Summary of Comments and Department Responses
10-144 C.M.R. ch. 104, Section 8,
Wholesale Prescription Drug Importation Program

The Department of Health and Human Services held a hearing on Monday, December 2, 2019 to obtain public comments on proposed rule changes. Written comments were accepted through Thursday December 12, 2019. This document combines, summarizes, and responds to all the comments received during the public comment period ending Thursday, December 12, 2019.

List of Commenters:

Commenter 1: Kara Jones
Commenter 2: John Adams – Best Medicines Coalition of Canada
Commenter 3: Curtis Picard – Retail Association of Maine
Commenter 4: Daniel Mickool and Amelia Arnold – Maine Pharmacy Association
Commenter 5: Roxolana Kozyckyj – Healthcare Distribution Alliance
Commenter 6: Christina Adams
Commenter 7: Kate Ende – Consumers for Affordable Health Care

General Comments:

Commenter 1:

1. The Commenter expressed support for the approval of state programs to import prescription drugs and asked: (1) How will the state decide which drugs are included in the program? Will the state cap importation at only the most expensive drug? (2) How often will this list of drugs be updated, and what will the process be? (3) How will consumers gain access to the new drugs imported from Canada – will they be included in local pharmacies, or will they have to be received another way?

   Response: The Department thanks the Commenter for this comment. The Department anticipates addressing these questions during the stakeholder engagement process described in the rule.

2. The Commenter stated that drug importation from Canada – while a laudable effort – is not a magic bullet for reducing drug prices in Maine. The Commenter stated that drug companies have a lot of experience with dealing with drug importation in the European Union and have learned how to manage their inventories in order to restrict the sale of drugs to foreign countries. The Commenter suggested reading the following research Paper: "Parallel Trading in Medicines: Europe's Experience and Its Implications for Commercial Drug Importation in the United States," published by the AARP Public Policy Institute.

   Response: The Department thanks the Commenter for this comment and suggestion.

3. The Commenter expressed concern that the quantity of drugs available from Canada and their prices may limit the effectiveness of the program, and asked whether the program might be expanded to include other countries, if the federal government approves such a measure.

   Response: The Department thanks the Commenter for this comment. The Maine statute establishing the Maine Wholesale Prescription Drug Importation Program specifies that the Department create a program for the importation of drugs from Canada.

4. The Commenter also noted that federal rules for the approval of drug importation programs exclude some particularly costly drugs, specifically biologics and infused drugs, and suggested that the State encourage the federal government to include those categories of drugs in their proposed rule governing importation programs.

   Response: The Department thanks the Commenter for this comment. The Department looks forward to the opportunity to provide feedback on the federal proposed rule for prescription drug importation, while recognizing that any eventual federal approval pathway will be governed by the requirements of 21 U.S.C. Section 384. 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. 21 C.F.R. Part 1 and Part 251.

Commenter 2:

1. The Commenter expressed concern about the capacity of the Canadian prescription drug market to support the exportation of drugs to the United States because of its relatively small population and existing drug shortages. The Commenter stated that "most of us" hope that proposals to import bulk quantities of drugs from Canada "never get off the ground." The Commenter stated that Canada suffers from drug shortages, and that if Canada gave all its medicines to the United States "we would suffer and die prematurely." The Commenter stated that Canada cannot ramp up drug production, since most of their drugs/medicines are made outside Canada. The Commenter suggested that Canada is not responsible for US drug prices and that the United States explore other options to address the cost of drugs.

   Response: The Department thanks the Commenter for this comment. The Department is aware of this concern, but it is the Department's belief that given Maine's small population, a state-level prescription drug importation program would not be highly disruptive to Canada's drug supply chain. In terms of the ongoing federal rulemaking to permit additional pilot projects, the Department believes the federal government is best positioned to address these concerns in the program requirements, or through negotiations with the Canadian government.

