FLORIDA BOARD OF PHARMACY
Rules Sub-Committee Agenda
June 27, 2019
Teleconference Call
1-888-585-9008
Public Number: 599196982
1:00 P.M.

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the board's website.

Thursday, June 27, 2019 at 1:00 p.m.

I. Call to Order/Roll Call

II. HB 19 – Prescription Drug Importation Program

- i. CS/HB 19
- ii. Rule 64B16-28.100, F.A.C.
- iii. Draft Application – International Export Pharmacy Permit

III. Old Business/New Business

IV. Public Comment

V. Adjournment

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.

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 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.

(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 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 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 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.

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

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

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

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

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

(5) 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.

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

776 requires.
777 (p) Documentation of the credentialing policies and
778 procedures required by s. 499.0121(15).
779 (q) For international prescription drug wholesale
780 distributors and nonresident prescription drug manufacturers to
781 participate in the International Prescription Drug Importation
782 Program established under s. 499.0285, documentation
783 demonstrating that the applicant is appropriately licensed or
784 permitted by a country with which the United States has a mutual
785 recognition agreement, cooperation agreement, memorandum of
786 understanding, or other mechanism recognizing the country's
787 adherence to current good manufacturing practices for
788 pharmaceutical products.
789 (10) The department may deny an application for a permit
790 or refuse to renew a permit for a prescription drug wholesale
791 distributor, an international prescription drug wholesale
792 distributor, or an out-of-state prescription drug wholesale
793 distributor if:
794 (a) The applicant has not met the requirements for the
795 permit.
796 (b) The management, officers, or directors of the
797 applicant or any affiliated party are found by the department to
798 be incompetent or untrustworthy.
799 (c) The applicant is so lacking in experience in managing
800 a wholesale distributor as to make the issuance of the proposed

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.

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.

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 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.

(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 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 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 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.

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

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

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

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

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

(5) 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.

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

776 requires.
777 (p) Documentation of the credentialing policies and
778 procedures required by s. 499.0121(15).
779 (q) For international prescription drug wholesale
780 distributors and nonresident prescription drug manufacturers to
781 participate in the International Prescription Drug Importation
782 Program established under s. 499.0285, documentation
783 demonstrating that the applicant is appropriately licensed or
784 permitted by a country with which the United States has a mutual
785 recognition agreement, cooperation agreement, memorandum of
786 understanding, or other mechanism recognizing the country's
787 adherence to current good manufacturing practices for
788 pharmaceutical products.
789 (10) The department may deny an application for a permit
790 or refuse to renew a permit for a prescription drug wholesale
791 distributor, an international prescription drug wholesale
792 distributor, or an out-of-state prescription drug wholesale
793 distributor if:
794 (a) The applicant has not met the requirements for the
795 permit.
796 (b) The management, officers, or directors of the
797 applicant or any affiliated party are found by the department to
798 be incompetent or untrustworthy.
799 (c) The applicant is so lacking in experience in managing
800 a wholesale distributor as to make the issuance of the proposed

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.

64B16-28.100 Pharmacy Permits – Applications and Permitting.

This rule section establishes the application and permitting requirements for pharmacies regulated under chapter 465, F.S. Any pharmacy establishment shall apply to the board for the appropriate permit on forms indicated in this rule. Applications and forms referenced in this section may be accessed or downloaded from the web at http://floridaspharmacy.gov/resources/ or may be obtained by contacting the Board the Board of Pharmacy, at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850)488-0595. Inquiries regarding the status of the application or license verification may be obtained at http://www.FLHealthsource.gov. The application must be accompanied by the appropriate fee as specified by rule 64B16-26.1022, F.A.C.

(1) All Permits:

(a) A permit is valid only for the name and, pursuant to rule 64B16-28.113, F.A.C., physical location (address) to which it is issued. The name in which the permit is issued must be the name in which the company is doing business, i.e., the name that appears on purchase and sales invoices.

