Legislature by a specified date;
33 providing requirements for such report; requiring the
34 agency to notify the Legislature upon federal approval
35 of the program and to submit a proposal to the
36 Legislature for program implementation and funding
37 before a certain date; requiring the agency to adopt
38 necessary rules; creating s. 465.0157, F.S.;

39 establishing an international export pharmacy permit
40 for participation in the International Prescription
41 Drug Importation Program; providing requirements for
42 permit application and renewal; amending s. 465.017,
43 F.S.; authorizing the Department of Health to inspect
44 international export pharmacy permittees; amending s.
45 499.005, F.S.; providing that the importation of a
46 prescription drug under the International Prescription
47 Drug Importation Program is not a prohibited act under
48 that chapter; amending s. 499.0051, F.S.; providing an
49 exemption from prosecution as a criminal offense for
50 the importation of a prescription drug for wholesale
51 distribution under the International Prescription Drug
52 Importation Program; amending s. 499.01, F.S.;

53 requiring an international prescription drug wholesale
54 distributor to be permitted before operating;
55 requiring nonresident prescription drug manufacturers
56 to register with the Department of Business and
57 Professional Regulation to participate in the program;
58 providing an exception; establishing an international

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59 prescription drug wholesale distributor drug permit;
60 providing permit requirements; amending s. 499.012,
61 F.S.; providing application requirements for
62 international prescription drug wholesale distributors
63 and nonresident prescription drug manufacturers to
64 participate in the program; amending s. 499.015, F.S.;
65 establishing that prescription drugs imported under
66 the International Prescription Drug Importation
67 Program are not required to be registered under a
68 specified provision; amending s. 499.065, F.S.;
69 requiring the department to inspect international
70 prescription drug wholesale distributor
71 establishments; authorizing the department to
72 determine that an international prescription drug
73 wholesale distributor establishment is an imminent
74 danger to the public and require its immediate closure
75 under certain conditions; creating s. 499.0285, F.S.;
76 requiring the Department of Business and Professional
77 Regulation to establish the International Prescription
78 Drug Importation Program for a specified purpose;
79 providing definitions; providing eligibility criteria
80 for prescription drugs, exporters, and importers under
81 the program; requiring participating importers to
82 submit certain documentation to the department for
83 prescription drugs imported under the program;
84 requiring the department to immediately suspend the
85 importation of specific prescription drug or the
86 importation of prescription drugs by a specific
87 importer if a violation has occurred under the

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88 program; authorizing the department to revoke such
89 suspension under certain circumstances; requiring the
90 department to adopt necessary rules; requiring the
91 agency, in collaboration with the Department of
92 Business and Professional Regulation and the
93 Department of Health, to negotiate a federal
94 arrangement to operate a pilot program for importing
95 prescription drugs into this state; providing that
96 implementation of the act is contingent upon the
97 federal authorization; requiring the department to
98 notify the Legislature before implementation of the
99 pilot program and to submit a proposal for pilot
100 program implementation and funding; providing an
101 effective date.

102
103 Be It Enacted by the Legislature of the State of Florida:

104
105 Section 1. Section 381.02035, Florida Statutes, is created
106 to read:

107 381.02035 Canadian Prescription Drug Importation Program.-

108 (1) PROGRAM ESTABLISHED.-The Agency for Health Care
109 Administration shall establish the Canadian Prescription Drug
110 Importation Program for the importation of safe and effective
111 prescription drugs from Canada which have the highest potential
112 for cost savings to the state.

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

114 (a) "Agency" means the Agency for Health Care
115 Administration.

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

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117 distributor, or pharmacy appropriately licensed or permitted
118 under Canadian law to manufacture, distribute, or dispense
119 prescription drugs.

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

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

123 (e) "Drug" or "prescription drug" has the same meaning as
124 "prescription drug" in s. 499.003, but is limited to drugs
125 intended for human use.

126 (f) "Federal act" means the Federal Food, Drug, and
127 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.
128 as amended by the Drug Quality and Security Act, 21 U.S.C. 351
129 et seq.

130 (g) "Free clinic" means a clinic that delivers only medical
131 diagnostic services or nonsurgical medical treatment free of
132 charge to low-income recipients.

133 (h) "Medicaid pharmacy" means a pharmacy licensed under
134 chapter 465 that has a Medicaid provider agreement in effect
135 with the agency and is in good standing with the agency.

136 (i) "Pharmacist" means a person who holds an active and
137 unencumbered license to practice pharmacy pursuant to chapter
138 465.

139 (j) "Program" means the Canadian Prescription Drug
140 Importation Program.

141 (k) "Track-and-trace" means the product-tracing process for
142 the components of the pharmaceutical distribution supply chain
143 as described in Title II of the Drug Quality and Security Act,
144 Drug Supply Chain Security Act, 21 U.S.C. 351 et seq.

145 (l) "Vendor" means the entity contracted by the agency to

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146 manage specified functions of the program.

147 (3) IMPORTATION PROCESS.—

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

150 (b) By December 1, 2019, and each year thereafter, the
151 vendor shall develop a Wholesale Prescription Drug Importation
152 List identifying the prescription drugs that have the highest
153 potential for cost savings to the state. In developing the list,
154 the vendor shall consider, at a minimum, which prescription
155 drugs will provide the greatest cost savings to state programs,
156 including prescriptions drugs for which there are shortages,
157 specialty prescription drugs, and high volume prescription
158 drugs. The agency, in consultation with the department, shall
159 review the Wholesale Prescription Drug Importation List every 3
160 months to ensure that it continues to meet the requirements of
161 the programs and may direct the vendor to revise the list, as
162 necessary.

163 (c) The vendor shall submit evidence of a surety bond with
164 any bid or initial contract negotiation documents and shall
165 maintain documentation of evidence of such a bond with the
166 agency throughout the contract term. The surety bond may be from
167 this state or any other state in the United States for at least
168 \$25,000. The surety bond or comparable security arrangement must
169 include the State of Florida as a beneficiary. In lieu of the
170 surety bond, the vendor may provide a comparable security
171 agreement, such as an irrevocable letter of credit or a deposit
172 into a trust account or financial institution, which includes
173 the State of Florida as a beneficiary, payable to the State of
174 Florida. The purposes of the bond or other security arrangement

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175 for the program are to:

176 1. Ensure payment of any administrative penalties imposed
177 by the agency or any other state agency under the contract, if
178 the vendor fails to pay within 30 days after assessment;

179 2. Ensure that the vendor meets contractual and statutory
180 obligations through use of a surety bond or other comparable
181 security arrangements to pay any other costs or fees incurred by
182 the agency, the state, or other entities acting on behalf of the
183 state if the vendor fails to meet its contractual and statutory
184 obligations. If the vendor is assessed a penalty under the
185 program and fails to pay within 30 days after that assessment,
186 the agency, the state, or an entity acting on behalf of the
187 state may file a claim for reimbursement against the bond or
188 other comparable security arrangement; and

189 3. Allow for claims to be made against the bond or other
190 comparable security arrangements for up to 1 year after the
191 vendor's contract under the program has ended with the agency or
192 the state or the program has ended, whichever occurs last.

193
194 A surety bond or comparable document is required, regardless of
195 the type of bid or negotiation process the agency used or the
196 type of final contract or agreement executed for services.

