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

(2) DEFINITIONS.—As used in this section, the term:
(a) “Agency” means the Agency for Health Care
Administration.
(b) “Canadian supplier” means a manufacturer, wholesale
distributor, or pharmacy appropriately licensed or permitted
under Canadian law to manufacture, distribute, or dispense
prescription drugs.
(c) “County health department” means a health care facility
established under part I of chapter 154.
(d) “Department” means the Department of Health.
(e) “Drug” or “prescription drug” has the same meaning as
“prescription drug” in s. 499.003, but is limited to drugs
intended for human use.
(f) “Federal act” means the Federal Food, Drug, and
as amended by the Drug Quality and Security Act, 21 U.S.C. 351
et seq.
(g) “Free clinic” means a clinic that delivers only medical
diagnostic services or nonsurgical medical treatment free of
charge to low-income recipients.
(h) “Medicaid pharmacy” means a pharmacy licensed under
chapter 465 that has a Medicaid provider agreement in effect
with the agency and is in good standing with the agency.
(i) “Pharmacist” means a person who holds an active and
unencumbered license to practice pharmacy pursuant to chapter
465.
(j) “Program” means the Canadian Prescription Drug
Importation Program.


(l) “Vendor” means the entity contracted by the agency to manage specified functions of the program.

(3) IMPORTATION PROCESS.—

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

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

(c) The vendor shall submit evidence of a surety bond with any bid or initial contract negotiation documents and shall maintain documentation of evidence of such a bond with the agency throughout the contract term. The surety bond may be from this state or any other state in the United States for at least $25,000. The surety bond or comparable security arrangement must
include the State of Florida as a beneficiary. In lieu of the surety bond, the vendor may provide a comparable security agreement, such as an irrevocable letter of credit or a deposit into a trust account or financial institution, which includes the State of Florida as a beneficiary, payable to the State of Florida. The purposes of the bond or other security arrangement for the program are to:

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

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

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

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

(d) The eligible vendor must submit evidence at the time of
contract award and throughout the contract term of a surety bond
or comparable security arrangement from this state or any other
state in the United States in an amount no less than $25,000.
The surety bond or comparable security arrangement must include
the State of Florida as a beneficiary. In lieu of the surety
bond, the vendor may provide a comparable security arrangement
such as an irrevocable letter of credit or a deposit into a
trust account or financial institution which names the State of
Florida as a beneficiary. The purposes of the bond or other
security arrangements for the program are to:

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

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

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

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

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

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

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

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

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

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

(a) The drug meets the United States Food and Drug Administration’s standards related to safety, effectiveness, misbranding, and adulteration;
(b) Importing the drug would not violate federal patent laws;
(c) Importing the drug is expected to generate cost savings; and
(d) The drug is not:
1. A controlled substance as defined in 21 U.S.C. s. 802;
2. A biological product as defined in 42 U.S.C. s. 262;
3. An infused drug;
4. An intravenously injected drug;
5. A drug that is inhaled during surgery; or
6. A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health.

(5) ELIGIBLE CANADIAN SUPPLIERS.—A Canadian supplier may export prescription drugs into the state under the program if the supplier is:

(a) In full compliance with relevant Canadian federal and provincial laws and regulations; and
(b) Identified by the vendor as eligible to participate in the program.

(6) ELIGIBLE IMPORTERS.—The following entities may import prescription drugs from a Canadian supplier under the program:

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

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

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

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

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

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

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

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

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

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

(b) Demonstrate how the prescription drugs imported into this state under the program will meet the applicable federal and state standards for safety and effectiveness.
(c) Demonstrate how the drugs imported into this state under the program will comply with federal tracing procedures.

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

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

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

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

(9) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

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

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

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

3. Certify that the drug:
   a. Is approved for marketing in the United States and is not adulterated or misbranded; and
   b. Meets all of the labeling requirements under 21 U.S.C.
s. 352.

