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LEGISLATIVE ACTION

Senate

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House

The Committee on Appropriations (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 the Canadian Prescription Drug
Importation Program for the importation of safe and effective



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11 prescription drugs from Canada which have the highest potential
12 for cost savings to the state.

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

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

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

20 (c) "County health department" means a health care facility
21 established under part I of chapter 154.

22 (d) "Department" means the Department of Health.

23 (e) "Drug" or "prescription drug" has the same meaning as
24 "prescription drug" in s. 499.003, but is limited to drugs
25 intended for human use.

26 (f) "Federal act" means the Federal Food, Drug, and
27 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.
28 as amended by the Drug Quality and Security Act, 21 U.S.C. 351
29 et seq.

30 (g) "Free clinic" means a clinic that delivers only medical
31 diagnostic services or nonsurgical medical treatment free of
32 charge to low-income recipients.

33 (h) "Medicaid pharmacy" means a pharmacy licensed under
34 chapter 465 that has a Medicaid provider agreement in effect
35 with the agency and is in good standing with the agency.

36 (i) "Pharmacist" means a person who holds an active and
37 unencumbered license to practice pharmacy pursuant to chapter
38 465.

39 (j) "Program" means the Canadian Prescription Drug



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40 Importation Program.

41 (k) "Track-and-trace" means the product-tracing process for
42 the components of the pharmaceutical distribution supply chain
43 as described in Title II of the Drug Quality and Security Act,
44 Drug Supply Chain Security Act, 21 U.S.C. 351 et seq.

45 (l) "Vendor" means the entity contracted by the agency to
46 manage specified functions of the program.

47 (3) IMPORTATION PROCESS.—

48 (a) The agency shall contract with a vendor to provide
49 services under the program.

50 (b) By December 1, 2019, and each year thereafter, the
51 vendor shall develop a Wholesale Prescription Drug Importation
52 List identifying the prescription drugs that have the highest
53 potential for cost savings to the state. In developing the list,
54 the vendor shall consider, at a minimum, which prescription
55 drugs will provide the greatest cost savings to state programs,
56 including prescriptions drugs for which there are shortages,
57 specialty prescription drugs, and high volume prescription
58 drugs. The agency, in consultation with the department, shall
59 review the Wholesale Prescription Drug Importation List every 3
60 months to ensure that it continues to meet the requirements of
61 the programs and may direct the vendor to revise the list, as
62 necessary.

63 (c) The vendor shall submit evidence of a surety bond with
64 any bid or initial contract negotiation documents and shall
65 maintain documentation of evidence of such a bond with the
66 agency throughout the contract term. The surety bond may be from
67 this state or any other state in the United States for at least
68 \$25,000. The surety bond or comparable security arrangement must



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69 include the State of Florida as a beneficiary. In lieu of the
70 surety bond, the vendor may provide a comparable security
71 agreement, such as an irrevocable letter of credit or a deposit
72 into a trust account or financial institution, which includes
73 the State of Florida as a beneficiary, payable to the State of
74 Florida. The purposes of the bond or other security arrangement
75 for the program are to:

76 1. Ensure payment of any administrative penalties imposed
77 by the agency or any other state agency under the contract, if
78 the vendor fails to pay within 30 days after assessment;

79 2. Ensure that the vendor meets contractual and statutory
80 obligations through use of a surety bond or other comparable
81 security arrangements to pay any other costs or fees incurred by
82 the agency, the state, or other entities acting on behalf of the
83 state if the vendor fails to meet its contractual and statutory
84 obligations. If the vendor is assessed a penalty under the
85 program and fails to pay within 30 days after that assessment,
86 the agency, the state, or an entity acting on behalf of the
87 state may file a claim for reimbursement against the bond or
88 other comparable security arrangement; and

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

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

97 (d) The eligible vendor must submit evidence at the time of



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98 contract award and throughout the contract term of a surety bond
99 or comparable security arrangement from this state or any other
100 state in the United States in an amount no less than \$25,000.

101 The surety bond or comparable security arrangement must include
102 the State of Florida as a beneficiary. In lieu of the surety
103 bond, the vendor may provide a comparable security arrangement
104 such as an irrevocable letter of credit or a deposit into a
105 trust account or financial institution which names the State of
106 Florida as a beneficiary. The purposes of the bond or other
107 security arrangements for the program are to:

108 1. Ensure participation of the vendor in any civil or
109 criminal legal action by the state, the agency, any other state
110 agency, or private individuals or entities against the vendor
111 because of the vendor's failure to perform under the contract,
112 including, but not limited to causes of actions for personal
113 injury, negligence, and wrongful death;

114 2. Ensure payment by the vendor through the use of a bond
115 or other comparable security arrangements of legal judgements
116 and claims that have been awarded to the agency, the state,
117 other entities acting on behalf of the state, individuals, or
118 organizations if the vendor is assessed a final judgement or
119 other monetary penalty in a court of law for a civil or criminal
120 action under the program. The bond or comparable security
121 arrangement will be accessed if the vendor fails to pay any
122 judgement or claim within 60 days after final judgement; and

123 3. Allow for civil and criminal litigation claims to be
124 made against the bond or other comparable security arrangements
125 for up to 1 year after the vendor's contract under the program
126 has ended with the agency or the state, the vendor's license is



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127 no longer valid, or the program has ended, whichever occurs
128 last.

129 (e) The vendor shall identify Canadian suppliers that are
130 in full compliance with relevant Canadian federal and provincial
131 laws and regulations and the federal act and who have agreed to
132 export drugs identified on the list at prices that will provide
133 cost savings to the state. The vendor must verify that such
134 Canadian suppliers meet all of the requirements of the program,
135 while meeting or exceeding the federal and state track-and-trace
136 laws and regulations.

137 (f) The vendor shall contract with such eligible Canadian
138 suppliers, or facilitate contracts between eligible importers
139 and Canadian suppliers, to import drugs under the program.

140 (g) The vendor shall maintain a list of all registered
141 importers that participate in the program.

142 (h) The vendor shall ensure compliance with Title II of the
143 federal Drug Quality and Security Act, Pub. L. No. 113-54, by
144 all suppliers, importers and other distributors, and
145 participants in the program.

146 (i) The vendor shall assist the agency in the preparation
147 of the annual report required by subsection (11), including the
148 timely provision of any information requested by the agency.

149 (j) The vendor shall provide an annual financial audit of
150 its operations to the agency as required by the agency. The
151 vendor shall also provide quarterly financial reports specific
152 to the program and shall include information on the performance
153 of its subcontractors and vendors. The agency shall determine
154 the format and contents of the reports.

155 (4) ELIGIBLE PRESCRIPTION DRUGS.—Eligible importers may



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156 import a drug from an eligible Canadian supplier if:
157 (a) The drug meets the United States Food and Drug
158 Administration's standards related to safety, effectiveness,
159 misbranding, and adulteration;
160 (b) Importing the drug would not violate federal patent
161 laws;
162 (c) Importing the drug is expected to generate cost
163 savings; and
164 (d) The drug is not:
165 1. A controlled substance as defined in 21 U.S.C. s. 802;
166 2. A biological product as defined in 42 U.S.C. s. 262;
167 3. An infused drug;
168 4. An intravenously injected drug;
169 5. A drug that is inhaled during surgery; or
170 6. A drug that is a parenteral drug, the importation of
171 which is determined by the United States Secretary of Health and
172 Human Services to pose a threat to the public health.
173 (5) ELIGIBLE CANADIAN SUPPLIERS.—A Canadian supplier may
174 export prescription drugs into the state under the program if
175 the supplier is:
176 (a) In full compliance with relevant Canadian federal and
177 provincial laws and regulations; and
178 (b) Identified by the vendor as eligible to participate in
179 the program.
180 (6) ELIGIBLE IMPORTERS.—The following entities may import
181 prescription drugs from a Canadian supplier under the program:
182 (a) A pharmacist or wholesaler employed by or under
183 contract with the department's central pharmacy, for
184 distribution to a county health department or free clinic for



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185 dispensing to clients treated in such department or clinic.

186 (b) A pharmacist or wholesaler employed by or under
187 contract with a Medicaid pharmacy, for dispensing to the
188 pharmacy's Medicaid recipients.