Commenter 3:

1. The Commenter stated that the rule proposes to adopt a process to develop the design of a wholesale prescription drug importation program, in anticipation of the release of federal rules which will hopefully establish a clear process to develop demonstration projects. According to the Commenter, this makes it challenging to submit comprehensive input as the commenters do not know what the federal rules will proposed. The Commenter stated that he is concerned that Maine will develop a process that will not be in line with whatever federal rules get promulgated.

   Response: The Department thanks the Commenter for this comment, and recognizes the challenges of developing such a program in parallel with the ongoing federal rulemaking process. This rule is intended to maintain the flexibility to adjust to federal requirements when they are finalized with the need to comply with deadlines laid out in the State statute directing the Department to establish the program's design.

2. The Commenter stated that the federal rules describe "demonstration projects" by the states, and urged the Department to make sure the demonstration projects have a robust mechanism for evaluating the success or shortcoming of the project, which would include ensuring the safety of imported drugs and the ability to track and trace the medications throughout the supply chain.

Response: The Department thanks the Commenter for this comment. The Department anticipates addressing these questions during the stakeholder engagement process described in the rule.

3. The Commenter urged the Department to examine the existing licensing requirements of the entities involved in the program, and suggested that any licensing requirements for additional entities that may be involved in the program, domestically or internationally, be on par with those requirements. The Commenter also encouraged the Department to closely examine the federal Drug Supply Chain Security Act as a basis for ensuring that drugs in the program are properly manufactured and preventing the introduction of counterfeit medications.

   Response: The Department thanks the Commenter for this comment. The Department anticipates addressing these issues during the stakeholder engagement process described in the rule.

4. The Commenter cautioned the Department to consider the role and functions of importers, wholesalers, or brokers, and noted that a Canadian broker which was involved in a previous and unrelated importation program in the state has since been cited for the United States Food and Drug Administration for importing unapproved and misbranded drugs.

   Response: The Department thanks the Commenter for this comment. The Department anticipates addressing this issue during the stakeholder engagement process described in the rule.

5. The Commenter stated that the question posed in the rule about how consumers will access imported drugs is the most important one, and needs input from a variety of stakeholders including pharmacies and pharmacists. The Commenter provided an illustrative scenario about a patient receiving a medication for which the branded drug is cheaper in Canada but for which a cheaper generic version is available domestically. The Commenter asked how the consumer would evaluate the varying price options and how the provider would know if they were required to submit the prescription through a specific channel.

   Response: The Department thanks the Commenter for this comment. The Department anticipates addressing these questions during the stakeholder engagement process described in the rule.

6. The Commenter asked whether imported medications would be tested for the correct amount of active ingredient and correct dosage, and suggested that Maine's accredited pharmacy colleges would be equipped to manage that testing, but also noted that the Department should explore federal requirements governing proper testing.

   Response: The Department thanks the Commenter for this comment. The Department anticipates addressing this issue during the stakeholder engagement process described in the rule, and further expects that when a final rule is released by the federal government, it would include specifications for required testing.

7. The Commenter noted that pharmacies and pharmacists are concerned about the affordability of drugs and work to assist patients in obtaining cost-effective medications, and suggested that the federal government should be encouraged to adopt pricing restrictions similar to those in effect in Canada and some other countries.

   Response: The Department thanks the Commenter for this comment, and for their interest in this topic, but notes that opportunities for greater regulation of drug prices at the federal level are outside the scope of the rule.

Commenter 4:

1. The Commenter stated support for comprehensive approaches to reduce the costs of prescription drugs without compromising safety, and emphasized the importance of the United States' secure chain of custody and state and federal regulations. The Commenter also expressed willingness to consult with the Department as outlined in 5 MRSA c. 167 Section 2043.

   Response: The Department thanks the Commenter for this comment, and looks forward to further engagement with pharmacists and pharmacy owners, along with other stakeholders, during development of the program design.

