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LEGISLATIVE ACTION

Senate

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House

Senator Bean moved the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

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

381.02035 Canadian Prescription Drug Importation Program.-

(1) PROGRAM ESTABLISHED.—The Agency for Health Care
Administration shall establish the Canadian Prescription Drug
Importation Program for the importation of safe and effective
prescription drugs from Canada which have the highest potential



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12 for cost savings to the state.

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

14 (a) "Agency" means the Agency for Health Care
15 Administration.

16 (b) "Canadian supplier" means a manufacturer, wholesale
17 distributor, or pharmacy appropriately licensed or permitted
18 under Canadian law to manufacture, distribute, or dispense
19 prescription drugs.

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

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

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

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

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

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

36 (i) "Pharmacist" means a person who holds an active and
37 unencumbered license to practice pharmacy pursuant to chapter
38 465.

39 (j) "Program" means the Canadian Prescription Drug
40 Importation Program.



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

45 (l) "Vendor" means the entity contracted by the agency to
46 manage specified functions of the program.

47 (3) IMPORTATION PROCESS.—

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

50 (b) By December 1, 2019, and each year thereafter, the
51 vendor shall develop a Wholesale Prescription Drug Importation
52 List identifying the prescription drugs that have the highest
53 potential for cost savings to the state. In developing the list,
54 the vendor shall consider, at a minimum, which prescription
55 drugs will provide the greatest cost savings to state programs,
56 including prescriptions drugs for which there are shortages,
57 specialty prescription drugs, and high volume prescription
58 drugs. The agency, in consultation with the department, shall
59 review the Wholesale Prescription Drug Importation List every 3
60 months to ensure that it continues to meet the requirements of
61 the programs and may direct the vendor to revise the list, as
62 necessary.

63 (c) The vendor shall identify Canadian suppliers that are
64 in full compliance with relevant Canadian federal and provincial
65 laws and regulations and the federal act and who have agreed to
66 export drugs identified on the list at prices that will provide
67 cost savings to the state. The vendor must verify that such
68 Canadian suppliers meet all of the requirements of the program,
69 while meeting or exceeding the federal and state track-and-trace



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70 laws and regulations.

71 (d) The vendor shall contract with such eligible Canadian
72 suppliers, or facilitate contracts between eligible importers
73 and Canadian suppliers, to import drugs under the program.

74 (e) The vendor shall maintain a list of all registered
75 importers that participate in the program.

76 (f) The vendor shall ensure compliance with Title II of the
77 federal Drug Quality and Security Act, Pub. L. No. 113-54, by
78 all suppliers, importers and other distributors, and
79 participants in the program.

80 (g) The vendor shall assist the agency in the preparation
81 of the annual report required by subsection (12), including the
82 timely provision of any information requested by the agency.

83 (h) The vendor shall provide an annual financial audit of
84 its operations to the agency as required by the agency. The
85 vendor shall also provide quarterly financial reports specific
86 to the program and shall include information on the performance
87 of its subcontractors and vendors. The agency shall determine
88 the format and contents of the reports.

89 (4) BOND REQUIREMENT.—The agency shall require a bond from
90 the vendor to mitigate the financial consequences of potential
91 acts of malfeasance or misfeasance or fraudulent or dishonest
92 acts committed by the vendor, any employees of the vendor, or
93 its subcontractors.

94 (5) ELIGIBLE PRESCRIPTION DRUGS.—Eligible importers, as
95 described in subsection (7), may import a drug from an eligible
96 Canadian supplier, as described in subsection (6), if:

97 (a) The drug meets the United States Food and Drug
98 Administration's standards related to safety, effectiveness,



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99 misbranding, and adulteration;

100 (b) Importing the drug would not violate federal patent
101 laws;

102 (c) Importing the drug is expected to generate cost
103 savings; and

104 (d) The drug is not:

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

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

107 3. An infused drug;

108 4. An intravenously injected drug;

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

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

113 (6) ELIGIBLE CANADIAN SUPPLIERS.—A Canadian supplier may
114 export prescription drugs into this state under the program if
115 the supplier:

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

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

120 (c) Submits an attestation that the supplier has a
121 registered agent in the United States, including the name and
122 United States address of the registered agent.

123 (7) ELIGIBLE IMPORTERS.—The following entities may import
124 prescription drugs from an eligible Canadian supplier under the
125 program:

126 (a) A pharmacist or wholesaler employed by or under
127 contract with the department's central pharmacy, for



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128 distribution to a county health department or free clinic for
129 dispensing to clients treated in such department or clinic.

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

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

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

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

142 (8) DISTRIBUTION REQUIREMENTS.—Eligible Canadian suppliers
143 and eligible importers participating under the program:

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

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

148 (9) FEDERAL APPROVAL.—By July 1, 2020, the agency shall
149 submit a request to the United States Secretary of Health and
150 Human Services for approval of the program under 21 U.S.C. s.
151 384(1). The agency shall begin operating the program within 6
152 months after receiving such approval. The request must, at a
153 minimum:

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

155 (b) Demonstrate how the prescription drugs imported into
156 this state under the program will meet the applicable federal



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157 and state standards for safety and effectiveness.

158 (c) Demonstrate how the drugs imported into this state
159 under the program will comply with federal tracing procedures.

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

163 (e) Estimate the total cost savings attributable to the
164 program.

165 (f) Provide the costs of program implementation to the
166 state.

167 (g) Include a list of potential Canadian suppliers from
168 which the state would import drugs and demonstrate that the
169 suppliers are in full compliance with relevant Canadian federal
170 and provincial laws and regulations as well as all applicable
171 federal and state laws and regulations.

172 (10) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

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

175 1. For an initial imported shipment of a specific drug by
176 an importer, ensure that each batch of the drug in the shipment
177 is statistically sampled and tested for authenticity and
178 degradation in a manner consistent with the federal act.

