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

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26 | timeframe after receiving federal approval; providing
27 | certain documentation requirements; requiring the
28 | agency to suspend the importation of drugs in
29 | violation of this section or any federal or state law
30 | or regulation; authorizing the agency to revoke the
31 | suspension under certain circumstances; requiring the
32 | agency to submit an annual report to the Governor and
33 | the Legislature by a specified date; providing
34 | requirements for such report; requiring the agency to
35 | notify the Legislature upon federal approval of the
36 | program and to submit a proposal to the Legislature
37 | for program implementation and funding before a
38 | certain date; requiring the agency to adopt necessary
39 | rules; creating s. 465.0157, F.S.; establishing an
40 | international export pharmacy permit for participation
41 | in the International Prescription Drug Importation
42 | Program; providing requirements for permit application
43 | and renewal; requiring the Department of Health to
44 | adopt certain rules governing the financial
45 | responsibility of the pharmacy permittee; amending s.
46 | 465.017, F.S.; authorizing the department to inspect
47 | international export pharmacy permittees; amending s.
48 | 499.005, F.S.; providing that the importation of a
49 | prescription drug under the International Prescription
50 | Drug Importation Program is not a prohibited act under

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51 that chapter; amending s. 499.0051, F.S.; providing an
52 exemption from prosecution as a criminal offense for
53 the importation of a prescription drug for wholesale
54 distribution under the International Prescription Drug
55 Importation Program; amending s. 499.01, F.S.;
56 requiring an international prescription drug wholesale
57 distributor to be permitted before operating;
58 requiring nonresident prescription drug manufacturers
59 to register with the Department of Business and
60 Professional Regulation to participate in the program;
61 providing an exception; establishing an international
62 prescription drug wholesale distributor drug permit;
63 providing permit requirements; requiring the
64 Department of Business and Professional Regulation to
65 adopt certain rules governing the financial
66 responsibility of nonresident prescription drug
67 manufacturer licensee or permittee and international
68 prescription drug wholesale distributor permittees;
69 amending s. 499.012, F.S.; providing application
70 requirements for international prescription drug
71 wholesale distributors and nonresident prescription
72 drug manufacturers to participate in the program;
73 amending s. 499.015, F.S.; establishing that
74 prescription drugs imported under the International
75 Prescription Drug Importation Program are not required

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76 | to be registered under a specified provision; amending
 77 | s. 499.065, F.S.; requiring the department to inspect
 78 | international prescription drug wholesale distributor
 79 | establishments; authorizing the department to
 80 | determine that an international prescription drug
 81 | wholesale distributor establishment is an imminent
 82 | danger to the public and require its immediate closure
 83 | under certain conditions; creating s. 499.0285, F.S.;
 84 | requiring the department to establish the
 85 | International Prescription Drug Importation Program
 86 | for a specified purpose; providing definitions;
 87 | providing eligibility criteria for prescription drugs,
 88 | exporters, and importers under the program; requiring
 89 | participating importers to submit certain
 90 | documentation to the department for prescription drugs
 91 | imported under the program; requiring the department
 92 | to immediately suspend the importation of specific
 93 | prescription drug or the importation of prescription
 94 | drugs by a specific importer if a violation has
 95 | occurred under the program; authorizing the department
 96 | to revoke such suspension under certain circumstances;
 97 | requiring the department to adopt necessary rules;
 98 | requiring the agency, in collaboration with the
 99 | Department of Business and Professional Regulation and
 100 | the Department of Health, to negotiate a federal

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101 arrangement to operate a pilot program for importing
 102 prescription drugs into this state; providing that
 103 implementation of the act is contingent upon the
 104 federal authorization; requiring the department to
 105 notify the Legislature before implementation of the
 106 pilot program and to submit a proposal for pilot
 107 program implementation and funding; providing an
 108 effective date.

109
 110 Be It Enacted by the Legislature of the State of Florida:

111
 112 Section 1. Section 381.02035, Florida Statutes, is created
 113 to read:

114 381.02035 Canadian Prescription Drug Importation Program.—

115 (1) PROGRAM ESTABLISHED.—The Agency for Health Care
 116 Administration shall establish the Canadian Prescription Drug
 117 Importation Program for the importation of safe and effective
 118 prescription drugs from Canada which have the highest potential
 119 for cost savings to the state.

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

121 (a) "Agency" means the Agency for Health Care
 122 Administration.

123 (b) "Canadian supplier" means a manufacturer, wholesale
 124 distributor, or pharmacy appropriately licensed or permitted
 125 under Canadian law to manufacture, distribute, or dispense

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126 prescription drugs.

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

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

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

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

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

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

143 (i) "Pharmacist" means a person who holds an active and
 144 unencumbered license to practice pharmacy pursuant to chapter
 145 465.

146 (j) "Program" means the Canadian Prescription Drug
 147 Importation Program.

148 (k) "Track-and-trace" means the product-tracing process
 149 for the components of the pharmaceutical distribution supply
 150 chain as described in Title II of the Drug Quality and Security

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151 Act, Drug Supply Chain Security Act, 21 U.S.C. 351 et seq.

152 (1) "Vendor" means the entity contracted by the agency to
 153 manage specified functions of the program.

154 (3) IMPORTATION PROCESS.—

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

157 (b) By December 1, 2019, and each year thereafter, the
 158 vendor shall develop a Wholesale Prescription Drug Importation
 159 List identifying the prescription drugs that have the highest
 160 potential for cost savings to the state. In developing the list,
 161 the vendor shall consider, at a minimum, which prescription
 162 drugs will provide the greatest cost savings to state programs,
 163 including prescriptions drugs for which there are shortages,
 164 specialty prescription drugs, and high volume prescription
 165 drugs. The agency, in consultation with the department, shall
 166 review the Wholesale Prescription Drug Importation List every 3
 167 months to ensure that it continues to meet the requirements of
 168 the programs and may direct the vendor to revise the list, as
 169 necessary.

