

By the Committee on Health Policy; and Senators Bean and Gruters

588-03459-19

20191528c1

1                                   A bill to be entitled  
2       An act relating to the Canadian Prescription Drug  
3       Importation Program; creating s. 381.02035, F.S.;  
4       requiring the Agency for Health Care Administration to  
5       establish the Canadian Prescription Drug Importation  
6       Program; defining terms; authorizing a Canadian  
7       supplier to export drugs into this state under the  
8       program under certain circumstances; providing  
9       eligibility criteria and requirements for drug  
10      importers; requiring the agency to contract with a  
11      vendor to facilitate wholesale prescription drug  
12      importation under the program; providing  
13      responsibilities for the vendor; providing eligibility  
14      criteria for prescription drugs, Canadian suppliers,  
15      and importers under the program; requiring  
16      participating Canadian suppliers and importers to  
17      comply with specified federal requirements for  
18      distributing prescription drugs imported under the  
19      program; prohibiting Canadian suppliers and importers  
20      from distributing, dispensing, or selling prescription  
21      drugs imported under the program outside the state;  
22      providing certain documentation requirements;  
23      requiring the agency to suspend the importation of  
24      drugs in violation of this section or any federal or  
25      state law or regulation; authorizing the agency to  
26      revoke the suspension under certain circumstances;  
27      requiring the agency to request federal approval of  
28      the program; requiring the request to include certain  
29      information; requiring the agency to begin operating

588-03459-19

20191528c1

30 the program within a specified timeframe after  
31 receiving federal approval; requiring the agency, in  
32 consultation with the vendor, to submit an annual  
33 report to the Governor and the Legislature by a  
34 specified date; providing requirements for such  
35 report; authorizing the agency to adopt rules;  
36 providing an effective date.

37  
38 Be It Enacted by the Legislature of the State of Florida:

39  
40 Section 1. Section 381.02035, Florida Statutes, is created  
41 to read:

42 381.02035 Canadian Prescription Drug Importation Program.—

43 (1) PROGRAM ESTABLISHED.—The Agency for Health Care  
44 Administration shall establish a program for the importation of  
45 safe and effective prescription drugs from Canada which have the  
46 highest potential for cost savings to the state.

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

48 (a) "Agency" means the Agency for Health Care  
49 Administration.

50 (b) "Canadian supplier" means a manufacturer, wholesale  
51 distributor, or pharmacy appropriately licensed or permitted  
52 under Canadian law to manufacture, distribute, or dispense  
53 prescription drugs.

54 (c) "Drug" or "prescription drug" has the same meaning as  
55 "prescription drug" in s. 499.003.

56 (d) "Federal Act" means the Federal Food, Drug, and  
57 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.  
58 as amended by the Drug Quality and Security Act, 21 U.S.C. 351

588-03459-19

20191528c1

59 et seq.

60 (e) "Importer" means a wholesale distributor, pharmacy, or  
61 pharmacist importing prescription drugs into this state under  
62 the program.

63 (f) "Pharmacist" means a person who holds an active and  
64 unencumbered license to practice pharmacy pursuant to chapter  
65 465.

66 (g) "Program" means the Canadian Prescription Drug  
67 Importation Program.

68 (h) "Track-and-trace" means the product-tracing process for  
69 the components of the pharmaceutical distribution supply chain  
70 as described in Title II of the Drug Quality and Security Act,  
71 Drug Supply Chain Security Act, 21 U.S.C. 351 et seq.

72 (i) "Vendor" means the entity contracted by the agency to  
73 manage specified functions of the program.

74 (3) ELIGIBLE CANADIAN SUPPLIERS.—A Canadian supplier may  
75 export drugs into this state under the program if the supplier  
76 meets all of the following requirements:

77 (a) Complies fully with relevant Canadian federal and  
78 provincial laws and regulations.

79 (b) Complies fully with the Federal Act, including all  
80 other state and federal law and regulations relating to the  
81 track-and-trace requirements at the package level.