189 (c) A pharmacist or wholesaler employed by or under
190 contract with the Department of Corrections, for dispensing to
191 inmates in the custody of the Department of Corrections.

192 (d) A pharmacist or wholesaler employed by or under
193 contract with a developmental disabilities center, as defined in
194 s. 393.063, for dispensing to clients treated in such center.

195 (e) A pharmacist or wholesaler employed by or under
196 contract with a treatment facility, as defined in s. 394.455,
197 for dispensing to patients treated in such facility.

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

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

202 (b) May not distribute, dispense, or sell prescription
203 drugs imported under the program outside of the state.

204 (8) FEDERAL APPROVAL.—By July 1, 2020, the agency shall
205 submit a request to the United States Secretary of Health and
206 Human Services for approval of the program under 21 U.S.C. s.
207 384(l). The agency shall begin operating the program within 6
208 months after receiving such approval. The request must, at a
209 minimum:

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

211 (b) Demonstrate how the prescription drugs imported into
212 this state under the program will meet the applicable federal
213 and state standards for safety and effectiveness.



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214 (c) Demonstrate how the drugs imported into this state
215 under the program will comply with federal tracing procedures.

216 (d) Include a list of proposed prescription drugs that have
217 the highest potential for cost savings to the state through
218 importation at the time that the request is submitted.

219 (e) Estimate the total cost savings attributable to the
220 program.

221 (f) Provide the costs of program implementation to the
222 state.

223 (g) Include a list of potential Canadian suppliers from
224 which the state would import drugs and demonstrate that the
225 suppliers are in full compliance with relevant Canadian federal
226 and provincial laws and regulations as well as all applicable
227 federal and state laws and regulations.

228 (9) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

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

231 1. For an initial imported shipment, ensure that each batch
232 of the drug in the shipment is statistically sampled and tested
233 for authenticity and degradation in a manner consistent with the
234 federal act.

235 2. For any subsequent imported shipment, ensure that a
236 statistically valid sample of the shipment was tested for
237 authenticity and degradation in a manner consistent with the
238 federal act.

239 3. Certify that the drug:

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

242 b. Meets all of the labeling requirements under 21 U.S.C.



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243 s. 352.

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

247 5. Maintain documentation demonstrating that the testing
248 required by this section was conducted at a qualified laboratory
249 in accordance with the federal act and any other applicable
250 federal and state laws and regulations governing laboratory
251 qualifications.

252 (b) All testing required by this section must be conducted
253 in a qualified laboratory that meets the standards under the
254 federal act and any other applicable federal and state laws and
255 regulations governing laboratory qualifications for drug
256 testing.

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

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

261 1. The name and quantity of the active ingredient of the
262 drug.

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

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

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

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

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

268 (e) A participating Canadian supplier must submit the
269 following information and documentation to the vendor specifying
270 all of the following:

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



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- 272 a. The name of the manufacturer of the drug.
273 b. The date on which the drug was manufactured.
274 c. The location (country, state or province, and city)
275 where the drug was manufactured.
276 2. The date on which the drug is shipped.
277 3. The quantity of the drug that is shipped.
278 4. The quantity of each lot of the drug originally received
279 and from which source.
280 5. The lot or control number and the batch number assigned
281 to the drug by the manufacturer.
282 (f) The agency may require that the vendor collect any
283 other information necessary to ensure the protection of the
284 public health.
285 (10) IMMEDIATE SUSPENSION.—The agency shall immediately
286 suspend the importation of a specific drug or the importation of
287 drugs by a specific importer if it discovers that any drug or
288 activity is in violation of this section or any federal or state
289 law or regulation. The agency may revoke the suspension if,
290 after conducting an investigation, it determines that the public
291 is adequately protected from counterfeit or unsafe drugs being
292 imported into this state.
293 (11) ANNUAL REPORT.—By December 1 of each year, the agency
294 shall submit a report to the Governor, the President of the
295 Senate, and the Speaker of the House of Representatives on the
296 operation of the program during the previous fiscal year. The
297 report must include, at a minimum:
298 (a) A list of the prescription drugs that were imported
299 under the program;
300 (b) The number of participating entities;



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301 (c) The number of prescriptions dispensed through the
302 program;

303 (d) The estimated cost savings during the previous fiscal
304 year and to date attributable the program;

305 (e) A description of the methodology used to determine
306 which drugs should be included on the Wholesale Prescription
307 Drug Importation List; and

308 (f) Documentation as to how the program ensures the
309 following:

310 1. That Canadian suppliers participating in the program are
311 of high quality, high performance, and in full compliance with
312 relevant Canadian federal and provincial laws and regulations as
313 well as all federal laws and regulations and state laws and
314 rules;

315 2. That prescription drugs imported under the program are
316 not shipped, sold, or dispensed outside of this state once in
317 the possession of the importer;

318 3. That prescription drugs imported under the program are
319 pure, unadulterated, potent, and safe;

320 4. That the program does not put consumers at a higher
321 health and safety risk than if the consumer did not participate;
322 and

323 5. That the program provides cost savings to the state on
324 imported prescription drugs.

325 (12) NOTIFICATION OF FEDERAL APPROVAL.—Upon receipt of
326 federal approval of the program, the agency shall notify the
327 President of the Senate, the Speaker of the House of
328 Representatives, and the relevant committees of the Senate and
329 the House of Representatives. After approval is received and



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330 before the start of the next regular session of the Legislature
331 in which the proposal could be funded, the agency shall submit
332 to all parties a proposal for program implementation and program
333 funding.

334 (13) RULEMAKING.—The agency shall adopt rules necessary to
335 implement this section.

336 Section 2. Section 465.0157, Florida Statutes, is created
337 to read:

338 465.0157 International export pharmacy permit.—

339 (1) To participate as an exporter of prescription drugs
340 into the state under the International Prescription Drug
341 Importation Program established in s. 499.0285, a pharmacy
342 located outside of the United States must hold an international
343 export pharmacy permit.

344 (2) An international export pharmacy shall maintain at all
345 times an active and unencumbered license or permit to operate
346 the pharmacy in compliance with the laws of the jurisdiction in
347 which the dispensing facility is located and from which the
348 prescription drugs will be exported. Such jurisdiction must be
349 in a country with which the United States has a current mutual
350 recognition agreement, cooperation agreement, memorandum of
351 understanding, or other federal mechanism recognizing the
352 country's adherence to current good manufacturing practices for
353 pharmaceutical products.

354 (3) An application for an international export pharmacy
355 permit must be submitted on a form developed and provided by the
356 board. The board may require an applicant to provide any
357 information it deems reasonably necessary to carry out the
358 purposes of this section.



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359 (4) An applicant shall submit the following to the board to
360 obtain an initial permit, or to the department to renew a
361 permit:

362 (a) Proof of an active and unencumbered license or permit
363 to operate the pharmacy in compliance with the laws of the
364 jurisdiction in which the dispensing facility is located and
365 from which the prescription drugs will be exported.

366 (b) Documentation demonstrating that the country in which
367 the pharmacy operates has a current mutual recognition
368 agreement, cooperation agreement, memorandum of understanding,
369 or other federal mechanism recognizing the country's adherence
370 to current good manufacturing practices for pharmaceutical
371 products.

372 (c) Evidence of a surety bond with any application or
373 filing for pharmacy permit under this section and shall maintain
374 documentation of evidence of such a bond with the Department of
375 Business and Professional Regulation throughout the permit term.
376 The surety bond may be from this state or any other state in the
377 United States for no less than \$25,000. The surety bond or
378 comparable security arrangement must include the State of
379 Florida as a beneficiary. In lieu of the surety bond, the
380 pharmacy may provide a comparable security agreement, such as an
381 irrevocable letter of credit or a deposit into a trust account
382 or financial institution which includes the State of Florida as
383 a beneficiary, payable to the State of Florida. The purposes of
384 the bond or other security arrangement for the program are to:

385 1. Ensure payment of any administrative penalties imposed
386 by the department or any other state agency under the contract
387 when the pharmacy fails to pay within 30 days after assessment;



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388 2. Ensure that the pharmacy meets contractual and statutory
389 obligations through use of a surety bond or other comparable
390 security arrangements to pay any other costs or fees incurred by
391 the Department of Business of Professional Regulation, the
392 state, or other entities acting on behalf of the state if the
393 pharmacy fails to meet its obligations. If the pharmacy is
394 assessed a penalty under the program and fails to pay within 30
395 days after that assessment, the Department of Business and
396 Professional Regulation, the state, or an entity acting on
397 behalf of the state may file a claim for reimbursement against
398 the bond or other comparable security arrangement; and

399 3. Allow for claims to be made against the bond or other
400 comparable security arrangements for up to 1 year after the
401 pharmacy's permit under the program has ended with this section
402 or the program has ended, whichever occurs last.