170 (c) The vendor shall identify Canadian suppliers that are
 171 in full compliance with relevant Canadian federal and provincial
 172 laws and regulations and the federal act and who have agreed to
 173 export drugs identified on the list at prices that will provide
 174 cost savings to the state. The vendor must verify that such
 175 Canadian suppliers meet all of the requirements of the program,

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176 while meeting or exceeding the federal and state track-and-trace
177 laws and regulations.

178 (d) The vendor shall contract with such eligible Canadian
179 suppliers, or facilitate contracts between eligible importers
180 and Canadian suppliers, to import drugs under the program.

181 (e) The vendor shall maintain a list of all registered
182 importers that participate in the program.

183 (f) The vendor shall ensure compliance with Title II of
184 the federal Drug Quality and Security Act, Pub. L. No. 113-54,
185 by all suppliers, importers and other distributors, and
186 participants in the program.

187 (g) The vendor shall assist the agency in the preparation
188 of the annual report required by subsection (12), including the
189 timely provision of any information requested by the agency.

190 (h) The vendor shall provide an annual financial audit of
191 its operations to the agency as required by the agency. The
192 vendor shall also provide quarterly financial reports specific
193 to the program and shall include information on the performance
194 of its subcontractors and vendors. The agency shall determine
195 the format and contents of the reports.

196 (4) BOND REQUIREMENT.—The agency shall require a bond from
197 the vendor to mitigate the financial consequences of potential
198 acts of malfeasance or misfeasance or fraudulent or dishonest
199 acts committed by the vendor, any employees of the vendor, or
200 its subcontractors.

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201 (5) ELIGIBLE PRESCRIPTION DRUGS.—Eligible importers, as
 202 described in subsection (7), may import a drug from an eligible
 203 Canadian supplier, as described in subsection (6), if:
 204 (a) The drug meets the United States Food and Drug
 205 Administration's standards related to safety, effectiveness,
 206 misbranding, and adulteration;
 207 (b) Importing the drug would not violate federal patent
 208 laws;
 209 (c) Importing the drug is expected to generate cost
 210 savings; and
 211 (d) The drug is not:
 212 1. A controlled substance as defined in 21 U.S.C. s. 802;
 213 2. A biological product as defined in 42 U.S.C. s. 262;
 214 3. An infused drug;
 215 4. An intravenously injected drug;
 216 5. A drug that is inhaled during surgery; or
 217 6. A drug that is a parenteral drug, the importation of
 218 which is determined by the United States Secretary of Health and
 219 Human Services to pose a threat to the public health.
 220 (6) ELIGIBLE CANADIAN SUPPLIERS.—A Canadian supplier may
 221 export prescription drugs into this state under the program if
 222 the supplier:
 223 (a) Is in full compliance with relevant Canadian federal
 224 and provincial laws and regulations;
 225 (b) Is identified by the vendor as eligible to participate

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226 | in the program; and

227 | (c) Submits an attestation that the supplier has a
 228 | registered agent in the United States, including the name and
 229 | United States address of the registered agent.

230 | (7) ELIGIBLE IMPORTERS.—The following entities may import
 231 | prescription drugs from an eligible Canadian supplier under the
 232 | program:

233 | (a) A pharmacist or wholesaler employed by or under
 234 | contract with the department's central pharmacy, for
 235 | distribution to a county health department or free clinic for
 236 | dispensing to clients treated in such department or clinic.

237 | (b) A pharmacist or wholesaler employed by or under
 238 | contract with a Medicaid pharmacy, for dispensing to the
 239 | pharmacy's Medicaid recipients.

240 | (c) A pharmacist or wholesaler employed by or under
 241 | contract with the Department of Corrections, for dispensing to
 242 | inmates in the custody of the Department of Corrections.

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

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

249 | (8) DISTRIBUTION REQUIREMENTS.—Eligible Canadian suppliers
 250 | and eligible importers participating under the program:

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

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

255 (9) FEDERAL APPROVAL.—By July 1, 2020, the agency shall
 256 submit a request to the United States Secretary of Health and
 257 Human Services for approval of the program under 21 U.S.C. s.
 258 384(l). The agency shall begin operating the program within 6
 259 months after receiving such approval. The request must, at a
 260 minimum:

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

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

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

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

270 (e) Estimate the total cost savings attributable to the
 271 program.

272 (f) Provide the costs of program implementation to the
 273 state.

274 (g) Include a list of potential Canadian suppliers from
 275 which the state would import drugs and demonstrate that the

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276 suppliers are in full compliance with relevant Canadian federal
 277 and provincial laws and regulations as well as all applicable
 278 federal and state laws and regulations.

279 (10) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

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

282 1. For an initial imported shipment of a specific drug by
 283 an importer, ensure that each batch of the drug in the shipment
 284 is statistically sampled and tested for authenticity and
 285 degradation in a manner consistent with the federal act.

286 2. For every subsequent imported shipment of that drug by
 287 that importer, ensure that a statistically valid sample of the
 288 shipment is tested for authenticity and degradation in a manner
 289 consistent with the federal act.

290 3. Certify that the drug:

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

293 b. Meets all of the labeling requirements under 21 U.S.C.
 294 s. 352.

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

298 5. Maintain documentation demonstrating that the testing
 299 required by this section was conducted at a qualified laboratory
 300 in accordance with the federal act and any other applicable

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301 federal and state laws and regulations governing laboratory
 302 qualifications.

303 (b) All testing required by this section must be conducted
 304 in a qualified laboratory that meets the standards under the
 305 federal act and any other applicable federal and state laws and
 306 regulations governing laboratory qualifications for drug
 307 testing.

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

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

313 1. The name and quantity of the active ingredient of the
 314 drug.

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

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

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

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

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

320 (e) A participating Canadian supplier must submit the
 321 following information and documentation to the vendor specifying
 322 all of the following:

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

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

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

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

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

329 3. The quantity of the drug that is shipped.

330 4. The quantity of each lot of the drug originally
 331 received and the source of the lot.

332 5. The lot or control number and the batch number assigned
 333 to the drug by the manufacturer.

334 (f) The agency may require that the vendor collect any
 335 other information necessary to ensure the protection of the
 336 public health.