197 (d) The vendor must submit evidence at the time of contract
198 award and throughout the contract term of a surety bond or
199 comparable security arrangement from this state or any other
200 state in the United States in an amount no less than \$25,000.
201 The surety bond or comparable security arrangement must include
202 the State of Florida as a beneficiary. In lieu of the surety
203 bond, the vendor may provide a comparable security arrangement

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204 such as an irrevocable letter of credit or a deposit into a
205 trust account or financial institution which names the State of
206 Florida as a beneficiary. The purposes of the bond or other
207 security arrangements for the program are to:

208 1. Ensure participation of the vendor in any civil or
209 criminal legal action by the state, the agency, any other state
210 agency, or private individuals or entities against the vendor
211 because of the vendor's failure to perform under the contract,
212 including, but not limited to causes of actions for personal
213 injury, negligence, and wrongful death;

214 2. Ensure payment by the vendor through the use of a bond
215 or other comparable security arrangements of legal judgements
216 and claims that have been awarded to the agency, the state,
217 other entities acting on behalf of the state, individuals, or
218 organizations if the vendor is assessed a final judgement or
219 other monetary penalty in a court of law for a civil or criminal
220 action under the program. The bond or comparable security
221 arrangement will be accessed if the vendor fails to pay any
222 judgement or claim within 60 days after final judgement; and

223 3. Allow for civil and criminal litigation claims to be
224 made against the bond or other comparable security arrangements
225 for up to 1 year after the vendor's contract under the program
226 has ended with the agency or the state, the vendor's license is
227 no longer valid, or the program has ended, whichever occurs
228 last.

229 (e) The vendor shall identify Canadian suppliers that are
230 in full compliance with relevant Canadian federal and provincial
231 laws and regulations and the federal act and who have agreed to
232 export drugs identified on the list at prices that will provide

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233 cost savings to the state. The vendor must verify that such
234 Canadian suppliers meet all of the requirements of the program,
235 while meeting or exceeding the federal and state track-and-trace
236 laws and regulations.

237 (f) The vendor shall contract with such eligible Canadian
238 suppliers, or facilitate contracts between eligible importers
239 and Canadian suppliers, to import drugs under the program.

240 (g) The vendor shall maintain a list of all registered
241 importers that participate in the program.

242 (h) The vendor shall ensure compliance with Title II of the
243 federal Drug Quality and Security Act, Pub. L. No. 113-54, by
244 all suppliers, importers and other distributors, and
245 participants in the program.

246 (i) The vendor shall assist the agency in the preparation
247 of the annual report required by subsection (11), including the
248 timely provision of any information requested by the agency.

249 (j) The vendor shall provide an annual financial audit of
250 its operations to the agency as required by the agency. The
251 vendor shall also provide quarterly financial reports specific
252 to the program and shall include information on the performance
253 of its subcontractors and vendors. The agency shall determine
254 the format and contents of the reports.

255 (4) ELIGIBLE PRESCRIPTION DRUGS.—Eligible importers, as
256 described in subsection (6), may import a drug from an eligible
257 Canadian supplier, as described in subsection (5), if:

258 (a) The drug meets the United States Food and Drug
259 Administration's standards related to safety, effectiveness,
260 misbranding, and adulteration;

261 (b) Importing the drug would not violate federal patent

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262 laws;

263 (c) Importing the drug is expected to generate cost
264 savings; and

265 (d) The drug is not:

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

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

268 3. An infused drug;

269 4. An intravenously injected drug;

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

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

274 (5) ELIGIBLE CANADIAN SUPPLIERS.—A Canadian supplier may
275 export prescription drugs into this state under the program if
276 the supplier:

277 (a) Is in full compliance with relevant Canadian federal
278 and provincial laws and regulations;

279 (b) Is identified by the vendor as eligible to participate
280 in the program; and

281 (c) Submits an attestation that the supplier has a
282 registered agent in the United States, including the name and
283 United States address of the registered agent.

284 (6) ELIGIBLE IMPORTERS.—The following entities may import
285 prescription drugs from an eligible Canadian supplier under the
286 program:

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

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

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

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

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

303 (7) DISTRIBUTION REQUIREMENTS.—Eligible Canadian suppliers
304 and eligible importers participating under the program:

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

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

309 (8) FEDERAL APPROVAL.—By July 1, 2020, the agency shall
310 submit a request to the United States Secretary of Health and
311 Human Services for approval of the program under 21 U.S.C. s.
312 384(1). The agency shall begin operating the program within 6
313 months after receiving such approval. The request must, at a
314 minimum:

315 (a) Describe the agency's plan for operating the program.

316 (b) Demonstrate how the prescription drugs imported into
317 this state under the program will meet the applicable federal
318 and state standards for safety and effectiveness.

319 (c) Demonstrate how the drugs imported into this state

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320 under the program will comply with federal tracing procedures.

321 (d) Include a list of proposed prescription drugs that have
322 the highest potential for cost savings to the state through
323 importation at the time that the request is submitted.

324 (e) Estimate the total cost savings attributable to the
325 program.

326 (f) Provide the costs of program implementation to the
327 state.

328 (g) Include a list of potential Canadian suppliers from
329 which the state would import drugs and demonstrate that the
330 suppliers are in full compliance with relevant Canadian federal
331 and provincial laws and regulations as well as all applicable
332 federal and state laws and regulations.

333 (9) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

334 (a) The vendor shall ensure the safety and quality of drugs
335 imported under the program. The vendor shall:

336 1. For an initial imported shipment, ensure that each batch
337 of the drug in the shipment is statistically sampled and tested
338 for authenticity and degradation in a manner consistent with the
339 federal act.

340 2. For any subsequent imported shipment, ensure that a
341 statistically valid sample of the shipment is tested for
342 authenticity and degradation in a manner consistent with the
343 federal act.

344 3. Certify that the drug:

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

347 b. Meets all of the labeling requirements under 21 U.S.C.
348 s. 352.

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349 4. Maintain qualified laboratory records, including
350 complete data derived from all tests necessary to ensure that
351 the drug is in compliance with the requirements of this section.

352 5. Maintain documentation demonstrating that the testing
353 required by this section was conducted at a qualified laboratory
354 in accordance with the federal act and any other applicable
355 federal and state laws and regulations governing laboratory
356 qualifications.

357 (b) All testing required by this section must be conducted
358 in a qualified laboratory that meets the standards under the
359 federal act and any other applicable federal and state laws and
360 regulations governing laboratory qualifications for drug
361 testing.

362 (c) The vendor shall maintain information and documentation
363 submitted under this section for a period of at least 7 years.

364 (d) A participating importer must submit the all of
365 following information to the vendor:

366 1. The name and quantity of the active ingredient of the
367 drug.

368 2. A description of the dosage form of the drug.

369 3. The date on which the drug is received.

370 4. The quantity of the drug that is received.

371 5. The point of origin and destination of the drug.

372 6. The price paid by the importer for the drug.

373 (e) A participating Canadian supplier must submit the
374 following information and documentation to the vendor specifying
375 all of the following:

376 1. The original source of the drug, including:

377 a. The name of the manufacturer of the drug.

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- 378 b. The date on which the drug was manufactured.
- 379 c. The location (country, state or province, and city)
380 where the drug was manufactured.
- 381 2. The date on which the drug is shipped.
- 382 3. The quantity of the drug that is shipped.
- 383 4. The quantity of each lot of the drug originally received
384 and the source of the lot.
- 385 5. The lot or control number and the batch number assigned
386 to the drug by the manufacturer.
- 387 (f) The agency may require that the vendor collect any
388 other information necessary to ensure the protection of the
389 public health.
- 390 (10) IMMEDIATE SUSPENSION.—The agency shall immediately
391 suspend the importation of a specific drug or the importation of
392 drugs by a specific importer if it discovers that any drug or
393 activity is in violation of this section or any federal or state
394 law or regulation. The agency may revoke the suspension if,
395 after conducting an investigation, it determines that the public
396 is adequately protected from counterfeit or unsafe drugs being
397 imported into this state.
- 398 (11) ANNUAL REPORT.—By December 1 of each year, the agency
399 shall submit a report to the Governor, the President of the
400 Senate, and the Speaker of the House of Representatives on the
401 operation of the program during the previous fiscal year. The
402 report must include, at a minimum:
- 403 (a) A list of the prescription drugs that were imported
404 under the program;
- 405 (b) The number of participating entities;
- 406 (c) The number of prescriptions dispensed through the

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407 program;

408 (d) The estimated cost savings during the previous fiscal
409 year and to date attributable the program;

410 (e) A description of the methodology used to determine
411 which drugs should be included on the Wholesale Prescription
412 Drug Importation List; and

413 (f) Documentation as to how the program ensures the
414 following:

415 1. That Canadian suppliers participating in the program are
416 of high quality, high performance, and in full compliance with
417 relevant Canadian federal and provincial laws and regulations as
418 well as all federal laws and regulations and state laws and
419 rules;

420 2. That prescription drugs imported under the program are
421 not shipped, sold, or dispensed outside of this state once in
422 the possession of the importer;

423 3. That prescription drugs imported under the program are
424 pure, unadulterated, potent, and safe;

425 4. That the program does not put consumers at a higher
426 health and safety risk than if the consumer did not participate;
427 and

428 5. That the program provides cost savings to the state on
429 imported prescription drugs.