403 (b) The eligible pharmacy must submit evidence at the time
404 of application and throughout the permit term of a surety bond
405 or comparable security arrangement from this state or any other
406 state in the United States in an amount no less than \$25,000.
407 The surety bond or comparable security arrangement must include
408 the State of Florida as a beneficiary. In lieu of the surety
409 bond, the pharmacy may provide a comparable security arrangement
410 such as an irrevocable letter of credit or a deposit into a
411 trust account or financial institution which names the State of
412 Florida as a beneficiary. The purposes of the bond or other
413 security arrangements for the program are to:

414 1. Ensure participation of the pharmacy in any civil or
415 criminal legal action by the state, the Department of Business
416 of Professional Regulation, any other state agency, or private



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417 individuals or entities against the pharmacy or because of the
418 pharmacy's failure to perform under the contract, including, but
419 not limited to causes of actions for personal injury,
420 negligence, and wrongful death;

421 2. Ensure payment by the pharmacy through the use of a bond
422 or other comparable security arrangements of legal judgements
423 and claims that have been awarded to the Department of Business
424 and Professional Regulation, the state, other entities acting on
425 behalf of the state, individuals, or organizations if the
426 pharmacy is assessed a final judgement or other monetary penalty
427 in a court of law for a civil or criminal action under the
428 program. The bond or comparable security arrangement will be
429 accessed if the pharmacy fails to pay any judgement or claim
430 within 60 days after final judgement; and

431 3. Allow for civil and criminal litigation claims to be
432 made against the bond or other comparable security arrangements
433 for up to 1 year after the pharmacy's contract under the program
434 has ended with the agency or the state, the pharmacy's license
435 is no longer valid, or the program has ended, whichever occurs
436 last.

437 (c) The location, names, and titles of all principal
438 corporate officers and the pharmacist who serves as the
439 prescription department manager for prescription drugs exported
440 into this state under the International Prescription Drug
441 Importation Program.

442 (d) Written attestation by an owner or officer of the
443 applicant, and by the applicant's prescription department
444 manager, that:

445 1. The attestor has read and understands the laws and rules



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446 governing the manufacture, distribution, and dispensing of
447 prescription drugs in this state.

448 2. A prescription drug shipped, mailed, or delivered into
449 this state meets or exceeds this state's standards for safety
450 and efficacy.

451 3. A prescription drug product shipped, mailed, or
452 delivered into this state must not have been, and may not be,
453 manufactured or distributed in violation of the laws and rules
454 of the jurisdiction in which the applicant is located and from
455 which the prescription drugs shall be exported.

456 (e) A current inspection report from an inspection
457 conducted by the regulatory or licensing agency of the
458 jurisdiction in which the applicant is located. The inspection
459 report must reflect compliance with this section. An inspection
460 report is current if the inspection was conducted within 6
461 months before the date of submitting the application for the
462 initial permit or within 1 year before the date of submitting an
463 application for permit renewal. If the applicant is unable to
464 submit a current inspection report conducted by the regulatory
465 or licensing agency of the jurisdiction in which the applicant
466 is located and from which the prescription drugs will be
467 exported, due to acceptable circumstances, as established by
468 rule, or if an inspection has not been performed, the department
469 must:

470 1. Conduct, or contract with an entity to conduct, an
471 onsite inspection, with all related costs borne by the
472 applicant;

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



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

478 Section 3. Subsection (2) of section 465.017, Florida
479 Statutes, is amended to read:

480 465.017 Authority to inspect; disposal.—

481 (2) Duly authorized agents and employees of the department
482 may inspect a nonresident pharmacy registered under s. 465.0156,
483 an international export pharmacy permittee under s. 465.0157, or
484 a nonresident sterile compounding permittee under s. 465.0158
485 pursuant to this section. The costs of such inspections shall be
486 borne by such pharmacy or permittee.

487 Section 4. Subsection (20) of section 499.005, Florida
488 Statutes, is amended to read:

489 499.005 Prohibited acts.—It is unlawful for a person to
490 perform or cause the performance of any of the following acts in
491 this state:

492 (20) The importation of a prescription drug except as
493 provided by s. 801(d) of the Federal Food, Drug, and Cosmetic
494 Act or s. 499.0285.

495 Section 5. Paragraph (e) of subsection (12) of section
496 499.0051, Florida Statutes, is amended to read:

497 499.0051 Criminal acts.—

498 (12) REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR
499 TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO
500 PRESCRIPTION DRUGS.—Any person who violates any of the following
501 provisions commits a felony of the third degree, punishable as
502 provided in s. 775.082, s. 775.083, or s. 775.084, or as
503 otherwise provided in this part:



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504 (e) The importation of a prescription drug for wholesale
505 distribution, except as provided by s. 801(d) of the Federal
506 Food, Drug, and Cosmetic Act or s. 499.0285.

507 Section 6. Subsection (1) and paragraph (c) of subsection
508 (2) of section 499.01, Florida Statutes, are amended, and
509 paragraph (s) is added to subsection (2) of that section, to
510 read:

511 499.01 Permits.—

512 (1) Before operating, a permit is required for each person
513 and establishment that intends to operate as:

514 (a) A prescription drug manufacturer;

515 (b) A prescription drug repackager;

516 (c) A nonresident prescription drug manufacturer;

517 (d) A nonresident prescription drug repackager;

518 (e) A prescription drug wholesale distributor;

519 (f) An out-of-state prescription drug wholesale
520 distributor;

521 (g) A retail pharmacy drug wholesale distributor;

522 (h) A restricted prescription drug distributor;

523 (i) A complimentary drug distributor;

524 (j) A freight forwarder;

525 (k) A veterinary prescription drug retail establishment;

526 (l) A veterinary prescription drug wholesale distributor;

527 (m) A limited prescription drug veterinary wholesale
528 distributor;

529 (n) An over-the-counter drug manufacturer;

530 (o) A device manufacturer;

531 (p) A cosmetic manufacturer;

532 (q) A third party logistics provider; ~~or~~



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533 (r) A health care clinic establishment

534 (s) An international prescription drug wholesale
535 distributor.

536 (2) The following permits are established:

537 (c) *Nonresident prescription drug manufacturer permit.*—A
538 nonresident prescription drug manufacturer permit is required
539 for any person that is a manufacturer of prescription drugs,
540 unless permitted as a third party logistics provider, located
541 outside of this state or outside the United States and that
542 engages in the distribution in this state of such prescription
543 drugs. Each such manufacturer must be permitted by the
544 department and comply with all of the provisions required of a
545 prescription drug manufacturer under this part. The department
546 shall adopt rules for issuing a virtual nonresident prescription
547 drug manufacturer permit to a person who engages in the
548 manufacture of prescription drugs but does not make or take
549 physical possession of any prescription drugs. The rules adopted
550 by the department under this section may exempt virtual
551 nonresident manufacturers from certain establishment, security,
552 and storage requirements set forth in s. 499.0121.

553 1. A person that distributes prescription drugs for which
554 the person is not the manufacturer must also obtain an out-of-
555 state prescription drug wholesale distributor permit, an
556 international prescription drug wholesale distributor permit, or
557 third party logistics provider permit pursuant to this section
558 to engage in the distribution of such prescription drugs when
559 required by this part. This subparagraph does not apply to a
560 manufacturer that distributes prescription drugs only for the
561 manufacturer of the prescription drugs where both manufacturers



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562 are affiliates.

563 2. Any such person must comply with the licensing or
564 permitting requirements of the jurisdiction in which the
565 establishment is located and the federal act, and any
566 prescription drug distributed into this state must comply with
567 this part. If a person intends to import prescription drugs from
568 a foreign country into this state, the nonresident prescription
569 drug manufacturer must provide to the department a list
570 identifying each prescription drug it intends to import and
571 document approval by the United States Food and Drug
572 Administration for such importation.