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

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

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

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

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

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

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

3. The date on which the drug is received.

4. The quantity of the drug that is received.

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

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

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

1. The original source of the drug, including:
a. The name of the manufacturer of the drug.

b. The date on which the drug was manufactured.

c. The location (country, state or province, and city)

where the drug was manufactured.

2. The date on which the drug is shipped.

3. The quantity of the drug that is shipped.

4. The quantity of each lot of the drug originally received

and from which source.

5. The lot or control number and the batch number assigned

to the drug by the manufacturer.

(f) The agency may require that the vendor collect any

other information necessary to ensure the protection of the

public health.

(10) IMMEDIATE SUSPENSION.—The agency shall immediately

suspend the importation of a specific drug or the importation of

drugs by a specific importer if it discovers that any drug or

activity is in violation of this section or any federal or state

law or regulation. The agency may revoke the suspension if,

after conducting an investigation, it determines that the public

is adequately protected from counterfeit or unsafe drugs being

imported into this state.

(11) ANNUAL REPORT.—By December 1 of each year, the agency

shall submit a report to the Governor, the President of the

Senate, and the Speaker of the House of Representatives on the

operation of the program during the previous fiscal year. The

report must include, at a minimum:

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

under the program;

(b) The number of participating entities;
(c) The number of prescriptions dispensed through the program;

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

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

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

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

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

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

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

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

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

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

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

465.0157 International export pharmacy permit.—
(1) To participate as an exporter of prescription drugs
into the state under the International Prescription Drug
Importation Program established in s. 499.0285, a pharmacy
located outside of the United States must hold an international
export pharmacy permit.

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

(3) An application for an international export pharmacy
permit must be submitted on a form developed and provided by the
board. The board may require an applicant to provide any
information it deems reasonably necessary to carry out the
purposes of this section.
(4) An applicant shall submit the following to the board to obtain an initial permit, or to the department to renew a permit:

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

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

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

1. Ensure payment of any administrative penalties imposed by the department or any other state agency under the contract when the pharmacy fails to pay within 30 days after assessment;}
2. Ensure that the pharmacy meets contractual and statutory obligations through use of a surety bond or other comparable security arrangements to pay any other costs or fees incurred by the Department of Business of Professional Regulation, the state, or other entities acting on behalf of the state if the pharmacy fails to meet its obligations. If the pharmacy is assessed a penalty under the program and fails to pay within 30 days after that assessment, the Department of Business and Professional Regulation, the state, or an entity acting on behalf of the state may file a claim for reimbursement against the bond or other comparable security arrangement; and

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

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

1. Ensure participation of the pharmacy in any civil or criminal legal action by the state, the Department of Business of Professional Regulation, any other state agency, or private
individuals or entities against the pharmacy or because of the
pharmacy’s failure to perform under the contract, including, but
not limited to causes of actions for personal injury,
negligence, and wrongful death;

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

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

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

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

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

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

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

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

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

2. Accept a current and satisfactory inspection report, as
determined by rule, from an entity approved by the board; or
3. Accept a current inspection report from the United States Food and Drug Administration conducted pursuant to the federal Drug Quality and Security Act, Pub. L. No. 113-54.

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

465.017 Authority to inspect; disposal.—

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

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

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

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

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

499.0051 Criminal acts.—

(12) REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO PRESCRIPTION DRUGS.—Any person who violates any of the following provisions commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:
(e) The importation of a prescription drug for wholesale distribution, except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act or s. 499.0285.

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

499.01 Permits.—
(1) Before operating, a permit is required for each person and establishment that intends to operate as:
(a) A prescription drug manufacturer;
(b) A prescription drug repackager;
(c) A nonresident prescription drug manufacturer;
(d) A nonresident prescription drug repackager;
(e) A prescription drug wholesale distributor;
(f) An out-of-state prescription drug wholesale distributor;
(g) A retail pharmacy drug wholesale distributor;
(h) A restricted prescription drug distributor;
(i) A complimentary drug distributor;
(j) A freight forwarder;
(k) A veterinary prescription drug retail establishment;
(l) A veterinary prescription drug wholesale distributor;
(m) A limited prescription drug veterinary wholesale distributor;
(n) An over-the-counter drug manufacturer;
(o) A device manufacturer;
(p) A cosmetic manufacturer;
(q) A third party logistics provider;
(r) A health care clinic establishment

(s) An international prescription drug wholesale distributor.