430 (12) NOTIFICATION OF FEDERAL APPROVAL.—Upon receipt of
431 federal approval of the program, the agency shall notify the
432 President of the Senate, the Speaker of the House of
433 Representatives, and the relevant committees of the Senate and
434 the House of Representatives. After approval is received and
435 before the start of the next regular session of the Legislature

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436 in which the proposal could be funded, the agency shall submit
437 to all parties a proposal for program implementation and program
438 funding.

439 (13) RULEMAKING.—The agency shall adopt rules necessary to
440 implement this section.

441 Section 2. Section 465.0157, Florida Statutes, is created
442 to read:

443 465.0157 International export pharmacy permit.—

444 (1) To participate as an exporter of prescription drugs
445 into this state under the International Prescription Drug
446 Importation Program established in s. 499.0285, a pharmacy
447 located outside of the United States must hold an international
448 export pharmacy permit.

449 (2) An international export pharmacy shall maintain at all
450 times an active and unencumbered license or permit to operate
451 the pharmacy in compliance with the laws of the jurisdiction in
452 which the dispensing facility is located and from which the
453 prescription drugs will be exported. Such jurisdiction must be
454 in a country with which the United States has a current mutual
455 recognition agreement, cooperation agreement, memorandum of
456 understanding, or other federal mechanism recognizing the
457 country's adherence to current good manufacturing practices for
458 pharmaceutical products.

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

464 (4) An applicant shall submit the following to the board to

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465 obtain an initial permit, or to the department to renew a
466 permit:

467 (a) Proof of an active and unencumbered license or permit
468 to operate the pharmacy in compliance with the laws of the
469 jurisdiction in which the dispensing facility is located and
470 from which the prescription drugs will be exported.

471 (b) Documentation demonstrating that the country in which
472 the pharmacy operates has a current mutual recognition
473 agreement, cooperation agreement, memorandum of understanding,
474 or other federal mechanism recognizing the country's adherence
475 to current good manufacturing practices for pharmaceutical
476 products.

477 (c) Evidence of a surety bond with any application or
478 filing for pharmacy permit under this section and shall maintain
479 documentation of evidence of such a bond with the Department of
480 Business and Professional Regulation throughout the permit term.
481 The surety bond may be from this state or any other state in the
482 United States for no less than \$25,000. The surety bond or
483 comparable security arrangement must include the State of
484 Florida as a beneficiary. In lieu of the surety bond, the
485 pharmacy may provide a comparable security agreement, such as an
486 irrevocable letter of credit or a deposit into a trust account
487 or financial institution which includes the State of Florida as
488 a beneficiary, payable to the State of Florida. The purposes of
489 the bond or other security arrangement for the program are to:

- 490 1. Ensure payment of any administrative penalties imposed
491 by the department or any other state agency under the contract
492 when the pharmacy fails to pay within 30 days after assessment;
493 2. Ensure that the pharmacy meets contractual and statutory

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494 obligations through use of a surety bond or other comparable
495 security arrangements to pay any other costs or fees incurred by
496 the Department of Business of Professional Regulation, the
497 state, or other entities acting on behalf of the state if the
498 pharmacy fails to meet its obligations. If the pharmacy is
499 assessed a penalty under the program and fails to pay within 30
500 days after that assessment, the Department of Business and
501 Professional Regulation, the state, or an entity acting on
502 behalf of the state may file a claim for reimbursement against
503 the bond or other comparable security arrangement; and

504 3. Allow for claims to be made against the bond or other
505 comparable security arrangements for up to 1 year after the
506 pharmacy's permit under the program has ended with this section
507 or the program has ended, whichever occurs last.

508 (d) The eligible pharmacy must submit evidence at the time
509 of application and throughout the permit term of a surety bond
510 or comparable security arrangement from this state or any other
511 state in the United States in an amount no less than \$25,000.
512 The surety bond or comparable security arrangement must include
513 the State of Florida as a beneficiary. In lieu of the surety
514 bond, the pharmacy may provide a comparable security arrangement
515 such as an irrevocable letter of credit or a deposit into a
516 trust account or financial institution which names the State of
517 Florida as a beneficiary. The purposes of the bond or other
518 security arrangements for the program are to:

519 1. Ensure participation of the pharmacy in any civil or
520 criminal legal action by the state, the Department of Business
521 of Professional Regulation, any other state agency, or private
522 individuals or entities against the pharmacy or because of the

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523 pharmacy's failure to perform under the contract, including, but
524 not limited to causes of actions for personal injury,
525 negligence, and wrongful death;

526 2. Ensure payment by the pharmacy through the use of a bond
527 or other comparable security arrangements of legal judgements
528 and claims that have been awarded to the Department of Business
529 and Professional Regulation, the state, other entities acting on
530 behalf of the state, individuals, or organizations if the
531 pharmacy is assessed a final judgement or other monetary penalty
532 in a court of law for a civil or criminal action under the
533 program. The bond or comparable security arrangement will be
534 accessed if the pharmacy fails to pay any judgement or claim
535 within 60 days after final judgement; and

536 3. Allow for civil and criminal litigation claims to be
537 made against the bond or other comparable security arrangements
538 for up to 1 year after the pharmacy's contract under the program
539 has ended with the agency or the state, the pharmacy's license
540 is no longer valid, or the program has ended, whichever occurs
541 last.

542 (e) The location, names, and titles of all principal
543 corporate officers and the pharmacist who serves as the
544 prescription department manager for prescription drugs exported
545 into this state under the International Prescription Drug
546 Importation Program.

547 (f) Written attestation by an owner or officer of the
548 applicant, and by the applicant's prescription department
549 manager, that:

550 1. The attestor has read and understands the laws and rules
551 governing the manufacture, distribution, and dispensing of

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552 prescription drugs in this state.

553 2. A prescription drug shipped, mailed, or delivered into
554 this state meets or exceeds this state's standards for safety
555 and efficacy.

556 3. A prescription drug product shipped, mailed, or
557 delivered into this state must not have been, and may not be,
558 manufactured or distributed in violation of the laws and rules
559 of the jurisdiction in which the applicant is located and from
560 which the prescription drugs shall be exported.

561 (g) A current inspection report from an inspection
562 conducted by the regulatory or licensing agency of the
563 jurisdiction in which the applicant is located. The inspection
564 report must reflect compliance with this section. An inspection
565 report is current if the inspection was conducted within 6
566 months before the date of submitting the application for the
567 initial permit or within 1 year before the date of submitting an
568 application for permit renewal. If the applicant is unable to
569 submit a current inspection report conducted by the regulatory
570 or licensing agency of the jurisdiction in which the applicant
571 is located and from which the prescription drugs will be
572 exported, due to acceptable circumstances, as established by
573 rule, or if an inspection has not been performed, the department
574 must:

575 1. Conduct, or contract with an entity to conduct, an
576 onsite inspection, with all related costs borne by the
577 applicant;

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

580 3. Accept a current inspection report from the United

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581 States Food and Drug Administration conducted pursuant to the
582 federal Drug Quality and Security Act, Pub. L. No. 113-54.

