

HOUSE BILL NO. 4978

September 17, 2019, Introduced by Reps. Brann and 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:

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

3 Sec. 3. As used in this act:

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



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

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

6 (c) "Eligible Canadian supplier" means a Canadian supplier
7 that the vender determines meets the requirements described in
8 section 11.

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

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

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

15 (g) "Prescription drug" means that term as defined in section
16 17708 of the public health code, 1978 PA 368, MCL 333.17708, except
17 that it only includes drugs that are intended for use in human
18 beings.

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

21 (i) "State wholesaler" means a wholesale distributor as that
22 term is defined in section 17709 of the public health code, 1978 PA
23 368, MCL 333.17709.

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

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



1 services under the program.

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

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

7 (2) Subject to subsection (3), by January 1, 2021, the
8 department shall submit a request to the United States Secretary of
9 the federal Department of Health and Human Services for approval of
10 the program under 21 USC 384.

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

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

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

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

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

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

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

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



1 federal and state laws and Canadian federal and provincial laws.

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

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

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

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

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

14 (a) Subject to section 9, by January 1, 2021, and each year
15 after that, develop in consultation with the department a wholesale
16 prescription drug importation list that identifies each
17 prescription drug that may be imported into this state under the
18 program. In developing the list, the vender shall consider, at a
19 minimum, which prescription drugs are available for sale at retail
20 for less in Canada than in this state and provide the greatest cost
21 savings to this state, including prescription drugs for which there
22 are shortages, specialty prescription drugs, and high-volume
23 prescription drugs. The department shall review the wholesale
24 prescription drug importation list every 3 months to ensure that it
25 meets the requirements of the program and may direct the vendor to
26 revise the list if the department considers it necessary.

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

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



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

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

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

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

22 (3) The department shall require a bond from the vendor to
23 mitigate the financial consequences of potential acts of
24 malfeasance or misfeasance or fraudulent or dishonest acts
25 committed by the vendor, an employee of the vendor, or a
26 subcontractor of the vendor.

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

29 (a) Importing the prescription drug would not violate federal



1 patent laws.

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

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

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

8 (i) A controlled substance as that term is defined in section
9 7104 of the public health code, 1978 PA 368, MCL 333.7104.

10 (ii) A biological product as that term is defined in 42 USC
11 262.

12 (iii) An infused drug.

13 (iv) A drug that is intravenously injected.

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

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

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

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

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

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



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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

18 Sec. 19. By October 1, 2021 and annually after that, the
19 department shall submit a report to the governor, the senate
20 majority leader, and the speaker of the house of representatives on
21 the operation of the program during the previous fiscal year. The
22 report must include, at a minimum, all of the following:

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

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

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

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



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

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

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

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

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

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

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

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

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

