

HOUSE BILL NO. 4979

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

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

3 Sec. 3. As used in this act:

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



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

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

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

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

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

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

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

19 (i) "International manufacturer" means a prescription drug
20 manufacturer that is located outside of the United States and is
21 licensed under part 177 of the public health code, 1978 PA 368, MCL
22 333.17701 to 333.17780.

23 (j) "International wholesale distributor" means a prescription
24 drug wholesale distributor that is located outside of the United
25 States and is licensed under part 177 of the public health code,
26 1978 PA 368, MCL 333.17701 to 333.17780.

27 (k) "Prescription drug" means that term as defined in section
28 17708 of the public health code, 1978 PA 368, MCL 333.17708, except
29 that it only includes prescription drugs that are intended for use



1 in human beings.

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

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

8 (n) "State pharmacy" means a pharmacy as that term is defined
9 in section 17707 of the public health code, 1978 PA 368, MCL
10 333.17707.

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

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

17 Sec. 5. (1) Subject to subsection (4) and this act, by January
18 1, 2021, the department shall develop and implement an
19 international wholesale prescription drug importation program for
20 the purposes of importing safe and effective drugs from foreign
21 nations with which the United States has a mutual recognition
22 agreement, cooperation agreement, memorandum of understanding, or
23 other federal mechanism that recognizes the nation's adherence to
24 good manufacturing practice regulations for pharmaceutical products
25 under 21 CFR parts 210 and 211.

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

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

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

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

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

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

13 (i) A controlled substance as that term is defined in section
14 7104 of the public health code, 1978 PA 368, MCL 333.7104.

15 (ii) A biological product as that term is defined in 42 USC
16 262.

17 (iii) An infused drug.

18 (iv) An intravenously injected drug.

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

20 (vi) A drug that is a parenteral drug, the importation of
21 which is determined by the United States Secretary of the federal
22 department of Health and Human Services to pose a threat to public
23 health.

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



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

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

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

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

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

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

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

21 Sec. 9. (1) An eligible importer that imports prescription
22 drugs into this state under the program shall submit all of the
23 following to the department in a form and manner required by the
24 department for each prescription drug that is imported under the
25 program:

26 (a) The name and quantity of the active ingredient of the
27 prescription drug.

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

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



- 1 (d) The quantity of the prescription drug that is shipped.
- 2 (e) The point of origin and destination of the prescription
3 drug.
- 4 (f) The price paid by the importer for the prescription drug.
- 5 (g) Documentation from the exporter specifying each of the
6 following:
- 7 (i) The original source of the prescription drug.
- 8 (ii) The quantity of each lot of the prescription drug
9 originally received and the source of the lot.
- 10 (h) The lot or control number assigned to the prescription
11 drug by its manufacturer.
- 12 (i) The name, address, telephone number, and license number of
13 the importer.
- 14 (j) If the prescription drug is shipped directly by a foreign
15 recipient, documentation demonstrating each of the following:
- 16 (i) That the prescription drug was received by the foreign
17 recipient from the manufacturer and was subsequently shipped by the
18 foreign recipient to the importer.
- 19 (ii) That the quantity of each lot of the prescription drug
20 being imported into this state is not more than the quantity of
21 each lot of the prescription drug that was received by the foreign
22 recipient.
- 23 (iii) That each batch of the prescription drug in an initial
24 imported shipment was statistically sampled and tested for
25 authenticity and degradation.
- 26 (k) If the prescription drug is not shipped directly by a
27 foreign recipient, documentation demonstrating that each batch of
28 the prescription drug in each shipment offered for importation into
29 this state was statistically sampled and tested for authenticity

1 and degradation.

2 (l) A statement certifying that the prescription drug is
3 approved for marketing in the United States, is not adulterated or
4 misbranded, and meets all of the labeling requirements of 21 USC
5 352.

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

8 (2) An eligible importer shall ensure that each test required
9 by this section is performed at a laboratory described in section
10 13 and shall maintain records from the laboratory demonstrating
11 compliance with this section.

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

15 (a) The original source of the drug, including, but not
16 limited to, each of the following:

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

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

19 (iii) The location, including the country, state or province,
20 and city, where the prescription drug was manufactured.

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

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

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

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

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

29 (g) Any other information considered necessary by the



1 department to ensure the protection of the public health.

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

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

14 (3) The department shall maintain any information received by
15 it under sections 9 and 11 for at least 7 years.

16 Sec. 15. The department shall immediately suspend the
17 importation of a specific prescription drug or the importation of a
18 prescription drug by an eligible importer if the department
19 determines that the prescription drug or the activity is in
20 violation of this act or a rule promulgated under this act. The
21 department may revoke the suspension if, after conducting an
22 investigation, it determines that the public is adequately
23 protected from counterfeit or unsafe prescription drugs being
24 imported into this state.

25 Sec. 17. The department shall promulgate rules under the
26 administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to
27 24.328, to implement this act.