583 Section 3. Subsection (2) of section 465.017, Florida
584 Statutes, is amended to read:

585 465.017 Authority to inspect; disposal.—

586 (2) Duly authorized agents and employees of the department
587 may inspect a nonresident pharmacy registered under s. 465.0156,
588 an international export pharmacy permittee under s. 465.0157, or
589 a nonresident sterile compounding permittee under s. 465.0158
590 pursuant to this section. The costs of such inspections shall be
591 borne by such pharmacy or permittee.

592 Section 4. Subsection (20) of section 499.005, Florida
593 Statutes, is amended to read:

594 499.005 Prohibited acts.—It is unlawful for a person to
595 perform or cause the performance of any of the following acts in
596 this state:

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

600 Section 5. Paragraph (e) of subsection (12) of section
601 499.0051, Florida Statutes, is amended to read:

602 499.0051 Criminal acts.—

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

609 (e) The importation of a prescription drug for wholesale

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610 distribution, except as provided by s. 801(d) of the Federal
611 Food, Drug, and Cosmetic Act or s. 499.0285.

612 Section 6. Subsection (1) and paragraph (c) of subsection
613 (2) of section 499.01, Florida Statutes, are amended, and
614 paragraph (s) is added to subsection (2) of that section, to
615 read:

616 499.01 Permits.—

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

619 (a) A prescription drug manufacturer;

620 (b) A prescription drug repackager;

621 (c) A nonresident prescription drug manufacturer;

622 (d) A nonresident prescription drug repackager;

623 (e) A prescription drug wholesale distributor;

624 (f) An out-of-state prescription drug wholesale
625 distributor;

626 (g) A retail pharmacy drug wholesale distributor;

627 (h) A restricted prescription drug distributor;

628 (i) A complimentary drug distributor;

629 (j) A freight forwarder;

630 (k) A veterinary prescription drug retail establishment;

631 (l) A veterinary prescription drug wholesale distributor;

632 (m) A limited prescription drug veterinary wholesale
633 distributor;

634 (n) An over-the-counter drug manufacturer;

635 (o) A device manufacturer;

636 (p) A cosmetic manufacturer;

637 (q) A third party logistics provider; ~~or~~

638 (r) A health care clinic establishment; or

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639 (s) An international prescription drug wholesale
640 distributor.

641 (2) The following permits are established:

642 (c) *Nonresident prescription drug manufacturer permit.*—A
643 nonresident prescription drug manufacturer permit is required
644 for any person that is a manufacturer of prescription drugs,
645 unless permitted as a third party logistics provider, located
646 outside of this state or outside the United States and that
647 engages in the distribution in this state of such prescription
648 drugs. Each such manufacturer must be permitted by the
649 department and comply with all of the provisions required of a
650 prescription drug manufacturer under this part. The department
651 shall adopt rules for issuing a virtual nonresident prescription
652 drug manufacturer permit to a person who engages in the
653 manufacture of prescription drugs but does not make or take
654 physical possession of any prescription drugs. The rules adopted
655 by the department under this section may exempt virtual
656 nonresident manufacturers from certain establishment, security,
657 and storage requirements set forth in s. 499.0121.

658 1. A person that distributes prescription drugs for which
659 the person is not the manufacturer must also obtain an out-of-
660 state prescription drug wholesale distributor permit, an
661 international prescription drug wholesale distributor permit, or
662 third party logistics provider permit pursuant to this section
663 to engage in the distribution of such prescription drugs when
664 required by this part. This subparagraph does not apply to a
665 manufacturer that distributes prescription drugs only for the
666 manufacturer of the prescription drugs where both manufacturers
667 are affiliates.

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668 2. Any such person must comply with the licensing or
669 permitting requirements of the jurisdiction in which the
670 establishment is located and the federal act, and any
671 prescription drug distributed into this state must comply with
672 this part. If a person intends to import prescription drugs from
673 a foreign country into this state, the nonresident prescription
674 drug manufacturer must provide to the department a list
675 identifying each prescription drug it intends to import and
676 document approval by the United States Food and Drug
677 Administration for such importation.

678 3.a. A nonresident prescription drug manufacturer that has
679 registered to participate in the International Prescription Drug
680 Importation Program pursuant to this section is not required to
681 provide the list and approval required by subparagraph 2. for
682 prescription drugs imported under that program.

683 b. To participate as an exporter of prescription drugs into
684 this state under the International Prescription Drug Importation
685 Program established under s. 499.0285, a nonresident
686 prescription drug manufacturer located outside of the United
687 States must register with the Department of Business and
688 Professional Regulation before engaging in any activities under
689 that section. Such manufacturer must be licensed or permitted in
690 a country with which the United States has a current mutual
691 recognition agreement, cooperation agreement, memorandum of
692 understanding, or other federal mechanism recognizing the
693 country's adherence to current good manufacturing practices for
694 pharmaceutical products.

695 c. The nonresident prescription drug manufacturer shall
696 submit evidence of a surety bond with any application or filing

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697 for registration under this section and shall maintain
698 documentation of evidence of such a bond with the Department of
699 Business and Professional Regulation throughout the registration
700 term. The surety bond may be from this state or any other state
701 in the United States in an amount equal to 10 percent of the
702 manufacturer's annual sales or \$1 million, whichever is higher.
703 The surety bond or comparable security arrangement must include
704 the State of Florida as a beneficiary. In lieu of the surety
705 bond, the manufacturer may provide a comparable security
706 agreement, such as an irrevocable letter of credit or a deposit
707 into a trust account or financial institution which includes the
708 State of Florida as a beneficiary, payable to the State of
709 Florida. The purposes of the bond or other security arrangement
710 for the program are to:

711 (I) Ensure payment of any administrative penalties imposed
712 by the Department of Business and Professional Regulation or any
713 other state agency under the contract when the manufacturer
714 fails to pay within 30 days after assessment;

715 (II) Ensure that if the manufacturer fails to meets its
716 obligations through use of a surety bond or other comparable
717 security arrangements to pay any other costs or fees incurred by
718 the Department of Business of Professional Regulation, the
719 state, or other entities acting on behalf of the state if the
720 manufacturer fails to meet its obligations. If the manufacturer
721 is assessed a penalty under the program and fails to pay within
722 30 days after that assessment, the Department of Business and
723 Professional Regulation, the state, or an entity acting on
724 behalf of the state may file a claim for reimbursement against
725 the bond or other comparable security arrangement; and

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726 (III) Allow for claims to be made against the bond or other
727 comparable security arrangements for up to 1 year after the
728 manufacturer's permit under the program has ended with this
729 section or the program has ended, whichever occurs last.

730 4. The eligible manufacturer must submit evidence at the
731 time of application and throughout the permit term of a surety
732 bond or comparable security arrangement from this state or any
733 other state in the United States in an amount equal to 10
734 percent of the manufacturer's annual sales or \$1 million,
735 whichever is greater. The surety bond or comparable security
736 arrangement must include the State of Florida as a beneficiary.
737 In lieu of the surety bond, the manufacturer may provide a
738 comparable security arrangement such as an irrevocable letter of
739 credit or a deposit into a trust account or financial
740 institution which names the State of Florida as a beneficiary.
741 The purposes of the bond or other security arrangements for the
742 program are to:

743 a. Ensure participation of the manufacturer in any civil or
744 criminal legal action by the state, the Department of Business
745 of Professional Regulation, any other state agency, or private
746 individuals or entities against the manufacturer or because of
747 the manufacturer's failure to perform according to the contract,
748 permit, or federal or state law and regulations, including, but
749 not limited to causes of actions for personal injury,
750 negligence, and wrongful death;

751 b. Ensure payment by the manufacturer through the use of a
752 bond or other comparable security arrangements of legal
753 judgements and claims that have been awarded to the Department
754 of Business and Professional Regulation, the state, other

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755 entities acting on behalf of the state, individuals, or
756 organizations if the pharmacy is assessed a final judgement or
757 other monetary penalty in a court of law for a civil or criminal
758 action under the program. The bond or comparable security
759 arrangement will be accessed if the manufacturer fails to pay
760 any judgement or claim within 60 days after final judgement; and

761 c. Allow for civil and criminal litigation claims to be
762 made against the bond or other comparable security arrangements
763 for up to 1 year after the manufacturer's permit under the
764 program has ended with the Department of Professional and
765 Business Regulation or the state, the manufacturer's permit or
766 comparable legal document is no longer valid, or the program has
767 ended, whichever occurs last.