1. The name in which a permit is issued may be changed upon notification to the board. To change the name in which a permit is issued the person or establishment must file with the board an original Form DH-MQA 1227 "Pharmacy Permit Name Change Form" effective December 2010, which is incorporated by reference herein, and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02297 or on the web at http://floridaspharmacy.gov/resources/.

2. A pharmacy permit holder may request a change of practice location by completing the appropriate section(s) of the application form for the permit type.

3. Pharmacy permits are non-transferrable. However, pursuant to rule 64B16-28.2021, F.A.C., transfers of ownership interests of business entities holding a permit may be allowed. A pharmacy permit holder shall notify the Board of changes of ownership interests of business entities by completing the appropriate section(s) of the application form for the permit type.

(b) Each applicant must comply with the fingerprinting requirements in section 465.022, F.S. Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications.

(c) Passing an onsite inspection is a prerequisite to issuance of a new permit, whether based on an initial application, change of ownership, or change of address. At the time of the onsite inspection, the board inspector will document the applicant's compliance with all applicable rules and statutes.

(d) Pursuant to subsection 465.022(4), F.S., each applicant must attach to the application the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. The policy and procedure manual shall contain, at a minimum, the following:

1. Provisions to identify and guard against invalid practitioner-patient relationships.

2. Provisions to guard against filling fraudulent prescriptions for controlled substances.

3. Provisions to identify prescriptions that are communicated or transmitted legally.

4. Provisions to identify the characteristics of a forged or altered prescription.

(2) A Community Pharmacy Permit, as authorized by section 465.018, F.S., is required for every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis. Applicants for a community pharmacy permit must complete an application for a permit using an original Form DH-MQA 1214, "Community Pharmacy Permit Application and Information," Rev 01/18, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09431. Applicants for a Community Pharmacy Permit must comply with all permitting requirement found in subsection (1) of this rule and designate a prescription department manager as required by section 465.018, F.S.

(3) An Institutional Pharmacy Permit, as authorized by section 465.019, F.S., is required for any location in any health care institution where medicinal drugs are compounded, dispensed, stored or sold. Applicants for an Institutional Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1215, "Institutional Pharmacy Permit Application and Information," Rev 01/18, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09432. Applicants for an Institutional Pharmacy Permit must comply with

all permitting requirements found in subsection (1) of this rule and designate a consultant pharmacist of record as required by section 465.019, F.S.

(4) A Nuclear Pharmacy Permit, as authorized by section 465.0193, F.S., is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. Applicants for a Nuclear Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1218, "Nuclear Pharmacy Permit Application and Information," Rev 01/18, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09433. Applicants for a Nuclear Pharmacy Permit must comply with all permitting requirements found in subsection (1), of this rule and designate a nuclear pharmacist as the prescription department manager as required by subsection 64B16-28.901(1), F.A.C.

(5) A Special Pharmacy Permits as authorized by section 465.0196, F.S., is required for any location where medicinal drugs are compounded, dispensed, stored, or sold and which is not a community pharmacy, institutional pharmacy, nuclear pharmacy or internet pharmacy. Applicants for a Special-Limited Community, Special – Parenteral and Enteral, Special – Closed System Pharmacy, Special – End Stage Renal Disease (ESRD), Special – Parenteral/Enteral Extended Scope, and Special – Assisted Living Facility (ALF) permits must complete an application for a permit using an original Form DH-MQA 1220, "Special Pharmacy Permit Application and Information," Rev 01/18, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09434.

(a) Applicants for a Special Pharmacy Permit must comply with all permitting requirement found in subsection (1) of this rule; and designate a prescription department manager or consultant pharmacist of record as required by section 465.0196, F.S.

(b) The Board recognized the following types of Special Pharmacy permits:

1. A Special Limited Community Permit is required for any Institutional Class II Pharmacy that dispenses medicinal drugs to employees, medical staff, emergency room patients, and other patients on continuation of a course of therapy.