337 (11) IMMEDIATE SUSPENSION.—The agency shall immediately
 338 suspend the importation of a specific drug or the importation of
 339 drugs by a specific importer if it discovers that any drug or
 340 activity is in violation of this section or any federal or state
 341 law or regulation. The agency may revoke the suspension if,
 342 after conducting an investigation, it determines that the public
 343 is adequately protected from counterfeit or unsafe drugs being
 344 imported into this state.

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

350 (a) A list of the prescription drugs that were imported

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- 351 under the program;
- 352 (b) The number of participating entities;
- 353 (c) The number of prescriptions dispensed through the
354 program;
- 355 (d) The estimated cost savings during the previous fiscal
356 year and to date attributable the program;
- 357 (e) A description of the methodology used to determine
358 which drugs should be included on the Wholesale Prescription
359 Drug Importation List; and
- 360 (f) Documentation as to how the program ensures the
361 following:
- 362 1. That Canadian suppliers participating in the program
363 are of high quality, high performance, and in full compliance
364 with relevant Canadian federal and provincial laws and
365 regulations as well as all federal laws and regulations and
366 state laws and rules;
- 367 2. That prescription drugs imported under the program are
368 not shipped, sold, or dispensed outside of this state once in
369 the possession of the importer;
- 370 3. That prescription drugs imported under the program are
371 pure, unadulterated, potent, and safe;
- 372 4. That the program does not put consumers at a higher
373 health and safety risk than if the consumer did not participate;
374 and
- 375 5. That the program provides cost savings to the state on

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376 | imported prescription drugs.

377 | (13) NOTIFICATION OF FEDERAL APPROVAL.—Upon receipt of
 378 | federal approval of the program, the agency shall notify the
 379 | President of the Senate, the Speaker of the House of
 380 | Representatives, and the relevant committees of the Senate and
 381 | the House of Representatives. After approval is received and
 382 | before the start of the next regular session of the Legislature
 383 | in which the proposal could be funded, the agency shall submit
 384 | to all parties a proposal for program implementation and program
 385 | funding.

386 | (14) RULEMAKING.—The agency shall adopt rules necessary to
 387 | implement this section.

388 | Section 2. Section 465.0157, Florida Statutes, is created
 389 | to read:

390 | 465.0157 International export pharmacy permit.—

391 | (1) To participate as an exporter of prescription drugs
 392 | into this state under the International Prescription Drug
 393 | Importation Program established in s. 499.0285, a pharmacy
 394 | located outside of the United States must hold an international
 395 | export pharmacy permit.

396 | (2) An international export pharmacy shall maintain at all
 397 | times an active and unencumbered license or permit to operate
 398 | the pharmacy in compliance with the laws of the jurisdiction in
 399 | which the dispensing facility is located and from which the
 400 | prescription drugs will be exported. Such jurisdiction must be

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401 in a country with which the United States has a current mutual
402 recognition agreement, cooperation agreement, memorandum of
403 understanding, or other federal mechanism recognizing the
404 country's adherence to current good manufacturing practices for
405 pharmaceutical products.

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

411 (4) An applicant shall submit the following to the board
412 to obtain an initial permit, or to the department to renew a
413 permit:

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

418 (b) Documentation demonstrating that the country in which
419 the pharmacy operates has a current mutual recognition
420 agreement, cooperation agreement, memorandum of understanding,
421 or other federal mechanism recognizing the country's adherence
422 to current good manufacturing practices for pharmaceutical
423 products.

424 (c) The location, names, and titles of all principal
425 corporate officers and the pharmacist who serves as the

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426 prescription department manager for prescription drugs exported
427 into this state under the International Prescription Drug
428 Importation Program.

429 (d) Written attestation by an owner or officer of the
430 applicant, and by the applicant's prescription department
431 manager, that:

432 1. The attestor has read and understands the laws and
433 rules governing the manufacture, distribution, and dispensing of
434 prescription drugs in this state.

435 2. A prescription drug shipped, mailed, or delivered into
436 this state meets or exceeds this state's standards for safety
437 and efficacy.

438 3. A prescription drug product shipped, mailed, or
439 delivered into this state must not have been, and may not be,
440 manufactured or distributed in violation of the laws and rules
441 of the jurisdiction in which the applicant is located and from
442 which the prescription drugs shall be exported.

443 (e) A current inspection report from an inspection
444 conducted by the regulatory or licensing agency of the
445 jurisdiction in which the applicant is located. The inspection
446 report must reflect compliance with this section. An inspection
447 report is current if the inspection was conducted within 6
448 months before the date of submitting the application for the
449 initial permit or within 1 year before the date of submitting an
450 application for permit renewal. If the applicant is unable to

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451 submit a current inspection report conducted by the regulatory
 452 or licensing agency of the jurisdiction in which the applicant
 453 is located and from which the prescription drugs will be
 454 exported, due to acceptable circumstances, as established by
 455 rule, or if an inspection has not been performed, the department
 456 must:

457 1. Conduct, or contract with an entity to conduct, an
 458 onsite inspection, with all related costs borne by the
 459 applicant;

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

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

465 (5) The department shall adopt rules governing the
 466 financial responsibility of the pharmacy permittee. The rules
 467 must establish, at a minimum, financial reporting requirements,
 468 standards for financial capability to perform the functions
 469 governed by the permit, and requirements for ensuring permittees
 470 and their contractors can be held accountable for the financial
 471 consequences of any act of malfeasance or misfeasance or
 472 fraudulent or dishonest act or acts committed by the permittee
 473 or its contractors.

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

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476 465.017 Authority to inspect; disposal.—

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

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

485 499.005 Prohibited acts.—It is unlawful for a person to
 486 perform or cause the performance of any of the following acts in
 487 this state:

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

491 Section 5. Paragraph (e) of subsection (12) of section
 492 499.0051, Florida Statutes, is amended to read:

493 499.0051 Criminal acts.—

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

500 (e) The importation of a prescription drug for wholesale

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501 distribution, except as provided by s. 801(d) of the Federal
 502 Food, Drug, and Cosmetic Act or s. 499.0285.

