

HOUSE No. 1972

The Commonwealth of Massachusetts

PRESENTED BY:

Lenny Mirra

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act to permit the wholesale importation of prescription drugs into the Commonwealth.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
<i>Lenny Mirra</i>	<i>2nd Essex</i>	<i>1/15/2019</i>
<i>Michael S. Day</i>	<i>31st Middlesex</i>	<i>1/29/2019</i>
<i>Mathew J. Muratore</i>	<i>1st Plymouth</i>	<i>1/31/2019</i>
<i>Brian M. Ashe</i>	<i>2nd Hampden</i>	<i>2/1/2019</i>

HOUSE No. 1972

By Mr. Mirra of West Newbury, a petition (accompanied by bill, House, No. 1972) of Lenny Mirra and others relative to the wholesale importation of prescription drugs into the Commonwealth. Public Health.

The Commonwealth of Massachusetts

**In the One Hundred and Ninety-First General Court
(2019-2020)**

An Act to permit the wholesale importation of prescription drugs into the Commonwealth.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 SECTION 1. (a) For the purposes of this section:

2 1) “wholesale importation program” shall mean a state-administered wholesale
3 importation program where the state is the licensed wholesaler, importing drugs from a licensed,
4 regulated Canadian supplier, solely for distribution to voluntarily participating, state-licensed, in-
5 state pharmacies and administering providers for the exclusive purpose of dispensing state
6 residents with a valid prescription

7 2) “department” shall mean the executive office of health and human services

8 (b) Notwithstanding any general or special law to the contrary, the executive office of
9 health and human services, in consultation with interested stakeholders and appropriate federal
10 officials, shall design a wholesale prescription drug importation program that complies with the
11 applicable requirements of 21 U.S.C. 384, including the requirements regarding safety and cost
12 savings. The program design shall:

- 13 1) designate a state agency that shall either become a licensed drug wholesaler or
14 contract with a licensed drug wholesaler in order to seek federal certification and approval to
15 import safe prescription drugs and provide significant prescription drug cost savings to the
16 commonwealth's consumers;
- 17 2) use Canadian prescription drug suppliers regulated under laws of Canada or of
18 one or more Canadian provinces, or both;
- 19 3) include a process to sample the purity, chemical composition, and potency of the
20 imported products;
- 21 4) import only those prescription drugs expected to generate substantial savings for
22 the commonwealth's consumers;
- 23 5) ensure that only prescription drugs meeting the U.S. Food and Drug
24 Administration's safety, effectiveness, and other standards shall be imported by or on behalf of
25 the commonwealth;
- 26 6) ensure that the program complies with the tracking and tracing requirements of 21
27 U.S.C. 360eee and 360eee-1 to the extent feasible and practical prior to imported drugs coming
28 into the possession of the state wholesaler and that it complies fully after imported drugs are in
29 the possession of the state wholesaler;
- 30 7) prohibit the distribution, dispensing, or sale of imported products outside the
31 commonwealth's borders;

- 32 8) ensure the voluntary participant, state-licensed pharmacies and administering
33 providers charge individual consumers and health plans the actual acquisition cost of the
34 imported, dispensed product;
- 35 9) ensure health plan payment of the product component of pharmacy and provider
36 billing reimburses no more than the actual acquisition cost of the dispensed, imported product;
- 37 10) ensure participating health plans keep their formularies and claims payment
38 systems up to date with the prescription drugs provided through the wholesale importation
39 program;
- 40 11) ensure participating health plans base patient cost sharing on no more than the
41 actual acquisition cost of the dispensed, imported product;
- 42 12) recommend a charge per prescription or another method of support to ensure that
43 the program is funded adequately in a manner that does not jeopardize significant consumer
44 savings;
- 45 13) require participating health plans to demonstrate to the department how savings
46 on imported drugs are reflected in premiums;
- 47 14) enlist the assistance of the attorney general to identify the potential for
48 anticompetitive behavior in industries that would be affected by a program of importation;
- 49 15) limit the profit margin of any participating wholesaler and/or distributor(s) of
50 imported pharmaceutical products to a specified amount established by the department; and
- 51 16) ensure the program does not import generic products that would violate the U.S.
52 patent laws on U.S. branded products.

53 (c) The department shall enlist the assistance of the attorney general to identify the
54 potential for anticompetitive behavior in industries that would be affected by a program of
55 importation.

56 (d) The department shall submit the proposed design for a wholesale prescription drug
57 importation program to the house and senate committees on ways and means, the joint
58 committee on health care financing, and the clerks of the house of representatives and the senate
59 within [six months from the passage of this act].

60 (e) Upon approval of the importation program from the general court, the department
61 shall submit a formal request to the Secretary of the U.S. Department of Health and Human
62 Services for certification of the commonwealth's wholesale prescription drug importation
63 program. The department shall seek the appropriate federal approvals, waivers, exemptions, or
64 agreements, or a combination thereof, as needed to enable all covered entities enrolled in or
65 eligible for the federal 340B Drug Pricing Program to participate in the commonwealth's
66 wholesale prescription drug importation program to the fullest extent possible without
67 jeopardizing their eligibility for said drug pricing program.

68 (f) The department shall not implement the wholesale prescription drug importation
69 program until the general court enacts legislation establishing a charge per prescription or
70 another method of financial support for the program.

71 (g) Upon the last to occur of the general court enacting a method of financial support
72 pursuant to subsection (f) of this section and receipt of certification and approval by the U.S.
73 Department of Health and Human Services, the department shall begin implementation of the
74 wholesale prescription drug importation program and shall begin operating the program within

75 six months. As part of the implementation process, the department shall, in accordance with state
76 procurement and contracting and rules as appropriate:

77 1) become licensed as a wholesaler or enter into a contract with a state-licensed
78 wholesaler;

79 2) contract with one or more state-licensed distributors;

80 3) contract with one or more licensed and regulated Canadian suppliers;

81 4) engage with health insurance plans, employers, pharmacies, health care providers,
82 and consumers;

83 5) develop a registration process for health insurance plans, pharmacies, and
84 prescription drug-administering health care providers who are willing to participate in the
85 program;

86 6) create a publicly available source for listing the prices of imported prescription
87 drug products that shall be made available to all participating entities and consumers;

88 7) create an outreach and marketing plan to generate program awareness;

89 8) starting in the weeks before the program becomes operational, create and staff a
90 hotline to answer questions and address the needs of consumers, employers, health insurance
91 plans, pharmacies, health care providers, and other affected sectors;

92 9) establish the audit function and a two-year audit work-plan cycle; and

93 10) conduct any other activities that the department determines to be important for
94 successful implementation of the program.

95 (h) Biannually, commencing with either the first June or December after implementation,
96 whichever is the nearest date to the date that is six months following program implementation,
97 the department shall report to the house and senate committees on ways and means, the joint
98 committee on health care financing, and the clerks of the house of representatives and the senate
99 regarding the operation of the wholesale prescription drug importation program, including:

100 1) which prescription drugs were included in the wholesale importation program;

101 2) the number of participating pharmacies, health care providers, and health
102 insurance plans;

103 3) the number of prescriptions dispensed through the program;

104 4) the estimated savings to consumers, health plans, employers, and the
105 commonwealth during the previous calendar year and to date;

106 5) information regarding implementation of the audit plan and audit findings; and

107 6) any other information the department deems relevant.