(2) The following permits are established:

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

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

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

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

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

c. The nonresident prescription drug manufacturer shall
submit evidence of a surety bond with any application or filing for registration under this section and shall maintain documentation of evidence of such a bond with the Department of Business and Professional Regulation throughout the registration term. The surety bond may be from this state or any other state in the United States in an amount equal to 10 percent of the manufacturer’s annual sales or $1 million, whichever is higher. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the manufacturer may provide a comparable security agreement, such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary, payable to the State of Florida. The purposes of the bond or other security arrangement for the program are to:

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

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

   (III) Allow for claims to be made against the bond or other comparable security arrangements for up to 1 year after the manufacturer’s permit under the program has ended with this section or the program has ended, whichever occurs last.

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

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

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

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

(s) International prescription drug wholesale distributor.—
1. A wholesale distributor located outside of the United
States must obtain an international prescription drug wholesale
distributor permit to engage in the wholesale exportation and
distribution of prescription drugs in the state under the
International Prescription Drug Importation Program established
in s. 499.0285. The wholesale distributor must be licensed or
permitted to operate in a country with which the United States
has a mutual recognition agreement, cooperation agreement,
memorandum of understanding, or other federal mechanism
recognizing the country’s adherence to current good
manufacturing practices for pharmaceutical products. The
wholesale distributor must maintain at all times a license or
permit to engage in the wholesale distribution of prescription
drugs in compliance with the laws of the jurisdiction in which
it operates. An international prescription drug wholesale distributor permit may not be issued to a wholesale distributor if the jurisdiction in which the wholesale distributor operates does not require a license to engage in the wholesale distribution of prescription drugs.

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

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

b. Ensure that the wholesale distributor meets contractual and statutory obligations through use of a surety bond or other comparable security arrangements to pay any other costs or fees
incurred by the Department of Business of Professional
Regulation, the state, or other entities acting on behalf of the
state if the wholesale distributor fails to meet its
obligations. If the wholesale distributor is assessed a penalty
under the program and fails to pay within 30 days after that
assessment, the Department of Business and Professional
Regulation, the state, or an entity acting on behalf of the
state may file a claim for reimbursement against the bond or
other comparable security arrangement; and

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

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

a. Ensure participation of the wholesale distributor in any
civil or criminal legal action by the state, the Department of
Business of Professional Regulation, any other state agency, or
private individuals or entities against the wholesale
distributor or because of the wholesale distributor’s failure to
perform under the contract, including, but not limited to causes
of actions for personal injury, negligence, and wrongful death;

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

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

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

499.012 Permit application requirements.—
(2) Notwithstanding subsection (6), a permitted person in
good standing may change the type of permit issued to that
person by completing a new application for the requested permit,
paying the amount of the difference in the permit fees if the fee for the new permit is more than the fee for the original permit, and meeting the applicable permitting conditions for the new permit type. The new permit expires on the expiration date of the original permit being changed; however, a new permit for a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, an international prescription drug wholesale distributor, or a retail pharmacy drug wholesale distributor shall expire on the expiration date of the original permit or 1 year after the date of issuance of the new permit, whichever is earlier. A refund may not be issued if the fee for the new permit is less than the fee that was paid for the original permit.

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

1. The name, full business address, and telephone number of the applicant;
2. All trade or business names used by the applicant;
3. The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs;
4. The type of ownership or operation, such as a partnership, corporation, or sole proprietorship; and
5. The names of the owner and the operator of the establishment, including:
   a. If an individual, the name of the individual;
   b. If a partnership, the name of each partner and the name
of the partnership;

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

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

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

f. Any other relevant information that the department
requires.