82 (c) Submits evidence at time of contract award and  
83 throughout the contract term of a surety bond or comparable  
84 security arrangement from this state or any other state in the  
85 United States in the minimum amount of \$1 million. The agency  
86 shall reevaluate and adjust the amount of the bond annually,  
87 based on program volume. The surety bond or comparable security

588-03459-19

20191528c1

88 arrangement must include the State of Florida as a beneficiary.  
89 In lieu of the surety bond, the supplier may provide a  
90 comparable security arrangement such as an irrevocable letter of  
91 credit or a deposit into a trust account or financial  
92 institution which includes the State of Florida as a  
93 beneficiary. The purposes of the bond or other security  
94 arrangements for the program are to:

95 1. Ensure payment of any administrative penalties imposed  
96 by the agency or any other state agency under the contract when  
97 the supplier fails to pay within 30 days after assessment;

98 2. Ensure performance of contractual and statutory  
99 obligations by the supplier through use of a bond or other  
100 comparable security arrangements to receive payment of any other  
101 costs or fees incurred by the agency, the state, or other  
102 entities acting on behalf of the state if the supplier is non-  
103 compliant with its contractual and statutory obligations. If the  
104 supplier is assessed a penalty under the program and fails to  
105 pay within 30 days after that assessment, the agency, the state,  
106 or an entity acting on behalf of the state may file a claim for  
107 reimbursement against the bond or other comparable security  
108 arrangement; and

109 3. Allow for claims to be made against the bond or other  
110 comparable security arrangements for up to 1 year after the  
111 supplier's contract under the program has ended with the agency  
112 or the state, the supplier's license is no longer valid, or the  
113 program has ended, whichever occurs last.

114  
115 A surety bond or other comparable security arrangement is  
116 required regardless of the time of bid or negotiation process

588-03459-19

20191528c1

117 used by the agency or the type of final contract or agreement  
118 executed for services.

119 (d) Is identified by the vendor as eligible to participate  
120 in the program.

121 (e) Submits evidence at the time of contract award and  
122 throughout the contract term of a surety bond or comparable  
123 security arrangement from this state or any other state in the  
124 United States in the minimum amount of \$1 million. The agency  
125 shall reevaluate and adjust the amount of the bond annually,  
126 based on program volume. The surety bond or comparable security  
127 arrangement must include the State of Florida as a beneficiary.  
128 In lieu of the surety bond, the supplier may provide a  
129 comparable security arrangement such as an irrevocable letter of  
130 credit or a deposit into a trust account or financial  
131 institution which includes the State of Florida as a  
132 beneficiary. The purposes of the bond or other security  
133 arrangements for the program are to:

134 1. Indemnify the supplier in the event that any civil or  
135 criminal legal action is brought by the state, the agency, any  
136 other state agency, or private individuals or entities against  
137 the supplier because of the supplier's failure to perform under  
138 the contract, including, but not limited to, causes of actions  
139 for personal injury, negligence, and wrongful death;

140 2. Ensure payment by the supplier of legal judgements and  
141 claims that have been awarded to the state, the agency, other  
142 entities acting on behalf of the state, individuals, or  
143 organizations if the supplier is assessed a final judgement or  
144 other monetary penalty in a court of law for a civil or criminal  
145 action related to participation in the program. The bond or

588-03459-19

20191528c1

146 comparable security arrangement may be accessed if the supplier  
147 fails to pay any judgement or claim within 60 days after final  
148 judgement; and

149 3. Allow for civil and criminal litigation claims to be  
150 made against the bond or other comparable security arrangements  
151 for up to 1 year after the supplier's contract under the program  
152 has ended with the agency or the state, the supplier's license  
153 is no longer valid, or the program has ended, whichever occurs  
154 last.

155 (4) ELIGIBLE IMPORTERS.—

156 (a) The following entities or persons may import  
157 prescription drugs from a Canadian supplier under the program:

158 1. A wholesale distributor.

159 2. A pharmacy.

160 3. A pharmacist.

161 (b) An eligible importer must meet all of the following  
162 requirements at time of contract award and throughout the  
163 contract term:

164 1. Register with the vendor before importing drugs into the  
165 state under the program and be deemed in compliance with all  
166 requirements, including any relevant provisions of the Federal  
167 Act.

168 2. Submit evidence at time of contract award and throughout  
169 the contract term of a surety bond or other comparable security  
170 arrangement from this state or any other state in the United  
171 States in the amount of \$1 million. The surety bond or  
172 comparable security arrangement must include the State of  
173 Florida as a beneficiary. In lieu of the surety bond, the  
174 supplier may provide a comparable security agreement such as an

