



December 12, 2019

Megan Garratt-Reed, Senior Advisor for Coverage and Affordability
Maine Department of Health and Human Services
11 State House Station, 109 Capitol Street, ME 04333-0102

Re: Proposed Wholesale Prescription Drug Importation Program

Dear Ms. Garratt-Reed:

On behalf of Consumers for Affordable Health Care, I submit comments regarding the proposed rule noted above.

Consumers for Affordable Health Care (CAHC) is a nonprofit, nonpartisan organization with the mission to advocate for Maine people to be heard, respected, and well-served in a health system that provides coverage, access and quality, affordable care to all. CAHC serves as Maine's Health Insurance Consumer Assistance Program, which provides toll-free access to certified application counselors, who help Mainers understand their health coverage options and how to apply and enroll in private health insurance. Through this work, we often hear from people who have difficulty affording the prescription drug medicine they need. Callers to our Helpline have shared their concerns about rising prescription drug costs, and we know that the experiences of our HelpLine callers are not unique. In fact, polling conducted last year by Critical Insights revealed that prescription drug affordability is the most common healthcare-related concern among Maine people, with more than two thirds of Mainers reporting they are concerned that they won't be able to afford the prescription drugs they need.¹ This is no surprise considering the skyrocketing prices of prescription drugs in America, which have been rising 10 times faster than the rate of inflation.² Our review of private insurance rate filings also shows us that rising drug costs are contributing, in part, to higher private health insurance premiums in Maine.

Data from the Maine Health Data Organization show the 25 most prescribed and expensive drugs in Maine, and those that had the highest cost increases over the last year.³ These include many drugs used to treat chronic diseases, such as diabetes, or to fight cancer. Some of the drugs with the highest price increases are those prescribed to stave off potentially fatal blood clots and strokes. Additionally, older consumers pay for more than half of prescription drug expenditures out-of-pocket.⁴

For these and other issues related to rising prescription drug costs, we are pleased that the Maine Department of Health and Human Services has proposed rules, as required by P.L. 2019, ch. 472. Until high prescription drug costs are adequately addressed in this country, we believe a state wholesale importation program is essential to helping Mainers afford the medicine they need. We hope the Department will take all steps necessary to establish a state importation program as swiftly as possible.

¹ Summary Report of Findings from the Critical Insights on Maine™ Survey for the Consumers for Affordable Healthcare; October 2018.

http://www.maineahc.org/wp-content/uploads/2019/02/CriticalInsights_MaineSurvey_181115.pdf

² <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2018.05147>

³ <https://mhdo.maine.gov/tableau/prescriptionReports.cshtml>

⁴ <https://hpi.georgetown.edu/rxdrugs/#>



CAHC appreciates your thoughtful consideration of the following comments:

10-144 Chapter 104 Maine State Services Manual

Section 8: Wholesale Prescription Drug Importation Program

CAHC appreciates the Department's thorough and collaborative approach to developing an effective and practical design for a state wholesale importation program. However, CAHC is concerned with the proposed timeframe for soliciting stakeholder input and the overall timeline for submitting a request for approval to the U.S. Department of Health and Human Services (HHS) to establish a state importation program. Pursuant to P.L. 2019, ch. 472, the Department is required to "submit a request for approval and certification of the [state importation] program to the United States Department of Health and Human Services no later than May 1, 2020." While we can understand why the Department may want to wait for HHS to release rules governing prescription drug importation demonstration projects by states, wholesalers, and pharmacists prior to submitting its application for federal approval, we do not believe that is necessary.

HHS and the U.S. Food and Drug Administration (FDA) released the Safe Importation Action Plan on July 31, 2019, which states their intent to promulgate rules governing prescription drug importation demonstration projects by states, wholesalers, and pharmacists. However, as of December 12, 2019, nearly four and a half months later, the federal government has neither published proposed rules, nor indicated a specific timeline for releasing such rules. We are concerned that waiting for a lengthy rulemaking process, particularly one that has not yet begun, will impede timely implementation of the program. We encourage the Department to move forward with developing the program design and submitting an application for federal approval and certification grounded on Section 804 of the Federal Food, Drug and Cosmetic Act (FDCA), in the absence of federal rules. However, if the Department decides to wait for the adoption of federal rules to submit Maine's application, Maine should position itself to submit its application immediately after the federal rules are published.

We urge the Department to take all necessary steps to develop the design of its program and ensure its application for federal approval is ready to be submitted by May 1, 2020, or as promptly soon thereafter as federal rules are finalized. Other states continue to make progress on advancing state importation programs, such as Vermont, despite lacking a clear pathway designated by federal rules; we hope Maine will do the same.

We are pleased the Department plans to consult with appropriate federal agencies, other State of Maine agencies, other state officials, and interested parties in the development of the design for a wholesale prescription drug importation program. Engaging with a broad range of stakeholders throughout this process can provide invaluable expertise and experience, to help ensure the program design is effective, efficient, and able to achieve the goals of the law. For this reason, we appreciate and support the Department's proposal to provide multiple avenues for stakeholders to be involved in the development of the program and provide input on the program design. However, for reasons previously outlined, we encourage the Department to adjust the timeframe of the stakeholder input process, to maintain the proposed opportunities for stakeholder input and engagement, while also allowing for timely submission of an application to HHS, as specified by P.L. 2019, ch. 472.

We also urge the Department not to condition the submission of its application to HHS on the "appropriation of funds deemed necessary," since such a requirement is not established under P.L. 2019, ch. 472. Rather, the law already stipulates that the design of the program must "[r]ecommend a charge per prescription or another method of financing to ensure that the program is adequately funded in a manner



that does not jeopardize significant cost savings to consumers, including adequate funding for the initial start-up costs of the program,”⁵ and “[a]pply for and receive funds, grants or contracts from public and private sources”.⁶ While additional funding may be necessary to run the program, it is not required to submit Maine’s application for approval to HHS.

We hope the Department will vigorously pursue the establishment of a state importation program in Maine and, to the extent possible, work to minimize and avoid any delays in designing, requesting federal approval of, and implementing such program.

CAHC understands that developing and implementing a plan for a state wholesale importation program is an immense and extremely lofty undertaking. We appreciate all the time and effort the Department has already, and no doubt will continue, to dedicate to this important endeavor to make prescription drugs more affordable for Maine people.

We thank you for you for considering these comments. Please feel free to contact me at 207-480-2136 if you have any questions regarding our interest or comments regarding these proposed rules.

Sincerely,

Kate Ende
Policy Director

⁵ §2042(1)(H)

⁶ §2042(1)(I)