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

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

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

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

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

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

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

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

3. If a corporation:
   a. The name, address, and title of each corporate officer
      and director.
   b. The name and address of the corporation, resident agent
      of the corporation, the resident agent’s address, and the
      corporation’s state of incorporation.
   c. The name and address of each shareholder of the
      corporation that owns 5 percent or more of the outstanding stock
      of the corporation.

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

5. If a limited liability company:
   a. The name and address of each member.
   b. The name and address of each manager.
   c. The name and address of the limited liability company,
      the resident agent of the limited liability company, and the
      name of the state in which the limited liability company was
      organized.
   f) If applicable, the name and address of each affiliate
      of the applicant.
   g) The applicant’s gross annual receipts attributable to
      prescription drug wholesale distribution activities for the
      previous tax year.
   h) The tax year of the applicant.
   i) A copy of the deed for the property on which
      applicant’s establishment is located, if the establishment is
      owned by the applicant, or a copy of the applicant’s lease for
      the property on which applicant’s establishment is located that
has an original term of not less than 1 calendar year, if the
establishment is not owned by the applicant.

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

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

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

(m) Evidence of a surety bond in this state or any other
state in the United States in the amount of $100,000. If the
annual gross receipts of the applicant’s previous tax year are
$10 million or less, evidence of a surety bond in the amount of
$25,000. The specific language of the surety bond must include
the State of Florida as a beneficiary, payable to the
Professional Regulation Trust Fund. In lieu of the surety bond,
the applicant may provide other equivalent security such as an
irrevocable letter of credit, or a deposit in a trust account or
financial institution, which includes the State of Florida as a
beneficiary, payable to the Professional Regulation Trust Fund.
The purpose of the bond or other security is to secure payment
of any administrative penalties imposed by the department and
any fees and costs incurred by the department regarding that
permit which are authorized under state law and which the
permittee fails to pay 30 days after the fine or costs become
final. The department may make a claim against such bond or
security until 1 year after the permittee’s license ceases to be
valid or until 60 days after any administrative or legal
proceeding authorized in this part which involves the permittee
is concluded, including any appeal, whichever occurs later.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) To be certified as a designated representative, a natural person must:
1. Submit an application on a form furnished by the department and pay the appropriate fees.

2. Be at least 18 years of age.

3. Have at least 2 years of verifiable full-time:
   a. Work experience in a pharmacy licensed in this state or another state or jurisdiction, where the person’s responsibilities included, but were not limited to, recordkeeping for prescription drugs;
   b. Managerial experience with a prescription drug wholesale distributor licensed in this state or in another state or jurisdiction; or
   c. Managerial experience with the United States Armed Forces, where the person’s responsibilities included, but were not limited to, recordkeeping, warehousing, distributing, or other logistics services pertaining to prescription drugs.

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

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

(f) A wholesale distributor may not operate under a prescription drug wholesale distributor permit, an international prescription drug wholesale distributor permit, or an out-of-
state prescription drug wholesale distributor permit for more
than 10 business days after the designated representative leaves
the employ of the wholesale distributor, unless the wholesale
distributor employs another designated representative and
notifies the department within 10 business days of the identity
of the new designated representative.

Section 8. Subsection (1) of section 499.015, Florida
Statutes, is amended to read:
499.015 Registration of drugs and devices; issuance of
certificates of free sale.—
(1)(a) Except for those persons exempted from the
definition of manufacturer in s. 499.003, any person who
manufactures, packages, repackages, labels, or relabels a drug
or device in this state must register such drug or device
biennially with the department; pay a fee in accordance with the
fee schedule provided by s. 499.041; and comply with this
section. The registrant must list each separate and distinct
drug or device at the time of registration.
(b) The department may not register any product that does
not comply with the Federal Food, Drug, and Cosmetic Act, as
amended, or Title 21 C.F.R. Registration of a product by the
department does not mean that the product does in fact comply
with all provisions of the Federal Food, Drug, and Cosmetic Act,
as amended.
(c) Registration under this section is not required for
prescription drugs imported under the International Prescription
Drug Importation Program established in s. 499.0285.