573 3.a. A nonresident prescription drug manufacturer that has
574 registered to participate in the International Prescription Drug
575 Importation Program pursuant to this section is not required to
576 provide the list and approval required by subparagraph 2. for
577 prescription drugs imported under that program.

578 b. To participate as an exporter of prescription drugs into
579 the state under the International Prescription Drug Importation
580 Program established under s. 499.0285, a nonresident
581 prescription drug manufacturer located outside of the United
582 States must register with the Department of Business and
583 Professional Regulation before engaging in any activities under
584 that section. Such manufacturer must be licensed or permitted in
585 a country with which the United States has a current mutual
586 recognition agreement, cooperation agreement, memorandum of
587 understanding, or other federal mechanism recognizing the
588 country's adherence to current good manufacturing practices for
589 pharmaceutical products.

590 c. The nonresident prescription drug manufacturer shall



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591 submit evidence of a surety bond with any application or filing
592 for registration under this section and shall maintain
593 documentation of evidence of such a bond with the Department of
594 Business and Professional Regulation throughout the registration
595 term. The surety bond may be from this state or any other state
596 in the United States in an amount equal to 10 percent of the
597 manufacturer's annual sales or \$1 million, whichever is higher.
598 The surety bond or comparable security arrangement must include
599 the State of Florida as a beneficiary. In lieu of the surety
600 bond, the manufacturer may provide a comparable security
601 agreement, such as an irrevocable letter of credit or a deposit
602 into a trust account or financial institution which includes the
603 State of Florida as a beneficiary, payable to the State of
604 Florida. The purposes of the bond or other security arrangement
605 for the program are to:

606 (I) Ensure payment of any administrative penalties imposed
607 by the Department of Business and Professional Regulation or any
608 other state agency under the contract when the manufacturer
609 fails to pay within 30 days after assessment;

610 (II) Ensure that if the manufacturer fails to meets its
611 obligations through use of a surety bond or other comparable
612 security arrangements to pay any other costs or fees incurred by
613 the Department of Business of Professional Regulation, the
614 state, or other entities acting on behalf of the state if the
615 manufacturer fails to meet its obligations. If the manufacturer
616 is assessed a penalty under the program and fails to pay within
617 30 days after that assessment, the Department of Business and
618 Professional Regulation, the state, or an entity acting on
619 behalf of the state may file a claim for reimbursement against



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620 the bond or other comparable security arrangement; and
621 (III) Allow for claims to be made against the bond or other
622 comparable security arrangements for up to 1 year after the
623 manufacturer's permit under the program has ended with this
624 section or the program has ended, whichever occurs last.

625 (b) The eligible manufacturer must submit evidence at the
626 time of application and throughout the permit term of a surety
627 bond or comparable security arrangement from this state or any
628 other state in the United States in an amount equal to 10
629 percent of the manufacturer's annual sales or \$1 million,
630 whichever is greater. The surety bond or comparable security
631 arrangement must include the State of Florida as a beneficiary.
632 In lieu of the surety bond, the manufacturer may provide a
633 comparable security arrangement such as an irrevocable letter of
634 credit or a deposit into a trust account or financial
635 institution which names the State of Florida as a beneficiary.
636 The purposes of the bond or other security arrangements for the
637 program are to:

638 1. Ensure participation of the manufacturer in any civil or
639 criminal legal action by the state, the Department of Business
640 of Professional Regulation, any other state agency, or private
641 individuals or entities against the manufacturer or because of
642 the manufacturer's failure to perform according to the contract,
643 permit, or federal or state law and regulations, including, but
644 not limited to causes of actions for personal injury,
645 negligence, and wrongful death;

646 2. Ensure payment by the manufacturer through the use of a
647 bond or other comparable security arrangements of legal
648 judgements and claims that have been awarded to the Department



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649 of Business and Professional Regulation, the state, other
650 entities acting on behalf of the state, individuals, or
651 organizations if the pharmacy is assessed a final judgement or
652 other monetary penalty in a court of law for a civil or criminal
653 action under the program. The bond or comparable security
654 arrangement will be accessed if the manufacturer fails to pay
655 any judgement or claim within 60 days after final judgement; and

656 3. Allow for civil and criminal litigation claims to be
657 made against the bond or other comparable security arrangements
658 for up to 1 year after the manufacturer's permit under the
659 program has ended with the Department of Professional and
660 Business Regulation or the state, the manufacturer's permit or
661 comparable legal document is no longer valid, or the program has
662 ended, whichever occurs last.

663 (s) International prescription drug wholesale distributor.—

664 1. A wholesale distributor located outside of the United
665 States must obtain an international prescription drug wholesale
666 distributor permit to engage in the wholesale exportation and
667 distribution of prescription drugs in the state under the
668 International Prescription Drug Importation Program established
669 in s. 499.0285. The wholesale distributor must be licensed or
670 permitted to operate in a country with which the United States
671 has a mutual recognition agreement, cooperation agreement,
672 memorandum of understanding, or other federal mechanism
673 recognizing the country's adherence to current good
674 manufacturing practices for pharmaceutical products. The
675 wholesale distributor must maintain at all times a license or
676 permit to engage in the wholesale distribution of prescription
677 drugs in compliance with the laws of the jurisdiction in which



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678 it operates. An international prescription drug wholesale
679 distributor permit may not be issued to a wholesale distributor
680 if the jurisdiction in which the wholesale distributor operates
681 does not require a license to engage in the wholesale
682 distribution of prescription drugs.

683 2. In order to participate in the International
684 Prescription Drug Importation Program established under s.
685 499.0285, the international wholesale distributor shall submit
686 evidence of a surety bond with any application or filing for a
687 permit under this section and shall maintain documentation of
688 evidence of such a bond with the Department of Business and
689 Professional Regulation throughout the permit term. The surety
690 bond may be from this state or any other state in the United
691 States in an amount equal to 10 percent of the international
692 wholesale distributor's annual sales or \$1 million, whichever is
693 greater. The surety bond or comparable security arrangement must
694 include the State of Florida as a beneficiary. In lieu of the
695 surety bond, the wholesale distributor may provide a comparable
696 security agreement, such as an irrevocable letter of credit or a
697 deposit into a trust account or financial institution which
698 names the State of Florida as a beneficiary. The purposes of the
699 bond or other security arrangement for the program are to:

700 a. Ensure payment of any administrative penalties imposed
701 by the Department of Business and Professional Regulation or any
702 other state agency under the contract when the wholesale
703 distributor fails to pay within 30 days after assessment;

704 b. Ensure that the wholesale distributor meets contractual
705 and statutory obligations through use of a surety bond or other
706 comparable security arrangements to pay any other costs or fees



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707 incurred by the Department of Business of Professional
708 Regulation, the state, or other entities acting on behalf of the
709 state if the wholesale distributor fails to meet its
710 obligations. If the wholesale distributor is assessed a penalty
711 under the program and fails to pay within 30 days after that
712 assessment, the Department of Business and Professional
713 Regulation, the state, or an entity acting on behalf of the
714 state may file a claim for reimbursement against the bond or
715 other comparable security arrangement; and

716 c. Allow for claims to be made against the bond or other
717 comparable security arrangements for up to 1 year after the
718 wholesale distributor's permit under the program has ended with
719 this section or the program has ended, whichever occurs last.