2. A Special Parenteral and Enteral Permit is required for any pharmacy which provides parenteral (IV), enteral, and cytotoxic pharmacy services to outpatients. The applicant must be compliant with the Standard for Compounding Sterile Preparations found in rule 64B16-27.797, F.A.C. Special – Parenteral and Enteral Pharmacy Permits may stand-alone or be used in conjunction with a Community Pharmacy or Special – Closed System Pharmacy Permit. The permittee must provide 24-hour telephone accessibility.

3. A Special Closed System Pharmacy Permit is required for any pharmacy not open to the public and where prescriptions are individually prepared for dispensing utilizing closed delivery systems, for ultimate consumers in health care institutions including nursing homes, jails, Assisted Living Facilities (ALFs), Intermediate Care Facilities for the Developmentally Delayed (ICF-IID) or other custodial care facilities when defined by AHCA rules which the Board may approve. This permit may not provide medications to in-patients in a hospital.

4. A Special Pharmacy – End Stage Renal Disease (ESRD) Permit is required for any pharmacy which is limited in scope of pharmacy practice to the provision of dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address.

5. A Special Pharmacy – Parenteral/Enteral Extended Scope Permit is required for any pharmacy which compounds patient specific parenteral/enteral preparations in conjunction with institutional pharmacy permits, as provided in rule 64B16-28.560, F.A.C.

6. Special – Assisted Living Facility (ALF) Permit is an optional facility license for those Assisted Living Facilities providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.

(6) An Internet Pharmacy Permit, as authorized by section 465.0197, F.S., is required for any location not otherwise licensed or issued a permit under this chapter, within or outside this state that uses the Internet to communicate with or obtain information from consumers and uses the information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Applicants for an Internet Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1216, "Internet Pharmacy Permit Application and Information" which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09435 Rev 01/18. Applicants for an Internet Pharmacy Permit must comply with all permitting requirements found in subsection (1) of this rule and designate a prescription department manager or consultant pharmacist of record as required by section 465.0197, F.S.

(7) Special Sterile Compounding Permit: Except those pharmacies which already hold an active stand-alone Special Parenteral/Enteral or Special Parenteral/Enteral Extended Scope Compounding permit, or a Modified Class II-B pharmacy that meets the requirements of subsection 64B16-28.802(6), F.A.C., any pharmacy, including an outsourcing facility, engaged in sterile compounding must obtain a special sterile compounding permit by filing an application on form DH-MQA 1270, "Special Sterile

Compounding Permit Application and Information," Rev 01/18, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09436.

Applicants for a Special Sterile Compounding Permit must comply with all permitting requirements in subsection (1) of this rule and designate a prescription department manager or consultant pharmacist of record.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 456.013, 456.025(3), 456.0635, 465.003, 465.018, 465.019, 465.0193, 465.0196, 465.0197, 465.022 FS. History–New 2-21-13, Amended 9-23-13, 5-31-17, 6-5-18.

DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4474

INTERNATIONAL EXPORT PHARMACY PERMIT APPLICATION

XXXX 20XX

International Export Pharmacy Permit Application Information

An International Export Pharmacy Permit as authorized by Section 465.0157, *Florida Statutes* is required to participate as an exporter of prescription drugs into Florida.

Definition:

For the purposes of this application:

1. "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.
2. "Affiliated persons" means any person who has an ownership interest of 5% or greater in the pharmacy and any person who directly or indirectly manages, oversees, or controls the operation of the pharmacy."
3. "PDM" means the designated pharmacist that insures compliance with all requirements pertaining to International Export Drug Program licensees.
4. "Pharmacist" means a person who is licensed or otherwise authorized to practice pharmacy in the jurisdiction in which they are located.