588-03459-19

20191528c1

175 irrevocable letter of credit or a deposit into a trust account  
176 or financial institution which includes the State of Florida as  
177 a beneficiary, payable to the State of Florida. The purposes of  
178 the bond or other security arrangements for the program are to:  
179     a. Ensure payment of any administrative penalties imposed  
180 by the agency or any other state agency under the contract when  
181 the importer fails to pay within 30 days after assessment;  
182     b. Ensure performance of contractual and statutory  
183 obligations by the importer through use of a bond or other  
184 comparable security arrangements to receive payment of any other  
185 costs or fees incurred by the agency, the state, or other  
186 entities acting on behalf of the state if the importer is non-  
187 compliant with its contractual and statutory obligations. If the  
188 importer is assessed a penalty under the program and fails to  
189 pay within 30 days after that assessment, the agency, the state,  
190 or an entity acting on behalf of the state may file a claim for  
191 reimbursement against the bond or other comparable security  
192 arrangement; and  
193     c. Allow for claims to be made against the bond or other  
194 comparable security arrangements for up to 1 year after the  
195 importer's contract under the program has ended with the agency  
196 or the state, the importer's license is no longer valid, or the  
197 program has ended, whichever occurs last.  
198  
199 A surety bond or comparable document is required regardless of  
200 the time of bid or negotiation process used by the agency or the  
201 type of final contract or agreement executed for services.  
202     (c) Submits evidence at the time of contract award and  
203 throughout the contract term of a surety bond or comparable

588-03459-19

20191528c1

204 security arrangement from this state or any other state in the  
205 United States in the minimum amount of \$1 million. The agency  
206 shall reevaluate and adjust the amount of the bond annually,  
207 based on program volume. The surety bond or comparable security  
208 arrangement must include the State of Florida as a beneficiary.  
209 In lieu of the surety bond, the supplier may provide a  
210 comparable security agreement such as an irrevocable letter of  
211 credit or a deposit into a trust account or financial  
212 institution which includes the State of Florida as a  
213 beneficiary, payable to the State of Florida. The purposes of  
214 the bond or other security arrangements for the program are to:

215 1. Ensure participation of the supplier in any civil or  
216 criminal legal action by the state, the agency, any other state  
217 agency, or private individuals or entities against the supplier  
218 because of the supplier's failure to perform under the contract,  
219 including, but not limited to causes of actions for personal  
220 injury, negligence, and wrongful death;

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

230 3. Allow for civil and criminal litigation claims to be  
231 made against the bond or other comparable security arrangements  
232 for up to 1 year after the supplier's contract under the program

588-03459-19

20191528c1

233 has ended with the agency or the state, the supplier's license  
234 is no longer valid, or the program has ended, whichever occurs  
235 last.

236 (5) IMPORTATION PROCESS.—

237 (a) The agency shall contract with a vendor to provide  
238 services under the program. The vendor must submit evidence of a  
239 surety bond with any bid or initial contract negotiation  
240 documents and maintain documentation of evidence of such a bond  
241 with the agency throughout the contract term of a surety bond  
242 from this state or any other state in the United States in the  
243 same amount of \$1 million. The surety bond or comparable  
244 security arrangement must include the State of Florida as a  
245 beneficiary. In lieu of the surety bond, the supplier may  
246 provide a comparable security agreement such as an irrevocable  
247 letter of credit or a deposit into a trust account or financial  
248 institution which includes the State of Florida as a  
249 beneficiary, payable to the State of Florida. The purposes of  
250 the bond or other security arrangements for the program are to:

251 1. Ensure payment of any administrative penalties imposed  
252 by the agency or any other state agency under the contract when  
253 the vendor fails to pay within 30 days after assessment;

254 2. Ensure performance of contractual and statutory  
255 obligations by the vendor through use of a surety bond or other  
256 comparable security arrangements to receive payment of any other  
257 costs or fees incurred by the agency, the state, or other  
258 entities acting on behalf of the state if the vendor is non-  
259 compliant with its contractual and statutory obligations. If the  
260 vendor is assessed a penalty under the program and fails to pay  
261 within 30 days after that assessment, the agency, the state, or

588-03459-19

20191528c1

262 an entity acting on behalf of the state may file a claim for  
263 reimbursement against the bond or other comparable security  
264 arrangement; and

265 3. Allow for claims to be made against the bond or other  
266 comparable security arrangements for up to 1 year after the  
267 vendor's contract under the program has ended with the agency or  
268 the state, the importer's license is no longer valid, or the  
269 program has ended, whichever occurs last.

270  
271 A surety bond or comparable document is required regardless of  
272 the time of bid or negotiation process used by the agency or the  
273 type of final contract or agreement executed for services.