179 2. For every subsequent imported shipment of that drug by
180 that importer, ensure that a statistically valid sample of the
181 shipment is tested for authenticity and degradation in a manner
182 consistent with the federal act.

183 3. Certify that the drug:

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



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186 b. Meets all of the labeling requirements under 21 U.S.C.
187 s. 352.

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

191 5. Maintain documentation demonstrating that the testing
192 required by this section was conducted at a qualified laboratory
193 in accordance with the federal act and any other applicable
194 federal and state laws and regulations governing laboratory
195 qualifications.

196 (b) All testing required by this section must be conducted
197 in a qualified laboratory that meets the standards under the
198 federal act and any other applicable federal and state laws and
199 regulations governing laboratory qualifications for drug
200 testing.

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

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

205 1. The name and quantity of the active ingredient of the
206 drug.

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

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

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

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

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

212 (e) A participating Canadian supplier must submit the
213 following information and documentation to the vendor specifying
214 all of the following:



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- 215 1. The original source of the drug, including:
216 a. The name of the manufacturer of the drug.
217 b. The date on which the drug was manufactured.
218 c. The location (country, state or province, and city)
219 where the drug was manufactured.
220 2. The date on which the drug is shipped.
221 3. The quantity of the drug that is shipped.
222 4. The quantity of each lot of the drug originally received
223 and the source of the lot.
224 5. The lot or control number and the batch number assigned
225 to the drug by the manufacturer.
226 (f) The agency may require that the vendor collect any
227 other information necessary to ensure the protection of the
228 public health.
229 (11) IMMEDIATE SUSPENSION.—The agency shall immediately
230 suspend the importation of a specific drug or the importation of
231 drugs by a specific importer if it discovers that any drug or
232 activity is in violation of this section or any federal or state
233 law or regulation. The agency may revoke the suspension if,
234 after conducting an investigation, it determines that the public
235 is adequately protected from counterfeit or unsafe drugs being
236 imported into this state.
237 (12) ANNUAL REPORT.—By December 1 of each year, the agency
238 shall submit a report to the Governor, the President of the
239 Senate, and the Speaker of the House of Representatives on the
240 operation of the program during the previous fiscal year. The
241 report must include, at a minimum:
242 (a) A list of the prescription drugs that were imported
243 under the program;



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244 (b) The number of participating entities;
245 (c) The number of prescriptions dispensed through the
246 program;
247 (d) The estimated cost savings during the previous fiscal
248 year and to date attributable the program;
249 (e) A description of the methodology used to determine
250 which drugs should be included on the Wholesale Prescription
251 Drug Importation List; and
252 (f) Documentation as to how the program ensures the
253 following:
254 1. That Canadian suppliers participating in the program are
255 of high quality, high performance, and in full compliance with
256 relevant Canadian federal and provincial laws and regulations as
257 well as all federal laws and regulations and state laws and
258 rules;
259 2. That prescription drugs imported under the program are
260 not shipped, sold, or dispensed outside of this state once in
261 the possession of the importer;
262 3. That prescription drugs imported under the program are
263 pure, unadulterated, potent, and safe;
264 4. That the program does not put consumers at a higher
265 health and safety risk than if the consumer did not participate;
266 and
267 5. That the program provides cost savings to the state on
268 imported prescription drugs.
269 (13) NOTIFICATION OF FEDERAL APPROVAL.—Upon receipt of
270 federal approval of the program, the agency shall notify the
271 President of the Senate, the Speaker of the House of
272 Representatives, and the relevant committees of the Senate and



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273 the House of Representatives. After approval is received and
274 before the start of the next regular session of the Legislature
275 in which the proposal could be funded, the agency shall submit
276 to all parties a proposal for program implementation and program
277 funding.

278 (14) RULEMAKING.—The agency shall adopt rules necessary to
279 implement this section.

280 Section 2. Section 465.0157, Florida Statutes, is created
281 to read:

282 465.0157 International export pharmacy permit.—

283 (1) To participate as an exporter of prescription drugs
284 into this state under the International Prescription Drug
285 Importation Program established in s. 499.0285, a pharmacy
286 located outside of the United States must hold an international
287 export pharmacy permit.

288 (2) An international export pharmacy shall maintain at all
289 times an active and unencumbered license or permit to operate
290 the pharmacy in compliance with the laws of the jurisdiction in
291 which the dispensing facility is located and from which the
292 prescription drugs will be exported. Such jurisdiction must be
293 in a country with which the United States has a current mutual
294 recognition agreement, cooperation agreement, memorandum of
295 understanding, or other federal mechanism recognizing the
296 country's adherence to current good manufacturing practices for
297 pharmaceutical products.

298 (3) An application for an international export pharmacy
299 permit must be submitted on a form developed and provided by the
300 board. The board may require an applicant to provide any
301 information it deems reasonably necessary to carry out the



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302 purposes of this section.

303 (4) An applicant shall submit the following to the board to
304 obtain an initial permit, or to the department to renew a
305 permit:

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

310 (b) Documentation demonstrating that the country in which
311 the pharmacy operates has a current mutual recognition
312 agreement, cooperation agreement, memorandum of understanding,
313 or other federal mechanism recognizing the country's adherence
314 to current good manufacturing practices for pharmaceutical
315 products.

316 (c) The location, names, and titles of all principal
317 corporate officers and the pharmacist who serves as the
318 prescription department manager for prescription drugs exported
319 into this state under the International Prescription Drug
320 Importation Program.

321 (d) Written attestation by an owner or officer of the
322 applicant, and by the applicant's prescription department
323 manager, that:

324 1. The attestor has read and understands the laws and rules
325 governing the manufacture, distribution, and dispensing of
326 prescription drugs in this state.