Application Processing

1. Please mail the application and the $255.00 application fee (check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

Department of Health
Board of Pharmacy
P.O. Box 6330
Tallahassee, Florida 32314-6320

OR, use the following address if you are using express mail:

Department of Health
4052 Bald Cypress Way, Bin C-04
Tallahassee, FL 32399-3254

2. Along with the application, International Export Pharmacies must submit the following:

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

b. Documentation demonstrating such jurisdiction is in a country with which the United States has a current mutual recognition agreement, cooperative agreement, memorandum of understanding, or other federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

c. Submit the address, city, country, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager, as provided for in 64B16-27.450, F.A.C., for the prescription drugs exported into this state under the International Prescription Drug Importation Program.

d. Submit a written attestation by an owner or officer of the applicant and by the applicant's prescription department manager that:

- The attestor has read and understands the laws and rules governing the manufacture, distribution, and dispensing of prescription drugs in this state;
- A prescription drug shipped, mailed, or delivered into this state meets or exceeds this state's standards for safety and efficacy; and
- A prescription drug product shipped, mailed, or delivered into this state must not have been, or 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. Submit 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 and is only valid if the inspection was conducted within **six (6) months** before the date of applying for an initial permit:

- If an applicant is unable to submit a current inspection report due to acceptable circumstances as stated in rule 64BXX-XX.XXX, the Department , or if an inspection has not been performed within the six (6) months before the date of applying for an initial permit, shall:
  - Conduct, or contract with an entity to conduct, an onsite inspection for which all costs shall be borne by the applicant;
  - Accept a satisfactory inspection report, as determined by rule 64BXX-XX.XXX, from an entity approved by the Board completed within six (6) months before the date of the application; or
  - Accept an inspection report from the United States Food and Drug Administration conducted pursuant to the federal Drug Quality and Security Act, Pu. L. No. 113-54 completed within six (6) months before the date of the application.

f. Submit documentation establishing that the applicant is in compliance with the financial responsibility and requirements as established in rule 64BXX-XX.XXX.

g. Submit documentation establishing the Prescription Department Manager's license as a pharmacist, or authorization to dispense prescription drugs in the jurisdiction where the applicant is located.

3. Submit fingerprint results.

Failure to submit fingerprints will delay your application. All owners, officers, and Consultant Pharmacists of Record (CORs) are required to submit a set of fingerprints unless the corporation is exempt under Section 465.022, Florida Statutes, for corporations having more than $100 million of business taxable assets in this state. These corporations are only required to have the COR to submit fingerprints.

Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications. **Note: If your officer, owner, or Consultant Pharmacist of Record has already been fingerprinted at the time you are completing this Institutional Pharmacy permit application, please ensure to provide the Transaction Control Number (TCN), if known, with the requested**

information in the application.

Applicants may use any Livescan vendor that has been approved by the Florida Department of Law Enforcement to submit their fingerprints to the department. Please ensure that the Originating Agency Identification (ORI) number is provided to the vendor when you submit your fingerprints. If you do not provide an ORI number or if you provide an incorrect ORI number to the vendor, the Board of Pharmacy will not receive your fingerprint results. The applicant is fully responsible for selecting the vendor and ensuring submission of the prints to the Department.

How do I find a Livescan vendor in order to submit my fingerprints to the Department?

The Department of Health accepts electronic fingerprinting service offered by Livescan device vendors that are approved by the Florida Department of Law Enforcement and listed at their site. You can view the vendor options and contact information at:

http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html

What information must I provide to the Livescan vendor I choose?

- If you are an applicant seeking a license for any profession regulated by the Department of Health, which requires a criminal background search as a condition of licensure, you must provide accurate demographic information at the time your fingerprints are taken, ***including your Social Security number***. The Department will not be able to process a submission that does not include your Social Security number.

- You must provide the correct ORI number.

  Where do I get the ORI number to submit to the vendor?

  The ORI number for the pharmacy profession is **EDOH4680Z**.

Attestation for Business Taxable Assets

If the applicant has more than $100 million dollars of business taxable assets in this state, please submit a formal opinion letter from a Certified Public Accountant duly licensed in the state of your principal place of business affirming the corporation has more than $100 million of business taxable assets in this state for the previous tax year. In lieu of submitting a formal opinion letter from a Certified Public Accountant, the applicant may submit its Florida Corporate Income/Franchise and Emergency Excise Tax Return (Form F-1120, Effective 01/09).