503 Section 6. Subsection (1) and paragraph (c) of subsection
 504 (2) of section 499.01, Florida Statutes, are amended, and
 505 paragraph (s) is added to subsection (2) of that section, to
 506 read:

507 499.01 Permits.—

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

- 510 (a) A prescription drug manufacturer;
- 511 (b) A prescription drug repackager;
- 512 (c) A nonresident prescription drug manufacturer;
- 513 (d) A nonresident prescription drug repackager;
- 514 (e) A prescription drug wholesale distributor;
- 515 (f) An out-of-state prescription drug wholesale
 516 distributor;
- 517 (g) A retail pharmacy drug wholesale distributor;
- 518 (h) A restricted prescription drug distributor;
- 519 (i) A complimentary drug distributor;
- 520 (j) A freight forwarder;
- 521 (k) A veterinary prescription drug retail establishment;
- 522 (l) A veterinary prescription drug wholesale distributor;
- 523 (m) A limited prescription drug veterinary wholesale
 524 distributor;
- 525 (n) An over-the-counter drug manufacturer;

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- 526 (o) A device manufacturer;
- 527 (p) A cosmetic manufacturer;
- 528 (q) A third party logistics provider; ~~or~~
- 529 (r) A health care clinic establishment; or
- 530 (s) An international prescription drug wholesale
- 531 distributor.

532 (2) The following permits are established:

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

549 1. A person that distributes prescription drugs for which
 550 the person is not the manufacturer must also obtain an out-of-

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551 | state prescription drug wholesale distributor permit, an
552 | international prescription drug wholesale distributor permit, or
553 | third party logistics provider permit pursuant to this section
554 | to engage in the distribution of such prescription drugs when
555 | required by this part. This subparagraph does not apply to a
556 | manufacturer that distributes prescription drugs only for the
557 | manufacturer of the prescription drugs where both manufacturers
558 | are affiliates.

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

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

574 | b. To participate as an exporter of prescription drugs
575 | into this state under the International Prescription Drug

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576 Importation Program established under s. 499.0285, a nonresident
577 prescription drug manufacturer located outside of the United
578 States must register with the Department of Business and
579 Professional Regulation before engaging in any activities under
580 that section. Such manufacturer must be licensed or permitted in
581 a country with which the United States has a current mutual
582 recognition agreement, cooperation agreement, memorandum of
583 understanding, or other federal mechanism recognizing the
584 country's adherence to current good manufacturing practices for
585 pharmaceutical products.

586 c. The department shall adopt rules governing the
587 financial responsibility of a nonresident prescription drug
588 manufacturer licensee or permittee. The rules will establish, at
589 a minimum, financial reporting requirements, standards for
590 financial capability to perform the functions governed by the
591 permit, and requirements for ensuring permittees and their
592 contractors can be held accountable for the financial
593 consequences of any act of malfeasance or misfeasance or
594 fraudulent or dishonest act or acts committed by the permittee
595 or its contractors.

596 (s) International prescription drug wholesale
597 distributor.—

598 1. A wholesale distributor located outside of the United
599 States must obtain an international prescription drug wholesale
600 distributor permit to engage in the wholesale exportation and

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601 distribution of prescription drugs in the state under the
602 International Prescription Drug Importation Program established
603 in s. 499.0285. The wholesale distributor must be licensed or
604 permitted to operate in a country with which the United States
605 has a mutual recognition agreement, cooperation agreement,
606 memorandum of understanding, or other federal mechanism
607 recognizing the country's adherence to current good
608 manufacturing practices for pharmaceutical products. The
609 wholesale distributor must maintain at all times a license or
610 permit to engage in the wholesale distribution of prescription
611 drugs in compliance with the laws of the jurisdiction in which
612 it operates. An international prescription drug wholesale
613 distributor permit may not be issued to a wholesale distributor
614 if the jurisdiction in which the wholesale distributor operates
615 does not require a license to engage in the wholesale
616 distribution of prescription drugs.

617 2. The department shall adopt rules governing the
618 financial responsibility of an international prescription drug
619 wholesale distributor permittee. The rules will establish, at a
620 minimum, financial reporting requirements, standards for
621 financial capability to perform the functions governed by the
622 permit, and requirements for ensuring permittees and their
623 contractors can be held accountable for the financial
624 consequences of any act of malfeasance or misfeasance or
625 fraudulent or dishonest act or acts committed by the permittee

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626 | or its contractors.

627 | Section 7. Subsection (2), paragraph (a) of subsection
628 | (4), subsections (8), (10), (11), and (14), and paragraphs (a),
629 | (b), and (f) of subsection (15) of section 499.012, Florida
630 | Statutes, are amended to read:

631 | 499.012 Permit application requirements.—

632 | (2) Notwithstanding subsection (6), a permitted person in
633 | good standing may change the type of permit issued to that
634 | person by completing a new application for the requested permit,
635 | paying the amount of the difference in the permit fees if the
636 | fee for the new permit is more than the fee for the original
637 | permit, and meeting the applicable permitting conditions for the
638 | new permit type. The new permit expires on the expiration date
639 | of the original permit being changed; however, a new permit for
640 | a prescription drug wholesale distributor, an out-of-state
641 | prescription drug wholesale distributor, an international
642 | prescription drug wholesale distributor, or a retail pharmacy
643 | drug wholesale distributor shall expire on the expiration date
644 | of the original permit or 1 year after the date of issuance of
645 | the new permit, whichever is earlier. A refund may not be issued
646 | if the fee for the new permit is less than the fee that was paid
647 | for the original permit.

