

**TO: Representatives Kitty Toll, Bill Lippert, and Janet Ancel
Senators Jane Kitchel, Ginny Lyons, and Ann Cummings**

FROM: Ena Backus, Director of Health Care Reform, Agency of Human Services

DATE: October 1, 2019

**SUBJECT: Update on Wholesale Prescription Drug Importation Program
(Sec. E.300.7 of Act 72 of 2019)**

In keeping with Sec. E.300.7 of Act 72 of 2019 the Agency of Human Services respectfully submits the following update.

Legislative charge:

- (a) The Agency of Human Services shall consult with the National Academy for State Health Policy (NASHP) and with states pursuing or interested in pursuing a wholesale prescription drug importation program to identify opportunities to coordinate and work collaboratively in these efforts. On or before October 1, 2019, the Agency shall provide an update on its progress in obtaining federal approval for a wholesale prescription drug importation program pursuant to 18 V.S.A. §4653, including the results of its consultations with NASHP and with other states, to the House Committees on Appropriations, on Health Care, and on Ways and Means; the Senate Committees on Appropriations, on Health and Welfare, and on Finance; and the Joint Fiscal Committee.

Beginning May 9, 2019, the State of Vermont has been participating in state collaboration calls convened by the National Academy for State Health Policy (NASHP) for the purposes of discussing wholesale importation of prescription drugs from Canada amongst those states with active or pending legislation. As of September 26, 2019, NASHP has convened 10 collaboration calls.

The collaboration calls give states the opportunity to learn about one another's respective laws calling for programs of prescription drug importation from Canada and to receive guidance and expertise from NASHP and its contractors. In addition to Vermont, states participating in collaboration calls include: Maine, Colorado, Florida, and Utah.

On July 31, 2019, the U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA) announced the Safe Importation Action Plan. The Safe Importation Action Plan describes two potential pathways for importation of drugs from foreign markets. Pathway One describes a notice of proposed rulemaking that would act on Section 804 of the existing Federal Food, Drug and Cosmetic Act ("FD&C Act"). This notice would be issued by HHS and the FDA and would authorize demonstration projects developed by states to import certain drugs from Canada. This pathway would require states to guarantee the safety of the imported drugs and to demonstrate savings to consumers; both key principles of Section 804 that Vermont has already incorporated into its early work to design a program of wholesale prescription drug importation from Canada. The second pathway would allow manufacturers to import drugs from foreign markets at the foreign market list price. Attached is a set of slides provided during a media briefing on August 15, 2019 that outlines the two pathways and next steps.

Vermont is encouraged by the creation of a formal pathway for states to pursue prescription drug importation from Canada. Absent a clear pathway, the state would still propose a program of importation grounded in Section 804, but

with no guidance about the review or approval process. Despite this encouraging development, Vermont is concerned that a lengthy rulemaking process could hamper program implementation. Given these concerns, Governor Scott sent the attached letter to HHS requesting clarification about the Safe Importation Action Plan.

In response to the letter, Governor Scott’s staff were invited to and participated in a call hosted by HHS about the Safe Importation Action Plan. On this call Vermont articulated its concerns about the rulemaking process impeding the implementation of an importation program and asked if states that demonstrated readiness could pilot a program prior to the completion of final rulemaking. The conversation was productive and the lines of communication with HHS are open.

As Vermont is learning more about other states’ approaches to a program of importation and preparing to submit a proposal to HHS, the state needs to revisit the savings estimates generated for the initial phase of program design. Today, Vermont payers (BCBSVT and MVP) have been asked to submit refreshed data to NASHP in order to arrive at the most current estimate of savings.

