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LEGISLATIVE ACTION

Senate . House

. . . . .

Senator Bean moved 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 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq. 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.


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

(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 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.

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

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

(f) 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.

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

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

(5) ELIGIBLE PRESCRIPTION DRUGS.—Eligible importers, as described in subsection (7), may import a drug from an eligible Canadian supplier, as described in subsection (6), 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.

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

(a) Is in full compliance with relevant Canadian federal and provincial laws and regulations;

(b) Is identified by the vendor as eligible to participate in the program; and

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

(7) ELIGIBLE IMPORTERS.—The following entities may import prescription drugs from an eligible 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.

(8) DISTRIBUTION REQUIREMENTS.—Eligible Canadian suppliers and eligible 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.

(9) 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.

(10) 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 of a specific drug by an importer, 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 every subsequent imported shipment of that drug by that importer, ensure that a statistically valid sample of the shipment is 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 the source of the lot.

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.

(11) 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.

(12) 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.

(13) 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


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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.

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

(d) 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.

(e) Written attestation by an owner or officer of the

applicant, and by the applicant's prescription department manager, that:

1. The attestor 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.

(f) 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; ~~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. 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 this 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 department shall adopt rules governing the financial responsibility of a nonresident prescription drug manufacturer licensee or permittee. The rules will establish, at a minimum, financial reporting requirements, standards for financial capability to perform the functions governed by the permit, and requirements for ensuring permittees and their contractors can be held accountable for the financial consequences of any act of malfeasance or misfeasance or fraudulent or dishonest act or acts committed by the permittee or its contractors.

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

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 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 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.

(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 this state under the program.

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

(c) "Foreign recipient" means an entity other than the original prescription drug manufacturer which receives the prescription drug before its importation into this 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 this 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 this 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 this 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 this 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 this 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 this 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 this 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 this 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 this state was statistically sampled and tested for authenticity and degradation.

12. For an initial imported shipment of a specific drug by an importer, the department 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 every subsequent imported shipment of that drug by that importer, 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 this 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 this 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 10 of this act is contingent upon authorization granted under federal law, rule, or approval. 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 before 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.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to prescription 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, including the payment of a bond; 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 necessary 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; requiring the Department of Health to adopt certain rules governing the financial responsibility of the pharmacy permittee; amending s. 465.017, F.S.; authorizing the department 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 not a prohibited act under that chapter; amending s. 499.0051, F.S.; providing an exemption from prosecution as a criminal offense for the importation of a prescription drug for wholesale distribution under the International Prescription Drug Importation Program; 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; requiring the Department of Business and Professional Regulation to adopt certain rules governing the financial responsibility of nonresident prescription drug manufacturer licensee or permittee and international prescription drug wholesale distributor permittees; 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 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 specific prescription drug or the importation of prescription drugs 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 necessary 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 this state; providing that implementation of the act is contingent upon the federal authorization; requiring the department to notify the Legislature before implementation of the pilot program and to submit a proposal for pilot program implementation and funding; providing an effective date.