327 2. A prescription drug shipped, mailed, or delivered into
328 this state meets or exceeds this state's standards for safety
329 and efficacy.

330 3. A prescription drug product shipped, mailed, or



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331 delivered into this state must not have been, and may not be,
332 manufactured or distributed in violation of the laws and rules
333 of the jurisdiction in which the applicant is located and from
334 which the prescription drugs shall be exported.

335 (e) A current inspection report from an inspection
336 conducted by the regulatory or licensing agency of the
337 jurisdiction in which the applicant is located. The inspection
338 report must reflect compliance with this section. An inspection
339 report is current if the inspection was conducted within 6
340 months before the date of submitting the application for the
341 initial permit or within 1 year before the date of submitting an
342 application for permit renewal. If the applicant is unable to
343 submit a current inspection report conducted by the regulatory
344 or licensing agency of the jurisdiction in which the applicant
345 is located and from which the prescription drugs will be
346 exported, due to acceptable circumstances, as established by
347 rule, or if an inspection has not been performed, the department
348 must:

349 1. Conduct, or contract with an entity to conduct, an
350 onsite inspection, with all related costs borne by the
351 applicant;

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

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

357 (5) The department shall adopt rules governing the
358 financial responsibility of the pharmacy permittee. The rules
359 must establish, at a minimum, financial reporting requirements,



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360 standards for financial capability to perform the functions
361 governed by the permit, and requirements for ensuring permittees
362 and their contractors can be held accountable for the financial
363 consequences of any act of malfeasance or misfeasance or
364 fraudulent or dishonest act or acts committed by the permittee
365 or its contractors.

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

368 465.017 Authority to inspect; disposal.—

369 (2) Duly authorized agents and employees of the department
370 may inspect a nonresident pharmacy registered under s. 465.0156,
371 an international export pharmacy permittee under s. 465.0157, or
372 a nonresident sterile compounding permittee under s. 465.0158
373 pursuant to this section. The costs of such inspections shall be
374 borne by such pharmacy or permittee.

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

377 499.005 Prohibited acts.—It is unlawful for a person to
378 perform or cause the performance of any of the following acts in
379 this state:

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

383 Section 5. Paragraph (e) of subsection (12) of section
384 499.0051, Florida Statutes, is amended to read:

385 499.0051 Criminal acts.—

386 (12) REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR
387 TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO
388 PRESCRIPTION DRUGS.—Any person who violates any of the following



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389 provisions commits a felony of the third degree, punishable as
390 provided in s. 775.082, s. 775.083, or s. 775.084, or as
391 otherwise provided in this part:

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

395 Section 6. Subsection (1) and paragraph (c) of subsection
396 (2) of section 499.01, Florida Statutes, are amended, and
397 paragraph (s) is added to subsection (2) of that section, to
398 read:

399 499.01 Permits.—

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

- 402 (a) A prescription drug manufacturer;
- 403 (b) A prescription drug repackager;
- 404 (c) A nonresident prescription drug manufacturer;
- 405 (d) A nonresident prescription drug repackager;
- 406 (e) A prescription drug wholesale distributor;
- 407 (f) An out-of-state prescription drug wholesale
408 distributor;
- 409 (g) A retail pharmacy drug wholesale distributor;
- 410 (h) A restricted prescription drug distributor;
- 411 (i) A complimentary drug distributor;
- 412 (j) A freight forwarder;
- 413 (k) A veterinary prescription drug retail establishment;
- 414 (l) A veterinary prescription drug wholesale distributor;
- 415 (m) A limited prescription drug veterinary wholesale
416 distributor;
- 417 (n) An over-the-counter drug manufacturer;



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418 (o) A device manufacturer;
419 (p) A cosmetic manufacturer;
420 (q) A third party logistics provider; ~~or~~
421 (r) A health care clinic establishment; or
422 (s) An international prescription drug wholesale
423 distributor.

424 (2) The following permits are established:

425 (c) *Nonresident prescription drug manufacturer permit.*—A
426 nonresident prescription drug manufacturer permit is required
427 for any person that is a manufacturer of prescription drugs,
428 unless permitted as a third party logistics provider, located
429 outside of this state or outside the United States and that
430 engages in the distribution in this state of such prescription
431 drugs. Each such manufacturer must be permitted by the
432 department and comply with all of the provisions required of a
433 prescription drug manufacturer under this part. The department
434 shall adopt rules for issuing a virtual nonresident prescription
435 drug manufacturer permit to a person who engages in the
436 manufacture of prescription drugs but does not make or take
437 physical possession of any prescription drugs. The rules adopted
438 by the department under this section may exempt virtual
439 nonresident manufacturers from certain establishment, security,
440 and storage requirements set forth in s. 499.0121.

441 1. A person that distributes prescription drugs for which
442 the person is not the manufacturer must also obtain an out-of-
443 state prescription drug wholesale distributor permit, an
444 international prescription drug wholesale distributor permit, or
445 third party logistics provider permit pursuant to this section
446 to engage in the distribution of such prescription drugs when



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447 required by this part. This subparagraph does not apply to a
448 manufacturer that distributes prescription drugs only for the
449 manufacturer of the prescription drugs where both manufacturers
450 are affiliates.

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

461 3.a. A nonresident prescription drug manufacturer that has
462 registered to participate in the International Prescription Drug
463 Importation Program pursuant to this section is not required to
464 provide the list and approval required by subparagraph 2. for
465 prescription drugs imported under that program.

466 b. To participate as an exporter of prescription drugs into
467 this state under the International Prescription Drug Importation
468 Program established under s. 499.0285, a nonresident
469 prescription drug manufacturer located outside of the United
470 States must register with the Department of Business and
471 Professional Regulation before engaging in any activities under
472 that section. Such manufacturer must be licensed or permitted in
473 a country with which the United States has a current mutual
474 recognition agreement, cooperation agreement, memorandum of
475 understanding, or other federal mechanism recognizing the



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476 country's adherence to current good manufacturing practices for
477 pharmaceutical products.

