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LEGISLATIVE ACTION

Senate

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House

The Committee on Health Policy (Bean) recommended 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 a program for the importation of
safe and effective prescription drugs from Canada which have the
highest potential for cost savings to the state.



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

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

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

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

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

25 (e) "Importer" means a wholesale distributor, pharmacy, or
26 pharmacist importing prescription drugs into this state under
27 the program.

28 (f) "Pharmacist" means a person who holds an active and
29 unencumbered license to practice pharmacy pursuant to chapter
30 465.

31 (g) "Program" means the Canadian Prescription Drug
32 Importation Program.

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

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

39 (3) ELIGIBLE CANADIAN SUPPLIERS.—A Canadian supplier may
40 export drugs into this state under the program if the supplier



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41 meets all of the following requirements:

42 (a) Complies fully with relevant Canadian federal and
43 provincial laws and regulations.

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

47 (c) Submits evidence at time of contract award and
48 throughout the contract term of a surety bond or comparable
49 security arrangement from this state or any other state in the
50 United States in the minimum amount of \$1 million. The agency
51 shall reevaluate and adjust the amount of the bond annually,
52 based on program volume. The surety bond or comparable security
53 arrangement must include the State of Florida as a beneficiary.
54 In lieu of the surety bond, the supplier may provide a
55 comparable security arrangement such as an irrevocable letter of
56 credit or a deposit into a trust account or financial
57 institution which includes the State of Florida as a
58 beneficiary. The purposes of the bond or other security
59 arrangements for the program are to:

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

63 2. Ensure performance of contractual and statutory
64 obligations by the supplier through use of a bond or other
65 comparable security arrangements to receive payment of any other
66 costs or fees incurred by the agency, the state, or other
67 entities acting on behalf of the state if the supplier is non-
68 compliant with its contractual and statutory obligations. If the
69 supplier is assessed a penalty under the program and fails to



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70 pay within 30 days after that assessment, the agency, the state,
71 or an entity acting on behalf of the state may file a claim for
72 reimbursement against the bond or other comparable security
73 arrangement; and

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

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80 A surety bond or other comparable security arrangement is
81 required regardless of the time of bid or negotiation process
82 used by the agency or the type of final contract or agreement
83 executed for services.

84 (d) Is identified by the vendor as eligible to participate
85 in the program.

86 (e) Submits evidence at the time of contract award and
87 throughout the contract term of a surety bond or comparable
88 security arrangement from this state or any other state in the
89 United States in the minimum amount of \$1 million. The agency
90 shall reevaluate and adjust the amount of the bond annually,
91 based on program volume. The surety bond or comparable security
92 arrangement must include the State of Florida as a beneficiary.
93 In lieu of the surety bond, the supplier may provide a
94 comparable security arrangement such as an irrevocable letter of
95 credit or a deposit into a trust account or financial
96 institution which includes the State of Florida as a
97 beneficiary. The purposes of the bond or other security
98 arrangements for the program are to:



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

105 2. Ensure payment by the supplier of legal judgements and
106 claims that have been awarded to the state, the agency, other
107 entities acting on behalf of the state, individuals, or
108 organizations if the supplier is assessed a final judgement or
109 other monetary penalty in a court of law for a civil or criminal
110 action related to participation in the program. The bond or
111 comparable security arrangement may be accessed if the supplier
112 fails to pay any judgement or claim within 60 days after final
113 judgement; and

114 3. Allow for civil and criminal litigation claims to be
115 made against the bond or other comparable security arrangements
116 for up to 1 year after the supplier's contract under the program
117 has ended with the agency or the state, the supplier's license
118 is no longer valid, or the program has ended, whichever occurs
119 last.

120 (4) ELIGIBLE IMPORTERS.—

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

123 1. A wholesale distributor.

124 2. A pharmacy.

125 3. A pharmacist.

126 (b) An eligible importer must meet all of the following
127 requirements at time of contract award and throughout the



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128 contract term:

129 1. Register with the vendor before importing drugs into the
130 state under the program and be deemed in compliance with all
131 requirements, including any relevant provisions of the Federal
132 Act.