274 (b) Submits evidence at the time of contract award and  
275 throughout the contract term of a surety bond or comparable  
276 security arrangement from this state or any other state in the  
277 United States in the minimum amount of \$1 million. The agency  
278 shall reevaluate and adjust the amount of the bond annually,  
279 based on program volume. The surety bond or comparable security  
280 arrangement must include the State of Florida as a beneficiary.  
281 In lieu of the surety bond, the supplier may provide a  
282 comparable security arrangement such as an irrevocable letter of  
283 credit or a deposit into a trust account or financial  
284 institution which names the State of Florida as a beneficiary.  
285 The purposes of the bond or other security arrangements for the  
286 program are to:

287 1. Ensure participation of the vendor in any civil or  
288 criminal legal action by the state, the agency, any other state  
289 agency, or private individuals or entities against the vendor  
290 because of the vendor's failure to perform under the contract,

588-03459-19

20191528c1

291 including, but not limited to causes of actions for personal  
292 injury, negligence, and wrongful death;

293 2. Ensure payment by the vendor through the use of a bond  
294 or other comparable security arrangements of legal judgements  
295 and claims that have been awarded to the agency, the state,  
296 other entities acting on behalf of the state, individuals, or  
297 organizations if the vendor is assessed a final judgement or  
298 other monetary penalty in a court of law for a civil or criminal  
299 action under the program. The bond or comparable security  
300 arrangement will be accessed if the vendor fails to pay any  
301 judgement or claim within 60 days after final judgement; and

302 3. Allow for civil and criminal litigation claims to be  
303 made against the bond or other comparable security arrangements  
304 for up to 1 year after the vendor's contract under the program  
305 has ended with the agency or the state, the vendor's license is  
306 no longer valid, or the program has ended, whichever occurs  
307 last.

308 (c) The vendor shall provide all of the following services  
309 at a minimum:

310 1. Develop a list every 3 month of drugs that have the  
311 highest potential for cost savings to the state if imported from  
312 Canada. In developing the list, the vendor shall consider, at a  
313 minimum, which drugs will provide the greatest cost savings to  
314 the state, including drugs for which there are shortages,  
315 specialty drugs, and high-volume drugs. The agency may direct  
316 the vendor to revise the list, as necessary.

317 2. Identify Canadian suppliers that are in full compliance  
318 with relevant Canadian federal and provincial laws and  
319 regulations and the Federal Act and who have agreed to export

588-03459-19

20191528c1

320 drugs identified on the list. The vendor must verify that such  
321 Canadian suppliers meet all of the requirements of the program  
322 and will export drugs at prices that will provide cost savings  
323 to the state while meeting or exceeding the track-and-trace  
324 federal and state laws and regulations.

325 3. Contract with such eligible Canadian suppliers, or  
326 facilitate contracts between eligible importers and Canadian  
327 suppliers, to import drugs under the program.

328 4. Maintain a listing of all registered importers that  
329 participate in the program.

330 5. Ensure compliance with Title II of the federal Drug  
331 Quality and Security Act P.L. 113-54 by all suppliers, importers  
332 and other distributors and participants in the program.

333 6. Assist the agency with the annual report as required in  
334 subsection (12) and provide any information requested by the  
335 agency for such report on a timely basis.

336 (d) The profit margin and administrative fees of any  
337 participating wholesaler, pharmacy, or pharmacist on imported  
338 drug products is limited to a maximum amount as specified  
339 annually in the General Appropriations Act.

340 (6) ELIGIBLE PRESCRIPTION DRUGS.—Eligible importers may  
341 import a drug from an eligible Canadian supplier if:

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

345 (b) Importing the drug would not violate the patent laws of  
346 the United States;

347 (c) Importing the drug is expected to generate cost  
348 savings; and

588-03459-19

20191528c1

- 349       (d) The drug is not:  
350       1. A controlled substance as defined in 21 U.S.C. s. 802;  
351       2. A biological product as defined in 42 U.S.C. s. 262;  
352       3. An infused drug;  
353       4. An intravenously injected drug;  
354       5. A drug that is inhaled during surgery; or  
355       6. A drug that is a parenteral drug, the importation of  
356 which is determined by the United States Secretary of Health and  
357 Human Services to pose a threat to the public health.

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

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

362       (b) May not distribute, dispense, or sell drugs imported  
363 under the program outside of the program or outside of this  
364 state.

365       (8) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

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

368       1. For an initial imported shipment, ensure that each batch  
369 of the drug in the shipment is statistically sampled and tested  
370 for authenticity and degradation in a manner consistent with the  
371 Federal Act.

372       2. For any subsequent imported shipment, ensure that a  
373 statistically valid sample of the shipment was tested for  
374 authenticity and degradation in a manner consistent with the  
375 Federal Act.

376       3. Certify that the drug:

377       a. Is approved for marketing in the United States and is

588-03459-19

20191528c1

378 not adulterated or misbranded; and

379 b. Meets all of the labeling requirements under 21 U.S.C.  
380 s. 352.