Section 9. Subsections (1) and (3) of section 499.065,
Florida Statutes, are amended to read:
499.065 Inspections; imminent danger.—

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

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

Section 10. Section 499.0285, Florida Statutes, is created to read:
499.0285 International Prescription Drug Importation Program.—

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

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

(a) “Exporter” means an international prescription drug wholesale distributor, a nonresident prescription drug manufacturer registered to participate in the program, or an international export pharmacy that exports prescription drugs into the state under the program.


(c) “Foreign recipient” means an entity other than the original prescription drug manufacturer which receives the prescription drug before its importation into the state under the program.

(d) “Good manufacturing practice” refers to the good manufacturing practice regulations in 21 C.F.R. parts 210 and 211.

(e) “Importer” means a wholesale distributor, pharmacy, or
pharmacist importing prescription drugs into the state under the program.

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

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

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

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

(j) “Pharmacy” means an entity that holds an active and unencumbered permit under chapter 465.

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

(l) “Program” means the International Prescription Drug Importation Program established under this section.

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

(3) ELIGIBLE PRESCRIPTION DRUGS.—An eligible importer may import a prescription drug from an eligible exporter if:
(a) The drug meets the United States Food and Drug Administration’s standards related to safety, effectiveness, misbranding, and adulteration;

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

(c) The drug is not:
   1. A controlled substance as defined in 21 U.S.C. s. 802;
   2. A biological product as defined in 42 U.S.C. s. 262;
   3. An infused drug;
   4. An intravenously injected drug;
   5. A drug that is inhaled during surgery; or
   6. A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health.

(4) EXPORTERS.—

(a) The following entities may export prescription drugs into the state under the program:
   1. An international prescription drug wholesale distributor.
   2. A nonresident prescription drug manufacturer.
   3. An international export pharmacy.

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

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

(5) IMPORTERS.—

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

1. A wholesale distributor.
2. A pharmacy.
3. A pharmacist.

(b) An eligible importer must register with the department before importing prescription drugs into the state under the program.

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

(6) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

(a) A participating importer must submit the following information and documentation to the department:

1. The name and quantity of the active ingredient of the prescription drug.
2. A description of the dosage form of the prescription drug.
3. The date on which the prescription drug is shipped.
4. The quantity of the prescription drug that is shipped.
5. The point of origin and destination of the prescription drug.
6. The price paid by the importer for the prescription drug.
7. Documentation from the exporter specifying:
   a. The original source of the prescription drug; and
   b. The quantity of each lot of the prescription drug originally received by the seller from that source.
8. The lot or control number assigned to the prescription drug by the manufacturer.
9. The name, address, telephone number, and professional license or permit number of the importer.

10. In the case of a prescription drug that is shipped directly by the first foreign recipient from the manufacturer:
   a. Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.
   b. Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the state is not more than the quantity that was received by the first foreign recipient.
   c. For an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

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

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

13. For any subsequent imported shipment, the department shall ensure that a statistically valid sample of the shipment
was tested for authenticity and degradation in a manner consistent with the federal act.

14. Certify that the drug:
   a. Is approved for marketing in the United States and is not adulterated or misbranded; and
   b. Meets all of the labeling requirements under 21 U.S.C. s. 352.

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

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

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

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

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

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

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

      3. The date on which the drug is received.

      4. The quantity of the drug that is received.
5. The point of origin and destination of the drug.

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

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

1. The original source of the drug, including:
   a. The name of the manufacturer of the drug.
   b. The date on which the drug was manufactured.
   c. The location (country, state or province, and city) where the drug was manufactured.