2. The Commenter noted that the wholesale prescription drug importation program design should take into account lessons learned from previous approaches to drug importation. The Commenter described LD 171, a 2013 state law to permit importation from specific countries' licensed retail pharmacies. The Commenter noted that the law provided little oversight or enforcement, and that drugs under the program were represented to have been imported from Canadian pharmacies that were not approved for use in Canada and were found to be substandard, exposing Maine residents to misbranded and substandard pharmaceuticals. The Commenter also noted that LD 171 was struck down in federal court.

   Response: The Department thanks the Commenter for this comment. The Department anticipates that this topic will be discussed during the stakeholder engagement process described in the rule.

3. The Commenter suggested that the importation program should be based on established processes outlined in federal and state laws governing pharmacies and wholesalers, and should include licensure of both entities in the same manner currently specified in U.S. laws. The Commenter noted that current laws provide guidance for safe practices as well as recourse for non-compliance. The Commenter stated that wholesalers and pharmacies that dispense medications to Maine residents must be licensed by the Board of Pharmacy, and noted that there are extensive requirements for both entities to protect public safety.

   Response: The Department thanks the Commenter for this comment. The Department anticipates that this topic will be discussed during the stakeholder engagement process described in the rule.

4. The Commenter stated that the issue of the affordability of prescription drugs would be more effectively addressed at the federal level, and specifically that importation may be less disruptive to both the Canadian and American markets if facilitated through the federal government and the pharmaceutical industry.

   Response: The Department thanks the Commenter for this comment, but alternative approaches to address affordability at the federal level are outside the scope of this rulemaking.

5. The Commenter concluded with three suggestions related to the program design: 1) ensure pharmacies and wholesalers participating in the program are licensed by the Maine Board of Pharmacy, 2) involve all stakeholders in the development of the program, 3) conduct ongoing evaluation to ensure safety and cost savings.

   Response: The Department thanks the Commenter for this comment. The Department expects that issues of licensing and program evaluation will be discussed during the stakeholder engagement process described in the rule, and looks forward to consultation with all interested parties during that process.

Commenter 5:

1. The Commenter noted that this rulemaking is predicated on forthcoming federal "Safe Importation Action Plan" rules. The Commenter expressed opposition to the federal government's Safe Importation Action Plan, and state that both the federal Plan and any program developed by the State would violate safety standards, put patients at risk, and fail to achieve substantial savings.

   Response: The Department thanks the Commenter for this comment. The Department intends, through its program development process, to create a wholesale prescription drug importation program which ensures safety standards comparable to those that exist in the current drug supply chain and provides substantial savings to consumers, as required by statute, and in conformance with an eventual finalized federal rule.

2. The Commenter pointed out that since passage of LD 1272, the acting Canadian ambassador to the United States has made a statement about the potential US importation of drugs from Canada, expressing concerns about the Canadian market's ability to meet US demand, her belief that importation would not significantly lower U.S. prices, and that Canada's priority is ensuring adequate access and affordability for Canadians. The Commenter also noted that fifteen Canadian patient and healthcare advocacy organizations have written to Prime Minister Trudeau expressing concerns about the impact of U.S. importation programs on Canada's drug supply and urging the Prime Minister to prevent the transfer of Canada's drug supply to the U.S.

   Response: The Department thanks the Commenter for this comment. The Department is aware of this concern, but it is the Department's belief that given Maine's small population, a state-level prescription drugs importation program would not be highly disruptive to Canada's drug supply chain. In terms of federal rulemaking to permit additional pilot projects, the Department believes the federal government is best positioned to address these concerns in the program requirements, or through negotiations with the Canadian government.

3. The Commenter restated the position that any wholesale prescription drug importation program that would comply with the approach outlined in the Safe Importation Action Plan would pose a risk to patients and the supply chain and would not result in substantial cost savings for consumers.

   Response: The Department thanks the Commenter for this comment. The Department intends, through its program development process, to create a wholesale prescription drug importation program which ensures safety standards comparable to those that exist in the current drug supply chain and provides substantial savings to consumers, as required by statute.

