Janet T. Mills
Governor

Jeanne M. Lambrew, Ph.D.
Commissioner

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TTY: Dial 711 (Maine Relay)

DATE: January 13, 2020

TO: Interested Parties

FROM: Jeanne M. Lambrew, Commissioner

SUBJECT: Provisionally Adopted Major Substantive Rule: 10-144 C.M.R. ch. 104, Section 8, Wholesale Prescription Drug Importation Program
MAJOR SUBSTANTIVE RULE

This letter gives notice of the provisional adoption of major substantive rule: 10-144 C.M.R. ch. 104, Section 8, Wholesale Prescription Drug Importation Program.

This rule is a major substantive rule and requires approval by the Maine Legislature before it can be finally adopted and legally effective.

The Department is provisionally adopting this rule to implement P.L. 2019, ch. 472, An Act to Increase Access to Low-cost Prescription Drugs, as codified in 5 M.R.S. §§ 2041-2044. That law directs the Department to develop a program to allow for the wholesale importation of prescription drugs from Canada and to submit a proposal to the federal Secretary of Health and Human Services to approve the Maine program.

This provisionally adopted rule creates a process for the design of a wholesale prescription drug importation program, in anticipation of the release of federal rules establishing an application pathway for demonstration projects allowing importation by states and other entities. On December 18, 2019 the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration issued a notice of proposed rulemaking that, if finalized, would allow for the importation of certain prescription drugs from Canada by states and certain other non-federal government entities. Those regulations will be codified in 21 C.F.R. Parts 1 and 251. The federal rules will be based on 21 U.S.C. § 384, the same federal law that P.L. 2019, ch. 472 requires the Department to comply with.

The provisionally adopted rule also provides that the Department of Health and Human Services will submit an application under such a pathway on behalf of the State of Maine, as soon as is practicable after the release of the final Federal rule.

The provisionally adopted rule provides for a stakeholder engagement process, which includes public meetings hosted and facilitated by the Department, with opportunities for comments and questions from attendees.

The costs of the program will be evaluated in the process of the program design, and may be significantly different depending on the requirements laid out in the anticipated Federal rule creating a pathway for approval. This rulemaking will not impose any costs on municipal or county governments, or on small businesses employing twenty or fewer employees.

The provisionally adopted rule provides, in § 8.03 that should the Department determine that further rulemaking is necessary to implement the requirements of the program design, additional rules will be proposed.

Pursuant to 5 M.R.S. § 8072, the Department will submit this provisionally adopted rule to the Maine Legislature for its review and action. This rule will have legal effect only after review by the Legislature followed by final adoption by the Department.

The provisionally adopted rule can be found at https://www.maine.gov/dhhs/dhhs-rulemaking.shtml

Notice of Agency Rule-making Adoption

AGENCY: Department of Health and Human Services

CHAPTER NUMBER AND TITLE: 10-144 C.M.R. ch. 104, Maine State Services Manual, Section 8, Wholesale Prescription Drug Importation Program

MAJOR SUBSTANTIVE PROVISIONAL ADOPTION

ADOPTED RULE NUMBER:

CONCISE SUMMARY:
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https://www.maine.gov/dhhs/dhhs-rulemaking.shtml for rules and related rulemaking documents.

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SECTION 8	WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM MAJOR SUBSTANTIVE RULE	Provisional Adoption 1/10/20

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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. The Department subsequently engaged in discussions with federal officials but received no additional information on the substance and timing of federal regulations to inform state regulations. As of November 13th 2019, neither a proposed nor a final rule has 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 as soon as is 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;

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 July 1st, 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.

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 as soon as is practicable after the release of the final federal rule, and contingent on appropriation of funds deemed necessary, the Department shall submit an application to the U.S. Department of Health and Human Services to establish a state importation program. Should the Department determine that further rulemaking is necessary to implement the requirements of the program design, additional rules will be proposed.