Progress: NASHP Overview of States Implementing Canadian Drug Importation Laws

State	Deadline to submit application to feds	Responsible Agency	Payers	Potential Drug Classes Considered for Importation (TBD)	Savings / Notes
VT	Originally Jul 1 2019; now Jul 1 2020	Agency of Human Services	Commercial plans; no Medicaid (may phase in later)	Diabetes, HIV/AIDS, MS, Hep C, COPD, VTE prevention	1-5 mil/year (Dec 2018 report*)
FL (1) – Canadian importation for state health departments	Jul 1 2020 deadline with momentum to submit earlier	Agency for Health Care Administration	Public payers	HIV, Asthma, Hep C, COPD, VTE prevention	Anticipating savings for some public payers
FL (2) – International import program for the commercial market;	“ ”	Dept. of Business and Professional Regulation	Commercial plans; state employees	(Analysis in progress)	Starting w/ Canadian importation
CO	Sept. 1 2020	Dept. of Health Care Policy & Financing	Public and private payers are eligible	(Analysis in progress)	-
ME	May 1, 2020	DHHS to designate a state agency	Health insurance carriers	Not yet determined	Charged with considering if the program may be developed on a multistate basis

PHILIP B. SCOTT
Governor



State of Vermont
OFFICE OF THE GOVERNOR

August 13, 2019

Alex M. Azar, II, Secretary
Department of Health and Human Services
Hubert H. Humphrey Bldg.
200 Independence Ave., S.W.
Washington, DC 20201

Dear Secretary Azar:

We applaud the Administration's recent release of its Safe Importation Action Plan to support efforts to lower prescription prices through importation. Vermont was the first states in the nation to pass a prescription drug importation law, recognizing health care and pharmacy costs are too high for too many. For our policy to be viable, we know we will need federal collaboration and approval. **Accordingly, I am writing to formally request a meeting with your Agency to discuss our plans and how the Administration's approach may impact them.**

We are eager to have this conversation soon given our work to date and state statutory requirements to submit applications as soon as July 1, 2020.

I would also value an opportunity to learn more about both of your proposed pathways and how they will relate to state activity. My team and I have several questions we would like to discuss with your Agency to assure maximum collaboration and coordination between Vermont and the federal government so that importation may in fact provide significantly lower costs for our residents.

We have been working with the National Academy for State Health Policy (NASHP) who we'd like to have join us, along with representatives from the other states who have passed importation laws – if they are interested. NASHP will coordinate among the states if you approve of this request.

Thank you for your leadership on this important issue. We look forward to hearing from you and to scheduling a meeting soon.

Sincerely,

A handwritten signature in black ink, appearing to read "Philip B. Scott", with a long horizontal line extending to the right.

Philip B. Scott
Governor

PBS/kp

c: Trish Riley, Executive Director, National Academy for State Health Policy
Two Monument Square, Suite 910, Portland ME 04101

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Wholesale Prescription Drug Importation from Canada: State and Federal Efforts

August 15, 2019



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Agenda

- Federal Law
- Vermont Law: Act 133 of 2018
- Vermont Law: Act 72 of 2019
- Agency of Human Services Legislative Report
- State Progress with National Academy for State Health Policy (NASHP)
- Safe Importation Action Plan
- Next Steps: Meeting Request made to HHS

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Federal Law: Section 804 of the Food, Drug, and Cosmetic Act (FDCA)

- The Food and Drug Administration Modernization Act of 1997 amended the FDCA to include Section 804
- Section 804 of FDCA allows the HHS Secretary to approve a *program* of wholesale importation of prescription drugs that will:
 - Pose no additional risk to the public's health and safety; and
 - Result in a significant reduction in the cost of the covered products to the American consumer
- 804 has never been used
 - States have submitted personal importation proposals and been denied for safety and cost savings concerns

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Federal Law: Section 804 of the Food, Drug, and Cosmetic Act (FDCA) cont.