Commenter 6:

1. The Commenter expressed concern about the capacity of the Canadian prescription drug market to support the exportation of drugs to the United States because of its relatively small population, and particularly noted concern that such an arrangement could exacerbate existing drug shortages in Canada. The Commenter noted that the United States represents 22% of the global drug supply while Canada represents 4%. The Commenter expressed support the importation of drugs from Canada to help in the event of a drug shortage in the U.S. when there is a reasonable supply in Canada but opposition to importation as a means of accessing more affordable medications.

   Response: The Department thanks the Commenter for this comment. The Department is aware of this concern, but it is the Department's belief that given Maine's small population, a state-level

prescription drugs importation program would not be highly disruptive to Canada's drug supply chain.

2. The Commenter recommended that instead of creating importation programs, the U.S. consider implementing policies and regulations similar to Canada's.

   Response: The Department thanks the Commenter for this comment, but alternative approaches to address affordability of prescription drugs are outside the scope of this rulemaking.

Commenter 7:

1. The Commenter expressed concern about the proposed timeline for submitting a request for approval for the program to the federal government. The Commenter stated their belief that it would not be necessary to wait for the finalization of federal rules before submitting an application to the federal government for program approval. The Commenter expressed concern that waiting for the conclusion of the federal rulemaking process would impede timely implementation of the program, and encouraged the Department to submit an application by the May 1, 2020 deadline specified in statute even if federal rules are not finalized by that date. The Commenter went on to suggest that at minimum the Department should ensure that an application can be submitted immediately after the finalization of the federal rules. The Commenter stated that other states, including Vermont, continue to make progress on the design of state importation programs in the absence of federal rules. The Commenter expressed support for the avenues for broad stakeholder engagement provided for in the bill, noting that such a process can provide valuable expertise and improve the final program design. The Commenter also suggested adjusting the timeframe for stakeholder input to allow for timely submission of an application to CMS.

   Response: The Department thanks the Commenter for this comment. The Department understands the sense of urgency to provide relief to consumers who are struggling to afford prescription drugs. While the Department recognizes and shares the desire to provide that relief as quickly as possible, it also recognizes that federal approval will be necessary in order for the wholesale prescription drug importation program to become operational, and that aspects of the federal rules governing the program will impact the ability of the state to meet program requirements outlined in statute. This rule seeks to make continued progress toward the creation of the wholesale prescription drug importation program while maintaining the flexibility to meet those operational realities, in order to ensure that time and resources are not devoted to developing a program which, given federal requirements, cannot be approved or would not meet the intent of the law. The Department does wish to clarify that the timeline in the rule would not foreclose on the Department moving more quickly through the stakeholder engagement process or the submission of an application.

2. The Commenter urged the Department not to condition the submission of an application for federal approval on the appropriation of funds deemed necessary and noted that the Department is required in the law to recommend methods of financing the program, and authorized to apply for funds, grants, or sources from public or private sources. The Commenter stated that while additional funding may be necessary to run the program, it is not required to submit Maine's application for approval to the federal government.

   Response: The Department thanks the Commenter for this comment. The Department takes seriously its responsibility under the statute to ensure that the wholesale prescription drug importation program design protects patient safety and results in significant savings to consumers. The Department expects that in advance of receiving federal approval to operate a

prescription drug importation program, it will be necessary for the State to demonstrate that the program design developed would meet those conditions. Depending on the specificity of federal application requirements, the development and submission of an application may require specialized expertise and significant staff time not available within existing Department resources. The Department will consider methods to generate revenue through the program's operation, and opportunities to apply for grants from non-profit organizations or other external sources. Should those sources of funding not be sufficient or available in advance of the submission of an application to the federal government, an appropriation may be required in order to meet federal requirements.

LIST OF CHANGES TO FINAL RULE

No changes were made to the rule as a result of comments.