HOUSE OF REPRESENTATIVES
THIRTY-SECOND LEGISLATURE, 2024
STATE OF HAWAII

H.B. NO. 1979

A BILL FOR AN ACT

RELATING TO PRESCRIPTION DRUGS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. Chapter 321, Hawaii Revised Statutes, is amended by adding a new part to be appropriately designated and to read as follows:

"PART . CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM

§321-A Definitions. As used in this part, unless the context otherwise requires:

"Canadian supplier" means a manufacturer, wholesale distributor, or pharmacy appropriately licensed or permitted under Canadian law to manufacture, distribute, or dispense prescription drugs.

"Department" means the department of health.

"Drug" or "prescription drug" has the same meaning as "prescription drug" in section 328-1.

"Federal Act" means the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040; 21 U.S.C. 301-395).

"Medicaid pharmacy" means a pharmacy licensed under chapter 461 that is authorized to dispense to medicaid recipients.

"Pharmacist" means a person who holds an active and unencumbered license to practice pharmacy pursuant to chapter 461.

"Program" means the Canadian prescription drug importation program established under section 321-B.

"Track-and-trace" means the product-tracing process for the components of the pharmaceutical distribution supply chain as described in title II of the federal Drug Quality and Security Act, the Drug Supply Chain Security Act (21 U.S.C. 360eee to 360eee-4).

"Vendor" means the entity contracted by the department to manage specified functions of the program.

§321-B Canadian prescription drug importation program; established. There shall be established within the department the Canadian prescription drug importation program for the importation of safe and effective prescription drugs from Canada that have the highest potential for cost savings to the State.

§321-C Importation process; reports. (a) The department shall contract with a vendor to provide services under the program. Contracts executed pursuant to this subsection shall be subject to chapter 103D.

(b) By December 1, 2024, 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 prescription drugs for which there are shortages, specialty prescription drugs, and high volume prescription drugs. The department shall review the wholesale prescription drug importation list every three months to ensure that it continues to meet the requirements of the state 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 that have agreed to export drugs identified on the list at prices that will provide cost savings to the State. The vendor shall verify that the Canadian suppliers meet all the requirements of the program, while meeting or exceeding federal and state track-and-trace laws, rules, and regulations.

(d) The vendor shall contract with 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, the Drug Supply Chain Security Act (21 U.S.C. 360eee to 360eee-4), by all Canadian suppliers, importers and other distributors, and participants in the program.

(g) The vendor shall assist the department in the preparation of the annual report required by section 321-L, including the timely provision of any information requested by the department.

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

§321-D Bond requirement. The department 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 subcontractors of the vendor.

§321-E Eligible prescription drugs. Eligible importers, as described in section 321-G, may import a drug from an eligible Canadian supplier, as described in section 321-F, if:

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

(2) Importing the drug would not violate federal patent laws;

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

(4) The drug is not:

(A) A controlled substance as defined in title 21 United States Code section 802;

(B) A biological product as defined in title 42 United States Code section 262;

(C) An infused drug;

(D) An intravenously injected drug;

(E) A drug that is inhaled during surgery; or

(F) 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.

§321-F Eligible Canadian suppliers. A Canadian supplier may export prescription drugs into the State under the program if the Canadian supplier:

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

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

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

§321-G Eligible importers. The following entities may import prescription drugs from an eligible Canadian supplier under the program:

(1) A pharmacist or wholesaler employed by or under contract with a medicaid pharmacy, for dispensing to the pharmacy's medicaid recipients;

(2) A pharmacist or wholesaler employed by or under contract with the department of corrections and rehabilitation, for dispensing to committed persons in the custody of the department of corrections and rehabilitation;

(3) A pharmacist or wholesaler employed by or under contract with a forensic facility of the department for dispensing to forensic patients treated in the forensic facility;

(4) A pharmacist or wholesaler employed by or under contract with a licensed developmental disabilities domiciliary home as defined in section 321-15.9 for dispensing to residents treated in the home; and

(5) A pharmacist or wholesaler employed by or under contract with a state-owned, state-operated, or state-supported hospital, center, or clinic designated by the department for extended treatment and hospitalization, beyond that provided for by a

receiving facility, of persons who have a mental illness.

§321-H Distribution requirements. Eligible Canadian suppliers and eligible importers participating under the program:

(1) Shall comply with the track-and-trace requirements of title II of the federal Drug Quality and Security Act, the Drug Supply Chain Security Act (21 U.S.C. 360eee to 360eee 4); and

(2) Shall not distribute, dispense, or sell prescription drugs imported under the program outside of the State.

