THE SENATE
THIRTIETH LEGISLATURE, 2020
STATE OF HAWAII

S.B. NO. 2444

JAN 17 2020

A BILL FOR AN ACT

RELATING TO THE CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM.

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

SECTION 1. The legislature finds that United States consumers pay more for their prescription drugs than any other developed country in the world. The Canadian government has estimated that United States consumers pay twice as much as Canadians for patented prescription drugs and twenty per cent more for generics. In some cases, drugs sell for ten times as much in the United States than in Canada.

The legislature also finds that under the federal Medicare Modernization Act, a state may establish a wholesale drug importation program that imports and reimports prescription drugs from Canada by pharmacists or wholesalers; provided that the United States Secretary of Health and Human Services approves the program, certifies to Congress that implementation of the program with not pose additional risk to the public's health and safety, and will result in a significant reduction in the cost of covered products.

Therefore, the purpose of this Act is to:

(1) Establish a Canadian Prescription Drug Importation Program for the exclusive benefit of Hawaii residents, to be implemented and administered by the department of health, to provide Hawaii consumers access to safe and less expensive prescription drugs; and

(2) Make an appropriation to the department of health for the purposes of implementing and administering the program.

SECTION 2. The Hawaii Revised Statutes is amended by adding a new chapter to title 19 to be appropriately designated and to read as follows:

"CHAPTER

CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM

§ -1 **Short title.** This chapter may be cited as the Canadian Prescription Drug Importation Program Act.

§ -2 **Definitions.** As used in this chapter, unless the context otherwise requires:

"Canadian supplier" means a manufacturer, wholesale distributor, or pharmacy that is appropriately licensed or permitted under Canadian federal and provincial laws and

regulations to manufacture, distribute, or dispense prescription drugs.

"Department" means the department of health.

"Eligible importer" means an importer that is described in section -4.

"Federal Act" means the Federal Food, Drug, and Cosmetic Act, title 21 United States Code section 301, et seq.

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

"Pharmacist" means a person licensed under chapter 461 to practice pharmacy.

"Prescription drug" means a drug that:

(1) Is required by any applicable federal or state law or rule to be dispensed only pursuant to an order;

(2) Is restricted by any applicable federal or state law or rule to use by practitioners only; or

(3) Prior to being dispensed or delivered, is required under federal law to be labeled with one of the following statements:

(A) "Rx only"; or

(B) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

"Program" means the Canadian Prescription Drug Importation Program established under this chapter.

"Vendor" means a vendor with which the department contracts for the supervision of services under the program pursuant to section -3.

§ -3 **Canadian prescription drug importation program; established; importation process; contract with vendor; vendor duties.** (a) There is established within the department the Canadian prescription drug importation program. Upon receiving federal approval of the program as described in -5, the department shall contract with one or more vendors to provide services under the program. For three years following the effective date of this Act, the selection of any vendor pursuant to this section shall be exempt from chapter 103D.

(b) Each vendor, in consultation with the department and any other vendors, shall establish 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, each vendor shall consider, at minimum,

which prescription drugs will provide the greatest cost savings to the State, including prescription drugs for which there are shortages, specialty prescriptions drugs, and high-volume prescription drugs. Each vendor shall revise the list at least annually and at the direction of the department pursuant to subsection (c).

(c) The department shall review the wholesale prescription drug importation list at least every three months to ensure that it continues to meet the requirements of the program. The department may direct a vendor to review the list, as necessary.

(d) Each vendor, in consultation with the department, 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 wholesale prescription drug importation list. Each vendor shall 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. Each vendor shall contract with such eligible Canadian suppliers, or facilitate contracts between eligible importers

and Canadian suppliers, to import prescription drugs under the program.

(e) Each vendor shall assist the department in developing and administering a distribution program within the program.

(f) Each vendor shall assist the department with the annual report described in -6 and provide any information requested by the department for the report.

(g) Each vendor shall ensure the safety and quality of drugs imported under the program as follows:

(1) (A) For an initial imported shipment, 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; and

(B) For any subsequent imported shipment, ensure that a statistically valid sample of the shipment is tested for authenticity and degradation in a manner consistent with the Federal Act;

(2) Certify that each 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 title 21 United States Code section 352;

(3) 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; and

(4) 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.

(h) 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.

(i) Each vendor shall maintain a list of all eligible importers that participate in the program.

(j) Each vendor shall ensure compliance with Title II of the Federal Drug Quality and Security Act (Public Law 113-54),

by all Canadian suppliers, eligible importers, distributors, and other participants in the program.

(k) Each vendor shall provide an annual financial audit of its operations to the department. Each vendor shall also provide quarterly financial reports specific to the program and shall include information concerning the performance of its subcontractors and vendors. The director of health may adopt rules pursuant to chapter 91 to prescribe the form and contents of the financial reports.

