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LEGISLATIVE ACTION

Senate

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House

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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;



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 department shall adopt rules governing the  
317 financial responsibility of the pharmacy permittee. The rules  
318 must establish, at a minimum, financial reporting requirements,  
319 standards for financial capability to perform the functions  
320 governed by the permit, and requirements for ensuring permittees  
321 and their contractors can be held accountable for the financial  
322 consequences of any act of malfeasance or misfeasance or  
323 fraudulent or dishonest act or acts committed by the permittee  
324 or its contractors.

325 (d) The location, names, and titles of all principal  
326 corporate officers and the pharmacist who serves as the  
327 prescription department manager for prescription drugs exported  
328 into this state under the International Prescription Drug  
329 Importation Program.

330 (e) Written attestation by an owner or officer of the



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331 applicant, and by the applicant's prescription department  
332 manager, that:

333 1. The attestor has read and understands the laws and rules  
334 governing the manufacture, distribution, and dispensing of  
335 prescription drugs in this state.

336 2. A prescription drug shipped, mailed, or delivered into  
337 this state meets or exceeds this state's standards for safety  
338 and efficacy.

339 3. A prescription drug product shipped, mailed, or  
340 delivered into this state must not have been, and may not be,  
341 manufactured or distributed in violation of the laws and rules  
342 of the jurisdiction in which the applicant is located and from  
343 which the prescription drugs shall be exported.

344 (f) A current inspection report from an inspection  
345 conducted by the regulatory or licensing agency of the  
346 jurisdiction in which the applicant is located. The inspection  
347 report must reflect compliance with this section. An inspection  
348 report is current if the inspection was conducted within 6  
349 months before the date of submitting the application for the  
350 initial permit or within 1 year before the date of submitting an  
351 application for permit renewal. If the applicant is unable to  
352 submit a current inspection report conducted by the regulatory  
353 or licensing agency of the jurisdiction in which the applicant  
354 is located and from which the prescription drugs will be  
355 exported, due to acceptable circumstances, as established by  
356 rule, or if an inspection has not been performed, the department  
357 must:

358 1. Conduct, or contract with an entity to conduct, an  
359 onsite inspection, with all related costs borne by the



360 applicant;

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

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

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.



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



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



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



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.