



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.

A handwritten signature in black ink, appearing to read 'D M Grant'.

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: FECTION of Biddeford, FOLEY of Biddeford, MASTRACCIO of Sanford,
PERRY of Calais, TEPLER of Topsham.

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

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

3 **CHAPTER 167**

4 **WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM**

5 **§2041. Authorization**

6 The Wholesale Prescription Drug Importation Program, referred to in this chapter as
7 "the program," is established to provide for the wholesale importation of prescription
8 drugs from Canada by or on behalf of the State. The program must be designed in
9 accordance with the requirements of this chapter. The program may not be implemented
10 unless the State obtains approval and certification, pursuant to section 2042, subsection 3,
11 from the United States Department of Health and Human Services.

12 **§2042. Design of program**

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

18 A. Designate a state agency to become a licensed drug wholesaler or to contract with
19 a licensed drug wholesaler in order to seek federal certification and approval,
20 pursuant to section 2042, subsection 3, to import safe prescription drugs and provide
21 cost savings to consumers in the State;

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

24 C. Ensure that only prescription drugs meeting the federal Food and Drug
25 Administration's safety, effectiveness and other standards are imported by or on
26 behalf of the State;

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

29 E. Ensure that the program complies with the transaction and tracing requirements of
30 21 United States Code, Sections 360eee and 360eee-1 to the extent feasible and
31 practical prior to imported prescription drugs coming into the possession of the
32 licensed drug wholesaler and that the program complies fully with those federal
33 requirements after imported prescription drugs are in the possession of the licensed
34 drug wholesaler;

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

1 G. Recommend a charge per prescription or another method of financing to ensure
2 that the program is adequately funded in a manner that does not jeopardize significant
3 cost savings to consumers; and

4 H. Include an audit function.

5 **2. Rules.** The Department of Health and Human Services shall adopt rules to design
6 the program in accordance with the requirements of subsection 1 no later than January 1,
7 2020. Rules adopted pursuant to this subsection are major substantive rules as defined in
8 chapter 375, subchapter 2-A.

9 **3. Request for federal approval and certification.** The Department of Health and
10 Human Services shall submit a request for approval and certification of the program to
11 the United States Department of Health and Human Services no later than May 1, 2020.

12 **§2043. Implementation**

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

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

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

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

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

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

27 E. Develop a registration process for health insurance carriers, pharmacies and health
28 care providers authorized to prescribe and administer prescription drugs that are
29 willing to participate in the program;

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

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

34 H. Provide a telephone hotline to answer questions and address needs of consumers,
35 employers, health insurance carriers, pharmacies, health care providers and others
36 affected by the program;

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