2. The date on which the drug is shipped.

3. The quantity of the drug that is shipped.

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

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

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

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

(7) IMMEDIATE SUSPENSION.—The department shall immediately suspend the importation of a specific prescription drug or the importation of prescription drugs by a specific importer if it discovers that any prescription drug or activity is in violation of this section. The department may revoke the suspension if, after conducting an investigation, it determines that the public is adequately protected from counterfeit or unsafe prescription drugs being imported into the state.
(8) RULEMAKING AUTHORITY.—The department shall adopt rules necessary to implement this section.

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

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to drug importation programs; creating
s. 381.02035, F.S.; requiring the Agency for Health Care Administration to establish the Canadian Prescription Drug Importation Program; defining terms; requiring the agency to contract with a vendor to facilitate wholesale prescription drug importation under the program; providing responsibilities for the vendor; providing eligibility criteria for prescription drugs, Canadian suppliers, and importers under the program; authorizing a Canadian supplier to export drugs into this state under the program under certain circumstances; providing eligibility criteria and requirements for drug importers; requiring participating Canadian suppliers and importers to comply with specified federal requirements for distributing prescription drugs imported under the program; prohibiting Canadian suppliers and importers from distributing, dispensing, or selling prescription drugs imported under the program outside of this state; requiring the agency to request federal approval of the program; requiring the request to include certain information; requiring the agency to begin operating the program within a specified timeframe after receiving federal approval; providing certain documentation requirements; requiring the agency to suspend the importation of drugs in violation of this section or any federal or state law or regulation; authorizing the agency to revoke the suspension under certain circumstances; requiring the agency to submit an annual report to the Governor and
the Legislature by a specified date; providing
requirements for such report; requiring the agency to
notify the Legislature upon federal approval of the
program and to submit a proposal to the Legislature
for program implementation and funding before a
certain date; requiring the agency to adopt rules;
creating s. 465.0157, F.S.; establishing an
international export pharmacy permit for participation
in the International Prescription Drug Importation
Program; providing requirements for permit application
and renewal; amending s. 465.017, F.S.; authorizing
the Department of Health to inspect international
export pharmacy permittees; amending s. 499.005, F.S.;
providing that the importation of a prescription drug
under the International Prescription Drug Importation
Program is an exception from a prohibited act;
amending s. 499.0051, F.S.; providing that the
importation of a prescription drug for wholesale
distribution under the International Prescription Drug
Importation Program is an exception from criminal
offenses; amending s. 499.01, F.S.; requiring an
international prescription drug wholesale distributor
to be permitted before operating; requiring
nonresident prescription drug manufacturers to
register with the Department of Business and
Professional Regulation to participate in the program;
providing an exception; establishing an international
prescription drug wholesale distributor drug permit;
providing permit requirements; amending s. 499.012,
F.S.; providing application requirements for
international prescription drug wholesale distributors
and nonresident prescription drug manufacturers to
participate in the program; amending s. 499.015, F.S.;
establishing that prescription drugs imported under
the International Prescription Drug Importation
Program are not required to be registered under a
specified provision; amending s. 499.065, F.S.;
requiring the department to inspect international
prescription drug wholesale distributor
establishments; authorizing the department to
determine that an international prescription drug
wholesale distributor establishment is an imminent
danger to the public and require its immediate closure
under certain conditions; creating s. 499.0285, F.S.;
requiring the Department of Business and Professional
Regulation to establish the International Prescription
Drug Importation Program for a specified purpose;
providing definition; providing eligibility criteria
for prescription drugs, exporters, and importers under
the program; requiring participating importers to
submit certain documentation to the department for
prescription drugs imported under the program;
requiring the department to immediately suspend the
importation of specific prescription drug or
importation by a specific importer if a violation has
occurred under the program; authorizing the department
to revoke such suspension under certain suspension
under certain circumstances; requiring the department
to adopt rules; requiring the agency, in collaboration with the Department of Business and Professional Regulation and the Department of Health, to negotiate a federal arrangement to operate a pilot program for importing prescription drugs into the state; providing that implementation of the act is contingent upon the authority of federal law or regulation; providing an effective date.