478 c. The department shall adopt rules governing the financial
479 responsibility of a nonresident prescription drug manufacturer
480 licensee or permittee. The rules will establish, at a minimum,
481 financial reporting requirements, standards for financial
482 capability to perform the functions governed by the permit, and
483 requirements for ensuring permittees and their contractors can
484 be held accountable for the financial consequences of any act of
485 malfeasance or misfeasance or fraudulent or dishonest act or
486 acts committed by the permittee or its contractors.

487 (s) International prescription drug wholesale distributor.-

488 1. A wholesale distributor located outside of the United
489 States must obtain an international prescription drug wholesale
490 distributor permit to engage in the wholesale exportation and
491 distribution of prescription drugs in the state under the
492 International Prescription Drug Importation Program established
493 in s. 499.0285. The wholesale distributor must be licensed or
494 permitted to operate in a country with which the United States
495 has a mutual recognition agreement, cooperation agreement,
496 memorandum of understanding, or other federal mechanism
497 recognizing the country's adherence to current good
498 manufacturing practices for pharmaceutical products. The
499 wholesale distributor must maintain at all times a license or
500 permit to engage in the wholesale distribution of prescription
501 drugs in compliance with the laws of the jurisdiction in which
502 it operates. An international prescription drug wholesale
503 distributor permit may not be issued to a wholesale distributor
504 if the jurisdiction in which the wholesale distributor operates



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505 does not require a license to engage in the wholesale
506 distribution of prescription drugs.

507 2. The department shall adopt rules governing the financial
508 responsibility of an international prescription drug wholesale
509 distributor permittee. The rules will establish, at a minimum,
510 financial reporting requirements, standards for financial
511 capability to perform the functions governed by the permit, and
512 requirements for ensuring permittees and their contractors can
513 be held accountable for the financial consequences of any act of
514 malfeasance or misfeasance or fraudulent or dishonest act or
515 acts committed by the permittee or its contractors.

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

520 499.012 Permit application requirements.—

521 (2) Notwithstanding subsection (6), a permitted person in
522 good standing may change the type of permit issued to that
523 person by completing a new application for the requested permit,
524 paying the amount of the difference in the permit fees if the
525 fee for the new permit is more than the fee for the original
526 permit, and meeting the applicable permitting conditions for the
527 new permit type. The new permit expires on the expiration date
528 of the original permit being changed; however, a new permit for
529 a prescription drug wholesale distributor, an out-of-state
530 prescription drug wholesale distributor, an international
531 prescription drug wholesale distributor, or a retail pharmacy
532 drug wholesale distributor shall expire on the expiration date
533 of the original permit or 1 year after the date of issuance of



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534 the new permit, whichever is earlier. A refund may not be issued
535 if the fee for the new permit is less than the fee that was paid
536 for the original permit.

537 (4) (a) Except for a permit for a prescription drug
538 wholesale distributor, an international prescription drug
539 wholesale distributor, or an out-of-state prescription drug
540 wholesale distributor, an application for a permit must include:

541 1. The name, full business address, and telephone number of
542 the applicant;

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

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

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

549 5. The names of the owner and the operator of the
550 establishment, including:

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

552 b. If a partnership, the name of each partner and the name
553 of the partnership;

554 c. If a corporation, the name and title of each corporate
555 officer and director, the corporate names, and the name of the
556 state of incorporation;

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

559 e. If a limited liability company, the name of each member,
560 the name of each manager, the name of the limited liability
561 company, and the name of the state in which the limited
562 liability company was organized; and



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563 f. Any other relevant information that the department
564 requires.

565 (8) An application for a permit or to renew a permit for a
566 prescription drug wholesale distributor, an international
567 prescription drug wholesale distributor, or an out-of-state
568 prescription drug wholesale distributor submitted to the
569 department must include:

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

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

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

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

578 (e) The names of the owner and the operator of the
579 establishment, including:

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

581 2. If a partnership, the name of each partner and the name
582 of the partnership.

583 3. If a corporation:

584 a. The name, address, and title of each corporate officer
585 and director.

586 b. The name and address of the corporation, resident agent
587 of the corporation, the resident agent's address, and the
588 corporation's state of incorporation.

589 c. The name and address of each shareholder of the
590 corporation that owns 5 percent or more of the outstanding stock
591 of the corporation.



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592 4. If a sole proprietorship, the full name of the sole
593 proprietor and the name of the business entity.

594 5. If a limited liability company:

595 a. The name and address of each member.

596 b. The name and address of each manager.

597 c. The name and address of the limited liability company,
598 the resident agent of the limited liability company, and the
599 name of the state in which the limited liability company was
600 organized.

601 (f) If applicable, the name and address of each affiliate
602 of the applicant.

603 (g) The applicant's gross annual receipts attributable to
604 prescription drug wholesale distribution activities for the
605 previous tax year.

606 (h) The tax year of the applicant.

607 (i) A copy of the deed for the property on which
608 applicant's establishment is located, if the establishment is
609 owned by the applicant, or a copy of the applicant's lease for
610 the property on which applicant's establishment is located that
611 has an original term of not less than 1 calendar year, if the
612 establishment is not owned by the applicant.

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

616 (k) The name of the manager of the establishment that is
617 applying for the permit or to renew the permit, the next four
618 highest ranking employees responsible for prescription drug
619 wholesale operations for the establishment, and the name of all
620 affiliated parties for the establishment, together with the



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621 personal information statement and fingerprints required
622 pursuant to subsection (9) for each of such persons.

