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S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2021

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A N A C T

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

Introduced By: Senators DiPalma, Gallo, Felag, Coyne, and Algiere

Date Introduced: March 04, 2021

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

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

CHAPTER 38

WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM

21-38-1. Authorization.

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

21-38-2. Design of program.

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

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

2(c), to import safe prescription drugs and provide cost savings to consumers in the state;

(2) Use prescription drug suppliers in Canada regulated under the laws of Canada or of one or more Canadian provinces, or both;

(3) Ensure that only prescription drugs meeting the federal Food and Drug Administration's safety, effectiveness and other standards are imported by or on behalf of the state;

(4) Import only those prescription drugs expected to generate substantial cost savings for consumers in the state;

(5) Ensure that the program complies with the transaction and tracing requirements of 21 U.S.C. §§ 360eee and 360eee-1 to the extent feasible and practical prior to imported prescription drugs coming into the possession of the licensed drug wholesaler and that the program complies fully with those federal requirements after imported prescription drugs are in the possession of the licensed drug wholesaler;

(6) Consider whether the program may be developed on a multistate basis through collaboration with other states;

(7) Prohibit the distribution, dispensing or sale of imported prescription drugs outside of the state;

(8) Recommend a charge per prescription or another method of financing to ensure that the program is adequately funded in a manner that does not jeopardize significant cost savings to consumers, including adequate funding for the initial start-up costs of the program;

(9) Apply for and receive funds, grants or contracts from public and private sources; and

(10) Include an audit function.

(b) Rules. The executive office of health and human services shall adopt and promulgate rules and regulations to design the program in accordance with the requirements of subsection (a) of this section no later than January 1, 2022.

(c) Request for federal approval and certification. The executive office of health and human services shall submit a request for approval and certification of the program to the United States Department of Health and Human Services no later than May 1, 2022.

21-38-3. Implementation.

(a) Implementation of operation. Upon receipt of federal approval and certification under § 21-38-2(c), the state agency designated to oversee the program pursuant to this chapter shall implement the program as required in subsection (b) of this section. The program must begin operating no later than six (6) months following receipt of federal approval and certification.

(b) Requirements. Prior to operating the program, the state agency designated to oversee the program pursuant to this chapter shall:

(1) Become a licensed drug wholesaler or enter into a contract with a licensed drug wholesaler in the state;

(2) Contract with one or more distributors licensed in the state;

(3) Contract with one or more licensed and regulated prescription drug suppliers in Canada;

(4) Consult with health insurance carriers, employers, pharmacies, pharmacists, health care providers and consumers;

(5) Develop a registration process for health insurance carriers, pharmacies and health care providers authorized to prescribe and administer prescription drugs that are willing to participate in the program;

(6) Create a publicly accessible website for listing the prices of prescription drugs to be imported under the program;

(7) Create an outreach and marketing plan to generate public awareness of the program;

(8) Provide a telephone hotline to answer questions and address needs of consumers, employers, health insurance carriers, pharmacies, health care providers and others affected by the program;

(9) Develop a two (2) year audit work plan; and

(10) Conduct any other activity determined necessary to successfully implement and operate the program.

21-38-4. Annual reporting.

Beginning January 2023, and annually thereafter, the executive office of health and human services, or other state agency designated to oversee the program pursuant to this chapter, shall report to the speaker of the house and president of the senate regarding the implementation and operation of the program during the previous calendar year, including:

(1) The prescription drugs included in the program;

(2) The number of participating pharmacies, health care providers and health insurance carriers;

(3) The number of prescription drugs dispensed through the program;

(4) The estimated cost savings to consumers, health insurance carriers, employers and the state during the previous calendar year and to date;

(5) Information regarding implementation of the audit work plan and audit findings; and

(6) Any other information the executive office of health and human services, or other state agency designated to oversee the program pursuant to this chapter, considers relevant.

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

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This act would create the wholesale prescription drug importation program which allows for the wholesale importation of prescription drugs from Canada by or on behalf of the state.

This act would take effect upon passage.

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