A bill to be entitled
An act relating to prescription drug importation programs; creating s. 381.02035, F.S.; establishing the Canadian Prescription Drug Importation Program within the Agency for Health Care Administration for a specified purpose; providing definitions; requiring the agency to contract with a vendor to facilitate wholesale prescription drug importation under the program; providing responsibilities for the vendor; providing eligibility criteria for prescription drugs, Canadian suppliers, and importers under the program; requiring participating Canadian suppliers and importers to comply with specified federal requirements for distributing prescription drugs imported under the program; prohibiting Canadian suppliers and importers from distributing, dispensing, or selling prescription drugs imported under the program outside of the state; requiring the agency to request federal approval of the program; providing requirements for such request; requiring the agency to begin operating the program within a specified timeframe after receiving federal approval; requiring the agency, in consultation with the vendor, to submit an annual report to the Governor and Legislature by a specified date; providing requirements for such
report; requiring the agency to adopt rules; 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 definitions; 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 a 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 circumstances; requiring the department 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 to inspect international export pharmacy permittees; amending s. 499.01, F.S.; requiring nonresident prescription drug manufacturers to register with the department to participate in the program; providing an exception;
establishing an international prescription drug wholesale distributor permit; providing requirements for such permit; amending s. 499.012, F.S.; providing permit application requirements for international prescription drug wholesale distributors and nonresident prescription drug manufacturers to participate in the program; amending ss. 499.005, 499.0051, and 499.015, F.S.; conforming provisions to changes made by the act; amending s. 499.065, F.S.; requiring the department to inspect international prescription drug wholesale distributor establishments and require their immediate closure under certain circumstances; requiring the Department of Business and Professional Regulation, in collaboration with 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 such federal arrangement or obtaining federal guidance; providing an effective date.

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

Section 1. Section 381.02035, Florida Statutes, is created to read:
381.02035 Canadian Prescription Drug Importation Program.—
(1) PROGRAM ESTABLISHED.—The agency shall establish a
program for the importation of safe and effective prescription
drugs from Canada that 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) "Free clinic" means a clinic that delivers only
medical diagnostic services or nonsurgical medical treatment
free of charge to low-income recipients.
(f) "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.
(g) "Pharmacist" means a person who holds an active and
unencumbered license to practice pharmacy pursuant to chapter
465.
(h) "Prescription drug" has the same meaning as in s.
499.003.

(i) “Program” means the Canadian Prescription Drug Importation Program.

(3) IMPORTATION PROCESS.—

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

(b) The vendor shall develop by December 1, 2019, and each year thereafter revise, 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 prescription 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 program and may direct the vendor to revise the list, as necessary.

(c) The vendor shall identify Canadian suppliers who are in full compliance with relevant Canadian federal and provincial laws and regulations and who have agreed to export prescription drugs identified on the list. The vendor must verify that such Canadian suppliers meet all of the requirements of the program and will export prescription drugs at prices that will provide
cost savings to the state. The vendor shall contract with such
eligible Canadian suppliers, or facilitate contracts between
eligible importers and Canadian suppliers, to import
prescription drugs under the program.

(d) The vendor must assist the agency with the annual
report required in subsection (9) and provide any information
requested by the agency for such report.

(4) ELIGIBLE PRESCRIPTION DRUGS.—Eligible importers may
import a prescription 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 the patent laws
of the United States;

(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 shall, at a minimum:

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

(b) Demonstrate how the prescription drugs imported into the state under the program will meet the applicable federal and state standards for safety and effectiveness;

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

(d) Estimate the total cost savings attributable to the program; and

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

(9) ANNUAL REPORTING.—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;

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

(f) Documentation demonstrating how the program ensures that:

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

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

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

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

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

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

Section 2. 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.

(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.

(b) "Foreign recipient" means an entity other than the
original prescription drug manufacturer that receives the
prescription drug before its importation into the state under
the program.

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

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

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

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

(g) "Nonresident prescription drug manufacturer" means an
entity located outside of the United States that 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.

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

(i) "Pharmacy" means an entity that holds an active and unencumbered permit under chapter 465.
(j) "Program" means the International Prescription Drug Importation Program established under this section.
(k) "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.

d. For any subsequent imported shipment, documentation
demonstrating that a statistically valid sample of the shipment
was 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. Certification from the importer or manufacturer that
the prescription 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.

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

14. Documentation demonstrating that the testing required
by this section was conducted at a qualified laboratory.

15. Any other information the department determines is
necessary to ensure the protection of the public health.

(b) All testing required by this section must be conducted
in a qualified laboratory.

(c) The department shall maintain information and
documentation submitted under this section for a period of at
least 4 years.

(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 3. 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 must 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 shall 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 shall 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 must 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

CODING: Words *stricken* are deletions; words *underlined* are additions.
from which the prescription drugs shall 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) 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 attester 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 shall be exported, due to acceptable circumstances, as established by rule, or if an inspection has not been performed, the department shall:

1. Conduct, or contract with an entity to conduct, an onsite inspection for which all costs shall be 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 4. 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 5.  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; or
(r) A health care clinic establishment; or
(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. To participate as an exporter of prescription drugs into the state under the International Prescription Drug Importation Program established in s. 499.0285, a nonresident prescription drug manufacturer located outside of the United States must register with the
department 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. 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, 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. 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 such documentation for prescription drugs imported under that program. 

(s) International prescription drug wholesale distributor.—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.

Section 6. Subsection (2), paragraph (a) of subsection (4), subsections (8), (10), (11), and (14), and paragraphs (a), (b), and (f) of subsection (15) 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
counter, the name of each manager, the name of the limited
liability company, 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
(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.
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.
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 after the identity of the new designated representative.

Section 7. 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 8. 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 9. Paragraph (c) is added to subsection (1) of section 499.015, Florida Statutes, to read:

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

(1)

(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 10. 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 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
DESCRIPTION

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
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 such federal
arrangement or upon obtaining federal guidance.

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