

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(l). 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.