

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2023

A N A C T

RELATING TO FOOD AND DRUGS -- WHOLESALE PRESCRIPTION DRUG
IMPORTATION PROGRAM

Introduced By: Senators DiPalma, Miller, Pearson, DiMario, Valverde, and Goodwin

Date Introduced: February 01, 2023

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

1 SECTION 1. Title 21 of the General Laws entitled "FOOD AND DRUGS" is hereby
2 amended by adding thereto the following chapter:

3 CHAPTER 38

4 WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM

5 **21-38-1. Authorization.**

6 The wholesale prescription drug importation program, referred to in this chapter as the
7 ("program,") is established to provide for the wholesale importation of prescription drugs from
8 Canada by or on behalf of the state. The program shall be designed in accordance with the
9 requirements of this chapter. The program may not be implemented unless the state obtains
10 approval and certification, pursuant to § 21-38-2(c), from the United States Department of Health
11 and Human Services.

12 **21-38-2. Design of program.**

13 (a) Design requirements. The executive office of health and human services, in consultation
14 with appropriate federal and other state agencies, other states and interested parties, shall design
15 the program to comply with the applicable requirements of 21 U.S.C. § 384, including requirements
16 regarding safety and cost savings. The program design shall:

17 (1) Designate a state agency to become a licensed drug wholesaler or to contract with a
18 licensed drug wholesaler in order to seek federal certification and approval, pursuant to § 21-38-

1 2(c), to import safe prescription drugs and provide cost savings to consumers in the state;
2 (2) Use prescription drug suppliers in Canada regulated under the laws of Canada or of one
3 or more Canadian provinces, or both;
4 (3) Ensure that only prescription drugs meeting the federal Food and Drug Administration's
5 safety, effectiveness and other standards are imported by or on behalf of the state;
6 (4) Import only those prescription drugs expected to generate substantial cost savings for
7 consumers in the state;
8 (5) Ensure that the program complies with the transaction and tracing requirements of 21
9 U.S.C. §§ 360eee and 360eee-1 to the extent feasible and practical prior to imported prescription
10 drugs coming into the possession of the licensed drug wholesaler and that the program complies
11 fully with those federal requirements after imported prescription drugs are in the possession of the
12 licensed drug wholesaler;
13 (6) Consider whether the program may be developed on a multistate basis through
14 collaboration with other states;
15 (7) Prohibit the distribution, dispensing or sale of imported prescription drugs outside of
16 the state;
17 (8) Recommend a charge per prescription or another method of financing to ensure that the
18 program is adequately funded in a manner that does not jeopardize significant cost savings to
19 consumers, including adequate funding for the initial start-up costs of the program;
20 (9) Apply for and receive funds, grants or contracts from public and private sources; and
21 (10) Include an audit function.
22 (b) Rules. The executive office of health and human services shall adopt and promulgate
23 rules and regulations to design the program in accordance with the requirements of subsection (a)
24 of this section no later than January 1, 2024.
25 (c) Request for federal approval and certification. The executive office of health and human
26 services shall submit a request for approval and certification of the program to the United States
27 Department of Health and Human Services no later than May 1, 2024.
28 **21-38-3. Implementation.**
29 (a) Implementation of operation. Upon receipt of federal approval and certification under
30 § 21-38-2(c), the state agency designated to oversee the program pursuant to this chapter shall
31 implement the program as required in subsection (b) of this section. The program shall begin
32 operating no later than six (6) months following receipt of federal approval and certification.
33 (b) Requirements. Prior to operating the program, the state agency designated to oversee
34 the program pursuant to this chapter shall:

- 1 (1) Become a licensed drug wholesaler or enter into a contract with a licensed drug
2 wholesaler in the state;
- 3 (2) Contract with one or more distributors licensed in the state;
- 4 (3) Contract with one or more licensed and regulated prescription drug suppliers in Canada;
- 5 (4) Consult with health insurance carriers, employers, pharmacies, pharmacists, health care
6 providers and consumers;
- 7 (5) Develop a registration process for health insurance carriers, pharmacies and health care
8 providers authorized to prescribe and administer prescription drugs that are willing to participate
9 in the program;
- 10 (6) Create a publicly accessible website for listing the prices of prescription drugs to be
11 imported under the program;
- 12 (7) Create an outreach and marketing plan to generate public awareness of the program;
- 13 (8) Provide a telephone hotline to answer questions and address needs of consumers,
14 employers, health insurance carriers, pharmacies, health care providers and others affected by the
15 program;
- 16 (9) Develop a two (2) year audit work plan; and
- 17 (10) Conduct any other activity determined necessary to successfully implement and
18 operate the program.

19 **21-38-4. Annual reporting.**

20 Beginning January 2025, and annually thereafter, the executive office of health and human
21 services, or other state agency designated to oversee the program pursuant to this chapter, shall
22 report to the speaker of the house and president of the senate regarding the implementation and
23 operation of the program during the previous calendar year, including:

- 24 (1) The prescription drugs included in the program;
- 25 (2) The number of participating pharmacies, health care providers and health insurance
26 carriers;
- 27 (3) The number of prescription drugs dispensed through the program;
- 28 (4) The estimated cost savings to consumers, health insurance carriers, employers and the
29 state during the previous calendar year and to date;
- 30 (5) Information regarding implementation of the audit work plan and audit findings; and
- 31 (6) Any other information the executive office of health and human services, or other state
32 agency designated to oversee the program pursuant to this chapter, considers relevant.

1 SECTION 2. This act shall take effect upon passage.

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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF

A N A C T

RELATING TO FOOD AND DRUGS -- WHOLESALE PRESCRIPTION DRUG
IMPORTATION PROGRAM

1 This act would establish the Wholesale Prescription Drug Importation Program for the
2 importation of wholesale prescription drugs from Canada to provide savings to Rhode Island
3 consumers. The program would require the designation of a state agency to become a licensed drug
4 wholesaler, or to contract with a licensed drug wholesaler, use of prescription drug suppliers in
5 Canada; ensure that only drugs approved by the US Food and Drug Administration are imported;
6 and import only drugs expected to generate savings; and prohibit the distribution or sale of these
7 drugs outside of Rhode Island.

8 This act would take effect upon passage.

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