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Proposed Committee Substitute by the Committee on Appropriations
(Appropriations Subcommittee on Health and Human Services)

A bill to be entitled

An act relating to the Canadian Prescription Drug
Importation Program; creating s. 381.02035, F.S.;
requiring the Agency for Health Care Administration to
establish the Canadian Prescription Drug Importation
Program; defining terms; authorizing a Canadian
supplier to export drugs into this state under the
program under certain circumstances; providing
eligibility criteria and requirements for drug
importers; requiring the agency to contract with a
vendor to facilitate wholesale prescription drug
importation under the program; providing
responsibilities for the vendor; providing eligibility
criteria for prescription drugs, Canadian suppliers,
and importers under the program; requiring
participating Canadian suppliers and importers to
comply with specified federal requirements for
distributing prescription drugs imported under the
program; prohibiting Canadian suppliers and importers
from distributing, dispensing, or selling prescription
drugs imported under the program outside of this
state; providing certain documentation requirements;
requiring the agency to suspend the importation of
drugs in violation of this section or any federal or
state law or regulation; authorizing the agency to
revoke the suspension under certain circumstances;
requiring the agency to request federal approval of



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28 the program; requiring the request to include certain
29 information; requiring the agency to begin operating
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.

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

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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



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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
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



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86 shall reevaluate and adjust the amount of the bond annually,
87 based on program volume. The surety bond or comparable security
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.

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115 A surety bond or other comparable security arrangement is
116 required regardless of the type of bid or negotiation process
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 a 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
130 of 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 arrangement 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 action
139 for personal injury, negligence, and wrongful death;

140 2. Ensure payment by the supplier of legal judgments 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 judgment or



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

149 3. Allow for civil and criminal litigation claims to be
150 made against the bond or other comparable security arrangement
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 the time of contract award and throughout the
163 contract term:

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

168 2. Submit evidence at the time of contract award and
169 throughout the contract term of a surety bond or other
170 comparable security arrangement from this state or any other
171 state in the United States in the minimum amount of \$1 million.
172 The surety bond or comparable security arrangement must include



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173 the State of Florida as a beneficiary. In lieu of the surety
174 bond, the importer may provide a comparable security agreement,
175 such as an irrevocable letter of credit or a deposit into a
176 trust account or financial institution which includes the State
177 of Florida as a beneficiary, payable to the State of Florida.
178 The purposes of the bond or other security arrangement for the
179 program are to:

180 a. Ensure payment of any administrative penalties imposed
181 by the agency or any other state agency under the contract when
182 the importer fails to pay within 30 days after assessment;

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

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199 A surety bond or comparable document is required, regardless of
200 the type of bid or negotiation process the agency used or the
201 type of final contract or agreement executed for services.



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

215 1. Ensure the importer's participation 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 importer
218 because of the importer's failure to perform under the contract,
219 including, but not limited to causes of action for personal
220 injury, negligence, and wrongful death;

221 2. Ensure payment by the importer through the use of a bond
222 or other comparable security arrangements of legal judgments and
223 claims that have been awarded to the agency, the state, other
224 entities acting on behalf of the state, individuals, or
225 organizations if the importer is assessed a final judgment 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 may be accessed if the importer fails to pay any
229 judgment or claim within 60 days after final judgment; and

230 3. Allow for civil and criminal litigation claims to be



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231 made against the bond or other comparable security arrangements
232 for up to 1 year after the importer's contract under the program
233 has ended with the agency or the state, the importer'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 shall submit evidence of
239 a surety bond with any bid or initial contract negotiation
240 documents and shall maintain documentation of evidence of such a
241 bond with the agency throughout the contract term. The surety
242 bond may be from this state or any other state in the United
243 States in the minimum amount of \$1 million. The surety bond or
244 comparable security arrangement must include the State of
245 Florida as a beneficiary. In lieu of the surety bond, the vendor
246 may provide a comparable security agreement, such as an
247 irrevocable letter of credit or a deposit into a trust account
248 or financial institution which includes the State of Florida as
249 a beneficiary, payable to the State of Florida. The purposes of
250 the bond or other security arrangement 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 that the vendor meets contractual and statutory
255 obligations through use of a surety bond or other comparable
256 security arrangements to pay any other costs or fees incurred by
257 the agency, the state, or other entities acting on behalf of the
258 state if the vendor fails to meet its contractual and statutory
259 obligations. If the vendor is assessed a penalty under the



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260 program and fails to pay within 30 days after that assessment,
261 the agency, the state, or an entity acting on behalf of the
262 state may file a claim for reimbursement against the bond or
263 other comparable security arrangement; and

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

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

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

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



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

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

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

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

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

315 2. Identify Canadian suppliers that are in full compliance
316 with relevant Canadian federal and provincial laws and
317 regulations and the federal act and who have agreed to export



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318 drugs identified on the list. The vendor must verify that such
319 Canadian suppliers meet all of the requirements of the program,
320 while meeting or exceeding the federal and state track-and-trace
321 laws and regulations.

322 3. Contract with such eligible Canadian suppliers, or
323 facilitate contracts between eligible importers and Canadian
324 suppliers, to import drugs under the program.

325 4. Maintain a list of all registered importers that
326 participate in the program.

