129th MAINE LEGISLATURE

FIRST REGULAR SESSION-2019

Legislative Document **No. 1272**

S.P. 392 In Senate, March 14, 2019

An Act To Increase Access to Low-cost Prescription Drugs

Reference to the Committee on Health Coverage, Insurance and Financial Services suggested and ordered printed.

DAREK M. GRANT
Secretary of the Senate

Presented by President JACKSON of Aroostook.
Cosponsored by Speaker GIDEON of Freeport and
Senators: CLAXTON of Androscoggin, MOORE of Washington, VITELLI of Sagadahoc,
Representatives: FECTEAU of Biddeford, FOLEY of Biddeford, MASTRACCIO of Sanford, PERRY of Calais, TEPLER of Topsham.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 5 MRSA c. 167 is enacted to read:

CHAPTER 167

WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM

§2041. 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 section 2042, subsection 3, from the United States Department of Health and Human Services.

§2042. Design of program

1. Design requirements. The Department of Health and Human Services, in consultation with appropriate federal and other state agencies and interested parties, shall design the program to comply with the applicable requirements of 21 United States Code, Section 384, including requirements regarding safety and cost savings. The program design must:

A. 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 section 2042, subsection 3, to import safe prescription drugs and provide cost savings to consumers in the State;

B. Use prescription drug suppliers in Canada regulated under the laws of Canada or of one or more Canadian provinces, or both;

C. 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;

D. Import only those prescription drugs expected to generate substantial cost savings for consumers in the State;

E. Ensure that the program complies with the transaction and tracing requirements of 21 United States Code, Sections 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;

F. Prohibit the distribution, dispensing or sale of imported prescription drugs outside of the State;

G. 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; and

H. Include an audit function.

2. Rules. The Department of Health and Human Services shall adopt rules to design the program in accordance with the requirements of subsection 1 no later than January 1, 2020. Rules adopted pursuant to this subsection are major substantive rules as defined in chapter 375, subchapter 2-A.

3. Request for federal approval and certification. The Department 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, 2020.

§2043. Implementation

1. Implementation; operation. Upon receipt of federal approval and certification under section 2042, subsection 3, the state agency designated to oversee the program pursuant to this chapter shall implement the program as required in subsection 2. The program must begin operating no later than 6 months following receipt of federal approval and certification.

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

A. Become a licensed drug wholesaler or enter into a contract with a licensed drug wholesaler in the State;

B. Contract with one or more distributors licensed in the State;

C. Contract with one or more licensed and regulated prescription drug suppliers in Canada;

D. Consult with health insurance carriers, employers, pharmacies, pharmacists, health care providers and consumers;

E. 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;

F. Create a publicly accessible website for listing the prices of prescription drugs to be imported under the program;

G. Create an outreach and marketing plan to generate public awareness of the program;

H. 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;

I. Develop a 2-year audit work plan; and

J. Conduct any other activity determined necessary to successfully implement and operate the program.

§2044. Annual reporting

Beginning January 2021, and annually thereafter, the Department of Health and Human Services, or other state agency designated to oversee the program pursuant to this chapter, shall report to the joint standing committee of the Legislature having jurisdiction over health coverage and prescription drugs regarding the implementation and operation of the program during the previous calendar year, including:

1. Prescription drugs included. The prescription drugs included in the program;

2. Participation. The number of participating pharmacies, health care providers and health insurance carriers;

3. Prescriptions dispensed. The number of prescription drugs dispensed through the program;

4. Estimated savings. The estimated cost savings to consumers, health insurance carriers, employers and the State during the previous calendar year and to date;

5. Audit findings. Information regarding implementation of the audit work plan and audit findings; and

6. Other relevant information. Any other information the Department of Health and Human Services, or other state agency designated to oversee the program pursuant to this chapter, considers relevant.

SUMMARY

This bill establishes a wholesale importation program for prescription drugs from Canada by or on behalf of the State in order to provide cost savings to consumers. The bill requires the Department of Health and Human Services to design the program through rulemaking by January 1, 2020. The rules are designated as major substantive and must be submitted to the Legislature for final approval. The bill also specifies that the program may not be implemented until the State has received federal approval and certification. The bill directs the Department of Health and Human Services to apply for federal approval no later than May 1, 2020.