720 3. The eligible wholesale distributor must submit evidence
721 at the time of application and throughout the permit term of a
722 surety bond or comparable security arrangement from this state
723 or any other state in the United States in an amount equal to 10
724 percent of the international wholesale distributor's annual
725 sales or \$1 million, whichever is greater. The surety bond or
726 comparable security arrangement must include the State of
727 Florida as a beneficiary. In lieu of the surety bond, the
728 wholesale distributor may provide a comparable security
729 arrangement such as an irrevocable letter of credit or a deposit
730 into a trust account or financial institution which names the
731 State of Florida as a beneficiary. The purposes of the bond or
732 other security arrangements for the program are to:

733 a. Ensure participation of the wholesale distributor in any
734 civil or criminal legal action by the state, the Department of
735 Business of Professional Regulation, any other state agency, or



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736 private individuals or entities against the wholesale
737 distributor or because of the wholesale distributor's failure to
738 perform under the contract, including, but not limited to causes
739 of actions for personal injury, negligence, and wrongful death;

740 b. Ensure payment by the wholesale distributor through the
741 use of a bond or other comparable security arrangements of legal
742 judgements and claims that have been awarded to the Department
743 of Business and Professional Regulation, the state, other
744 entities acting on behalf of the state, individuals, or
745 organizations if the wholesale distributor is assessed a final
746 judgement or other monetary penalty in a court of law for a
747 civil or criminal action under the program. The bond or
748 comparable security arrangement will be accessed if the
749 wholesale distributor fails to pay any judgement or claim within
750 60 days after final judgement; and

751 c. Allow for civil and criminal litigation claims to be
752 made against the bond or other comparable security arrangements
753 for up to 1 year after the wholesale distributor's permit under
754 the program has ended with the agency or the state, the
755 pharmacy's permit or comparable legal document is no longer
756 valid, or the program has ended, whichever occurs last.

757 Section 7. Subsection (2), paragraph (a) of subsection (4),
758 subsections (8), (10), (11), and (14), and paragraphs (a), (b),
759 and (f) of subsection (15) of section 499.012, Florida Statutes,
760 are amended to read:

761 499.012 Permit application requirements.—

762 (2) Notwithstanding subsection (6), a permitted person in
763 good standing may change the type of permit issued to that
764 person by completing a new application for the requested permit,



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765 paying the amount of the difference in the permit fees if the
766 fee for the new permit is more than the fee for the original
767 permit, and meeting the applicable permitting conditions for the
768 new permit type. The new permit expires on the expiration date
769 of the original permit being changed; however, a new permit for
770 a prescription drug wholesale distributor, an out-of-state
771 prescription drug wholesale distributor, an international
772 prescription drug wholesale distributor, or a retail pharmacy
773 drug wholesale distributor shall expire on the expiration date
774 of the original permit or 1 year after the date of issuance of
775 the new permit, whichever is earlier. A refund may not be issued
776 if the fee for the new permit is less than the fee that was paid
777 for the original permit.

778 (4) (a) Except for a permit for a prescription drug
779 wholesale distributor, an international prescription drug
780 wholesale distributor, or an out-of-state prescription drug
781 wholesale distributor, an application for a permit must include:

782 1. The name, full business address, and telephone number of
783 the applicant;

784 2. All trade or business names used by the applicant;

785 3. The address, telephone numbers, and the names of contact
786 persons for each facility used by the applicant for the storage,
787 handling, and distribution of prescription drugs;

788 4. The type of ownership or operation, such as a
789 partnership, corporation, or sole proprietorship; and

790 5. The names of the owner and the operator of the
791 establishment, including:

792 a. If an individual, the name of the individual;

793 b. If a partnership, the name of each partner and the name



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794 of the partnership;

795 c. If a corporation, the name and title of each corporate
796 officer and director, the corporate names, and the name of the
797 state of incorporation;

798 d. If a sole proprietorship, the full name of the sole
799 proprietor and the name of the business entity;

800 e. If a limited liability company, the name of each member,
801 the name of each manager, the name of the limited liability
802 company, and the name of the state in which the limited
803 liability company was organized; and

804 f. Any other relevant information that the department
805 requires.

806 (8) An application for a permit or to renew a permit for a
807 prescription drug wholesale distributor, an international
808 prescription drug wholesale distributor, or an out-of-state
809 prescription drug wholesale distributor submitted to the
810 department must include:

811 (a) The name, full business address, and telephone number
812 of the applicant.

813 (b) All trade or business names used by the applicant.

814 (c) The address, telephone numbers, and the names of
815 contact persons for each facility used by the applicant for the
816 storage, handling, and distribution of prescription drugs.

817 (d) The type of ownership or operation, such as a
818 partnership, corporation, or sole proprietorship.

819 (e) The names of the owner and the operator of the
820 establishment, including:

821 1. If an individual, the name of the individual.

822 2. If a partnership, the name of each partner and the name



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823 of the partnership.

824 3. If a corporation:

825 a. The name, address, and title of each corporate officer
826 and director.

827 b. The name and address of the corporation, resident agent
828 of the corporation, the resident agent's address, and the
829 corporation's state of incorporation.

830 c. The name and address of each shareholder of the
831 corporation that owns 5 percent or more of the outstanding stock
832 of the corporation.

833 4. If a sole proprietorship, the full name of the sole
834 proprietor and the name of the business entity.

835 5. If a limited liability company:

836 a. The name and address of each member.

837 b. The name and address of each manager.

838 c. The name and address of the limited liability company,
839 the resident agent of the limited liability company, and the
840 name of the state in which the limited liability company was
841 organized.

842 (f) If applicable, the name and address of each affiliate
843 of the applicant.

844 (g) The applicant's gross annual receipts attributable to
845 prescription drug wholesale distribution activities for the
846 previous tax year.

847 (h) The tax year of the applicant.

848 (i) A copy of the deed for the property on which
849 applicant's establishment is located, if the establishment is
850 owned by the applicant, or a copy of the applicant's lease for
851 the property on which applicant's establishment is located that



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852 has an original term of not less than 1 calendar year, if the
853 establishment is not owned by the applicant.

854 (j) A list of all licenses and permits issued to the
855 applicant by any other state or jurisdiction which authorize the
856 applicant to purchase or possess prescription drugs.

857 (k) The name of the manager of the establishment that is
858 applying for the permit or to renew the permit, the next four
859 highest ranking employees responsible for prescription drug
860 wholesale operations for the establishment, and the name of all
861 affiliated parties for the establishment, together with the
862 personal information statement and fingerprints required
863 pursuant to subsection (9) for each of such persons.

864 (l) The name of each of the applicant's designated
865 representatives as required by subsection (15), together with
866 the personal information statement and fingerprints required
867 pursuant to subsection (9) for each such person.

868 (m) Evidence of a surety bond in this state or any other
869 state in the United States in the amount of \$100,000. If the
870 annual gross receipts of the applicant's previous tax year are
871 \$10 million or less, evidence of a surety bond in the amount of
872 \$25,000. The specific language of the surety bond must include
873 the State of Florida as a beneficiary, payable to the
874 Professional Regulation Trust Fund. In lieu of the surety bond,
875 the applicant may provide other equivalent security such as an
876 irrevocable letter of credit, or a deposit in a trust account or
877 financial institution, which includes the State of Florida as a
878 beneficiary, payable to the Professional Regulation Trust Fund.
879 The purpose of the bond or other security is to secure payment
880 of any administrative penalties imposed by the department and



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881 any fees and costs incurred by the department regarding that
882 permit which are authorized under state law and which the
883 permittee fails to pay 30 days after the fine or costs become
884 final. The department may make a claim against such bond or
885 security until 1 year after the permittee's license ceases to be
886 valid or until 60 days after any administrative or legal
887 proceeding authorized in this part which involves the permittee
888 is concluded, including any appeal, whichever occurs later.

889 (n) For establishments used in wholesale distribution,
890 proof of an inspection conducted by the department, the United
891 States Food and Drug Administration, or another governmental
892 entity charged with the regulation of good manufacturing
893 practices related to wholesale distribution of prescription
894 drugs, within timeframes set forth by the department in
895 departmental rules, which demonstrates substantial compliance
896 with current good manufacturing practices applicable to
897 wholesale distribution of prescription drugs. The department may
898 recognize another state's or jurisdiction's inspection of a
899 wholesale distributor located in that state or jurisdiction if
900 such state's or jurisdiction's laws are deemed to be
901 substantially equivalent to the law of this state by the
902 department. The department may accept an inspection by a third-
903 party accreditation or inspection service which meets the
904 criteria set forth in department rule.

905 (o) Any other relevant information that the department
906 requires.

907 (p) Documentation of the credentialing policies and
908 procedures required by s. 499.0121(15).