§321-I Federal approval. By July 1, 2025, the department shall submit a request to the United States Secretary of Health and Human Services for approval of the program under title 21 United States Code section 384(l). The department shall begin operating the program within six months after receiving the approval. The request shall, at a minimum:

(1) Describe the department's plan for operating the program;

(2) Demonstrate how the prescription drugs imported into the State under the program will meet the applicable

federal and state standards for safety and effectiveness;

(3) Demonstrate how the drugs imported into the State under the program will comply with federal track-and-trace procedures;

(4) 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;

(5) Estimate the total cost savings attributable to the program;

(6) Provide the costs of program implementation to the State; and

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

§321-J 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 the labeling requirements under title 21 United States Code section 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 part; and

(5) Maintain documentation demonstrating that the testing required by this part was conducted at a qualified laboratory in accordance with the Federal Act and any other applicable federal and state laws, rules, and regulations laboratory qualifications.

(b) All testing required by this part shall be conducted in a qualified laboratory that meets the standards under the Federal Act and any other applicable federal and state laws, rules, and regulations governing laboratory qualifications for drug testing.

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

(d) A participating importer shall submit all the 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; and

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

(e) A participating Canadian supplier shall submit the following information and documentation to the vendor specifying all 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; and

(C) The location, including 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; and

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

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

§321-K Immediate suspension. The department 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 part or any federal or state law or regulation. The department may revoke the suspension if, after conducting an investigation, the department determines that the public is adequately protected from counterfeit or unsafe drugs being imported into the State.

§321-L Annual report. No later than twenty days prior to the convening of each regular session, the department shall submit a report to the governor and legislature on the operation of the program during the previous fiscal year. The report shall include, at a minimum:

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

(2) The number of participating entities;

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

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

(5) A description of the methodology used to determine which drugs should be included on the wholesale prescription drug importation list; and

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

(A) 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 and state laws, rules, and regulations;

(B) That prescription drugs imported under the program are not shipped, sold, or dispensed outside of the State once in the possession of the importer;

(C) That prescription drugs imported under the program are pure, unadulterated, potent, and safe;

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

(E) That the program provides cost savings to the State on imported prescription drugs.

§321-M Notification of federal approval. Upon receipt of federal approval of the program, the department shall notify the president of the senate, speaker of the house of representatives, and relevant standing committees of the senate and the house of representatives. After approval is received and before the convening of the next regular session of the legislature in which the proposal could be funded, the department shall submit to all parties a proposal for program implementation and program funding.

§321-N Rules. The department shall adopt rules pursuant to chapter 91 for the purposes of effectuating this part."

SECTION 2. There is appropriated out of the general revenues of the State of Hawaii the sum of $ or so much thereof as may be necessary for fiscal year 2024-2025 for the purposes of implementing and administering the Canadian prescription drug importation program.

The sum appropriated shall be expended by the department of health for the purposes of this Act.

SECTION 3. In accordance with section 9 of article VII of the Hawaii State Constitution and sections 37-91 and 37-93, Hawaii Revised Statutes, the legislature has determined that the appropriations contained in H.B. No. , will cause the state general fund expenditure ceiling for fiscal year 2024-2025 to be exceeded by $ or per cent. In addition, the appropriation contained in this Act will cause the general fund expenditure ceiling for fiscal year 2024-2025 to be further exceeded by $ or per cent. The combined total amount of general fund appropriations contained in only these two Acts will cause the state general fund expenditure ceiling for fiscal year 2024-2025 to be exceeded by $ or per cent. The reasons for exceeding the general fund expenditure ceiling are that:

(1) The appropriation made in this Act is necessary to serve the public interest; and

(2) The appropriation made in this Act meets the needs addressed by this Act.

SECTION 4. If any provision of this Act, or the application thereof to any person or circumstance, is held invalid, the invalidity does not affect other provisions or

applications of the Act that can be given effect without the invalid provision or application, and to this end the provisions of this Act are severable.

SECTION 5. This Act shall take effect upon its approval.

INTRODUCED BY: _____

JAN 19 2024

H.B. NO. 1979

Report Title:
Canadian Prescription Drug Importation Program; DOH; Appropriation; Expenditure Ceiling

Description:
Establishes the Canadian Prescription Drug Importation Program to be implemented and administered by the Department of Health. Requires the Department of Health to obtain federal approval, make reports, and adopt rules. Appropriates funds.

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