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

627 (m) Evidence of a surety bond in this state or any other
628 state in the United States in the amount of \$100,000. If the
629 annual gross receipts of the applicant's previous tax year are
630 \$10 million or less, evidence of a surety bond in the amount of
631 \$25,000. The specific language of the surety bond must include
632 the State of Florida as a beneficiary, payable to the
633 Professional Regulation Trust Fund. In lieu of the surety bond,
634 the applicant may provide other equivalent security such as an
635 irrevocable letter of credit, or a deposit in a trust account or
636 financial institution, which includes the State of Florida as a
637 beneficiary, payable to the Professional Regulation Trust Fund.
638 The purpose of the bond or other security is to secure payment
639 of any administrative penalties imposed by the department and
640 any fees and costs incurred by the department regarding that
641 permit which are authorized under state law and which the
642 permittee fails to pay 30 days after the fine or costs become
643 final. The department may make a claim against such bond or
644 security until 1 year after the permittee's license ceases to be
645 valid or until 60 days after any administrative or legal
646 proceeding authorized in this part which involves the permittee
647 is concluded, including any appeal, whichever occurs later.

648 (n) For establishments used in wholesale distribution,
649 proof of an inspection conducted by the department, the United



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650 States Food and Drug Administration, or another governmental
651 entity charged with the regulation of good manufacturing
652 practices related to wholesale distribution of prescription
653 drugs, within timeframes set forth by the department in
654 departmental rules, which demonstrates substantial compliance
655 with current good manufacturing practices applicable to
656 wholesale distribution of prescription drugs. The department may
657 recognize another state's or jurisdiction's inspection of a
658 wholesale distributor located in that state or jurisdiction if
659 such state's or jurisdiction's laws are deemed to be
660 substantially equivalent to the law of this state by the
661 department. The department may accept an inspection by a third-
662 party accreditation or inspection service which meets the
663 criteria set forth in department rule.

664 (o) Any other relevant information that the department
665 requires.

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

668 (q) For international prescription drug wholesale
669 distributors and nonresident prescription drug manufacturers to
670 participate in the International Prescription Drug Importation
671 Program established under s. 499.0285, documentation
672 demonstrating that the applicant is appropriately licensed or
673 permitted by a country with which the United States has a mutual
674 recognition agreement, cooperation agreement, memorandum of
675 understanding, or other mechanism recognizing the country's
676 adherence to current good manufacturing practices for
677 pharmaceutical products.

678 (10) The department may deny an application for a permit or



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679 refuse to renew a permit for a prescription drug wholesale
680 distributor, an international prescription drug wholesale
681 distributor, or an out-of-state prescription drug wholesale
682 distributor if:

683 (a) The applicant has not met the requirements for the
684 permit.

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

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

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

694 (e) The applicant is lacking in experience in the
695 distribution of prescription drugs.

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

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

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



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

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

716 (k) That a federal, state, or local government permit
717 currently or previously held by the applicant, or any affiliated
718 party, for the manufacture or distribution of any drugs,
719 devices, or cosmetics has been disciplined, suspended, or
720 revoked and has not been reinstated.

721 (l) The applicant does not possess the financial or
722 physical resources to operate in compliance with the permit
723 being sought, this chapter, and the rules adopted under this
724 chapter.

725 (m) The applicant or any affiliated party receives,
726 directly or indirectly, financial support and assistance from a
727 person who was an affiliated party of a permittee whose permit
728 was subject to discipline or was suspended or revoked, other
729 than through the ownership of stock in a publicly traded company
730 or a mutual fund.

731 (n) The applicant or any affiliated party receives,
732 directly or indirectly, financial support and assistance from a
733 person who has been found guilty of any violation of this part
734 or chapter 465, chapter 501, or chapter 893, any rules adopted
735 under this part or those chapters, any federal or state drug
736 law, or any felony where the underlying facts related to drugs,



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737 regardless of whether the person has been pardoned, had her or
738 his civil rights restored, or had adjudication withheld, other
739 than through the ownership of stock in a publicly traded company
740 or a mutual fund.

741 (o) The applicant for renewal of a permit under s.
742 499.01(2)(e) or (f) has not actively engaged in the wholesale
743 distribution of prescription drugs, as demonstrated by the
744 regular and systematic distribution of prescription drugs
745 throughout the year as evidenced by not fewer than 12 wholesale
746 distributions in the previous year and not fewer than three
747 wholesale distributions in the previous 6 months.

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

751 (q) The applicant does not possess the financial standing
752 and business experience for the successful operation of the
753 applicant.

754 (r) The applicant or any affiliated party has failed to
755 comply with the requirements for manufacturing or distributing
756 prescription drugs under this part, similar federal laws,
757 similar laws in other states, or the rules adopted under such
758 laws.

759 (11) Upon approval of the application by the department and
760 payment of the required fee, the department shall issue or renew
761 a prescription drug wholesale distributor, an international
762 prescription drug wholesale distributor, or an out-of-state
763 prescription drug wholesale distributor permit to the applicant.

764 (14) The name of a permittee or establishment on a
765 prescription drug wholesale distributor permit, an international



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766 prescription drug wholesale distributor permit, or an out-of-
767 state prescription drug wholesale distributor permit may not
768 include any indicia of attainment of any educational degree, any
769 indicia that the permittee or establishment possesses a
770 professional license, or any name or abbreviation that the
771 department determines is likely to cause confusion or mistake or
772 that the department determines is deceptive, including that of
773 any other entity authorized to purchase prescription drugs.

774 (15) (a) Each establishment that is issued an initial or
775 renewal permit as a prescription drug wholesale distributor, an
776 international prescription drug wholesale distributor, or an
777 out-of-state prescription drug wholesale distributor must
778 designate in writing to the department at least one natural
779 person to serve as the designated representative of the
780 wholesale distributor. Such person must have an active
781 certification as a designated representative from the
782 department.

