By Senator Bean

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A bill to be entitled

An act relating to prescription drug importation programs for public programs; creating s. 381.02035, F.S.; establishing the Canadian Prescription Drug Importation Program within the Agency for Health Care Administration for a specified purpose; providing definitions; requiring the agency to contract with a vendor to facilitate wholesale prescription drug importation under the program; providing responsibilities for the vendor; providing eligibility criteria for prescription drugs, Canadian suppliers, and importers under the program; requiring participating Canadian suppliers and importers to comply with specified federal requirements for distributing prescription drugs imported under the program; prohibiting Canadian suppliers and importers from distributing, dispensing, or selling prescription drugs imported under the program outside of the state; requiring the agency to request federal approval of the program; providing requirements for such request; requiring the agency to begin operating the program within a specified timeframe after receiving federal approval; requiring the agency, in consultation with the vendor, to submit an annual report to the Governor and Legislature by a specified date; providing requirements for such report; authorizing the agency to adopt rules; providing an effective date.

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

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

381.02035 Canadian Prescription Drug Importation Program.—

(1) PROGRAM ESTABLISHED.—The agency shall establish a program for the importation of safe and effective prescription drugs from Canada 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) "Free clinic" means a clinic that delivers only medical diagnostic services or nonsurgical medical treatment free of charge to low-income recipients.

(f) "Medicaid pharmacy" means a pharmacy licensed under chapter 465 which has a Medicaid provider agreement in effect with the agency and is in good standing with the agency.

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

(h) "Prescription drug" has the same meaning as in s. 499.003.

(i) "Program" means the Canadian Prescription Drug Importation Program.

(3) IMPORTATION PROCESS.—

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

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

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

(d) The vendor must assist the agency with the annual

report required in subsection (9) and provide any information requested by the agency for such report.

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

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

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

(c) Importing the drug is expected to generate cost savings; and

(d) The drug is not:

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

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

3. An infused drug;

4. An intravenously injected drug;

5. A drug that is inhaled during surgery; or

6. A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health.

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

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

(b) Identified by the vendor as eligible to participate in the program.

(6) ELIGIBLE IMPORTERS.—The following entities may import

prescription drugs from a Canadian supplier under the program:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) The number of participating entities;

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

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

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

(f) Documentation demonstrating how the program ensures

that:

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

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

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

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

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

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

Section 2. This act shall take effect July 1, 2019.