



MAINE PHARMACY
ASSOCIATION

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December 12, 2019

Via Email

Ms. Megan Garratt-Reed
Senior Advisor for Coverage and Affordability
11 State House Station
109 Capitol Street
Augusta, ME 04333-0011

RE: Proposed Major Substantive Rule: 10-144 C.M.R. ch. 104, Maine State Services Manual, Section 8, Wholesale Prescription Drug Importation Program.

Dear Ms. Garratt-Reed:

As stakeholders, we submit comments pursuant to proposed major substantive rule: 10-144 C.M.R. ch. 105, Maine State Services Manual, Section 8, Wholesale Prescription Drug Importation Program, on behalf of the Maine Pharmacy Association.

The Maine Pharmacy Association supports a comprehensive approach to reviewing drug pricing to ensure the people of the State of Maine have access to affordable and safe medications without compromising safety. Maine residents need safe medicines with the proper active pharmaceutical ingredient as expected from medications obtained in the secure chain of custody throughout the United States, protected by state and federal regulations. As outlined in 5 MRSA c. 167 SS 2043 (D), pharmacists welcome the opportunity to consult with the Department of Health and Human Services to implement a Wholesale Prescription Drug Importation Program that prioritizes public safety.

Any new efforts to create a wholesale drug importation program must include lessons learned from prior drug importation laws in Maine. In 2013, the Maine legislature passed LD 171, an Act to Facilitate Personal Importation of Prescription Medication from International Mail Order Prescription Pharmacies. This legislation permitted importation of prescription drugs from specific countries' licensed retail pharmacies in Australia, Canada, New Zealand and the United Kingdom. However, the law provided little oversight or enforcement provisions, and before LD 171 was struck down in federal court, medications (generic versions of Nexium, Plavix, Celebrex and Viagra) were sent to Maine from "Canadian pharmacies" that were not approved for use in Canada and that were found substandard upon testing. Unfortunately, Maine residents were subjected to misbranded and substandard pharmaceuticals.

The successful design and execution of a drug importation program should mirror established, rigorous processes outlined in federal and state laws governing both pharmacies and wholesalers. This design should include licensure of pharmacies and wholesalers in the same manner currently specified in U.S laws, ensuring accountability for all entities involved, and ultimately, public safety. Current laws provide guidance for safe practice as well as recourse for non-compliance. The Maine Pharmacy Association strongly feels that the design of an importation program from Canada into the State of Maine must be as safe as those medications currently dispensed by Maine pharmacies.

Both wholesalers and pharmacies that dispense medications to Maine residents **must** be licensed with the Maine Board of Pharmacy, and these wholesalers and pharmacies have very extensive requirements that the State Legislature and the Board of Pharmacy regulate in the interest of public safety.

Daily, Maine-licensed pharmacists guide patients toward cost-effective medications and share the State's concern about reduction of costs. The Maine Pharmacy Association urges the State of Maine in our local legislature, and in Washington, D.C., to tackle this important work on the national level where it might be most effective. The Canadian Health Service has stated concerns about their own drug supply should large U.S. markets start buying in, and interruptions in both countries could be avoided if change is facilitated through the Federal Government and our own pharmaceutical industry.

In conclusion, Maine Pharmacy Association would like to see the State be successful in their efforts to import Canadian drugs, even if this is a temporary solution. This can be accomplished by:

1. Ensuring that all pharmacies and wholesalers in the supply chain are appropriately licensed by the Board of Pharmacy in Maine to conduct business and dispense medications in Maine.
2. Involving all stakeholders including insurance carriers, employers, pharmacies, pharmacists, health care providers and consumers as outlined in 5 MRSA c. 167 SS 2043 (D) to develop a prescription drug importation program.
3. Conducting ongoing and thoughtful evaluations of any program that is implemented to ensure the prescriptions are demonstrating cost-savings and are safe.

Sincerely,



Daniel Mickool R.Ph, M.S., EdD
President, Maine Pharmacy Association



Amelia Arnold, PharmD
Immediate Past President, Maine Pharmacy Association