(l) Each vendor shall submit evidence of a surety bond with any bid or initial contract negotiation documents and shall maintain documentation of evidence of such a bond with the department throughout the contract term. The surety bond may be from this State or any other state in the United States and must be in an amount of at least $25,000. The surety bond or comparable security arrangement must include the State of Hawaii as a beneficiary. In lieu of the surety bond, a vendor may provide a comparable security agreement, such as an irrevocable letter of credit or a deposit into a trust account or financial institution that includes the State of Hawaii as a beneficiary,

payable to the State of Hawaii. The purposes of the bond or other security arrangement are to:

(1) Ensure participation of the vendor in any civil or criminal legal action by the department, any other state agency, or private individuals or entities against the vendor because of the vendor's failure to perform under the contract, including but not limited to causes of action for personal injury, negligence, or wrongful death;

(2) Ensure payment by the vendor through the use of a bond or other comparable security arrangement of any legal judgments and claims that are awarded to the State, other entities acting on behalf of the State, individuals, or organizations if the vendor is assessed a final judgment or other monetary penalty in a court of law for a civil or criminal action under the program; provided that the bond or comparable security arrangement may be accessed if the vendor fails to pay any judgment or claim within sixty days after final judgment; and

(3) Allow for civil and criminal litigation claims to be made against the bond or other comparable security arrangements for up to one year after the vendor's contract under the program has ended with the department, the vendor's license or permit is no longer valid, or the program has ended, whichever occurs last.

(m) Each vendor shall maintain information and documentation submitted under this section for a period of at least seven years.

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

§ -4 Eligible prescription drugs; eligible Canadian suppliers; eligible importers; distribution requirements. (a) An eligible importer may import a prescription drug from a Canadian supplier if:

(1) The drug that is to be imported 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(6);

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

(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 public health.

(b) A Canadian supplier may export prescription drugs into the State under the program if the 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 pursuant to section -3; and

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

(c) The following entities are eligible importers and may obtain imported prescription drugs:

(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 for dispensing to inmates in the custody of the department of corrections;

(3) Commercial plans, as defined by rules adopted by the director of health pursuant to chapter 91, and as approved by the federal government; and

(4) A licensed Hawaii pharmacist or wholesaler approved by the department;

(d) The department shall designate an office or division that must be a licensed wholesale prescription drug distributor or that shall contract with a licensed wholesale prescription drug distributor pursuant to chapter 461.

(e) The office or division designated by the department pursuant to subsection (d) shall:

(1) Set a maximum profit margin so that a wholesaler, distributor, pharmacy, or other licensed provider participating in the program maintains a profit margin that is no greater than the profit margin that the wholesaler, distributor, pharmacy, or other licensed provider would have earned on the equivalent nonimported drug;

(2) Exclude generic products if the importation of the products would violate United States patent laws applicable to United States-branded products;

(3) Comply with the requirements of title 21 United States Code section 360eee through section 360eee-4 as enacted in Title II of the Federal Drug Quality and Security Act; and

(4) Determine a method for covering the administrative costs of the program, which method may include a fee imposed on each prescription drug sold through the program or any other appropriate method as determined by the department; provided that the department shall not require a fee in an amount that would significantly reduce consumer savings.

(f) Canadian suppliers and eligible importers participating under the program:

(1) Shall comply with the tracking and tracing requirements of title 21 United States Code section 360eee et seq.; and

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

(g) A participating eligible importer shall submit to the vendor all of the following information about each drug to be acquired by the importer under the program:

(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.

(h) A participating Canadian supplier shall submit to the vendor the following information about each drug to be supplied by the Canadian supplier under the program:

(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 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.

(i) The department shall immediately suspend the importation of a specific drug or the importation of drugs by a specific eligible importer if it discovers that any drug or activity is in violation of this section or any federal or state

law or regulation. The department may revoke the suspension if, after conducting an investigation, it determines that the public is adequately protected from counterfeit or unsafe drugs being imported in this State.

§ -5 **Federal approval.** (a) On or before September 1, 2021, 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. The department shall begin operating the program no later than six months after receiving such approval. The request must, at 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, effectiveness, misbranding, and adulteration;

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

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

(5) 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.

(b) The department may expend money for the purpose of requesting approval of the program as described in subsection (a) but the department shall not spend any other money to implement the program until the department receives approval of the program pursuant to this section.

(c) Upon receipt of federal approval of the program, the department shall notify the president of the senate and the speaker of the house of representatives, as well as the chair of the commerce, consumer protection, and health committee of the senate, and the health committee of the house of representatives, or any successor committees. After approval is received and before the start of the next regular session of the legislature in which the proposal could be funded, the department shall submit to all parties specified in this

subsection a proposal for program implementation and program funding.

§ -6 **Reports.** On or before December 1, 2022, and on or before December 1 each year thereafter, the department shall submit a report to the governor, the president of the senate, and the speaker of the house of representatives concerning the operation of the program during the previous fiscal year. The report must include, at a minimum:

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

(2) The number of participating Canadian suppliers and eligible importers;

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

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

(5) A description of the methodology used to determine which prescription drugs should be included on the wholesale prescription drug importation list established pursuant to section -3; and

(6) Documentation demonstrating how the program ensures that:

(A) The vendor verifies that Canadian suppliers participating in the program are in full compliance with relevant Canadian federal and provincial laws and regulations;

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

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

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

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

§ -7 **Program authorized; rules.** (a) Upon approval by the United States Secretary of Health and Human Services pursuant to section -5, the department shall administer the program.

(b) The department shall approve a method of financing the administrative costs of the program, which method may include imposing a fee on each prescription drug sold through the program or any other appropriate method determined by the department to finance administrative costs. The department shall not require a fee in an amount that the department determines would significantly reduce consumer savings.

(c) The director of health shall adopt rules pursuant to chapter 91 necessary to carry out the purposes of this chapter."

SECTION 3. 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 2020-2021 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 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 on July 1, 2020.

INTRODUCED BY:

S.B. NO. 2444

Report Title:
Canadian Prescription Drug Importation Program; Pharmaceutical Products; Prescription Drugs; Wholesale Imports; Department of Health; Reports; Appropriation

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.

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.