909 (q) For international prescription drug wholesale



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910 distributors and nonresident prescription drug manufacturers to
911 participate in the International Prescription Drug Importation
912 Program established under s. 499.0285, documentation
913 demonstrating that the applicant is appropriately licensed or
914 permitted by a country with which the United States has a mutual
915 recognition agreement, cooperation agreement, memorandum of
916 understanding, or other mechanism recognizing the country's
917 adherence to current good manufacturing practices for
918 pharmaceutical products.

919 (10) The department may deny an application for a permit or
920 refuse to renew a permit for a prescription drug wholesale
921 distributor, an international prescription drug wholesale
922 distributor, or an out-of-state prescription drug wholesale
923 distributor if:

924 (a) The applicant has not met the requirements for the
925 permit.

926 (b) The management, officers, or directors of the applicant
927 or any affiliated party are found by the department to be
928 incompetent or untrustworthy.

929 (c) The applicant is so lacking in experience in managing a
930 wholesale distributor as to make the issuance of the proposed
931 permit hazardous to the public health.

932 (d) The applicant is so lacking in experience in managing a
933 wholesale distributor as to jeopardize the reasonable promise of
934 successful operation of the wholesale distributor.

935 (e) The applicant is lacking in experience in the
936 distribution of prescription drugs.

937 (f) The applicant's past experience in manufacturing or
938 distributing prescription drugs indicates that the applicant



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939 poses a public health risk.

940 (g) The applicant is affiliated directly or indirectly
941 through ownership, control, or other business relations, with
942 any person or persons whose business operations are or have been
943 detrimental to the public health.

944 (h) The applicant, or any affiliated party, has been found
945 guilty of or has pleaded guilty or nolo contendere to any felony
946 or crime punishable by imprisonment for 1 year or more under the
947 laws of the United States, any state, or any other country,
948 regardless of whether adjudication of guilt was withheld.

949 (i) The applicant or any affiliated party has been charged
950 with a felony in a state or federal court and the disposition of
951 that charge is pending during the application review or renewal
952 review period.

953 (j) The applicant has furnished false or fraudulent
954 information or material in any application made in this state or
955 any other state in connection with obtaining a permit or license
956 to manufacture or distribute drugs, devices, or cosmetics.

957 (k) That a federal, state, or local government permit
958 currently or previously held by the applicant, or any affiliated
959 party, for the manufacture or distribution of any drugs,
960 devices, or cosmetics has been disciplined, suspended, or
961 revoked and has not been reinstated.

962 (l) The applicant does not possess the financial or
963 physical resources to operate in compliance with the permit
964 being sought, this chapter, and the rules adopted under this
965 chapter.

966 (m) The applicant or any affiliated party receives,
967 directly or indirectly, financial support and assistance from a



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968 person who was an affiliated party of a permittee whose permit
969 was subject to discipline or was suspended or revoked, other
970 than through the ownership of stock in a publicly traded company
971 or a mutual fund.

972 (n) The applicant or any affiliated party receives,
973 directly or indirectly, financial support and assistance from a
974 person who has been found guilty of any violation of this part
975 or chapter 465, chapter 501, or chapter 893, any rules adopted
976 under this part or those chapters, any federal or state drug
977 law, or any felony where the underlying facts related to drugs,
978 regardless of whether the person has been pardoned, had her or
979 his civil rights restored, or had adjudication withheld, other
980 than through the ownership of stock in a publicly traded company
981 or a mutual fund.

982 (o) The applicant for renewal of a permit under s.
983 499.01(2)(e) or (f) has not actively engaged in the wholesale
984 distribution of prescription drugs, as demonstrated by the
985 regular and systematic distribution of prescription drugs
986 throughout the year as evidenced by not fewer than 12 wholesale
987 distributions in the previous year and not fewer than three
988 wholesale distributions in the previous 6 months.

989 (p) Information obtained in response to s. 499.01(2)(e) or
990 (f) demonstrates it would not be in the best interest of the
991 public health, safety, and welfare to issue a permit.

992 (q) The applicant does not possess the financial standing
993 and business experience for the successful operation of the
994 applicant.

995 (r) The applicant or any affiliated party has failed to
996 comply with the requirements for manufacturing or distributing



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997 prescription drugs under this part, similar federal laws,
998 similar laws in other states, or the rules adopted under such
999 laws.

1000 (11) Upon approval of the application by the department and
1001 payment of the required fee, the department shall issue or renew
1002 a prescription drug wholesale distributor, an international
1003 prescription drug wholesale distributor, or an out-of-state
1004 prescription drug wholesale distributor permit to the applicant.

1005 (14) The name of a permittee or establishment on a
1006 prescription drug wholesale distributor permit, an international
1007 prescription drug wholesale distributor permit, or an out-of-
1008 state prescription drug wholesale distributor permit may not
1009 include any indicia of attainment of any educational degree, any
1010 indicia that the permittee or establishment possesses a
1011 professional license, or any name or abbreviation that the
1012 department determines is likely to cause confusion or mistake or
1013 that the department determines is deceptive, including that of
1014 any other entity authorized to purchase prescription drugs.

1015 (15) (a) Each establishment that is issued an initial or
1016 renewal permit as a prescription drug wholesale distributor, an
1017 international prescription drug wholesale distributor, or an
1018 out-of-state prescription drug wholesale distributor must
1019 designate in writing to the department at least one natural
1020 person to serve as the designated representative of the
1021 wholesale distributor. Such person must have an active
1022 certification as a designated representative from the
1023 department.

1024 (b) To be certified as a designated representative, a
1025 natural person must:



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- 1026 1. Submit an application on a form furnished by the
1027 department and pay the appropriate fees.
- 1028 2. Be at least 18 years of age.
- 1029 3. Have at least 2 years of verifiable full-time:
- 1030 a. Work experience in a pharmacy licensed in this state or
1031 another state or jurisdiction, where the person's
1032 responsibilities included, but were not limited to,
1033 recordkeeping for prescription drugs;
- 1034 b. Managerial experience with a prescription drug wholesale
1035 distributor licensed in this state or in another state or
1036 jurisdiction; or
- 1037 c. Managerial experience with the United States Armed
1038 Forces, where the person's responsibilities included, but were
1039 not limited to, recordkeeping, warehousing, distributing, or
1040 other logistics services pertaining to prescription drugs.
- 1041 4. Receive a passing score of at least 75 percent on an
1042 examination given by the department regarding federal laws
1043 governing distribution of prescription drugs and this part and
1044 the rules adopted by the department governing the wholesale
1045 distribution of prescription drugs. This requirement shall be
1046 effective 1 year after the results of the initial examination
1047 are mailed to the persons that took the examination. The
1048 department shall offer such examinations at least four times
1049 each calendar year.
- 1050 5. Provide the department with a personal information
1051 statement and fingerprints pursuant to subsection (9).
- 1052 (f) A wholesale distributor may not operate under a
1053 prescription drug wholesale distributor permit, an international
1054 prescription drug wholesale distributor permit, or an out-of-



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1055 state prescription drug wholesale distributor permit for more
1056 than 10 business days after the designated representative leaves
1057 the employ of the wholesale distributor, unless the wholesale
1058 distributor employs another designated representative and
1059 notifies the department within 10 business days of the identity
1060 of the new designated representative.

1061 Section 8. Subsection (1) of section 499.015, Florida
1062 Statutes, is amended to read:

1063 499.015 Registration of drugs and devices; issuance of
1064 certificates of free sale.—

1065 (1) (a) Except for those persons exempted from the
1066 definition of manufacturer in s. 499.003, any person who
1067 manufactures, packages, repackages, labels, or relabels a drug
1068 or device in this state must register such drug or device
1069 biennially with the department; pay a fee in accordance with the
1070 fee schedule provided by s. 499.041; and comply with this
1071 section. The registrant must list each separate and distinct
1072 drug or device at the time of registration.

1073 (b) The department may not register any product that does
1074 not comply with the Federal Food, Drug, and Cosmetic Act, as
1075 amended, or Title 21 C.F.R. Registration of a product by the
1076 department does not mean that the product does in fact comply
1077 with all provisions of the Federal Food, Drug, and Cosmetic Act,
1078 as amended.

1079 (c) Registration under this section is not required for
1080 prescription drugs imported under the International Prescription
1081 Drug Importation Program established in s. 499.0285.