133 2. Submit evidence at time of contract award and throughout
134 the contract term of a surety bond or other comparable security
135 arrangement from this state or any other state in the United
136 States in the amount of \$1 million. The surety bond or
137 comparable security arrangement must include the State of
138 Florida as a beneficiary. In lieu of the surety bond, the
139 supplier may provide a comparable security agreement such as an
140 irrevocable letter of credit or a deposit into a trust account
141 or financial institution which includes the State of Florida as
142 a beneficiary, payable to the State of Florida. The purposes of
143 the bond or other security arrangements for the program are to:

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

147 b. Ensure performance of contractual and statutory
148 obligations by the importer through use of a bond or other
149 comparable security arrangements to receive payment of any other
150 costs or fees incurred by the agency, the state, or other
151 entities acting on behalf of the state if the importer is non-
152 compliant with its contractual and statutory obligations. If the
153 importer is assessed a penalty under the program and fails to
154 pay within 30 days after that assessment, the agency, the state,
155 or an entity acting on behalf of the state may file a claim for
156 reimbursement against the bond or other comparable security



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157 arrangement; and

158 c. Allow for claims to be made against the bond or other
159 comparable security arrangements for up to 1 year after the
160 importer's contract under the program has ended with the agency
161 or the state, the importer's license is no longer valid, or the
162 program has ended, whichever occurs last.

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164 A surety bond or comparable document is required regardless of
165 the time of bid or negotiation process used by the agency or the
166 type of final contract or agreement executed for services.

167 (c) Submits evidence at the time of contract award and
168 throughout the contract term of a surety bond or comparable
169 security arrangement from this state or any other state in the
170 United States in the minimum amount of \$1 million. The agency
171 shall reevaluate and adjust the amount of the bond annually,
172 based on program volume. The surety bond or comparable security
173 arrangement must include the State of Florida as a beneficiary.

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

180 1. Ensure participation of the supplier in any civil or
181 criminal legal action by the state, the agency, any other state
182 agency, or private individuals or entities against the supplier
183 because of the supplier's failure to perform under the contract,
184 including, but not limited to causes of actions for personal
185 injury, negligence, and wrongful death;



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186 2. Ensure payment by the supplier through the use of a bond
187 or other comparable security arrangements of legal judgements
188 and claims that have been awarded to the agency, the state,
189 other entities acting on behalf of the state, individuals, or
190 organizations if the supplier is assessed a final judgement or
191 other monetary penalty in a court of law for a civil or criminal
192 action under the program. The bond or comparable security
193 arrangement will be accessed if the supplier fails to pay any
194 judgement or claim within 60 days after final judgement; and

195 3. Allow for civil and criminal litigation claims to be
196 made against the bond or other comparable security arrangements
197 for up to 1 year after the supplier's contract under the program
198 has ended with the agency or the state, the supplier's license
199 is no longer valid, or the program has ended, whichever occurs
200 last.

201 (5) IMPORTATION PROCESS.—

202 (a) The agency shall contract with a vendor to provide
203 services under the program. The vendor must submit evidence of a
204 surety bond with any bid or initial contract negotiation
205 documents and maintain documentation of evidence of such a bond
206 with the agency throughout the throughout the contract term of a
207 surety bond from this state or any other state in the United
208 States in the same amount of \$1 million. The surety bond or
209 comparable security arrangement must include the State of
210 Florida as a beneficiary. In lieu of the surety bond, the
211 supplier may provide a comparable security agreement such as an
212 irrevocable letter of credit or a deposit into a trust account
213 or financial institution which includes the State of Florida as
214 a beneficiary, payable to the State of Florida. The purposes of



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215 the bond or other security arrangements for the program are to:
216 1. Ensure payment of any administrative penalties imposed
217 by the agency or any other state agency under the contract when
218 the vendor fails to pay within 30 days after assessment;
219 2. Ensure performance of contractual and statutory
220 obligations by the vendor through use of a surety bond or other
221 comparable security arrangements to receive payment of any other
222 costs or fees incurred by the agency, the state, or other
223 entities acting on behalf of the state if the vendor is non-
224 compliant with its contractual and statutory obligations. If the
225 vendor is assessed a penalty under the program and fails to pay
226 within 30 days after that assessment, the agency, the state, or
227 an entity acting on behalf of the state may file a claim for
228 reimbursement against the bond or other comparable security
229 arrangement; and
230 3. Allow for claims to be made against the bond or other
231 comparable security arrangements for up to 1 year after the
232 vendor's contract under the program has ended with the agency or
233 the state, the importer's license is no longer valid, or the
234 program has ended, whichever occurs last.
235
236 A surety bond or comparable document is required regardless of
237 the time of bid or negotiation process used by the agency or the
238 type of final contract or agreement executed for services.
239 (b) Submits evidence at the time of contract award and
240 throughout the contract term of a surety bond or comparable
241 security arrangement from this state or any other state in the
242 United States in the minimum amount of \$1 million. The agency
243 shall reevaluate and adjust the amount of the bond annually,



