

**HOUSE . . . . . No. 2377**

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**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>2/18/2021</i>

**HOUSE . . . . . No. 2377**

By Mr. Mirra of Georgetown, a petition (accompanied by bill, House, No. 2377) of Lenny Mirra relative to the wholesale importation of prescription drugs into the Commonwealth. Public Health.

[SIMILAR MATTER FILED IN PREVIOUS SESSION  
SEE HOUSE, NO. 1972 OF 2019-2020.]

**The Commonwealth of Massachusetts**

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**In the One Hundred and Ninety-Second General Court  
(2021-2022)**  
\_\_\_\_\_

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.