648 | (4) (a) Except for a permit for a prescription drug
649 | wholesale distributor, an international prescription drug
650 | wholesale distributor, or an out-of-state prescription drug

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651 wholesale distributor, an application for a permit must include:
 652 1. The name, full business address, and telephone number
 653 of the applicant;
 654 2. All trade or business names used by the applicant;
 655 3. The address, telephone numbers, and the names of
 656 contact persons for each facility used by the applicant for the
 657 storage, handling, and distribution of prescription drugs;
 658 4. The type of ownership or operation, such as a
 659 partnership, corporation, or sole proprietorship; and
 660 5. The names of the owner and the operator of the
 661 establishment, including:
 662 a. If an individual, the name of the individual;
 663 b. If a partnership, the name of each partner and the name
 664 of the partnership;
 665 c. If a corporation, the name and title of each corporate
 666 officer and director, the corporate names, and the name of the
 667 state of incorporation;
 668 d. If a sole proprietorship, the full name of the sole
 669 proprietor and the name of the business entity;
 670 e. If a limited liability company, the name of each
 671 member, the name of each manager, the name of the limited
 672 liability company, and the name of the state in which the
 673 limited liability company was organized; and
 674 f. Any other relevant information that the department
 675 requires.

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676 (8) An application for a permit or to renew a permit for a
 677 prescription drug wholesale distributor, an international
 678 prescription drug wholesale distributor, or an out-of-state
 679 prescription drug wholesale distributor submitted to the
 680 department must include:

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

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

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

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

689 (e) The names of the owner and the operator of the
 690 establishment, including:

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

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

694 3. If a corporation:

695 a. The name, address, and title of each corporate officer
 696 and director.

697 b. The name and address of the corporation, resident agent
 698 of the corporation, the resident agent's address, and the
 699 corporation's state of incorporation.

700 c. The name and address of each shareholder of the

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701 corporation that owns 5 percent or more of the outstanding stock
702 of the corporation.

703 4. If a sole proprietorship, the full name of the sole
704 proprietor and the name of the business entity.

705 5. If a limited liability company:

706 a. The name and address of each member.

707 b. The name and address of each manager.

708 c. The name and address of the limited liability company,
709 the resident agent of the limited liability company, and the
710 name of the state in which the limited liability company was
711 organized.

712 (f) If applicable, the name and address of each affiliate
713 of the applicant.

714 (g) The applicant's gross annual receipts attributable to
715 prescription drug wholesale distribution activities for the
716 previous tax year.

717 (h) The tax year of the applicant.

718 (i) A copy of the deed for the property on which
719 applicant's establishment is located, if the establishment is
720 owned by the applicant, or a copy of the applicant's lease for
721 the property on which applicant's establishment is located that
722 has an original term of not less than 1 calendar year, if the
723 establishment is not owned by the applicant.

724 (j) A list of all licenses and permits issued to the
725 applicant by any other state or jurisdiction which authorize the

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726 applicant to purchase or possess prescription drugs.

727 (k) The name of the manager of the establishment that is
728 applying for the permit or to renew the permit, the next four
729 highest ranking employees responsible for prescription drug
730 wholesale operations for the establishment, and the name of all
731 affiliated parties for the establishment, together with the
732 personal information statement and fingerprints required
733 pursuant to subsection (9) for each of such persons.

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

738 (m) Evidence of a surety bond in this state or any other
739 state in the United States in the amount of \$100,000. If the
740 annual gross receipts of the applicant's previous tax year are
741 \$10 million or less, evidence of a surety bond in the amount of
742 \$25,000. The specific language of the surety bond must include
743 the State of Florida as a beneficiary, payable to the
744 Professional Regulation Trust Fund. In lieu of the surety bond,
745 the applicant may provide other equivalent security such as an
746 irrevocable letter of credit, or a deposit in a trust account or
747 financial institution, which includes the State of Florida as a
748 beneficiary, payable to the Professional Regulation Trust Fund.
749 The purpose of the bond or other security is to secure payment
750 of any administrative penalties imposed by the department and

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751 any fees and costs incurred by the department regarding that
752 permit which are authorized under state law and which the
753 permittee fails to pay 30 days after the fine or costs become
754 final. The department may make a claim against such bond or
755 security until 1 year after the permittee's license ceases to be
756 valid or until 60 days after any administrative or legal
757 proceeding authorized in this part which involves the permittee
758 is concluded, including any appeal, whichever occurs later.

759 (n) For establishments used in wholesale distribution,
760 proof of an inspection conducted by the department, the United
761 States Food and Drug Administration, or another governmental
762 entity charged with the regulation of good manufacturing
763 practices related to wholesale distribution of prescription
764 drugs, within timeframes set forth by the department in
765 departmental rules, which demonstrates substantial compliance
766 with current good manufacturing practices applicable to
767 wholesale distribution of prescription drugs. The department may
768 recognize another state's or jurisdiction's inspection of a
769 wholesale distributor located in that state or jurisdiction if
770 such state's or jurisdiction's laws are deemed to be
771 substantially equivalent to the law of this state by the
772 department. The department may accept an inspection by a third-
773 party accreditation or inspection service which meets the
774 criteria set forth in department rule.

775 (o) Any other relevant information that the department

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776 requires.

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

779 (q) For international prescription drug wholesale
780 distributors and nonresident prescription drug manufacturers to
781 participate in the International Prescription Drug Importation
782 Program established under s. 499.0285, documentation
783 demonstrating that the applicant is appropriately licensed or
784 permitted by a country with which the United States has a mutual
785 recognition agreement, cooperation agreement, memorandum of
786 understanding, or other mechanism recognizing the country's
787 adherence to current good manufacturing practices for
788 pharmaceutical products.

789 (10) The department may deny an application for a permit
790 or refuse to renew a permit for a prescription drug wholesale
791 distributor, an international prescription drug wholesale
792 distributor, or an out-of-state prescription drug wholesale
793 distributor if:

794 (a) The applicant has not met the requirements for the
795 permit.

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

799 (c) The applicant is so lacking in experience in managing
800 a wholesale distributor as to make the issuance of the proposed

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801 permit hazardous to the public health.

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

805 (e) The applicant is lacking in experience in the
806 distribution of prescription drugs.

807 (f) The applicant's past experience in manufacturing or
808 distributing prescription drugs indicates that the applicant
809 poses a public health risk.

