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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:

The Retail Association of Maine represents chain and independent pharmacies throughout Maine and we advocate on their behalf on legislative and regulatory matters. Our association has a long history with this concept and we appreciate the opportunity to share our comments regarding the proposed rule.

The rule proposes to adopt a process, essentially, 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". This makes it very challenging to submit comprehensive input as we do not know what the federal rules will propose. In that regard, we think Maine is putting the cart before the horse and we are concerned that Maine may develop a process that will not be in line with whatever federal rules get promulgated.

Regardless, we will share some overreaching comments that should be helpful.

- The federal rules describe "demonstration projects" by states, wholesalers and pharmacists. We interpret that to mean that these would be pilot projects that may be temporary. We would urge the department to make sure the demonstration projects

have a robust mechanism for evaluating the success or shortcomings of the project. This would include ensuring the safety of imported drugs and the ability to track and trace the medications throughout the supply chain from manufacturing to distribution entities to consumer.

- Licensing: The department should examine the existing licensing requirements of pharmacists, pharmacies, drug wholesalers and other entities that may be involved with the program domestically and internationally. If the drugs are ultimately distributed to consumers through channels that are not existing pharmacies or pharmacists, the licensing of those entities should be on par with existing licensing requirements. Drug wholesalers are required to be licensed in Maine even if they are located out of state. The Department should also closely examine the federal Drug Supply Chain Security Act, also known as 'track and trace' and is the basis for ensuring that the medications supplied within the United States are manufactured correctly and traceable throughout the supply chain and to prevent the introduction of counterfeit medications.
- We would also caution the state to carefully examine how the process will work with importers, wholesalers or brokers. It is worth noting that the basis of the federal lawsuit that overturned Maine's previous law regarding foreign importation of prescription medications was related to a Canadian pharmaceutical broker, CanaRx, which has since been cited by the US FDA for bringing in unapproved drugs and misbranded drugs to the United States. [1]
- The rule asks the most important question: How will consumers access the imported prescription drugs? We believe this question needs input from a variety of stakeholders including pharmacies and pharmacists. Let's describe a familiar scenario: A Maine consumer visits a medical professional and receives a prescription. Most prescriptions are now electronically submitted to a pharmacy of choice. The prescription may also be for a drug that has a generic formulation that may be cheaper than branded medication. So, while the imported medication may be cheaper than the branded medication, how will a consumer evaluate the cost versus the generic? How will the health care provider know to send the prescription through a specific channel?
- Will the imported medications be tested to see if it has the correct amount of active ingredient or is the correct dosage as prescribed? Perhaps Maine's accredited pharmacy colleges (University of New England and/or Husson University) would be equipped to handle this task, but the Department should also explore what, if any, federal requirements would govern the proper testing of imported medications.
- Maine pharmacies and pharmacists share the state's concern about affordable medications and work regularly to help direct patients to cost-effective medications.

[1] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/canarx-services-inc-554740-02262019

We feel that a more effective means of lowering the cost of medications would be to push the federal government to adopt similar pricing regulations that other countries, like Canada, have adopted.

Thank you for the opportunity to share our thoughts.

Best regards,

Curtis Picard, CAE
President and CEO