SENATE BILL NO. 525

September 12, 2019, Introduced by Senators JOHNSON, IRWIN, RUNESTAD, ANANICH, HERTEL, LUCIDO, POLEHANKI, BAYER and HOLLIER and referred to the Committee on Health Policy and Human Services.

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 "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.

Sec. 5. The department, in consultation with interested stakeholders and appropriate federal officials, may 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 the program does not import generic

prescription drugs that would violate federal patent laws on brand name prescription drugs in the United States.

(f) Ensure that only prescription drugs that are expected to result in a significant reduction in the cost of those prescription drugs to consumers in this state are imported.

(g) Ensure that the tracking and tracing requirements of 21 USC 360eee and 360eee-1 are complied with to the extent possible before imported prescription drugs come into the possession of an eligible importer and that the tracking and tracing requirements of 21 USC 360eee and 360eee-1 are fully complied with after imported prescription drugs come into the possession of an eligible importer.

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

(i) Establish policies and procedures for record keeping and that allow for a periodic audit of the records to ensure the department's compliance with this section.

Sec. 7. (1) Before implementing the program, the department shall seek certification of the program from the secretary of the United States Department of Health and Human Services and, upon receiving the certification, 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 wholesale acquisition

cost of each prescription drug that is imported under the program. The department shall make the list available to the public and the entities described in subdivision (b).

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

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

(2) 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. (1) Beginning on the first January 15 after the date of the program's implementation, and annually after that, the department shall do all of the following:

(a) Prepare a report on the operation of the program during the previous calendar year.

(b) Publish the report described in subdivision (a) on the department's website in a location that is available to the public.

(c) Submit a copy of the report described in subdivision (a) to the senate and house of representatives standing committees on health policy.

(2) The report described in subsection (1) 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.