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

384 5. Maintain documentation demonstrating that the testing  
385 required by this section was conducted at a qualified laboratory  
386 in accordance with the Federal Act and any other applicable  
387 federal and state laws and regulations governing laboratory  
388 qualifications.

389 (b) All testing required by this section must be conducted  
390 in a qualified laboratory that meets the standards under the  
391 Federal Act and any other applicable federal and state laws and  
392 regulations governing laboratory qualifications for drug  
393 testing.

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

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

398 1. The name and quantity of the active ingredient of the  
399 drug.

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

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

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

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

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

405 (e) A participating Canadian supplier must submit the  
406 following information and documentation to the vendor specifying

588-03459-19

20191528c1

407 all of the following:

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

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

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

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

412 where the drug was manufactured.

413 2. The date on which the drug is shipped.

414 3. The quantity of the drug which is shipped.

415 4. The quantity of each lot of the drug originally received  
416 and from which source.

417 5. The lot or control number and the batch number assigned  
418 to the drug by the manufacturer.

419 (f) The agency may require that the vendor collect any  
420 other information necessary to ensure the protection of the  
421 public health.

422 (9) IMMEDIATE SUSPENSION.—The agency shall immediately  
423 suspend the importation of a specific drug or the importation of  
424 drugs by a specific importer if it discovers that any drug or  
425 activity is in violation of this section or any federal or state  
426 law or regulation. The agency may revoke the suspension if,  
427 after conducting an investigation, it determines that the public  
428 is adequately protected from counterfeit or unsafe drugs being  
429 imported into the state.

430 (10) FEDERAL APPROVAL.—By July 1, 2020, the agency shall  
431 submit a request to the United States Secretary of Health and  
432 Human Services for approval of the program under 21 U.S.C. s.  
433 384(1). At a minimum, the request must do all of the following:

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

435 (b) Demonstrate how the drugs imported into the state under

588-03459-19

20191528c1

436 the program will meet the applicable federal and state standards  
437 for safety and effectiveness.

438 (c) Demonstrate how the drugs imported into the state under  
439 the program will comply with federal tracing procedures.

440 (d) Include a list of proposed drugs that have the highest  
441 potential for cost savings to the state through importation at  
442 the time that the request is submitted.

443 (e) Estimate the total cost savings attributable to the  
444 program.

445 (f) Provide the costs of program implementation to the  
446 state.

447 (g) Include a list of potential Canadian suppliers from  
448 which the state would import drugs and demonstrate that the  
449 suppliers are in full compliance with relevant Canadian federal  
450 and provincial laws and regulations as well as all applicable  
451 federal and state laws and regulations.

452 (11) NOTIFICATION OF FEDERAL APPROVAL.—Upon receipt of  
453 federal approval of the program, the agency shall notify the  
454 President of the Senate, the Speaker of the House of  
455 Representatives, and the relevant committees of the Senate and  
456 the House of Representatives. The program may not be implemented  
457 until the Legislature approves the program as authorized by the  
458 federal government. As part of its review process for  
459 implementation approval, the Legislature shall consider the  
460 estimated cost savings to the state and whether the program has  
461 met the required safety standards.

462 (12) ANNUAL REPORT.—By December 1 of each year, the agency  
463 shall submit a report to the Governor, the President of the  
464 Senate, and the Speaker of the House of Representatives on the

588-03459-19

20191528c1

465 operation of the program during the previous fiscal year. The  
466 report must include, at a minimum:

467 (a) A list of the drugs that were imported under the  
468 program;

469 (b) The number of participating entities;

470 (c) The number of prescriptions dispensed through the  
471 program;

472 (d) The estimated cost savings during the previous fiscal  
473 year and to date in the program;

474 (e) A description of the methodology used to determine  
475 which drugs should be included; and

476 (f) Documentation of how the program ensures the following  
477 criteria:

478 1. Canadian suppliers participating in the program are of  
479 high quality, high performance, and in full compliance with  
480 relevant Canadian federal and provincial laws and regulations as  
481 well as all United States and Florida laws and regulations;

482 2. Drugs imported under the program are not shipped, sold,  
483 or dispensed outside of the state or the program once in the  
484 possession of the importer;

485 3. Drugs imported under the program are unadulterated,  
486 potent, and safe;

487 4. The program does not put consumers at a higher health  
488 and safety risk than if the consumer did not participate; and

489 5. The program provides cost savings to the state.

490 (13) RULEMAKING.—The agency may adopt rules necessary to  
491 implement this section.

492 Section 2. This act shall take effect July 1, 2019.