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

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

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

823 (j) The applicant has furnished false or fraudulent
824 information or material in any application made in this state or
825 any other state in connection with obtaining a permit or license

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826 | to manufacture or distribute drugs, devices, or cosmetics.

827 | (k) That a federal, state, or local government permit
828 | currently or previously held by the applicant, or any affiliated
829 | party, for the manufacture or distribution of any drugs,
830 | devices, or cosmetics has been disciplined, suspended, or
831 | revoked and has not been reinstated.

832 | (l) The applicant does not possess the financial or
833 | physical resources to operate in compliance with the permit
834 | being sought, this chapter, and the rules adopted under this
835 | chapter.

836 | (m) The applicant or any affiliated party receives,
837 | directly or indirectly, financial support and assistance from a
838 | person who was an affiliated party of a permittee whose permit
839 | was subject to discipline or was suspended or revoked, other
840 | than through the ownership of stock in a publicly traded company
841 | or a mutual fund.

842 | (n) The applicant or any affiliated party receives,
843 | directly or indirectly, financial support and assistance from a
844 | person who has been found guilty of any violation of this part
845 | or chapter 465, chapter 501, or chapter 893, any rules adopted
846 | under this part or those chapters, any federal or state drug
847 | law, or any felony where the underlying facts related to drugs,
848 | regardless of whether the person has been pardoned, had her or
849 | his civil rights restored, or had adjudication withheld, other
850 | than through the ownership of stock in a publicly traded company

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851 or a mutual fund.

852 (o) The applicant for renewal of a permit under s.
 853 499.01(2)(e) or (f) has not actively engaged in the wholesale
 854 distribution of prescription drugs, as demonstrated by the
 855 regular and systematic distribution of prescription drugs
 856 throughout the year as evidenced by not fewer than 12 wholesale
 857 distributions in the previous year and not fewer than three
 858 wholesale distributions in the previous 6 months.

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

862 (q) The applicant does not possess the financial standing
 863 and business experience for the successful operation of the
 864 applicant.

865 (r) The applicant or any affiliated party has failed to
 866 comply with the requirements for manufacturing or distributing
 867 prescription drugs under this part, similar federal laws,
 868 similar laws in other states, or the rules adopted under such
 869 laws.

870 (11) Upon approval of the application by the department
 871 and payment of the required fee, the department shall issue or
 872 renew a prescription drug wholesale distributor, an
 873 international prescription drug wholesale distributor, or an
 874 out-of-state prescription drug wholesale distributor permit to
 875 the applicant.

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876 (14) The name of a permittee or establishment on a
 877 prescription drug wholesale distributor permit, an international
 878 prescription drug wholesale distributor permit, or an out-of-
 879 state prescription drug wholesale distributor permit may not
 880 include any indicia of attainment of any educational degree, any
 881 indicia that the permittee or establishment possesses a
 882 professional license, or any name or abbreviation that the
 883 department determines is likely to cause confusion or mistake or
 884 that the department determines is deceptive, including that of
 885 any other entity authorized to purchase prescription drugs.

886 (15) (a) Each establishment that is issued an initial or
 887 renewal permit as a prescription drug wholesale distributor, an
 888 international prescription drug wholesale distributor, or an
 889 out-of-state prescription drug wholesale distributor must
 890 designate in writing to the department at least one natural
 891 person to serve as the designated representative of the
 892 wholesale distributor. Such person must have an active
 893 certification as a designated representative from the
 894 department.

895 (b) To be certified as a designated representative, a
 896 natural person must:

- 897 1. Submit an application on a form furnished by the
- 898 department and pay the appropriate fees.
- 899 2. Be at least 18 years of age.
- 900 3. Have at least 2 years of verifiable full-time:

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901 a. Work experience in a pharmacy licensed in this state or
 902 another state or jurisdiction, where the person's
 903 responsibilities included, but were not limited to,
 904 recordkeeping for prescription drugs;

905 b. Managerial experience with a prescription drug
 906 wholesale distributor licensed in this state or in another state
 907 or jurisdiction; or

908 c. Managerial experience with the United States Armed
 909 Forces, where the person's responsibilities included, but were
 910 not limited to, recordkeeping, warehousing, distributing, or
 911 other logistics services pertaining to prescription drugs.

912 4. Receive a passing score of at least 75 percent on an
 913 examination given by the department regarding federal laws
 914 governing distribution of prescription drugs and this part and
 915 the rules adopted by the department governing the wholesale
 916 distribution of prescription drugs. This requirement shall be
 917 effective 1 year after the results of the initial examination
 918 are mailed to the persons that took the examination. The
 919 department shall offer such examinations at least four times
 920 each calendar year.

921 5. Provide the department with a personal information
 922 statement and fingerprints pursuant to subsection (9).

923 (f) A wholesale distributor may not operate under a
 924 prescription drug wholesale distributor permit, an international
 925 prescription drug wholesale distributor permit, or an out-of-

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926 state prescription drug wholesale distributor permit for more
927 than 10 business days after the designated representative leaves
928 the employ of the wholesale distributor, unless the wholesale
929 distributor employs another designated representative and
930 notifies the department within 10 business days of the identity
931 of the new designated representative.

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

934 499.015 Registration of drugs and devices; issuance of
935 certificates of free sale.—

936 (1) (a) Except for those persons exempted from the
937 definition of manufacturer in s. 499.003, any person who
938 manufactures, packages, repackages, labels, or relabels a drug
939 or device in this state must register such drug or device
940 biennially with the department; pay a fee in accordance with the
941 fee schedule provided by s. 499.041; and comply with this
942 section. The registrant must list each separate and distinct
943 drug or device at the time of registration.

944 (b) The department may not register any product that does
945 not comply with the Federal Food, Drug, and Cosmetic Act, as
946 amended, or Title 21 C.F.R. Registration of a product by the
947 department does not mean that the product does in fact comply
948 with all provisions of the Federal Food, Drug, and Cosmetic Act,
949 as amended.

950 (c) Registration under this section is not required for

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951 prescription drugs imported under the International Prescription
 952 Drug Importation Program established in s. 499.0285.