783 (b) To be certified as a designated representative, a
784 natural person must:

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

787 2. Be at least 18 years of age.

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

789 a. Work experience in a pharmacy licensed in this state or
790 another state or jurisdiction, where the person's
791 responsibilities included, but were not limited to,
792 recordkeeping for prescription drugs;

793 b. Managerial experience with a prescription drug wholesale
794 distributor licensed in this state or in another state or



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795 jurisdiction; or

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

800 4. Receive a passing score of at least 75 percent on an
801 examination given by the department regarding federal laws
802 governing distribution of prescription drugs and this part and
803 the rules adopted by the department governing the wholesale
804 distribution of prescription drugs. This requirement shall be
805 effective 1 year after the results of the initial examination
806 are mailed to the persons that took the examination. The
807 department shall offer such examinations at least four times
808 each calendar year.

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

811 (f) A wholesale distributor may not operate under a
812 prescription drug wholesale distributor permit, an international
813 prescription drug wholesale distributor permit, or an out-of-
814 state prescription drug wholesale distributor permit for more
815 than 10 business days after the designated representative leaves
816 the employ of the wholesale distributor, unless the wholesale
817 distributor employs another designated representative and
818 notifies the department within 10 business days of the identity
819 of the new designated representative.

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

822 499.015 Registration of drugs and devices; issuance of
823 certificates of free sale.-



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824 (1) (a) Except for those persons exempted from the
825 definition of manufacturer in s. 499.003, any person who
826 manufactures, packages, repackages, labels, or relabels a drug
827 or device in this state must register such drug or device
828 biennially with the department; pay a fee in accordance with the
829 fee schedule provided by s. 499.041; and comply with this
830 section. The registrant must list each separate and distinct
831 drug or device at the time of registration.

832 (b) The department may not register any product that does
833 not comply with the Federal Food, Drug, and Cosmetic Act, as
834 amended, or Title 21 C.F.R. Registration of a product by the
835 department does not mean that the product does in fact comply
836 with all provisions of the Federal Food, Drug, and Cosmetic Act,
837 as amended.

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

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

843 499.065 Inspections; imminent danger.—

844 (1) Notwithstanding s. 499.051, the department shall
845 inspect each prescription drug wholesale distributor
846 establishment, international prescription drug wholesale
847 distributor establishment, prescription drug repackager
848 establishment, veterinary prescription drug wholesale
849 distributor establishment, limited prescription drug veterinary
850 wholesale distributor establishment, and retail pharmacy drug
851 wholesale distributor establishment that is required to be
852 permitted under this part as often as necessary to ensure



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853 compliance with applicable laws and rules. The department shall
854 have the right of entry and access to these facilities at any
855 reasonable time.

856 (3) The department may determine that a prescription drug
857 wholesale distributor establishment, international prescription
858 drug wholesale distributor establishment, prescription drug
859 repackager establishment, veterinary prescription drug wholesale
860 distributor establishment, limited prescription drug veterinary
861 wholesale distributor establishment, or retail pharmacy drug
862 wholesale distributor establishment that is required to be
863 permitted under this part is an imminent danger to the public
864 health and shall require its immediate closure if the
865 establishment fails to comply with applicable laws and rules
866 and, because of the failure, presents an imminent threat to the
867 public's health, safety, or welfare. Any establishment so deemed
868 and closed shall remain closed until allowed by the department
869 or by judicial order to reopen.

870 Section 10. Section 499.0285, Florida Statutes, is created
871 to read:

872 499.0285 International Prescription Drug Importation
873 Program.—

874 (1) PROGRAM ESTABLISHED.—The department shall establish a
875 program for the importation of safe and effective prescription
876 drugs from foreign nations with which the United States has
877 current mutual recognition agreements, cooperation agreements,
878 memoranda of understanding, or other federal mechanisms
879 recognizing their adherence to current good manufacturing
880 practices for pharmaceutical products.

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



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882 (a) "Exporter" means an international prescription drug
883 wholesale distributor, a nonresident prescription drug
884 manufacturer registered to participate in the program, or an
885 international export pharmacy that exports prescription drugs
886 into this state under the program.

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

891 (c) "Foreign recipient" means an entity other than the
892 original prescription drug manufacturer which receives the
893 prescription drug before its importation into this state under
894 the program.

895 (d) "Good manufacturing practice" refers to the good
896 manufacturing practice regulations in 21 C.F.R. parts 210 and
897 211.

898 (e) "Importer" means a wholesale distributor, pharmacy, or
899 pharmacist importing prescription drugs into this state under
900 the program.

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

905 (g) "International prescription drug wholesale distributor"
906 means a prescription drug wholesale distributor located outside
907 of the United States which holds an active and unencumbered
908 permit under this part to export and distribute prescription
909 drugs into this state under the program.

910 (h) "Nonresident prescription drug manufacturer" means an



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911 entity located outside of the United States which holds an
912 active and unencumbered permit under this part to manufacture
913 prescription drugs and has registered with the department to
914 export and distribute such prescription drugs into this state
915 under the program.

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

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

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

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

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

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

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

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

933 (c) The drug is not:

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

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

936 3. An infused drug;

937 4. An intravenously injected drug;

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

939 6. A drug that is a parenteral drug, the importation of



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940 which is determined by the United States Secretary of Health and
941 Human Services to pose a threat to the public health.

942 (4) EXPORTERS.—

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

945 1. An international prescription drug wholesale
946 distributor.

947 2. A nonresident prescription drug manufacturer.

948 3. An international export pharmacy.

949 (b) An eligible exporter must register with the department
950 before exporting prescription drugs into this state under the
951 program.