5. Privacy Statement and Attestation

In order for the Board of Pharmacy Office to receive your Livescan electronic fingerprinting results, you must affirm that you have been provided with and read the attached statement from the Florida Department of Law Enforcement regarding the sharing, retention, and right to challenge incorrect criminal history records, and the "Privacy Statement" document from the Federal Bureau of Investigation. The appropriate form(s) to provide this affirmation are included within Items #1 and #2 of the application.

6. Policies and procedures – requires committee and board discussion.

FLORIDA BOARD OF PHARMACY
P.O. Box 6330 | Tallahassee, FL 32314
(850) 245-4474 | www.floridaspharmacy.gov

INTERNATIONAL EXPORT PHARMACY PERMIT APPLICATION

Please submit the application fee and unlicensed activity fee totaling $255 with your application.

Federal Employer Identification Number (FEIN)

1. Corporate Name | **Telephone Number**

2. Doing Business As (d/b/a) | **E-Mail Address (Optional)**

3. Mailing Address

City | State | Zip Code | Country

4. Physical Address of dispensing facility

City | State | Zip Code | Country

5. Prescription Department Manager (PDM) or equivalent

Name | License No. | Start Date

6. Contact Person | **Telephone Number**

7. DEA Registration Number (If applicable)

8. Date of last inspection: Day_____Month _____Year _____

Inspecting Authority_____

9. Was this inspection in compliance with section 456.0157, Florida statutes? (Attach a copy of the inspection report, the floor plan and your policies and procedures manual).

_____Yes _____No

10. Operating Hours

Monday-Friday: Open_____Close: _____

Saturday: Open_____Close: _____

Sunday: Open_____Close: _____

11. Ownership Information

a. Type of Ownership

_____Individual_____Corporation_____Partnership_____Other:_____

CORPORATIONS & LIMITED PARTNERSHIPS: INCLUDE A COPY OF THE ARTICLES OF INCORPORATION ON FILE WITH THE STATE WHERE THE FACILITY IS LOCATED.

b. List each principal, officer, agent, managing employee or affiliated person of the applicant.

Attach a separate sheet if necessary.

Name/Title	Date of Birth	Mailing Address, City State, Zip Code	% Ownership
	/ /		%
	/ /		%
	/ /		%

Questions 12 through 18 are required pursuant to Section 456.0635(2), *Florida Statutes*. Please explain any "yes" answered to the following questions on a separate sheet, providing as much detail as possible. Supporting documentation must include at a minimum the official charging document and the official judgment and sentence.

12. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, Chapter 817, or Chapter 893, Florida Statutes or a similar felony offense committed in another state or jurisdiction? (If "no", skip to question 15.)

Yes_____ No _____

If "yes", for the felonies of the first or second degree (or the equivalent level of felony in another state or jurisdiction), has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?

Yes_____ No _____

If "yes", for the felonies of the third degree (or the equivalent level of felony in another state or jurisdiction), has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes or a similar felony offense committed in another state or jurisdiction.

Yes_____ No_____

If "yes", for the felonies of the third degree (or the equivalent level of felony in another state or jurisdiction) under Section 893.13(6)(a), Florida Statutes or a similar felony offense committed in another state or jurisdiction has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?

Yes_____ No_____

If "yes", has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed?

Yes_____ No _____

13. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication to a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)? (If "no", skip to question 16.)

Yes_____ No_____(If yes, explain on a separate sheet providing accurate details)

If *"yes"*, is the date of application more than 15 years after the sentence and any subsequent period of probation ended?

Yes_____ No_____

14. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If "no", skip to question 17.)

Yes_____ No _____

If "yes", has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been reinstated and in good standing with the Florida Medicaid Program for the most recent five years?