1082 Section 9. Subsections (1) and (3) of section 499.065,
1083 Florida Statutes, are amended to read:



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1084 499.065 Inspections; imminent danger.-

1085 (1) Notwithstanding s. 499.051, the department shall
1086 inspect each prescription drug wholesale distributor
1087 establishment, international prescription drug wholesale
1088 distributor establishment, prescription drug repackager
1089 establishment, veterinary prescription drug wholesale
1090 distributor establishment, limited prescription drug veterinary
1091 wholesale distributor establishment, and retail pharmacy drug
1092 wholesale distributor establishment that is required to be
1093 permitted under this part as often as necessary to ensure
1094 compliance with applicable laws and rules. The department shall
1095 have the right of entry and access to these facilities at any
1096 reasonable time.

1097 (3) The department may determine that a prescription drug
1098 wholesale distributor establishment, international prescription
1099 drug wholesale distributor establishment, prescription drug
1100 repackager establishment, veterinary prescription drug wholesale
1101 distributor establishment, limited prescription drug veterinary
1102 wholesale distributor establishment, or retail pharmacy drug
1103 wholesale distributor establishment that is required to be
1104 permitted under this part is an imminent danger to the public
1105 health and shall require its immediate closure if the
1106 establishment fails to comply with applicable laws and rules
1107 and, because of the failure, presents an imminent threat to the
1108 public's health, safety, or welfare. Any establishment so deemed
1109 and closed shall remain closed until allowed by the department
1110 or by judicial order to reopen.

1111 Section 10. Section 499.0285, Florida Statutes, is created
1112 to read:



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1113 499.0285 International Prescription Drug Importation
1114 Program.—

1115 (1) PROGRAM ESTABLISHED.—The department shall establish a
1116 program for the importation of safe and effective prescription
1117 drugs from foreign nations with which the United States has
1118 current mutual recognition agreements, cooperation agreements,
1119 memoranda of understanding, or other federal mechanisms
1120 recognizing their adherence to current good manufacturing
1121 practices for pharmaceutical products. The program shall be open
1122 to individual Florida residents and to those participating in
1123 the Canadian Drug Importation Program under s. 381.02035.

1124 (2) DEFINITIONS.—As used in this section, the term:

1125 (a) "Exporter" means an international prescription drug
1126 wholesale distributor, a nonresident prescription drug
1127 manufacturer registered to participate in the program, or an
1128 international export pharmacy that exports prescription drugs
1129 into the state under the program.

1130 (b) "Federal Act" means the Federal Food, Drug, and
1131 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.
1132 as amended by the Drug Quality and Security Act, 21 U.S.C. 351
1133 et seq.

1134 (c) "Foreign recipient" means an entity other than the
1135 original prescription drug manufacturer which receives the
1136 prescription drug before its importation into the state under
1137 the program.

1138 (d) "Good manufacturing practice" refers to the good
1139 manufacturing practice regulations in 21 C.F.R. parts 210 and
1140 211.

1141 (e) "Importer" means a wholesale distributor, pharmacy, or



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1142 pharmacist importing prescription drugs into the state under the
1143 program.

1144 (f) "International export pharmacy" means a pharmacy
1145 located outside of the United States which holds an active and
1146 unencumbered permit under chapter 465 to export prescription
1147 drugs into the state under the program.

1148 (g) "International prescription drug wholesale distributor"
1149 means a prescription drug wholesale distributor located outside
1150 of the United States which holds an active and unencumbered
1151 permit under this part to export and distribute prescription
1152 drugs into the state under the program.

1153 (h) "Nonresident prescription drug manufacturer" means an
1154 entity located outside of the United States which holds an
1155 active and unencumbered permit under this part to manufacture
1156 prescription drugs and has registered with the department to
1157 export and distribute such prescription drugs into the state
1158 under the program.

1159 (i) "Pharmacist" means a person who holds an active and
1160 unencumbered license to practice pharmacy under chapter 465.

1161 (j) "Pharmacy" means an entity that holds an active and
1162 unencumbered permit under chapter 465.

1163 (k) "Prescription drug" has the same meaning as defined in
1164 this part, but is limited to drugs intended for human use.

1165 (l) "Program" means the International Prescription Drug
1166 Importation Program established under this section.

1167 (m) "Qualified laboratory" means a laboratory that has been
1168 approved by the department for the purposes of this section.

1169 (3) ELIGIBLE PRESCRIPTION DRUGS.—An eligible importer may
1170 import a prescription drug from an eligible exporter if:



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1171 (a) The drug meets the United States Food and Drug
1172 Administration's standards related to safety, effectiveness,
1173 misbranding, and adulteration;

1174 (b) Importing the drug would not violate the patent laws of
1175 the United States; and

1176 (c) The drug is not:

1177 1. A controlled substance as defined in 21 U.S.C. s. 802;

1178 2. A biological product as defined in 42 U.S.C. s. 262;

1179 3. An infused drug;

1180 4. An intravenously injected drug;

1181 5. A drug that is inhaled during surgery; or

1182 6. A drug that is a parenteral drug, the importation of
1183 which is determined by the United States Secretary of Health and
1184 Human Services to pose a threat to the public health.

1185 (4) EXPORTERS.—

1186 (a) The following entities may export prescription drugs
1187 into the state under the program:

1188 1. An international prescription drug wholesale
1189 distributor.

1190 2. A nonresident prescription drug manufacturer.

1191 3. An international export pharmacy.

1192 (b) An eligible exporter must register with the department
1193 before exporting prescription drugs into the state under the
1194 program.

1195 (c) An exporter may not distribute, sell, or dispense
1196 prescription drugs imported under the program to any person
1197 residing outside of the state.

1198 (5) IMPORTERS.—

1199 (a) The following entities may import prescription drugs



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1200 under the program:
1201 1. A wholesale distributor.
1202 2. A pharmacy.
1203 3. A pharmacist.
1204 (b) An eligible importer must register with the department
1205 before importing prescription drugs into the state under the
1206 program.
1207 (c) An importer may not distribute, sell, or dispense
1208 prescription drugs imported under the program to any person
1209 residing outside of the state.
1210 (6) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—
1211 (a) A participating importer must submit the following
1212 information and documentation to the department:
1213 1. The name and quantity of the active ingredient of the
1214 prescription drug.
1215 2. A description of the dosage form of the prescription
1216 drug.
1217 3. The date on which the prescription drug is shipped.
1218 4. The quantity of the prescription drug that is shipped.
1219 5. The point of origin and destination of the prescription
1220 drug.
1221 6. The price paid by the importer for the prescription
1222 drug.
1223 7. Documentation from the exporter specifying:
1224 a. The original source of the prescription drug; and
1225 b. The quantity of each lot of the prescription drug
1226 originally received by the seller from that source.
1227 8. The lot or control number assigned to the prescription
1228 drug by the manufacturer.



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1229 9. The name, address, telephone number, and professional
1230 license or permit number of the importer.

1231 10. In the case of a prescription drug that is shipped
1232 directly by the first foreign recipient from the manufacturer:

1233 a. Documentation demonstrating that the prescription drug
1234 was received by the recipient from the manufacturer and
1235 subsequently shipped by the first foreign recipient to the
1236 importer.

1237 b. Documentation of the quantity of each lot of the
1238 prescription drug received by the first foreign recipient
1239 demonstrating that the quantity being imported into the state is
1240 not more than the quantity that was received by the first
1241 foreign recipient.

1242 c. For an initial imported shipment, documentation
1243 demonstrating that each batch of the prescription drug in the
1244 shipment was statistically sampled and tested for authenticity
1245 and degradation.

1246 11. In the case of a prescription drug that is not shipped
1247 directly from the first foreign recipient, documentation
1248 demonstrating that each batch in each shipment offered for
1249 importation into the state was statistically sampled and tested
1250 for authenticity and degradation.

1251 12. For an initial imported shipment, the agency shall
1252 ensure that each batch of the drug in the shipment is
1253 statistically sampled and tested for authenticity and
1254 degradation in a manner consistent with the federal act. The
1255 agency may contract with a vendor for these functions.

1256 13. For any subsequent imported shipment, the department
1257 shall ensure that a statistically valid sample of the shipment



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1258 was tested for authenticity and degradation in a manner
1259 consistent with the federal act.