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

955 499.065 Inspections; imminent danger.—

956 (1) Notwithstanding s. 499.051, the department shall
 957 inspect each prescription drug wholesale distributor
 958 establishment, international prescription drug wholesale
 959 distributor establishment, prescription drug repackager
 960 establishment, veterinary prescription drug wholesale
 961 distributor establishment, limited prescription drug veterinary
 962 wholesale distributor establishment, and retail pharmacy drug
 963 wholesale distributor establishment that is required to be
 964 permitted under this part as often as necessary to ensure
 965 compliance with applicable laws and rules. The department shall
 966 have the right of entry and access to these facilities at any
 967 reasonable time.

968 (3) The department may determine that a prescription drug
 969 wholesale distributor establishment, international prescription
 970 drug wholesale distributor establishment, prescription drug
 971 repackager establishment, veterinary prescription drug wholesale
 972 distributor establishment, limited prescription drug veterinary
 973 wholesale distributor establishment, or retail pharmacy drug
 974 wholesale distributor establishment that is required to be
 975 permitted under this part is an imminent danger to the public

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976 health and shall require its immediate closure if the
 977 establishment fails to comply with applicable laws and rules
 978 and, because of the failure, presents an imminent threat to the
 979 public's health, safety, or welfare. Any establishment so deemed
 980 and closed shall remain closed until allowed by the department
 981 or by judicial order to reopen.

982 Section 10. Section 499.0285, Florida Statutes, is created
 983 to read:

984 499.0285 International Prescription Drug Importation
 985 Program.—

986 (1) PROGRAM ESTABLISHED.—The department shall establish a
 987 program for the importation of safe and effective prescription
 988 drugs from foreign nations with which the United States has
 989 current mutual recognition agreements, cooperation agreements,
 990 memoranda of understanding, or other federal mechanisms
 991 recognizing their adherence to current good manufacturing
 992 practices for pharmaceutical products.

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

994 (a) "Exporter" means an international prescription drug
 995 wholesale distributor, a nonresident prescription drug
 996 manufacturer registered to participate in the program, or an
 997 international export pharmacy that exports prescription drugs
 998 into this state under the program.

999 (b) "Federal Act" means the Federal Food, Drug, and
 1000 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

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1001 as amended by the Drug Quality and Security Act, 21 U.S.C. 351
 1002 et seq.

1003 (c) "Foreign recipient" means an entity other than the
 1004 original prescription drug manufacturer which receives the
 1005 prescription drug before its importation into this state under
 1006 the program.

1007 (d) "Good manufacturing practice" refers to the good
 1008 manufacturing practice regulations in 21 C.F.R. parts 210 and
 1009 211.

1010 (e) "Importer" means a wholesale distributor, pharmacy, or
 1011 pharmacist importing prescription drugs into this state under
 1012 the program.

1013 (f) "International export pharmacy" means a pharmacy
 1014 located outside of the United States which holds an active and
 1015 unencumbered permit under chapter 465 to export prescription
 1016 drugs into this state under the program.

1017 (g) "International prescription drug wholesale
 1018 distributor" means a prescription drug wholesale distributor
 1019 located outside of the United States which holds an active and
 1020 unencumbered permit under this part to export and distribute
 1021 prescription drugs into this state under the program.

1022 (h) "Nonresident prescription drug manufacturer" means an
 1023 entity located outside of the United States which holds an
 1024 active and unencumbered permit under this part to manufacture
 1025 prescription drugs and has registered with the department to

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1026 export and distribute such prescription drugs into this state
 1027 under the program.

1028 (i) "Pharmacist" means a person who holds an active and
 1029 unencumbered license to practice pharmacy under chapter 465.

1030 (j) "Pharmacy" means an entity that holds an active and
 1031 unencumbered permit under chapter 465.

1032 (k) "Prescription drug" has the same meaning as defined in
 1033 this part, but is limited to drugs intended for human use.

1034 (l) "Program" means the International Prescription Drug
 1035 Importation Program established under this section.

1036 (m) "Qualified laboratory" means a laboratory that has
 1037 been approved by the department for the purposes of this
 1038 section.

1039 (3) ELIGIBLE PRESCRIPTION DRUGS.—An eligible importer may
 1040 import a prescription drug from an eligible exporter if:

1041 (a) The drug meets the United States Food and Drug
 1042 Administration's standards related to safety, effectiveness,
 1043 misbranding, and adulteration;

1044 (b) Importing the drug would not violate the patent laws
 1045 of the United States; and

1046 (c) The drug is not:

1047 1. A controlled substance as defined in 21 U.S.C. s. 802;

1048 2. A biological product as defined in 42 U.S.C. s. 262;

1049 3. An infused drug;

1050 4. An intravenously injected drug;

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1051 5. A drug that is inhaled during surgery; or
 1052 6. A drug that is a parenteral drug, the importation of
 1053 which is determined by the United States Secretary of Health and
 1054 Human Services to pose a threat to the public health.

1055 (4) EXPORTERS.—

1056 (a) The following entities may export prescription drugs
 1057 into this state under the program:

1058 1. An international prescription drug wholesale
 1059 distributor.

1060 2. A nonresident prescription drug manufacturer.

1061 3. An international export pharmacy.

1062 (b) An eligible exporter must register with the department
 1063 before exporting prescription drugs into this state under the
 1064 program.

1065 (c) An exporter may not distribute, sell, or dispense
 1066 prescription drugs imported under the program to any person
 1067 residing outside of the state.

1068 (5) IMPORTERS.—

1069 (a) The following entities may import prescription drugs
 1070 under the program:

1071 1. A wholesale distributor.

1072 2. A pharmacy.

1073 3. A pharmacist.

1074 (b) An eligible importer must register with the department
 1075 before importing prescription drugs into this state under the

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1076 program.

1077 (c) An importer may not distribute, sell, or dispense

1078 prescription drugs imported under the program to any person

1079 residing outside of the state.

1080 (6) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

1081 (a) A participating importer must submit the following

1082 information and documentation to the department:

1083 1. The name and quantity of the active ingredient of the

1084 prescription drug.

