HOUSE BILL NO. 5107

October 15, 2019, Introduced by Reps. Camilleri, Hood, Kennedy, Brixie, Stone, Rabhi, Chirkun, Sowerby, Ellison, Yancey, Haadsma, Tyrone Carter, Bolden, Hoadley, Garza, Sabo, Pohutsky, Robinson, Manoogian, Pagan, Hertel, Hope, Cynthia Johnson, Wittenberg, Shannon and Clemente and referred to the Committee on Health Policy.

A bill to allow 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 allow for the promulgation of rules.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 1. This act shall be known and may be cited as the "wholesale prescription drug importation act".

Sec. 3. As used in this act:

(a) "Canadian supplier" means a Canadian prescription drug

supplier that is regulated under the laws of Canada or a province of Canada.

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

(c) "Eligible importer" means a licensed drug wholesaler that contracts with the department under section 5.

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

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

(f) "Prescription drug" means that term as defined in section 17708 of the public health code, 1978 PA 368, MCL 333.17708.

(g) "Program" means the wholesale prescription drug importation program developed in section 5.

(h) "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.

Sec. 5. The department, in consultation with interested stakeholders and appropriate federal officials, shall develop a wholesale prescription drug importation program. The program must meet all of the following requirements:

(a) Comply with the applicable requirements of 21 USC 384, including requirements on safety and cost savings.

(b) Require the department to contract with a licensed drug wholesaler for the purposes of seeking federal certification and approval to import prescription drugs into this state.

(c) Require the use of a Canadian supplier.

(d) Ensure that only prescription drugs that meet safety, effectiveness, and other standards of the United States Food and Drug Administration are imported by or on behalf of this state.

(e) Ensure that only prescription drugs that are expected to generate substantial savings for consumers in this state are imported.

(f) Ensure that tracking-and-tracing requirements are complied with to the extent possible before imported prescription drugs come into the possession of an eligible importer and that tracking-and-tracing requirements are fully complied with after imported prescription drugs come into the possession of an eligible importer.

(g) Ensure that any prescription drug imported under the program is not distributed, dispensed, or sold outside of this state.

(h) Include an audit function and procedures for that function.

Sec. 7. (1) Before implementing the program and by October 1, 2020, the department shall seek certification of the program from the secretary of the United States Department of Health and Human Services. If the department receives certification of the program, the department shall begin implementing the program within 6 months from the date of the certification and shall do all of the following in implementing the program:

(a) Comply with the program requirements described in section 5.

(b) Develop a registration process for health insurers, pharmacies, and health care providers who administer prescription drugs, that are willing to participate in the program.

(c) Create and maintain a list of the price of each prescription drug that is imported under the program. The department shall make the list available to the public and the persons described in subdivision (b).

(d) Develop and implement an outreach and marketing plan to generate awareness about the program.

(e) Develop and implement a toll-free information hotline to answer questions about the program from consumers and the persons described in subdivision (b).

(f) Conduct any other activity that the department considers important for the successful implementation of the program.

(2) By October 1, 2020, the department shall also seek the appropriate federal approval, waiver, exemption, or agreement necessary to allow a covered entity enrolled in or eligible for the federal 340B program to participate in this state's program to the fullest extent possible without jeopardizing eligibility for the federal 340B program. As used in this subsection, "federal 340B program" means the 340B drug pricing program established under section 602 of the veterans health care act of 1992, Public Law 102-585.

Sec. 9. By the first March 1 after the date of the program's implementation, and annually after that, the department shall submit a report to the senate and house of representatives standing committees on health policy on the operation of the program during the previous calendar year. The report must include all of the following information for the calendar year covered by the report:

(a) A list of each prescription drug that was included in the program.

(b) The number of pharmacies, health care providers, and

health insurance plans that participated in the program.

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

(d) The estimated cost savings to consumers, health insurers, employers, and this state. The report must also include the total estimated cost savings to consumers, health insurance plans, employers, and this state since the date of the program's implementation.

(e) Information on the implementation of the auditing procedure developed by the department and any audit findings.

(f) Any other information that the department considers relevant.

Sec. 11. The department shall consult with the department of the attorney general to identify the potential for and to monitor anticompetitive behavior in industries that are affected by a wholesale prescription drug importation program.

Sec. 13. The department may promulgate rules under the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328, to implement this act.