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

955 (5) IMPORTERS.—

956 (a) The following entities may import prescription drugs
957 under the program:

958 1. A wholesale distributor.

959 2. A pharmacy.

960 3. A pharmacist.

961 (b) An eligible importer must register with the department
962 before importing prescription drugs into this state under the
963 program.

964 (c) An importer may not distribute, sell, or dispense
965 prescription drugs imported under the program to any person
966 residing outside of the state.

967 (6) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

968 (a) A participating importer must submit the following



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- 969 information and documentation to the department:
- 970 1. The name and quantity of the active ingredient of the
- 971 prescription drug.
- 972 2. A description of the dosage form of the prescription
- 973 drug.
- 974 3. The date on which the prescription drug is shipped.
- 975 4. The quantity of the prescription drug that is shipped.
- 976 5. The point of origin and destination of the prescription
- 977 drug.
- 978 6. The price paid by the importer for the prescription
- 979 drug.
- 980 7. Documentation from the exporter specifying:
- 981 a. The original source of the prescription drug; and
- 982 b. The quantity of each lot of the prescription drug
- 983 originally received by the seller from that source.
- 984 8. The lot or control number assigned to the prescription
- 985 drug by the manufacturer.
- 986 9. The name, address, telephone number, and professional
- 987 license or permit number of the importer.
- 988 10. In the case of a prescription drug that is shipped
- 989 directly by the first foreign recipient from the manufacturer:
- 990 a. Documentation demonstrating that the prescription drug
- 991 was received by the recipient from the manufacturer and
- 992 subsequently shipped by the first foreign recipient to the
- 993 importer.
- 994 b. Documentation of the quantity of each lot of the
- 995 prescription drug received by the first foreign recipient
- 996 demonstrating that the quantity being imported into this state
- 997 is not more than the quantity that was received by the first



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998 foreign recipient.

999 c. For an initial imported shipment, documentation
1000 demonstrating that each batch of the prescription drug in the
1001 shipment was statistically sampled and tested for authenticity
1002 and degradation.

1003 11. In the case of a prescription drug that is not shipped
1004 directly from the first foreign recipient, documentation
1005 demonstrating that each batch in each shipment offered for
1006 importation into this state was statistically sampled and tested
1007 for authenticity and degradation.

1008 12. For an initial imported shipment of a specific drug by
1009 an importer, the department shall ensure that each batch of the
1010 drug in the shipment is statistically sampled and tested for
1011 authenticity and degradation in a manner consistent with the
1012 federal act. The agency may contract with a vendor for these
1013 functions.

1014 13. For every subsequent imported shipment of that drug by
1015 that importer, the department shall ensure that a statistically
1016 valid sample of the shipment was tested for authenticity and
1017 degradation in a manner consistent with the federal act.

1018 14. Certify that the drug:

1019 a. Is approved for marketing in the United States and is
1020 not adulterated or misbranded; and

1021 b. Meets all of the labeling requirements under 21 U.S.C.
1022 s. 352.

1023 15. Maintain qualified laboratory records, including
1024 complete data derived from all tests necessary to ensure that
1025 the drug is in compliance with the requirements of this section.

1026 16. Maintain documentation demonstrating that the testing



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1027 required by this section was conducted at a qualified laboratory
1028 in accordance with the federal act and any other applicable
1029 federal and state laws and regulations governing laboratory
1030 qualifications.

1031 (b) All testing required by this section must be conducted
1032 in a qualified laboratory that meets the standards under the
1033 federal act and any other applicable federal and state laws and
1034 regulations governing laboratory qualifications for drug
1035 testing.

1036 (c) The vendor shall maintain information and documentation
1037 submitted under this section for a period of at least 7 years.

1038 (d) A participating importer must submit the all of
1039 following information to the department:

1040 1. The name and quantity of the active ingredient of the
1041 drug.

1042 2. A description of the dosage form of the drug.

1043 3. The date on which the drug is received.

1044 4. The quantity of the drug that is received.

1045 5. The point of origin and destination of the drug.

1046 6. The price paid by the importer for the drug.

1047 (e) A participating International Importation Drug supplier
1048 must submit the following information and documentation to the
1049 agency or the agency's designated vendor specifying all of the
1050 following:

1051 1. The original source of the drug, including:

1052 a. The name of the manufacturer of the drug.

1053 b. The date on which the drug was manufactured.

1054 c. The location (country, state or province, and city)

1055 where the drug was manufactured.



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1056 2. The date on which the drug is shipped.
1057 3. The quantity of the drug that is shipped.
1058 4. The quantity of each lot of the drug originally received
1059 and from which source.
1060 5. The lot or control number and the batch number assigned
1061 to the drug by the manufacturer.
1062 6. The name, address, and telephone number, and
1063 professional license or permit number of the importer.
1064 (f) The department may require any other information
1065 necessary to ensure the protection of the public health.
1066 (7) IMMEDIATE SUSPENSION.—The department shall immediately
1067 suspend the importation of a specific prescription drug or the
1068 importation of prescription drugs by a specific importer if it
1069 discovers that any prescription drug or activity is in violation
1070 of this section. The department may revoke the suspension if,
1071 after conducting an investigation, it determines that the public
1072 is adequately protected from counterfeit or unsafe prescription
1073 drugs being imported into this state.
1074 (8) RULEMAKING AUTHORITY.—The department shall adopt rules
1075 necessary to implement this section.
1076 Section 11. Notwithstanding the Federal Food, Drug, and
1077 Cosmetic Act, the Department of Business and Professional
1078 Regulation, in collaboration with the Department of Health,
1079 shall negotiate a federal arrangement to operate a pilot program
1080 for importing prescription drugs into this state. The proposal
1081 to operate such a pilot program shall demonstrate that the
1082 program sets safety standards consistent with the current
1083 federal requirements for the manufacturing and distribution of
1084 prescription drugs; limits the importation of prescription drugs



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1085 under the program to entities licensed or permitted by the state
1086 to manufacture, distribute, or dispense prescription drugs; and
1087 includes inspection and enforcement authority. Implementation of
1088 sections 2 through 10 of this act is contingent upon
1089 authorization granted under federal law, rule, or approval. The
1090 department shall notify the President of the Senate, the Speaker
1091 of the House of Representatives, and the relevant committees of
1092 the Senate and the House of Representatives before
1093 implementation of the pilot program. The department shall submit
1094 to all parties a proposal for program implementation and program
1095 funding.