768 (s) International prescription drug wholesale distributor.-

769 1. A wholesale distributor located outside of the United
770 States must obtain an international prescription drug wholesale
771 distributor permit to engage in the wholesale exportation and
772 distribution of prescription drugs in the state under the
773 International Prescription Drug Importation Program established
774 in s. 499.0285. The wholesale distributor must be licensed or
775 permitted to operate in a country with which the United States
776 has a mutual recognition agreement, cooperation agreement,
777 memorandum of understanding, or other federal mechanism
778 recognizing the country's adherence to current good
779 manufacturing practices for pharmaceutical products. The
780 wholesale distributor must maintain at all times a license or
781 permit to engage in the wholesale distribution of prescription
782 drugs in compliance with the laws of the jurisdiction in which
783 it operates. An international prescription drug wholesale

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784 distributor permit may not be issued to a wholesale distributor
785 if the jurisdiction in which the wholesale distributor operates
786 does not require a license to engage in the wholesale
787 distribution of prescription drugs.

788 2. In order to participate in the International
789 Prescription Drug Importation Program established under s.
790 499.0285, the international wholesale distributor shall submit
791 evidence of a surety bond with any application or filing for a
792 permit under this section and shall maintain documentation of
793 evidence of such a bond with the Department of Business and
794 Professional Regulation throughout the permit term. The surety
795 bond may be from this state or any other state in the United
796 States in an amount equal to 10 percent of the international
797 wholesale distributor's annual sales or \$1 million, whichever is
798 greater. The surety bond or comparable security arrangement must
799 include the State of Florida as a beneficiary. In lieu of the
800 surety bond, the wholesale distributor may provide a comparable
801 security agreement, such as an irrevocable letter of credit or a
802 deposit into a trust account or financial institution which
803 names the State of Florida as a beneficiary. The purposes of the
804 bond or other security arrangement for the program are to:

805 a. Ensure payment of any administrative penalties imposed
806 by the Department of Business and Professional Regulation or any
807 other state agency under the contract when the wholesale
808 distributor fails to pay within 30 days after assessment;

809 b. Ensure that the wholesale distributor meets contractual
810 and statutory obligations through use of a surety bond or other
811 comparable security arrangements to pay any other costs or fees
812 incurred by the Department of Business of Professional

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813 Regulation, the state, or other entities acting on behalf of the
814 state if the wholesale distributor fails to meet its
815 obligations. If the wholesale distributor is assessed a penalty
816 under the program and fails to pay within 30 days after that
817 assessment, the Department of Business and Professional
818 Regulation, the state, or an entity acting on behalf of the
819 state may file a claim for reimbursement against the bond or
820 other comparable security arrangement; and

821 c. Allow for claims to be made against the bond or other
822 comparable security arrangements for up to 1 year after the
823 wholesale distributor's permit under the program has ended with
824 this section or the program has ended, whichever occurs last.

825 3. The eligible wholesale distributor must submit evidence
826 at the time of application and throughout the permit term of a
827 surety bond or comparable security arrangement from this state
828 or any other state in the United States in an amount equal to 10
829 percent of the international wholesale distributor's annual
830 sales or \$1 million, whichever is greater. The surety bond or
831 comparable security arrangement must include the State of
832 Florida as a beneficiary. In lieu of the surety bond, the
833 wholesale distributor may provide a comparable security
834 arrangement such as an irrevocable letter of credit or a deposit
835 into a trust account or financial institution which names the
836 State of Florida as a beneficiary. The purposes of the bond or
837 other security arrangements for the program are to:

838 a. Ensure participation of the wholesale distributor in any
839 civil or criminal legal action by the state, the Department of
840 Business of Professional Regulation, any other state agency, or
841 private individuals or entities against the wholesale

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842 distributor or because of the wholesale distributor's failure to
843 perform under the contract, including, but not limited to causes
844 of actions for personal injury, negligence, and wrongful death;

845 b. Ensure payment by the wholesale distributor through the
846 use of a bond or other comparable security arrangements of legal
847 judgements and claims that have been awarded to the Department
848 of Business and Professional Regulation, the state, other
849 entities acting on behalf of the state, individuals, or
850 organizations if the wholesale distributor is assessed a final
851 judgement or other monetary penalty in a court of law for a
852 civil or criminal action under the program. The bond or
853 comparable security arrangement will be accessed if the
854 wholesale distributor fails to pay any judgement or claim within
855 60 days after final judgement; and

856 c. Allow for civil and criminal litigation claims to be
857 made against the bond or other comparable security arrangements
858 for up to 1 year after the wholesale distributor's permit under
859 the program has ended with the agency or the state, the
860 pharmacy's permit or comparable legal document is no longer
861 valid, or the program has ended, whichever occurs last.

862 Section 7. Subsection (2), paragraph (a) of subsection (4),
863 subsections (8), (10), (11), and (14), and paragraphs (a), (b),
864 and (f) of subsection (15) of section 499.012, Florida Statutes,
865 are amended to read:

866 499.012 Permit application requirements.—

867 (2) Notwithstanding subsection (6), a permitted person in
868 good standing may change the type of permit issued to that
869 person by completing a new application for the requested permit,
870 paying the amount of the difference in the permit fees if the

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871 fee for the new permit is more than the fee for the original
872 permit, and meeting the applicable permitting conditions for the
873 new permit type. The new permit expires on the expiration date
874 of the original permit being changed; however, a new permit for
875 a prescription drug wholesale distributor, an out-of-state
876 prescription drug wholesale distributor, an international
877 prescription drug wholesale distributor, or a retail pharmacy
878 drug wholesale distributor shall expire on the expiration date
879 of the original permit or 1 year after the date of issuance of
880 the new permit, whichever is earlier. A refund may not be issued
881 if the fee for the new permit is less than the fee that was paid
882 for the original permit.

883 (4) (a) Except for a permit for a prescription drug
884 wholesale distributor, an international prescription drug
885 wholesale distributor, or an out-of-state prescription drug
886 wholesale distributor, an application for a permit must include:

887 1. The name, full business address, and telephone number of
888 the applicant;

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

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

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

895 5. The names of the owner and the operator of the
896 establishment, including:

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

898 b. If a partnership, the name of each partner and the name
899 of the partnership;

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900 c. If a corporation, the name and title of each corporate
901 officer and director, the corporate names, and the name of the
902 state of incorporation;

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

905 e. If a limited liability company, the name of each member,
906 the name of each manager, the name of the limited liability
907 company, and the name of the state in which the limited
908 liability company was organized; and

909 f. Any other relevant information that the department
910 requires.

911 (8) An application for a permit or to renew a permit for a
912 prescription drug wholesale distributor, an international
913 prescription drug wholesale distributor, or an out-of-state
914 prescription drug wholesale distributor submitted to the
915 department must include:

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

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

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

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

924 (e) The names of the owner and the operator of the
925 establishment, including:

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

927 2. If a partnership, the name of each partner and the name
928 of the partnership.

