HOUSE BILL NO. 6476

November 09, 2022, Introduced by Rep. Steven Johnson and referred to the Committee on Health Policy.

A bill to provide for the establishment of a wholesale prescription drug importation program; to provide for the powers and duties of certain state and local governmental officers and entities; and to require the promulgation of rules.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 1. This act may be cited as the "prescription drug importation act".

Sec. 3. As used in this act:

(a) "Canadian supplier" means a manufacturer, wholesale

distributor, or pharmacy licensed or otherwise permitted under Canadian federal and provincial law to manufacture, distribute, or dispense a prescription drug.

(b) "Department" means the Michigan department of health and human services.

(c) "Eligible Canadian supplier" means a Canadian supplier that the vendor determines meets the requirements described in section 11.

(d) "Eligible importer" means a pharmacist or state wholesaler that is employed by or under contract with the department.

(e) "Federal act" means the federal food, drug, and cosmetic act, 21 USC 301 to 399i.

(f) "Pharmacist" means that term as defined in section 17707 of the public health code, 1978 PA 368, MCL 333.17707.

(g) "Prescription drug" means that term as defined in section 17708 of the public health code, 1978 PA 368, MCL 333.17708, except that it only includes drugs that are intended for use in human beings.

(h) "Program" means the prescription drug importation program established by the department under this act.

(i) "State wholesaler" means a wholesale distributor as that term is defined in section 17709 of the public health code, 1978 PA 368, MCL 333.17709.

(j) "Tracking-and-tracing requirement" means the product-tracing process for the components of the pharmaceutical distribution supply chain as described in the drug quality and security act and drug supply chain security act, Public Law 113-54.

(k) "Vendor" means the entity with which the department has entered into a contract under section 7 to manage and provide

services under the program.

(*l*) "Wholesale prescription drug importation list" means the wholesale prescription drug list developed under section 7.

Sec. 5. (1) The department shall establish a prescription drug importation program for the purposes of importing safe and effective drugs from Canada.

(2) Subject to subsection (3), by January 1, 2024, the department shall submit a request to the United States Secretary of the federal Department of Health and Human Services for approval of the program under 21 USC 384.

(3) The request submitted under subsection (2) must, at a minimum, contain all of the following:

(a) A description of the department's plan for operating the program.

(b) An explanation of how each prescription drug imported into this state under the program will meet applicable state and federal standards for safety and effectiveness.

(c) An explanation of how each prescription drug imported into this state under the program will comply with tracking-and-tracing requirements.

(d) A list of proposed prescription drugs that have the highest potential for cost savings to this state through importation at the time that the request is submitted.

(e) An estimate of the total cost savings attributable to the program.

(f) The cost of implementing the program to this state.

(g) A list of each potential Canadian supplier from which this state may import drugs and documentation demonstrating that each potential Canadian supplier is in compliance with applicable

federal and state laws and Canadian federal and provincial laws.

(4) If the department receives notice of federal approval of the program, the department shall do all of the following:

(a) Immediately notify the senate majority leader, the speaker of the house of representatives, and each standing committee on health policy of the approval.

(b) Begin operating the program within 180 days after the date on which the department receives notice of the approval.

Sec. 7. (1) If the United States Secretary of the federal Department of Health and Human Services approves the program, the department shall contract with a vendor to manage and provide services under the program.

(2) The vendor shall comply with all of the following:

(a) Subject to section 9, by January 1, 2024, and each year after that, develop in consultation with the department a wholesale prescription drug importation list that identifies each prescription drug that may be imported into this state under the program. In developing the list, the vendor shall consider, at a minimum, which prescription drugs are available for sale at retail for less in Canada than in this state and provide the greatest cost savings to this state, 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 3 months to ensure that it meets the requirements of the program and may direct the vendor to revise the list if the department considers it necessary.

(b) Develop and maintain a list identifying each eligible Canadian supplier.

(c) Contract with 1 or more eligible Canadian suppliers to

import prescription drugs under the program or facilitate contracts between eligible importers and eligible Canadian suppliers to import prescription drugs under the program.

(d) Ensure that, as a condition of participating in the program, each eligible Canadian supplier and eligible importer complies with the requirements of the program, the drug quality and security act, Public Law 113-54, and tracking-and-tracing requirements, and does not distribute, dispense, or sell prescription drugs imported under the program outside of this state.

(e) Assist the department in preparing the report required under section 19, and provide to the department any information that the department considers relevant to the report on the department's request.

(f) Provide an annual financial audit of the vendor's operations and a quarterly financial report on the program to the department in a form and manner required by the department. The documents required under this subdivision must contain any information that the department considers necessary. However, each quarterly financial report must include information on the performance of any subcontractor of the vendor.

(3) 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, an employee of the vendor, or a subcontractor of the vendor.

Sec. 9. A prescription drug must not be imported into this state under the program unless all of the following are met:

(a) Importing the prescription drug would not violate federal

patent laws.

(b) Importing the prescription drug is expected to generate a cost savings to this state.