Yes_____ No _____

15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state or from any other state Medicaid program? (If "no", skip to question 18)

Yes_____ No _____

If "yes", has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been in good standing with a state Medicaid program for the most recent five years?

Yes_____ No _____

If "yes", did the termination occur at least 20 years prior to the date of this application?

Yes_____ No _____

16. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant listed on the United States Department of Health Human Services Office of Inspector General's List of Excluded Individuals and Entities?

Yes_____ No_____

17. Are you currently registered or permitted in any other states? If yes, provide the state, permit type, and permit number for each permit. *Attach a separate sheet if necessary.*

Yes_____ No _____

State	Permit Type	Permit Number

18. Has the applicant or any principal, officer, agent, managing employee, or affiliated person ever owned a pharmacy? If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy.

Yes_____ No_____(If yes, please list them below, you may provide additional sheet)

Pharmacy Name	State	Status

19. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant in this state or any other?

Yes_____ No_____(If yes, explain on a separate sheet providing accurate details and submit documentation from the licensing agency who took the disciplinary action)

20. Has any principal, officer, agent, managing employee, affiliated person of the applicant ever been convicted of a felony or misdemeanor, excluding minor traffic convictions?

Yes_____ No_____(Include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

21. Is there any other permit issued by the Department of Health located at the physical location address on this application?

Yes_____ No_____(If yes, explain on a separate sheet providing accurate details)

22. Does the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant have any outstanding fines, liens or overpayments assessed by a final order of the department?

Yes_____ No_____(If yes, explain on a separate sheet providing accurate details)

***If "yes",* does the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant have a repayment plan approved by the department?**

Yes_____ No _____

23. Has the applicant received an FDA Form 483 or Warning Letter following an inspection conducted by the FDA within the last 3 years?

Yes_____ No_____(If yes, please submit the Form 483 or Warning Letter, any corrective action plan, and supporting documentation demonstrating how the corrective action plan was implemented. Supporting documentation may include but is not limited to pictures, facility diagrams and updated policies and procedures.)

APPLICANT SIGNATURE PAGE

Florida law requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application that takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department of board.

****

I, the undersigned, certify that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application. I do authorize the Florida Board of Pharmacy and the Department to make any investigations that they deem appropriate and to secure any additional information concerning the applicant or me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board, or any municipal, county, state, or federal governmental agencies or units. I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be denied, revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit.

I, the undersigned, hereby acknowledge that providing false information in relation to this application, may result in denial of licensure, discipline, and/ or criminal penalties pursuant to sections: XXX.XX, XX.XXX, XXX.XX, XXX.XX and XXX.XX, *Florida Statutes*.

I, the undersigned, have completely reviewed and read the foregoing document and state that the facts stated in it are true.

SIGNATURE _____ TITLE_____DATE_____
Owner/Officer

****

FLORIDA BOARD OF PHARMACY
P.O. Box 6330 • Tallahassee, FL 32314-6320
Phone: (850) 245-4474
www.floridaspharmacy.gov

ATTESTATION

Section 465.0157 F.S., requires that applicants submit a written attestation by an owner or officer of the applicant and by the applicant's Prescription Department Manager (PDM).

I hereby attest:

1. *That I have read and understand the laws and rules governing the manufacture, distribution, and dispending of prescription drugs in the State of Florida;*
2. *That any prescription drug shipped, mailed, or delivered into the State of Florida from our facility meets or exceeds the State of Florida's standards for safety and efficacy; and*
3. *That any prescription drug product shipped, mailed, or delivered into this state has not been, and may not be, manufactured or distributed in violation of the laws and rules of jurisdiction in which the applicant is located and from the jurisdiction in which the applicant is located and from which the prescription drugs shall be exported.*

I declare that I have read the foregoing Attestation and that the facts stated in it are true.

SIGNATURE_____ TITLE_____ DATE_____
(Owner/Officer)

SIGNATURE_____ TITLE_____ DATE_____
(PDM)