1260 14. Certify that the drug:

1261 a. Is approved for marketing in the United States and is
1262 not adulterated or misbranded; and

1263 b. Meets all of the labeling requirements under 21 U.S.C.
1264 s. 352.

1265 15. Maintain qualified laboratory records, including
1266 complete data derived from all tests necessary to ensure that
1267 the drug is in compliance with the requirements of this section.

1268 16. Maintain documentation demonstrating that the testing
1269 required by this section was conducted at a qualified laboratory
1270 in accordance with the federal act and any other applicable
1271 federal and state laws and regulations governing laboratory
1272 qualifications.

1273 (b) All testing required by this section must be conducted
1274 in a qualified laboratory that meets the standards under the
1275 federal act and any other applicable federal and state laws and
1276 regulations governing laboratory qualifications for drug
1277 testing.

1278 (c) The vendor shall maintain information and documentation
1279 submitted under this section for a period of at least 7 years.

1280 (d) A participating importer must submit the all of
1281 following information to the department:

1282 1. The name and quantity of the active ingredient of the
1283 drug.

1284 2. A description of the dosage form of the drug.

1285 3. The date on which the drug is received.

1286 4. The quantity of the drug that is received.



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1287 5. The point of origin and destination of the drug.
1288 6. The price paid by the importer for the drug.
1289 (e) A participating International Importation Drug supplier
1290 must submit the following information and documentation to the
1291 agency or the agency's designated vendor specifying all of the
1292 following:
1293 1. The original source of the drug, including:
1294 a. The name of the manufacturer of the drug.
1295 b. The date on which the drug was manufactured.
1296 c. The location (country, state or province, and city)
1297 where the drug was manufactured.
1298 2. The date on which the drug is shipped.
1299 3. The quantity of the drug that is shipped.
1300 4. The quantity of each lot of the drug originally received
1301 and from which source.
1302 5. The lot or control number and the batch number assigned
1303 to the drug by the manufacturer.
1304 6. The name, address, and telephone number, and
1305 professional license or permit number of the importer.
1306 (f) The department may require any other information
1307 necessary to ensure the protection of the public health.
1308 (7) IMMEDIATE SUSPENSION.—The department shall immediately
1309 suspend the importation of a specific prescription drug or the
1310 importation of prescription drugs by a specific importer if it
1311 discovers that any prescription drug or activity is in violation
1312 of this section. The department may revoke the suspension if,
1313 after conducting an investigation, it determines that the public
1314 is adequately protected from counterfeit or unsafe prescription
1315 drugs being imported into the state.



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1316 (8) RULEMAKING AUTHORITY.—The department shall adopt rules
1317 necessary to implement this section.

1318 Section 11. Notwithstanding the Federal Food, Drug, and
1319 Cosmetic Act, the Department of Business and Professional
1320 Regulation, in collaboration with the Department of Health,
1321 shall negotiate a federal arrangement to operate a pilot program
1322 for importing prescription drugs into the state. The proposal to
1323 operate such a pilot program shall demonstrate that the program
1324 sets safety standards consistent with the current federal
1325 requirements for the manufacturing and distribution of
1326 prescription drugs; limits the importation of prescription drugs
1327 under the program to entities licensed or permitted by the state
1328 to manufacture, distribute, or dispense prescription drugs; and
1329 includes inspection and enforcement authority. Implementation of
1330 sections 2 through 11 of this act is contingent upon authority
1331 granted under federal law or rule. The department shall notify
1332 the President of the Senate, the Speaker of the House of
1333 Representatives, and the relevant committees of the Senate and
1334 the House of Representatives prior to implementation of the
1335 pilot program. The department shall submit to all parties a
1336 proposal for program implementation and program funding.

1337 Section 12. This act shall take effect July 1, 2019.

1338
1339 ===== T I T L E A M E N D M E N T =====

1340 And the title is amended as follows:

1341 Delete everything before the enacting clause
1342 and insert:

1343 A bill to be entitled

1344 An act relating to drug importation programs; creating



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1345 s. 381.02035, F.S.; requiring the Agency for Health
1346 Care Administration to establish the Canadian
1347 Prescription Drug Importation Program; defining terms;
1348 requiring the agency to contract with a vendor to
1349 facilitate wholesale prescription drug importation
1350 under the program; providing responsibilities for the
1351 vendor; providing eligibility criteria for
1352 prescription drugs, Canadian suppliers, and importers
1353 under the program; authorizing a Canadian supplier to
1354 export drugs into this state under the program under
1355 certain circumstances; providing eligibility criteria
1356 and requirements for drug importers; requiring
1357 participating Canadian suppliers and importers to
1358 comply with specified federal requirements for
1359 distributing prescription drugs imported under the
1360 program; prohibiting Canadian suppliers and importers
1361 from distributing, dispensing, or selling prescription
1362 drugs imported under the program outside of this
1363 state; requiring the agency to request federal
1364 approval of the program; requiring the request to
1365 include certain information; requiring the agency to
1366 begin operating the program within a specified
1367 timeframe after receiving federal approval; providing
1368 certain documentation requirements; requiring the
1369 agency to suspend the importation of drugs in
1370 violation of this section or any federal or state law
1371 or regulation; authorizing the agency to revoke the
1372 suspension under certain circumstances; requiring the
1373 agency to submit an annual report to the Governor and



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1374 the Legislature by a specified date; providing
1375 requirements for such report; requiring the agency to
1376 notify the Legislature upon federal approval of the
1377 program and to submit a proposal to the Legislature
1378 for program implementation and funding before a
1379 certain date; requiring the agency to adopt rules;
1380 creating s. 465.0157, F.S.; establishing an
1381 international export pharmacy permit for participation
1382 in the International Prescription Drug Importation
1383 Program; providing requirements for permit application
1384 and renewal; amending s. 465.017, F.S.; authorizing
1385 the Department of Health to inspect international
1386 export pharmacy permittees; amending s. 499.005, F.S.;
1387 providing that the importation of a prescription drug
1388 under the International Prescription Drug Importation
1389 Program is an exception from a prohibited act;
1390 amending s. 499.0051, F.S.; providing that the
1391 importation of a prescription drug for wholesale
1392 distribution under the International Prescription Drug
1393 Importation Program is an exception from criminal
1394 offenses; amending s. 499.01, F.S.; requiring an
1395 international prescription drug wholesale distributor
1396 to be permitted before operating; requiring
1397 nonresident prescription drug manufacturers to
1398 register with the Department of Business and
1399 Professional Regulation to participate in the program;
1400 providing an exception; establishing an international
1401 prescription drug wholesale distributor drug permit;
1402 providing permit requirements; amending s. 499.012,



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1403 F.S.; providing application requirements for
1404 international prescription drug wholesale distributors
1405 and nonresident prescription drug manufacturers to
1406 participate in the program; amending s. 499.015, F.S.;
1407 establishing that prescription drugs imported under
1408 the International Prescription Drug Importation
1409 Program are not required to be registered under a
1410 specified provision; amending s. 499.065, F.S.;
1411 requiring the department to inspect international
1412 prescription drug wholesale distributor
1413 establishments; authorizing the department to
1414 determine that an international prescription drug
1415 wholesale distributor establishment is an imminent
1416 danger to the public and require its immediate closure
1417 under certain conditions; creating s. 499.0285, F.S.;
1418 requiring the Department of Business and Professional
1419 Regulation to establish the International Prescription
1420 Drug Importation Program for a specified purpose;
1421 providing definition; providing eligibility criteria
1422 for prescription drugs, exporters, and importers under
1423 the program; requiring participating importers to
1424 submit certain documentation to the department for
1425 prescription drugs imported under the program;
1426 requiring the department to immediately suspend the
1427 importation of specific prescription drug or
1428 importation by a specific importer if a violation has
1429 occurred under the program; authorizing the department
1430 to revoke such suspension under certain suspension
1431 under certain circumstances; requiring the department



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1432 to adopt rules; requiring the agency, in collaboration
1433 with the Department of Business and Professional
1434 Regulation and the Department of Health, to negotiate
1435 a federal arrangement to operate a pilot program for
1436 importing prescription drugs into the state; providing
1437 that implementation of the act is contingent upon the
1438 authority of federal law or regulation; providing an
1439 effective date.