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

(d) The prescription drug is not any of the following:

(*i*) A controlled substance as that term is defined in section 7104 of the public health code, 1978 PA 368, MCL 333.7104.

(*ii*) A biological product as that term is defined in 42 USC 262.

(*iii*) An infused drug.

(*iv*) A drug that is intravenously injected.

(*v*) A drug that is inhaled during surgery.

(*vi*) A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of the federal Department of Health and Human Services to pose a threat to public health.

Sec. 11. A Canadian supplier is eligible to participate in the program if all of the following apply:

(a) The vendor determines that the Canadian supplier is in compliance with the federal act and relevant Canadian federal and provincial laws.

(b) The Canadian supplier has agreed to export a prescription drug identified on the wholesale prescription drug importation list at a price that will provide a cost savings to this state.

(c) The vendor determines that the Canadian supplier complies with tracking-and-tracing requirements and meets the requirements of the program.

(d) The Canadian supplier submits to the vendor an attestation that the Canadian supplier has a registered agent in the United States and includes on the attestation the name and United States address of the registered agent.

Sec. 13. An eligible importer may import a prescription drug identified on the wholesale prescription drug importation list from an eligible Canadian supplier pursuant to a contract entered into under the program.

Sec. 15. (1) The vendor shall ensure the safety and quality of each prescription drug imported under the program by complying with all of the following:

(a) For an initial imported shipment of a specific prescription drug by an eligible importer, ensuring that each batch of the prescription drug in the shipment is statistically sampled and tested for authenticity and degradation in a manner consistent with the federal act and for each subsequent shipment of the prescription drug by the eligible importer, ensuring that a statistically valid sample of the shipment is tested for authenticity and degradation in a manner consistent with the federal act.

(b) Certifying that the prescription drug is approved for marketing in the United States, is not adulterated or misbranded, and meets the labeling requirements of 21 USC 352.

(c) Ensuring that each test required by this section is conducted in a laboratory that meets the standards under the federal act and any other applicable federal and state law governing laboratory qualifications for drug testing and maintaining documentation demonstrating that each test was conducted at a laboratory described in this subdivision.

(d) Maintaining laboratory records, including complete data derived from each test necessary to ensure that a prescription drug is in compliance with this section.

(2) An eligible importer that is participating in the program shall submit to the vendor all of the following information for each prescription drug that is imported under the program:

(a) The name and quantity of the active ingredient of the prescription drug.

(b) A description of the dosage form of the prescription drug.

(c) The date on which the prescription drug is shipped.

(d) The quantity of the prescription drug that is shipped.

(e) The point of origin and destination of the prescription drug.

(f) The price paid by the eligible importer for the prescription drug.

(g) Any other information that the department considers necessary to ensure the protection of the public health.

(3) An eligible Canadian supplier that is participating in the program shall submit to the vendor all of the following information for each prescription drug that is imported under the program:

(a) The original source of the prescription drug, including, but not limited to, each of the following:

(*i*) The name of the manufacturer of the prescription drug.

(*ii*) The date on which the prescription drug was manufactured.

(*iii*) The country, state or province, and city where the prescription drug was manufactured.

(b) The date on which the prescription drug is shipped.

(c) The quantity of the prescription drug that is shipped.

(d) The quantity of each lot of the prescription drug

originally received by the eligible Canadian supplier and the source of the lot.

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

(f) Any other information that the department considers necessary to ensure the protection of the public health.

(4) The vendor shall maintain information received by it under subsections (2) and (3) for at least 7 years.

Sec. 17. The department shall immediately suspend the importation of a specific prescription drug or the importation of a prescription drug by an eligible importer if the department determines that the prescription drug or the activity is in violation of a requirement of the program or a federal or state law. The department may revoke the suspension if, after conducting an investigation, the department determines that the public is adequately protected from counterfeit or unsafe prescription drugs being imported into this state.

Sec. 19. By October 1, 2024 and annually after that, the department shall submit a report to the governor, the senate majority leader, 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, all of the following:

(a) A list of each prescription drug that was imported under the program.

(b) The number of Canadian suppliers and eligible importers participating in the program.

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

(d) The estimated cost savings during the previous fiscal year and to date that are attributable to the program.

(e) A description of the methodology used to determine which prescription drugs are included on the wholesale prescription drug importation list.

(f) Documentation as to how the program ensures all of the following:

(*i*) That each eligible Canadian supplier participating in the program is of high quality, high performance, and in compliance with relevant Canadian federal and provincial laws and all federal and state laws.

(*ii*) The prescription drugs imported under the program are not shipped, sold, or dispensed outside of this state once in the possession of an eligible importer.

(*iii*) That prescription drugs imported under the program are pure, unadulterated, potent, and safe.

(*iv*) That the program does not put a consumer at a higher health and safety risk than if the program did not exist.

(*v*) That the program provides cost savings to this state on imported prescription drugs.

Sec. 21. The department shall promulgate rules under the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328, to implement this act.

Enacting section 1. This act takes effect 90 days after the date it is enacted into law.