1085 2. A description of the dosage form of the prescription

1086 drug.

1087 3. The date on which the prescription drug is shipped.

1088 4. The quantity of the prescription drug that is shipped.

1089 5. The point of origin and destination of the prescription

1090 drug.

1091 6. The price paid by the importer for the prescription

1092 drug.

1093 7. Documentation from the exporter specifying:

1094 a. The original source of the prescription drug; and

1095 b. The quantity of each lot of the prescription drug

1096 originally received by the seller from that source.

1097 8. The lot or control number assigned to the prescription

1098 drug by the manufacturer.

1099 9. The name, address, telephone number, and professional

1100 license or permit number of the importer.

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1101 10. In the case of a prescription drug that is shipped
 1102 directly by the first foreign recipient from the manufacturer:

1103 a. Documentation demonstrating that the prescription drug
 1104 was received by the recipient from the manufacturer and
 1105 subsequently shipped by the first foreign recipient to the
 1106 importer.

1107 b. Documentation of the quantity of each lot of the
 1108 prescription drug received by the first foreign recipient
 1109 demonstrating that the quantity being imported into this state
 1110 is not more than the quantity that was received by the first
 1111 foreign recipient.

1112 c. For an initial imported shipment, documentation
 1113 demonstrating that each batch of the prescription drug in the
 1114 shipment was statistically sampled and tested for authenticity
 1115 and degradation.

1116 11. In the case of a prescription drug that is not shipped
 1117 directly from the first foreign recipient, documentation
 1118 demonstrating that each batch in each shipment offered for
 1119 importation into this state was statistically sampled and tested
 1120 for authenticity and degradation.

1121 12. For an initial imported shipment of a specific drug by
 1122 an importer, the department shall ensure that each batch of the
 1123 drug in the shipment is statistically sampled and tested for
 1124 authenticity and degradation in a manner consistent with the
 1125 federal act. The agency may contract with a vendor for these

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1126 functions.

1127 13. For every subsequent imported shipment of that drug by
 1128 that importer, the department shall ensure that a statistically
 1129 valid sample of the shipment was tested for authenticity and
 1130 degradation in a manner consistent with the federal act.

1131 14. Certify that the drug:

1132 a. Is approved for marketing in the United States and is
 1133 not adulterated or misbranded; and

1134 b. Meets all of the labeling requirements under 21 U.S.C.
 1135 s. 352.

1136 15. Maintain qualified laboratory records, including
 1137 complete data derived from all tests necessary to ensure that
 1138 the drug is in compliance with the requirements of this section.

1139 16. Maintain documentation demonstrating that the testing
 1140 required by this section was conducted at a qualified laboratory
 1141 in accordance with the federal act and any other applicable
 1142 federal and state laws and regulations governing laboratory
 1143 qualifications.

1144 (b) All testing required by this section must be conducted
 1145 in a qualified laboratory that meets the standards under the
 1146 federal act and any other applicable federal and state laws and
 1147 regulations governing laboratory qualifications for drug
 1148 testing.

1149 (c) The vendor shall maintain information and
 1150 documentation submitted under this section for a period of at

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1151 least 7 years.

1152 (d) A participating importer must submit the all of
 1153 following information to the department:

1154 1. The name and quantity of the active ingredient of the
 1155 drug.

1156 2. A description of the dosage form of the drug.

1157 3. The date on which the drug is received.

1158 4. The quantity of the drug that is received.

1159 5. The point of origin and destination of the drug.

1160 6. The price paid by the importer for the drug.

1161 (e) A participating International Importation Drug
 1162 supplier must submit the following information and documentation
 1163 to the agency or the agency's designated vendor specifying all
 1164 of the following:

1165 1. The original source of the drug, including:

1166 a. The name of the manufacturer of the drug.

1167 b. The date on which the drug was manufactured.

1168 c. The location (country, state or province, and city)
 1169 where the drug was manufactured.

1170 2. The date on which the drug is shipped.

1171 3. The quantity of the drug that is shipped.

1172 4. The quantity of each lot of the drug originally
 1173 received and from which source.

1174 5. The lot or control number and the batch number assigned
 1175 to the drug by the manufacturer.

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1176 6. The name, address, and telephone number, and
 1177 professional license or permit number of the importer.

1178 (f) The department may require any other information
 1179 necessary to ensure the protection of the public health.

1180 (7) IMMEDIATE SUSPENSION.—The department shall immediately
 1181 suspend the importation of a specific prescription drug or the
 1182 importation of prescription drugs by a specific importer if it
 1183 discovers that any prescription drug or activity is in violation
 1184 of this section. The department may revoke the suspension if,
 1185 after conducting an investigation, it determines that the public
 1186 is adequately protected from counterfeit or unsafe prescription
 1187 drugs being imported into this state.

1188 (8) RULEMAKING AUTHORITY.—The department shall adopt rules
 1189 necessary to implement this section.

1190 Section 11. Notwithstanding the Federal Food, Drug, and
 1191 Cosmetic Act, the Department of Business and Professional
 1192 Regulation, in collaboration with the Department of Health,
 1193 shall negotiate a federal arrangement to operate a pilot program
 1194 for importing prescription drugs into this state. The proposal
 1195 to operate such a pilot program shall demonstrate that the
 1196 program sets safety standards consistent with the current
 1197 federal requirements for the manufacturing and distribution of
 1198 prescription drugs; limits the importation of prescription drugs
 1199 under the program to entities licensed or permitted by the state
 1200 to manufacture, distribute, or dispense prescription drugs; and

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1201 includes inspection and enforcement authority. Implementation of
1202 sections 2 through 10 of this act is contingent upon
1203 authorization granted under federal law, rule, or approval. The
1204 department shall notify the President of the Senate, the Speaker
1205 of the House of Representatives, and the relevant committees of
1206 the Senate and the House of Representatives before
1207 implementation of the pilot program. The department shall submit
1208 to all parties a proposal for program implementation and program
1209 funding.

1210 Section 12. This act shall take effect July 1, 2019.