1096 Section 12. This act shall take effect July 1, 2019.

1097
1098 ===== T I T L E A M E N D M E N T =====

1099 And the title is amended as follows:

1100 Delete everything before the enacting clause
1101 and insert:

1102 A bill to be entitled
1103 An act relating to prescription drug importation
1104 programs; creating s. 381.02035, F.S.; requiring the
1105 Agency for Health Care Administration to establish the
1106 Canadian Prescription Drug Importation Program;
1107 defining terms; requiring the agency to contract with
1108 a vendor to facilitate wholesale prescription drug
1109 importation under the program; providing
1110 responsibilities for the vendor, including the payment
1111 of a bond; providing eligibility criteria for
1112 prescription drugs, Canadian suppliers, and importers
1113 under the program; authorizing a Canadian supplier to



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1114 export drugs into this state under the program under
1115 certain circumstances; providing eligibility criteria
1116 and requirements for drug importers; requiring
1117 participating Canadian suppliers and importers to
1118 comply with specified federal requirements for
1119 distributing prescription drugs imported under the
1120 program; prohibiting Canadian suppliers and importers
1121 from distributing, dispensing, or selling prescription
1122 drugs imported under the program outside of this
1123 state; requiring the agency to request federal
1124 approval of the program; requiring the request to
1125 include certain information; requiring the agency to
1126 begin operating the program within a specified
1127 timeframe after receiving federal approval; providing
1128 certain documentation requirements; requiring the
1129 agency to suspend the importation of drugs in
1130 violation of this section or any federal or state law
1131 or regulation; authorizing the agency to revoke the
1132 suspension under certain circumstances; requiring the
1133 agency to submit an annual report to the Governor and
1134 the Legislature by a specified date; providing
1135 requirements for such report; requiring the agency to
1136 notify the Legislature upon federal approval of the
1137 program and to submit a proposal to the Legislature
1138 for program implementation and funding before a
1139 certain date; requiring the agency to adopt necessary
1140 rules; creating s. 465.0157, F.S.; establishing an
1141 international export pharmacy permit for participation
1142 in the International Prescription Drug Importation



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1143 Program; providing requirements for permit application
1144 and renewal; requiring the Department of Health to
1145 adopt certain rules governing the financial
1146 responsibility of the pharmacy permittee; amending s.
1147 465.017, F.S.; authorizing the department to inspect
1148 international export pharmacy permittees; amending s.
1149 499.005, F.S.; providing that the importation of a
1150 prescription drug under the International Prescription
1151 Drug Importation Program is not a prohibited act under
1152 that chapter; amending s. 499.0051, F.S.; providing an
1153 exemption from prosecution as a criminal offense for
1154 the importation of a prescription drug for wholesale
1155 distribution under the International Prescription Drug
1156 Importation Program; amending s. 499.01, F.S.;

1157 requiring an international prescription drug wholesale
1158 distributor to be permitted before operating;
1159 requiring nonresident prescription drug manufacturers
1160 to register with the Department of Business and
1161 Professional Regulation to participate in the program;
1162 providing an exception; establishing an international
1163 prescription drug wholesale distributor drug permit;
1164 providing permit requirements; requiring the
1165 Department of Business and Professional Regulation to
1166 adopt certain rules governing the financial
1167 responsibility of nonresident prescription drug
1168 manufacturer licensee or permittee and international
1169 prescription drug wholesale distributor permittees;
1170 amending s. 499.012, F.S.; providing application
1171 requirements for international prescription drug



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1172 wholesale distributors and nonresident prescription
1173 drug manufacturers to participate in the program;
1174 amending s. 499.015, F.S.; establishing that
1175 prescription drugs imported under the International
1176 Prescription Drug Importation Program are not required
1177 to be registered under a specified provision; amending
1178 s. 499.065, F.S.; requiring the department to inspect
1179 international prescription drug wholesale distributor
1180 establishments; authorizing the department to
1181 determine that an international prescription drug
1182 wholesale distributor establishment is an imminent
1183 danger to the public and require its immediate closure
1184 under certain conditions; creating s. 499.0285, F.S.;
1185 requiring the department to establish the
1186 International Prescription Drug Importation Program
1187 for a specified purpose; providing definitions;
1188 providing eligibility criteria for prescription drugs,
1189 exporters, and importers under the program; requiring
1190 participating importers to submit certain
1191 documentation to the department for prescription drugs
1192 imported under the program; requiring the department
1193 to immediately suspend the importation of specific
1194 prescription drug or the importation of prescription
1195 drugs by a specific importer if a violation has
1196 occurred under the program; authorizing the department
1197 to revoke such suspension under certain circumstances;
1198 requiring the department to adopt necessary rules;
1199 requiring the agency, in collaboration with the
1200 Department of Business and Professional Regulation and



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1201 the Department of Health, to negotiate a federal
1202 arrangement to operate a pilot program for importing
1203 prescription drugs into this state; providing that
1204 implementation of the act is contingent upon the
1205 federal authorization; requiring the department to
1206 notify the Legislature before implementation of the
1207 pilot program and to submit a proposal for pilot
1208 program implementation and funding; providing an
1209 effective date.