HOUSE BILL NO. 6477

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

A bill to provide for the establishment of an international 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 "international prescription drug importation act".

Sec. 3. As used in this act:

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

(b) "Eligible exporter" means an exporter that meets the requirements described in section 7(2).

(c) "Eligible importer" means an importer that meets the requirements described in section 7(1).

(d) "Exporter" means an international export pharmacy, international manufacturer, or an international wholesale distributor.

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

(f) "Foreign recipient" means an entity other than the original prescription drug manufacturer that receives the prescription drug from the manufacturer before it is imported into this state under the program.

(g) "Importer" means a state wholesale distributor, state pharmacy, or state pharmacist.

(h) "International export pharmacy" means a pharmacy that is located outside of the United States and is licensed under part 177 of the public health code, 1978 PA 368, MCL 333.17701 to 333.17780.

(i) "International manufacturer" means a prescription drug manufacturer that is located outside of the United States and is licensed under part 177 of the public health code, 1978 PA 368, MCL 333.17701 to 333.17780.

(j) "International wholesale distributor" means a prescription drug wholesale distributor that is located outside of the United States and is licensed under part 177 of the public health code, 1978 PA 368, MCL 333.17701 to 333.17780.

(k) "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 prescription drugs that are intended for use

in human beings.

(*l*) "Program" means the international wholesale prescription drug importation program developed by the department under this act.

(m) "State pharmacist" means a pharmacist as that term is defined in section 17707 of the public health code, 1978 PA 368, MCL 333.17707.

(n) "State pharmacy" means a pharmacy as that term is defined in section 17707 of the public health code, 1978 PA 368, MCL 333.17707.

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

(p) "Wholesale prescription drug importation list" means the wholesale prescription drug importation list developed under section 5.

Sec. 5. (1) Subject to subsection (4) and this act, by January 1, 2023, the department shall develop and implement an international wholesale prescription drug importation program for the purposes of importing safe and effective drugs from foreign nations with which the United States has a mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism that recognizes the foreign nation's adherence to good manufacturing practice regulations for pharmaceutical products under 21 CFR parts 210 and 211.

(2) In developing the program, the department shall create and maintain a wholesale prescription drug importation list that identifies each prescription drug that may be imported into this state under the program. The department shall review the wholesale

prescription drug importation list every 6 months and revise the list if the department considers it necessary. The department shall not include a prescription drug on the wholesale prescription drug importation list unless all of the following are met:

(a) The prescription drug is one that has been identified by the department under subsection (3).

(b) The department determines that the prescription drug meets the standards for safety, effectiveness, misbranding, and adulteration of the United States Food and Drug Administration.

(c) Importing the prescription drug would not violate federal patent laws.

(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*) An intravenously injected drug.

(*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.

(3) The department shall create and maintain a list identifying each prescription drug that retails for less in a foreign nation and that, if imported under the program, would provide a cost savings to this state. The department shall review the list described in this subsection every January and revise the list if the department considers it necessary.

(4) The department shall not implement the program unless the program is approved by or otherwise authorized under federal law.

Sec. 7. (1) An importer may import a prescription drug identified on the wholesale prescription drug importation list if the importer registers with the department on a form and in a manner required by the department before importing the prescription drug into this state and the importer does not do any of the following as a condition of participating in the program:

(a) Distribute, sell, or dispense a prescription drug imported under the program to any person residing outside of this state.

(b) Violate this act or any rule promulgated under this act.

(2) An exporter may export a prescription drug identified on the wholesale prescription drug importation list if the exporter registers with the department on a form and in a manner required by the department before exporting the prescription drug into this state and the exporter does not do any of the following as a condition of participating in the program:

(a) Distribute, sell, or dispense a prescription drug imported under the program to any person residing outside of this state.

(b) Violate this act or any rule promulgated under this act.

Sec. 9. (1) An eligible importer that imports prescription drugs into this state under the program shall submit all of the following to the department in a form and manner required by the department 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 importer for the prescription drug.

(g) Documentation from the exporter specifying each of the following:

(*i*) The original source of the prescription drug.

(*ii*) The quantity of each lot of the prescription drug originally received and the source of the lot.

(h) The lot or control number assigned to the prescription drug by its manufacturer.

(i) The name, address, telephone number, and license number of the importer.

(j) If the prescription drug is shipped directly by a foreign recipient, documentation demonstrating each of the following:

(*i*) That the prescription drug was received by the foreign recipient from the manufacturer and was subsequently shipped by the foreign recipient to the importer.

(*ii*) That the quantity of each lot of the prescription drug being imported into this state is not more than the quantity of each lot of the prescription drug that was received by the foreign recipient.

(*iii*) That each batch of the prescription drug in an initial imported shipment was statistically sampled and tested for authenticity and degradation.

(k) If the prescription drug is not shipped directly by a foreign recipient, documentation demonstrating that each batch of the prescription drug in each shipment offered for importation into this state was statistically sampled and tested for authenticity

and degradation.

(*l*) A statement certifying that the prescription drug is approved for marketing in the United States, is not adulterated or misbranded, and meets all of the labeling requirements of 21 USC 352.

(m) Any other information considered necessary by the department to ensure the protection of the public health.

(2) An eligible importer shall ensure that each test required by this section is performed at a laboratory described in section 13 and shall maintain records from the laboratory demonstrating compliance with this section.

Sec. 11. An eligible exporter that exports prescription drugs into this state under the program shall submit all of the following to the department in a form and manner required by the department:

(a) The original source of the 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 location, including the country, state or province, and city, where the prescription drug was manufactured.

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

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

(d) The quantity of each lot of the prescription drug originally received and from which source.

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

(f) The name, address, telephone number, and license number of the importer.

(g) Any other information considered necessary by the

department to ensure the protection of the public health.

Sec. 13. (1) The department shall create and maintain a list of each laboratory that meets standards under the federal act and that meets any other applicable federal and state law governing laboratory qualifications for drug testing.

(2) The department shall ensure that each batch of every shipment of a specific prescription drug being imported by an eligible importer under the program is statistically sampled and tested for authenticity and degradation by a laboratory identified by the department under this section and in a manner that is consistent with the federal act. The department may enter into 1 or more contractual agreements for the administration of this subsection.

(3) The department shall maintain any information received by it under sections 9 and 11 for not less than 7 years.

Sec. 15. 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 this act or a rule promulgated under this act. 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.

Sec. 17. 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.