

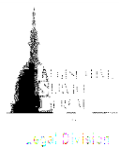
# HOUSE BILL NO. 5107

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:**

- 1           Sec. 1. This act shall be known and may be cited as the
- 2 "wholesale prescription drug importation act".
- 3           Sec. 3. As used in this act:
- 4           (a) "Canadian supplier" means a Canadian prescription drug



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

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

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

7 (d) "Licensed drug wholesaler" means a wholesale distributor  
8 as that term is defined in section 17709 of the public health code,  
9 1978 PA 368, MCL 333.17709.

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

12 (f) "Prescription drug" means that term as defined in section  
13 17708 of the public health code, 1978 PA 368, MCL 333.17708.

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

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

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

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

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

29 (c) Require the use of a Canadian supplier.



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

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

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

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

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

18 Sec. 7. (1) Before implementing the program and by October 1,  
19 2020, the department shall seek certification of the program from  
20 the secretary of the United States Department of Health and Human  
21 Services. If the department receives certification of the program,  
22 the department shall begin implementing the program within 6 months  
23 from the date of the certification and shall do all of the  
24 following in implementing the program:

25 (a) Comply with the program requirements described in section  
26 5.

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



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

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

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

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

12 (2) By October 1, 2020, the department shall also seek the  
13 appropriate federal approval, waiver, exemption, or agreement  
14 necessary to allow a covered entity enrolled in or eligible for the  
15 federal 340B program to participate in this state's program to the  
16 fullest extent possible without jeopardizing eligibility for the  
17 federal 340B program. As used in this subsection, "federal 340B  
18 program" means the 340B drug pricing program established under  
19 section 602 of the veterans health care act of 1992, Public Law  
20 102-585.

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

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

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



1 health insurance plans that participated in the program.

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

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

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

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

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

16 Sec. 13. The department may promulgate rules under the  
17 administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to  
18 24.328, to implement this act.