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244 based on program volume. The surety bond or comparable security
245 arrangement must include the State of Florida as a beneficiary.
246 In lieu of the surety bond, the supplier may provide a
247 comparable security arrangement such as an irrevocable letter of
248 credit or a deposit into a trust account or financial
249 institution which names the State of Florida as a beneficiary.
250 The purposes of the bond or other security arrangements for the
251 program are to:

252 1. Ensure participation of the vendor in any civil or
253 criminal legal action by the state, the agency, any other state
254 agency, or private individuals or entities against the vendor
255 because of the vendor's failure to perform under the contract,
256 including, but not limited to causes of actions for personal
257 injury, negligence, and wrongful death;

258 2. Ensure payment by the vendor through the use of a bond
259 or other comparable security arrangements of legal judgements
260 and claims that have been awarded to the agency, the state,
261 other entities acting on behalf of the state, individuals, or
262 organizations if the vendor is assessed a final judgement or
263 other monetary penalty in a court of law for a civil or criminal
264 action under the program. The bond or comparable security
265 arrangement will be accessed if the vendor fails to pay any
266 judgement or claim within 60 days after final judgement; and

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



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

275 1. Develop a list every 3 month of drugs that have the
276 highest potential for cost savings to the state if imported from
277 Canada. In developing the list, the vendor shall consider, at a
278 minimum, which drugs will provide the greatest cost savings to
279 the state, including drugs for which there are shortages,
280 specialty drugs, and high-volume drugs. The agency may direct
281 the vendor to revise the list, as necessary.

282 2. Identify Canadian suppliers that are in full compliance
283 with relevant Canadian federal and provincial laws and
284 regulations and the Federal Act and who have agreed to export
285 drugs identified on the list. The vendor must verify that such
286 Canadian suppliers meet all of the requirements of the program
287 and will export drugs at prices that will provide cost savings
288 to the state while meeting or exceeding the track-and-trace
289 federal and state laws and regulations.

290 3. Contract with such eligible Canadian suppliers, or
291 facilitate contracts between eligible importers and Canadian
292 suppliers, to import drugs under the program.

293 4. Maintain a listing of all registered importers that
294 participate in the program.

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

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

301 (d) The profit margin and administrative fees of any



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302 participating wholesaler, pharmacy, or pharmacist on imported
303 drug products is limited to a maximum amount as specified
304 annually in the General Appropriations Act.

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

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

310 (b) Importing the drug would not violate the patent laws of
311 the United States;

312 (c) Importing the drug is expected to generate cost
313 savings; and

314 (d) The drug is not:

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

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

317 3. An infused drug;

318 4. An intravenously injected drug;

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

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

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

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

327 (b) May not distribute, dispense, or sell drugs imported
328 under the program outside of the program or outside of this
329 state.

330 (8) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—



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

333 1. For an initial imported shipment, ensure that each batch
334 of the drug in the shipment is statistically sampled and tested
335 for authenticity and degradation in a manner consistent with the
336 Federal Act.

337 2. For any subsequent imported shipment, ensure that a
338 statistically valid sample of the shipment was tested for
339 authenticity and degradation in a manner consistent with the
340 Federal Act.

341 3. Certify that the drug:

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

344 b. Meets all of the labeling requirements under 21 U.S.C.
345 s. 352.

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

349 5. Maintain documentation demonstrating that the testing
350 required by this section was conducted at a qualified laboratory
351 in accordance with the Federal Act and any other applicable
352 federal and state laws and regulations governing laboratory
353 qualifications.

354 (b) All testing required by this section must be conducted
355 in a qualified laboratory that meets the standards under the
356 Federal Act and any other applicable federal and state laws and
357 regulations governing laboratory qualifications for drug
358 testing.

359 (c) The vendor shall maintain information and documentation



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360 submitted under this section for a period of at least 7 years.

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

363 1. The name and quantity of the active ingredient of the
364 drug.

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

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

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

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

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

370 (e) A participating Canadian supplier must submit the
371 following information and documentation to the vendor specifying
372 all of the following:

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

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

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

376 c. The location (country, state or province, and city)
377 where the drug was manufactured.