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- 929 3. If a corporation:
- 930 a. The name, address, and title of each corporate officer
931 and director.
- 932 b. The name and address of the corporation, resident agent
933 of the corporation, the resident agent's address, and the
934 corporation's state of incorporation.
- 935 c. The name and address of each shareholder of the
936 corporation that owns 5 percent or more of the outstanding stock
937 of the corporation.
- 938 4. If a sole proprietorship, the full name of the sole
939 proprietor and the name of the business entity.
- 940 5. If a limited liability company:
- 941 a. The name and address of each member.
- 942 b. The name and address of each manager.
- 943 c. The name and address of the limited liability company,
944 the resident agent of the limited liability company, and the
945 name of the state in which the limited liability company was
946 organized.
- 947 (f) If applicable, the name and address of each affiliate
948 of the applicant.
- 949 (g) The applicant's gross annual receipts attributable to
950 prescription drug wholesale distribution activities for the
951 previous tax year.
- 952 (h) The tax year of the applicant.
- 953 (i) A copy of the deed for the property on which
954 applicant's establishment is located, if the establishment is
955 owned by the applicant, or a copy of the applicant's lease for
956 the property on which applicant's establishment is located that
957 has an original term of not less than 1 calendar year, if the

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958 establishment is not owned by the applicant.

959 (j) A list of all licenses and permits issued to the
960 applicant by any other state or jurisdiction which authorize the
961 applicant to purchase or possess prescription drugs.

962 (k) The name of the manager of the establishment that is
963 applying for the permit or to renew the permit, the next four
964 highest ranking employees responsible for prescription drug
965 wholesale operations for the establishment, and the name of all
966 affiliated parties for the establishment, together with the
967 personal information statement and fingerprints required
968 pursuant to subsection (9) for each of such persons.

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

973 (m) Evidence of a surety bond in this state or any other
974 state in the United States in the amount of \$100,000. If the
975 annual gross receipts of the applicant's previous tax year are
976 \$10 million or less, evidence of a surety bond in the amount of
977 \$25,000. The specific language of the surety bond must include
978 the State of Florida as a beneficiary, payable to the
979 Professional Regulation Trust Fund. In lieu of the surety bond,
980 the applicant may provide other equivalent security such as an
981 irrevocable letter of credit, or a deposit in a trust account or
982 financial institution, which includes the State of Florida as a
983 beneficiary, payable to the Professional Regulation Trust Fund.
984 The purpose of the bond or other security is to secure payment
985 of any administrative penalties imposed by the department and
986 any fees and costs incurred by the department regarding that

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987 permit which are authorized under state law and which the
988 permittee fails to pay 30 days after the fine or costs become
989 final. The department may make a claim against such bond or
990 security until 1 year after the permittee's license ceases to be
991 valid or until 60 days after any administrative or legal
992 proceeding authorized in this part which involves the permittee
993 is concluded, including any appeal, whichever occurs later.

994 (n) For establishments used in wholesale distribution,
995 proof of an inspection conducted by the department, the United
996 States Food and Drug Administration, or another governmental
997 entity charged with the regulation of good manufacturing
998 practices related to wholesale distribution of prescription
999 drugs, within timeframes set forth by the department in
1000 departmental rules, which demonstrates substantial compliance
1001 with current good manufacturing practices applicable to
1002 wholesale distribution of prescription drugs. The department may
1003 recognize another state's or jurisdiction's inspection of a
1004 wholesale distributor located in that state or jurisdiction if
1005 such state's or jurisdiction's laws are deemed to be
1006 substantially equivalent to the law of this state by the
1007 department. The department may accept an inspection by a third-
1008 party accreditation or inspection service which meets the
1009 criteria set forth in department rule.

1010 (o) Any other relevant information that the department
1011 requires.

1012 (p) Documentation of the credentialing policies and
1013 procedures required by s. 499.0121(15).

1014 (q) For international prescription drug wholesale
1015 distributors and nonresident prescription drug manufacturers to

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1016 participate in the International Prescription Drug Importation
1017 Program established under s. 499.0285, documentation
1018 demonstrating that the applicant is appropriately licensed or
1019 permitted by a country with which the United States has a mutual
1020 recognition agreement, cooperation agreement, memorandum of
1021 understanding, or other mechanism recognizing the country's
1022 adherence to current good manufacturing practices for
1023 pharmaceutical products.

1024 (10) The department may deny an application for a permit or
1025 refuse to renew a permit for a prescription drug wholesale
1026 distributor, an international prescription drug wholesale
1027 distributor, or an out-of-state prescription drug wholesale
1028 distributor if:

1029 (a) The applicant has not met the requirements for the
1030 permit.

1031 (b) The management, officers, or directors of the applicant
1032 or any affiliated party are found by the department to be
1033 incompetent or untrustworthy.

1034 (c) The applicant is so lacking in experience in managing a
1035 wholesale distributor as to make the issuance of the proposed
1036 permit hazardous to the public health.

1037 (d) The applicant is so lacking in experience in managing a
1038 wholesale distributor as to jeopardize the reasonable promise of
1039 successful operation of the wholesale distributor.

1040 (e) The applicant is lacking in experience in the
1041 distribution of prescription drugs.

1042 (f) The applicant's past experience in manufacturing or
1043 distributing prescription drugs indicates that the applicant
1044 poses a public health risk.

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1045 (g) The applicant is affiliated directly or indirectly
1046 through ownership, control, or other business relations, with
1047 any person or persons whose business operations are or have been
1048 detrimental to the public health.

1049 (h) The applicant, or any affiliated party, has been found
1050 guilty of or has pleaded guilty or nolo contendere to any felony
1051 or crime punishable by imprisonment for 1 year or more under the
1052 laws of the United States, any state, or any other country,
1053 regardless of whether adjudication of guilt was withheld.

1054 (i) The applicant or any affiliated party has been charged
1055 with a felony in a state or federal court and the disposition of
1056 that charge is pending during the application review or renewal
1057 review period.

1058 (j) The applicant has furnished false or fraudulent
1059 information or material in any application made in this state or
1060 any other state in connection with obtaining a permit or license
1061 to manufacture or distribute drugs, devices, or cosmetics.

1062 (k) That a federal, state, or local government permit
1063 currently or previously held by the applicant, or any affiliated
1064 party, for the manufacture or distribution of any drugs,
1065 devices, or cosmetics has been disciplined, suspended, or
1066 revoked and has not been reinstated.

1067 (l) The applicant does not possess the financial or
1068 physical resources to operate in compliance with the permit
1069 being sought, this chapter, and the rules adopted under this
1070 chapter.

1071 (m) The applicant or any affiliated party receives,
1072 directly or indirectly, financial support and assistance from a
1073 person who was an affiliated party of a permittee whose permit

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1074 was subject to discipline or was suspended or revoked, other
1075 than through the ownership of stock in a publicly traded company
1076 or a mutual fund.

1077 (n) The applicant or any affiliated party receives,
1078 directly or indirectly, financial support and assistance from a
1079 person who has been found guilty of any violation of this part
1080 or chapter 465, chapter 501, or chapter 893, any rules adopted
1081 under this part or those chapters, any federal or state drug
1082 law, or any felony where the underlying facts related to drugs,
1083 regardless of whether the person has been pardoned, had her or
1084 his civil rights restored, or had adjudication withheld, other
1085 than through the ownership of stock in a publicly traded company
1086 or a mutual fund.

1087 (o) The applicant for renewal of a permit under s.
1088 499.01(2)(e) or (f) has not actively engaged in the wholesale
1089 distribution of prescription drugs, as demonstrated by the
1090 regular and systematic distribution of prescription drugs
1091 throughout the year as evidenced by not fewer than 12 wholesale
1092 distributions in the previous year and not fewer than three
1093 wholesale distributions in the previous 6 months.

1094 (p) Information obtained in response to s. 499.01(2)(e) or
1095 (f) demonstrates it would not be in the best interest of the
1096 public health, safety, and welfare to issue a permit.

1097 (q) The applicant does not possess the financial standing
1098 and business experience for the successful operation of the
1099 applicant.

1100 (r) The applicant or any affiliated party has failed to
1101 comply with the requirements for manufacturing or distributing
1102 prescription drugs under this part, similar federal laws,

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1103 similar laws in other states, or the rules adopted under such
1104 laws.

1105 (11) Upon approval of the application by the department and
1106 payment of the required fee, the department shall issue or renew
1107 a prescription drug wholesale distributor, an international
1108 prescription drug wholesale distributor, or an out-of-state
1109 prescription drug wholesale distributor permit to the applicant.