327 5. Ensure compliance with Title II of the federal Drug
328 Quality and Security Act, Pub. L. No. 113-54, by all suppliers,
329 importers and other distributors, and participants in the
330 program.

331 6. Assist the agency in the preparation of the annual
332 report required by subsection (12) and timely provide any
333 information requested by the agency for the report.

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

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

339 (b) Importing the drug would not violate the patent laws of
340 the United States;

341 (c) Importing the drug is expected to generate cost
342 savings; and

343 (d) The drug is not:

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

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

346 3. An infused drug;



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347 4. An intravenously injected drug;

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

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

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

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

356 (b) May not distribute, dispense, or sell drugs imported
357 under the program outside of the program or outside of this
358 state.

359 (8) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

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

362 1. For an initial imported shipment, ensure that each batch
363 of the drug in the shipment is statistically sampled and tested
364 for authenticity and degradation in a manner consistent with the
365 federal act.

366 2. For any subsequent imported shipment, ensure that a
367 statistically valid sample of the shipment was tested for
368 authenticity and degradation in a manner consistent with the
369 federal act.

370 3. Certify that the drug:

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

373 b. Meets all of the labeling requirements under 21 U.S.C.
374 s. 352.

375 4. Maintain qualified laboratory records, including



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376 complete data derived from all tests necessary to ensure that
377 the drug is in compliance with the requirements of this section.

378 5. Maintain documentation demonstrating that the testing
379 required by this section was conducted at a qualified laboratory
380 in accordance with the federal act and any other applicable
381 federal and state laws and regulations governing laboratory
382 qualifications.

383 (b) All testing required by this section must be conducted
384 in a qualified laboratory that meets the standards under the
385 federal act and any other applicable federal and state laws and
386 regulations governing laboratory qualifications for drug
387 testing.

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

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

392 1. The name and quantity of the active ingredient of the
393 drug.

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

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

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

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

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

399 (e) A participating Canadian supplier must submit the
400 following information and documentation to the vendor specifying
401 all of the following:

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

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

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



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- 405 c. The location (country, state or province, and city)
406 where the drug was manufactured.
- 407 2. The date on which the drug is shipped.
- 408 3. The quantity of the drug that is shipped.
- 409 4. The quantity of each lot of the drug originally received
410 and from which source.
- 411 5. The lot or control number and the batch number assigned
412 to the drug by the manufacturer.
- 413 (f) The agency may require that the vendor collect any
414 other information necessary to ensure the protection of the
415 public health.
- 416 (9) IMMEDIATE SUSPENSION.—The agency shall immediately
417 suspend the importation of a specific drug or the importation of
418 drugs by a specific importer if it discovers that any drug or
419 activity is in violation of this section or any federal or state
420 law or regulation. The agency may revoke the suspension if,
421 after conducting an investigation, it determines that the public
422 is adequately protected from counterfeit or unsafe drugs being
423 imported into this state.
- 424 (10) FEDERAL APPROVAL.—By July 1, 2020, the agency shall
425 submit a request to the United States Secretary of Health and
426 Human Services for approval of the program under 21 U.S.C. s.
427 384(l). At a minimum, the request must do all of the following:
- 428 (a) Describe the agency's plan for operating the program.
- 429 (b) Demonstrate how the drugs imported into this state
430 under the program will meet the applicable federal and state
431 standards for safety and effectiveness.
- 432 (c) Demonstrate how the drugs imported into this state
433 under the program will comply with federal tracing procedures.



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

437 (e) Estimate the total cost savings attributable to the
438 program.

439 (f) Provide the costs of program implementation to the
440 state.

441 (g) Include a list of potential Canadian suppliers from
442 which the state would import drugs and demonstrate that the
443 suppliers are in full compliance with relevant Canadian federal
444 and provincial laws and regulations as well as all applicable
445 federal and state laws and regulations.

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

456 (12) ANNUAL REPORT.—By December 1 of each year, the agency
457 shall submit a report to the Governor, the President of the
458 Senate, and the Speaker of the House of Representatives on the
459 operation of the program during the previous fiscal year. The
460 report must include, at a minimum:

461 (a) A list of the drugs that were imported under the
462 program;



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- 463 (b) The number of participating entities;
464 (c) The number of prescriptions dispensed through the
465 program;
466 (d) The estimated cost savings during the previous fiscal
467 year and to date in the program;
468 (e) A description of the methodology used to determine
469 which drugs should be included; and
470 (f) Documentation of how the program ensures the following
471 criteria:
472 1. Canadian suppliers participating in the program are of
473 high quality, high performance, and in full compliance with
474 relevant Canadian federal and provincial laws and regulations as
475 well as all United States and Florida laws and regulations;
476 2. Drugs imported under the program are not shipped, sold,
477 or dispensed outside of this state or the program once in the
478 possession of the importer;
479 3. Drugs imported under the program are unadulterated,
480 potent, and safe;
481 4. The program does not put consumers at a higher health
482 and safety risk than if the consumer did not participate; and
483 5. The program provides cost savings to the state.
484 (13) RULEMAKING.—The agency may adopt rules necessary to
485 implement this section.
486 Section 2. This act shall take effect July 1, 2019.