

DEPARTMENT OF HEALTH AND HUMAN SERVICES
10-144 Chapter 104
MAINE STATE SERVICES MANUAL

SECTION 8	WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM MAJOR SUBSTANTIVE RULE	ESTABLISHED 6/14/20 EFFECTIVE 6/14/20
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IMPORTATION PROGRAM
MAJOR SUBSTANTIVE RULE

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8.01 PURPOSE

This rule implements 5 MRSA c. 167, which directs the Department of Health and Human Services (“the Department”) to develop a program to allow for the wholesale importation of prescription drugs from Canada (the “program”), and to submit a proposal to the federal Secretary of Health and Human Services to approve the program. At the time that the law was enacted, there was no defined pathway for application to the federal government for approval of such a program. On July 31st 2019, the federal government released its Safe Importation Action Plan, which newly described its intent to promulgate rules governing prescription drug importation demonstration projects by states, wholesalers, and pharmacists. These federal rules will be based on 21 U.S.C. § 384, the same federal law that c. 167 requires the program to comply with. As of April 28th, 2020, a final rule has not been promulgated by the federal government.

This rule creates a process to inform the design of the program and provides that the Department will submit an application to the federal government no later than May 1, 2020, and, if the federal rule is not finalized prior to May 1st, 2020, that the Department shall submit a subsequent or revised application as soon as practicable after finalization of the federal rule.

8.02 PROCESS FOR DEVELOPING PROGRAM DESIGN

In preparation for an application to the federal government, the Department will consult with appropriate federal, other State of Maine agencies, other state officials, and interested parties. It will undertake a process to ensure the development of a program design that is effective, efficient, and practicable, meets state and federal requirements, and achieves the intent of the law. The program elements to be discussed include, but are not limited to:

- A. Infrastructure for the importation of the drugs. This includes (but is not limited to):
 - a. Determining the entities involved in the program domestically and internationally, and the licensing and oversight of them, including the creation of a new licensing pathway, if needed;
 - b. Evaluating the costs of establishment and ongoing administration of the program, and what fee structure would be necessary to support it;
 - c. Assessing the willingness of existing actors to participate in the program; and
 - d. Ensuring the safety of imported drugs.
- B. Access to imported drugs. This includes (but is not limited to):
 - a. How consumers would access the imported prescription drugs;

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- b. Whether and which employers and / or insurance carriers could access imported prescription drugs; and
 - c. The role of pharmacies and pharmaceutical benefit managers (PBMs) in the program.
- C. Identifying the prescription drugs included in the program and a means of updating that list as necessary. This includes (but is not limited to):
- a. The potential to achieve “significant savings” relative to current payment rates for specific drugs as required under federal law;
 - b. Whether the drugs are sole-source, competitive, and / or specialty drugs; and
 - c. The public health need for lower cost drugs.
- D. Establishing an effective and informative process for monitoring and evaluation of the program.

Between January 1st and March 16th, 2020, the Department will provide two avenues for input on the topics above, and other elements of program design as needed:

- A. Public meetings hosted and facilitated by the Department, with opportunity for comments and questions from attendees; and
- B. A request for information to solicit written comments.

The Department will allow for additional input from stakeholders as necessary after the federal rule is finalized.

8.03 APPLICATION TO THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES FOR APPROVAL AND CERTIFICATION

Following the conclusion of the stakeholder input process and no later than May 1st, 2020, the Department shall submit an application to the U.S. Department of Health and Human Services to establish a state importation program. If the final federal rule is not released before May 1, 2020, the department shall submit a subsequent or revised application to establish a state importation program as soon as is practicable after the release of the final federal rule. Should the Department determine that further rulemaking is necessary to implement the requirements of the program design, additional rules will be proposed.