1110 (14) The name of a permittee or establishment on a
1111 prescription drug wholesale distributor permit, an international
1112 prescription drug wholesale distributor permit, or an out-of-
1113 state prescription drug wholesale distributor permit may not
1114 include any indicia of attainment of any educational degree, any
1115 indicia that the permittee or establishment possesses a
1116 professional license, or any name or abbreviation that the
1117 department determines is likely to cause confusion or mistake or
1118 that the department determines is deceptive, including that of
1119 any other entity authorized to purchase prescription drugs.

1120 (15) (a) Each establishment that is issued an initial or
1121 renewal permit as a prescription drug wholesale distributor, an
1122 international prescription drug wholesale distributor, or an
1123 out-of-state prescription drug wholesale distributor must
1124 designate in writing to the department at least one natural
1125 person to serve as the designated representative of the
1126 wholesale distributor. Such person must have an active
1127 certification as a designated representative from the
1128 department.

1129 (b) To be certified as a designated representative, a
1130 natural person must:

1131 1. Submit an application on a form furnished by the

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1132 department and pay the appropriate fees.

1133 2. Be at least 18 years of age.

1134 3. Have at least 2 years of verifiable full-time:

1135 a. Work experience in a pharmacy licensed in this state or
1136 another state or jurisdiction, where the person's
1137 responsibilities included, but were not limited to,
1138 recordkeeping for prescription drugs;

1139 b. Managerial experience with a prescription drug wholesale
1140 distributor licensed in this state or in another state or
1141 jurisdiction; or

1142 c. Managerial experience with the United States Armed
1143 Forces, where the person's responsibilities included, but were
1144 not limited to, recordkeeping, warehousing, distributing, or
1145 other logistics services pertaining to prescription drugs.

1146 4. Receive a passing score of at least 75 percent on an
1147 examination given by the department regarding federal laws
1148 governing distribution of prescription drugs and this part and
1149 the rules adopted by the department governing the wholesale
1150 distribution of prescription drugs. This requirement shall be
1151 effective 1 year after the results of the initial examination
1152 are mailed to the persons that took the examination. The
1153 department shall offer such examinations at least four times
1154 each calendar year.

1155 5. Provide the department with a personal information
1156 statement and fingerprints pursuant to subsection (9).

1157 (f) A wholesale distributor may not operate under a
1158 prescription drug wholesale distributor permit, an international
1159 prescription drug wholesale distributor permit, or an out-of-
1160 state prescription drug wholesale distributor permit for more

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1161 than 10 business days after the designated representative leaves
1162 the employ of the wholesale distributor, unless the wholesale
1163 distributor employs another designated representative and
1164 notifies the department within 10 business days of the identity
1165 of the new designated representative.

1166 Section 8. Subsection (1) of section 499.015, Florida
1167 Statutes, is amended to read:

1168 499.015 Registration of drugs and devices; issuance of
1169 certificates of free sale.—

1170 (1) (a) Except for those persons exempted from the
1171 definition of manufacturer in s. 499.003, any person who
1172 manufactures, packages, repackages, labels, or relabels a drug
1173 or device in this state must register such drug or device
1174 biennially with the department; pay a fee in accordance with the
1175 fee schedule provided by s. 499.041; and comply with this
1176 section. The registrant must list each separate and distinct
1177 drug or device at the time of registration.

1178 (b) The department may not register any product that does
1179 not comply with the Federal Food, Drug, and Cosmetic Act, as
1180 amended, or Title 21 C.F.R. Registration of a product by the
1181 department does not mean that the product does in fact comply
1182 with all provisions of the Federal Food, Drug, and Cosmetic Act,
1183 as amended.

1184 (c) Registration under this section is not required for
1185 prescription drugs imported under the International Prescription
1186 Drug Importation Program established in s. 499.0285.

1187 Section 9. Subsections (1) and (3) of section 499.065,
1188 Florida Statutes, are amended to read:

1189 499.065 Inspections; imminent danger.—

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1190 (1) Notwithstanding s. 499.051, the department shall
1191 inspect each prescription drug wholesale distributor
1192 establishment, international prescription drug wholesale
1193 distributor establishment, prescription drug repackager
1194 establishment, veterinary prescription drug wholesale
1195 distributor establishment, limited prescription drug veterinary
1196 wholesale distributor establishment, and retail pharmacy drug
1197 wholesale distributor establishment that is required to be
1198 permitted under this part as often as necessary to ensure
1199 compliance with applicable laws and rules. The department shall
1200 have the right of entry and access to these facilities at any
1201 reasonable time.

1202 (3) The department may determine that a prescription drug
1203 wholesale distributor establishment, international prescription
1204 drug wholesale distributor establishment, prescription drug
1205 repackager establishment, veterinary prescription drug wholesale
1206 distributor establishment, limited prescription drug veterinary
1207 wholesale distributor establishment, or retail pharmacy drug
1208 wholesale distributor establishment that is required to be
1209 permitted under this part is an imminent danger to the public
1210 health and shall require its immediate closure if the
1211 establishment fails to comply with applicable laws and rules
1212 and, because of the failure, presents an imminent threat to the
1213 public's health, safety, or welfare. Any establishment so deemed
1214 and closed shall remain closed until allowed by the department
1215 or by judicial order to reopen.

1216 Section 10. Section 499.0285, Florida Statutes, is created
1217 to read:

1218 499.0285 International Prescription Drug Importation

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1219 Program.—

1220 (1) PROGRAM ESTABLISHED.—The department shall establish a
1221 program for the importation of safe and effective prescription
1222 drugs from foreign nations with which the United States has
1223 current mutual recognition agreements, cooperation agreements,
1224 memoranda of understanding, or other federal mechanisms
1225 recognizing their adherence to current good manufacturing
1226 practices for pharmaceutical products. The program shall be open
1227 to individual Florida residents and to those participating in
1228 the Canadian Drug Importation Program under s. 381.02035.

1229 (2) DEFINITIONS.—As used in this section, the term:

1230 (a) "Exporter" means an international prescription drug
1231 wholesale distributor, a nonresident prescription drug
1232 manufacturer registered to participate in the program, or an
1233 international export pharmacy that exports prescription drugs
1234 into this state under the program.

1235 (b) "Federal Act" means the Federal Food, Drug, and
1236 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.
1237 as amended by the Drug Quality and Security Act, 21 U.S.C. 351
1238 et seq.

1239 (c) "Foreign recipient" means an entity other than the
1240 original prescription drug manufacturer which receives the
1241 prescription drug before its importation into this state under
1242 the program.

1243 (d) "Good manufacturing practice" refers to the good
1244 manufacturing practice regulations in 21 C.F.R. parts 210 and
1245 211.

1246 (e) "Importer" means a wholesale distributor, pharmacy, or
1247 pharmacist importing prescription drugs into this state under

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1248 the program.

1249 (f) "International export pharmacy" means a pharmacy
1250 located outside of the United States which holds an active and
1251 unencumbered permit under chapter 465 to export prescription
1252 drugs into this state under the program.

1253 (g) "International prescription drug wholesale distributor"
1254 means a prescription drug wholesale distributor located outside
1255 of the United States which holds an active and unencumbered
1256 permit under this part to export and distribute prescription
1257 drugs into this state under the program.

1258 (h) "Nonresident prescription drug manufacturer" means an
1259 entity located outside of the United States which holds an
1260 active and unencumbered permit under this part to manufacture
1261 prescription drugs and has registered with the department to
1262 export and distribute such prescription drugs into this state
1263 under the program.

1264 (i) "Pharmacist" means a person who holds an active and
1265 unencumbered license to practice pharmacy under chapter 465.

1266 (j) "Pharmacy" means an entity that holds an active and
1267 unencumbered permit under chapter 465.

1268 (k) "Prescription drug" has the same meaning as defined in
1269 this part, but is limited to drugs intended for human use.