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

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

380 4. The quantity of each lot of the drug originally received
381 and from which source.

382 5. The lot or control number and the batch number assigned
383 to the drug by the manufacturer.

384 (f) The agency may require that the vendor collect any
385 other information necessary to ensure the protection of the
386 public health.

387 (9) IMMEDIATE SUSPENSION.—The agency shall immediately
388 suspend the importation of a specific drug or the importation of



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389 drugs by a specific importer if it discovers that any drug or
390 activity is in violation of this section or any federal or state
391 law or regulation. The agency may revoke the suspension if,
392 after conducting an investigation, it determines that the public
393 is adequately protected from counterfeit or unsafe drugs being
394 imported into the state.

395 (10) FEDERAL APPROVAL.—By July 1, 2020, the agency shall
396 submit a request to the United States Secretary of Health and
397 Human Services for approval of the program under 21 U.S.C. s.
398 384(1). At a minimum, the request must do all of the following:

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

400 (b) Demonstrate how the drugs imported into the state under
401 the program will meet the applicable federal and state standards
402 for safety and effectiveness.

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

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

408 (e) Estimate the total cost savings attributable to the
409 program.

410 (f) Provide the costs of program implementation to the
411 state.

412 (g) Include a list of potential Canadian suppliers from
413 which the state would import drugs and demonstrate that the
414 suppliers are in full compliance with relevant Canadian federal
415 and provincial laws and regulations as well as all applicable
416 federal and state laws and regulations.

417 (11) NOTIFICATION OF FEDERAL APPROVAL.—Upon receipt of



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418 federal approval of the program, the agency shall notify the
419 President of the Senate, the Speaker of the House of
420 Representatives, and the relevant committees of the Senate and
421 the House of Representatives. The program may not be implemented
422 until the Legislature approves the program as authorized by the
423 federal government. As part of its review process for
424 implementation approval, the Legislature shall consider the
425 estimated cost savings to the state and whether the program has
426 met the required safety standards.

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

432 (a) A list of the drugs that were imported under the
433 program;

434 (b) The number of participating entities;

435 (c) The number of prescriptions dispensed through the
436 program;

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

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

441 (f) Documentation of how the program ensures the following
442 criteria:

443 1. Canadian suppliers participating in the program are of
444 high quality, high performance, and in full compliance with
445 relevant Canadian federal and provincial laws and regulations as
446 well as all United States and Florida laws and regulations;



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447 2. Drugs imported under the program are not shipped, sold,
448 or dispensed outside of the state or the program once in the
449 possession of the importer;

450 3. Drugs imported under the program are unadulterated,
451 potent, and safe;

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

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

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

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

458
459 ===== T I T L E A M E N D M E N T =====

460 And the title is amended as follows:

461 Delete everything before the enacting clause
462 and insert:

463 A bill to be entitled
464 An act relating to the Canadian Prescription Drug
465 Importation Program; creating s. 381.02035, F.S.;
466 requiring the Agency for Health Care Administration to
467 establish the Canadian Prescription Drug Importation
468 Program; defining terms; authorizing a Canadian
469 supplier to export drugs into this state under the
470 program under certain circumstances; providing
471 eligibility criteria and requirements for drug
472 importers; requiring the agency to contract with a
473 vendor to facilitate wholesale prescription drug
474 importation under the program; providing
475 responsibilities for the vendor; providing eligibility



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476 criteria for prescription drugs, Canadian suppliers,
477 and importers under the program; requiring
478 participating Canadian suppliers and importers to
479 comply with specified federal requirements for
480 distributing prescription drugs imported under the
481 program; prohibiting Canadian suppliers and importers
482 from distributing, dispensing, or selling prescription
483 drugs imported under the program outside the state;
484 providing certain documentation requirements;
485 requiring the agency to suspend the importation of
486 drugs in violation of this section or any federal or
487 state law or regulation; authorizing the agency to
488 revoke the suspension under certain circumstances;
489 requiring the agency to request federal approval of
490 the program; requiring the request to include certain
491 information; requiring the agency to begin operating
492 the program within a specified timeframe after
493 receiving federal approval; requiring the agency, in
494 consultation with the vendor, to submit an annual
495 report to the Governor and the Legislature by a
496 specified date; providing requirements for such
497 report; authorizing the agency to adopt rules;
498 providing an effective date.