1270 (l) "Program" means the International Prescription Drug
1271 Importation Program established under this section.

1272 (m) "Qualified laboratory" means a laboratory that has been
1273 approved by the department for the purposes of this section.

1274 (3) ELIGIBLE PRESCRIPTION DRUGS.—An eligible importer may
1275 import a prescription drug from an eligible exporter if:

1276 (a) The drug meets the United States Food and Drug

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1277 Administration's standards related to safety, effectiveness,
1278 misbranding, and adulteration;

1279 (b) Importing the drug would not violate the patent laws of
1280 the United States; and

1281 (c) The drug is not:

1282 1. A controlled substance as defined in 21 U.S.C. s. 802;

1283 2. A biological product as defined in 42 U.S.C. s. 262;

1284 3. An infused drug;

1285 4. An intravenously injected drug;

1286 5. A drug that is inhaled during surgery; or

1287 6. A drug that is a parenteral drug, the importation of
1288 which is determined by the United States Secretary of Health and
1289 Human Services to pose a threat to the public health.

1290 (4) EXPORTERS.—

1291 (a) The following entities may export prescription drugs
1292 into this state under the program:

1293 1. An international prescription drug wholesale
1294 distributor.

1295 2. A nonresident prescription drug manufacturer.

1296 3. An international export pharmacy.

1297 (b) An eligible exporter must register with the department
1298 before exporting prescription drugs into this state under the
1299 program.

1300 (c) An exporter may not distribute, sell, or dispense
1301 prescription drugs imported under the program to any person
1302 residing outside of the state.

1303 (5) IMPORTERS.—

1304 (a) The following entities may import prescription drugs
1305 under the program:

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- 1306 1. A wholesale distributor.
1307 2. A pharmacy.
1308 3. A pharmacist.
1309 (b) An eligible importer must register with the department
1310 before importing prescription drugs into this state under the
1311 program.
1312 (c) An importer may not distribute, sell, or dispense
1313 prescription drugs imported under the program to any person
1314 residing outside of the state.
1315 (6) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—
1316 (a) A participating importer must submit the following
1317 information and documentation to the department:
1318 1. The name and quantity of the active ingredient of the
1319 prescription drug.
1320 2. A description of the dosage form of the prescription
1321 drug.
1322 3. The date on which the prescription drug is shipped.
1323 4. The quantity of the prescription drug that is shipped.
1324 5. The point of origin and destination of the prescription
1325 drug.
1326 6. The price paid by the importer for the prescription
1327 drug.
1328 7. Documentation from the exporter specifying:
1329 a. The original source of the prescription drug; and
1330 b. The quantity of each lot of the prescription drug
1331 originally received by the seller from that source.
1332 8. The lot or control number assigned to the prescription
1333 drug by the manufacturer.
1334 9. The name, address, telephone number, and professional

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1335 license or permit number of the importer.

1336 10. In the case of a prescription drug that is shipped
1337 directly by the first foreign recipient from the manufacturer:

1338 a. Documentation demonstrating that the prescription drug
1339 was received by the recipient from the manufacturer and
1340 subsequently shipped by the first foreign recipient to the
1341 importer.

1342 b. Documentation of the quantity of each lot of the
1343 prescription drug received by the first foreign recipient
1344 demonstrating that the quantity being imported into this state
1345 is not more than the quantity that was received by the first
1346 foreign recipient.

1347 c. For an initial imported shipment, documentation
1348 demonstrating that each batch of the prescription drug in the
1349 shipment was statistically sampled and tested for authenticity
1350 and degradation.

1351 11. In the case of a prescription drug that is not shipped
1352 directly from the first foreign recipient, documentation
1353 demonstrating that each batch in each shipment offered for
1354 importation into this state was statistically sampled and tested
1355 for authenticity and degradation.

1356 12. For an initial imported shipment, the agency shall
1357 ensure that each batch of the drug in the shipment is
1358 statistically sampled and tested for authenticity and
1359 degradation in a manner consistent with the federal act. The
1360 agency may contract with a vendor for these functions.

1361 13. For any subsequent imported shipment, the department
1362 shall ensure that a statistically valid sample of the shipment
1363 was tested for authenticity and degradation in a manner

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1364 consistent with the federal act.

1365 14. Certify that the drug:

1366 a. Is approved for marketing in the United States and is
1367 not adulterated or misbranded; and

1368 b. Meets all of the labeling requirements under 21 U.S.C.
1369 s. 352.

1370 15. Maintain qualified laboratory records, including
1371 complete data derived from all tests necessary to ensure that
1372 the drug is in compliance with the requirements of this section.

1373 16. Maintain documentation demonstrating that the testing
1374 required by this section was conducted at a qualified laboratory
1375 in accordance with the federal act and any other applicable
1376 federal and state laws and regulations governing laboratory
1377 qualifications.

1378 (b) All testing required by this section must be conducted
1379 in a qualified laboratory that meets the standards under the
1380 federal act and any other applicable federal and state laws and
1381 regulations governing laboratory qualifications for drug
1382 testing.

1383 (c) The vendor shall maintain information and documentation
1384 submitted under this section for a period of at least 7 years.

1385 (d) A participating importer must submit the all of
1386 following information to the department:

1387 1. The name and quantity of the active ingredient of the
1388 drug.

1389 2. A description of the dosage form of the drug.

1390 3. The date on which the drug is received.

1391 4. The quantity of the drug that is received.

1392 5. The point of origin and destination of the drug.

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- 1393 6. The price paid by the importer for the drug.
- 1394 (e) A participating International Importation Drug supplier
1395 must submit the following information and documentation to the
1396 agency or the agency's designated vendor specifying all of the
1397 following:
- 1398 1. The original source of the drug, including:
- 1399 a. The name of the manufacturer of the drug.
- 1400 b. The date on which the drug was manufactured.
- 1401 c. The location (country, state or province, and city)
1402 where the drug was manufactured.
- 1403 2. The date on which the drug is shipped.
- 1404 3. The quantity of the drug that is shipped.
- 1405 4. The quantity of each lot of the drug originally received
1406 and from which source.
- 1407 5. The lot or control number and the batch number assigned
1408 to the drug by the manufacturer.
- 1409 6. The name, address, and telephone number, and
1410 professional license or permit number of the importer.
- 1411 (f) The department may require any other information
1412 necessary to ensure the protection of the public health.
- 1413 (7) IMMEDIATE SUSPENSION.—The department shall immediately
1414 suspend the importation of a specific prescription drug or the
1415 importation of prescription drugs by a specific importer if it
1416 discovers that any prescription drug or activity is in violation
1417 of this section. The department may revoke the suspension if,
1418 after conducting an investigation, it determines that the public
1419 is adequately protected from counterfeit or unsafe prescription
1420 drugs being imported into this state.
- 1421 (8) RULEMAKING AUTHORITY.—The department shall adopt rules

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1422 necessary to implement this section.

1423 Section 11. Notwithstanding the Federal Food, Drug, and
1424 Cosmetic Act, the Department of Business and Professional
1425 Regulation, in collaboration with the Department of Health,
1426 shall negotiate a federal arrangement to operate a pilot program
1427 for importing prescription drugs into this state. The proposal
1428 to operate such a pilot program shall demonstrate that the
1429 program sets safety standards consistent with the current
1430 federal requirements for the manufacturing and distribution of
1431 prescription drugs; limits the importation of prescription drugs
1432 under the program to entities licensed or permitted by the state
1433 to manufacture, distribute, or dispense prescription drugs; and
1434 includes inspection and enforcement authority. Implementation of
1435 sections 2 through 10 of this act is contingent upon
1436 authorization granted under federal law or rule. The department
1437 shall notify the President of the Senate, the Speaker of the
1438 House of Representatives, and the relevant committees of the
1439 Senate and the House of Representatives before implementation of
1440 the pilot program. The department shall submit to all parties a
1441 proposal for program implementation and program funding.

1442 Section 12. This act shall take effect July 1, 2019.