- By law, prescription drugs may only be imported from Canada
- By law, NO importation of a controlled substance, biological product, infused drug, intravenously injected drug, or a drug inhaled during surgery
- By law, laboratory testing is required

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Vermont Law – Act 133 (S.175) of 2018

- Act 133 Permits the importation of Rx drugs from Canada, subject to HHS approval. Components of the act include:
 - Import drugs from Canadian-licensed and FDA registered supplier(s)
 - Program open to all Vermont payers
 - Import drugs that will generate significant consumer-level savings
 - Prohibits distribution, sale or dispensing of imported prescription drugs outside Vermont
 - Program must have an audit function
 - Requirement for the Agency of Human Services to submit an application to the United States Department of Health and Human Services no later than July 1, 2019—amended to 2020

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Vermont Law - Act 72 (H. 542) of 2019

- Act 72 amends Act 133 to require that Vermont submit an application to HHS on or before **July 1, 2020**
 - Establishes that the Vermont Agency of Human Services is responsible for the implementation and administration of a prescription drug importation program
 - Requires AHS to consult with the Board of Pharmacy to recommend whether new prescription drug wholesaler license categories are necessary for an importation program
 - Requires the Agency to consult with the National Academy for State Health Policy (NASHP) and other states pursuing wholesale importation of prescription drugs from Canada

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Wholesale Importation of Prescription Drugs: AHS Legislative Report Summary December 31, 2018

- The Department of Vermont Health Access (DVHA) estimated minimal if any benefit to Medicaid members from importation as their copays are typically \$0 and no more than \$3 dollars and Medicaid's existing prescription drug rebate program yields substantial savings
 - There may be a small number of specific drugs that may be more cost-effective for DVHA through Canada for a limited period-of-time
- First cut analysis concludes \$1-5 million in potential savings for two commercial payers (BCBSVT and MVP) who contributed data to NASHP
 - Note: this figure does not include patient data from other commercial insurers, the most statistically significant of which is CIGNA, due to the number of lives they cover in Vermont
 - Note: this figure was also derived under the incorrect interpretation of federal law that various type of insulin are eligible for importation. Unfortunately, they are not.
- Recommended licensure of wholesalers importing drugs from Canada and key activities to ensure imported drugs pose no additional risk to public's health and safety
- Further work required to determine costs to state for operating the program and best methods to ensure savings for consumers

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United States Food and Drug Administration Safe Importation Action Plan

- Describes steps HHS and FDA will take to allow the safe importation of certain drugs originally intended for foreign markets
- Action Plan describes two potential pathways to provide safe, lower cost drugs to consumers
- Pathway 1 Notice of Proposed Rulemaking would rely on authority in Section 804 of the FDCA

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United States Food and Drug Administration Safe Importation Action Plan, cont.

- **Pathway 1**
 - *Under this pathway, States, wholesalers, or pharmacists could submit plans for demonstration projects to HHS to review, outlining how they would import Health-Canada approved drugs that are in compliance with Section 505 of the FDCA. Importation would occur in a manner that adequately assures the drug is what it purports to be and that meets the cost requirements of the rulemaking. Demonstration projects would be time-limited and require regular reporting to ensure safety and cost conditions are being met.*

Safe Importation Action Plan, U.S Department of Health and Human Services and U.S. Food and Drug Administration, Published July 31, 2019

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United States Food and Drug Administration Safe Importation Action Plan

• Pathway 2

- *Manufacturers of FDA-approved drug products would be able to import versions of these FDA-approved drugs that they sell in foreign countries into the U.S. To use this pathway, the manufacturer or person authorized by the manufacturer would need to establish with FDA that the foreign version is the same as the U.S. version (such as through manufacturing records). If this condition is met, FDA would allow the drug to be labeled for sale in the U.S. (potentially with labeling that identifies the product as originally manufactured for sale abroad) and imported pursuant to section 801 (d) of the FDCA under the existing approval for the U.S. approved version.*

Safe Importation Action Plan, U.S. Department of Health and Human Services and U.S. Food and Drug Administration, Published July 31, 2019

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Next Steps

Program Design

- Identifying interested wholesalers in Canada and Vermont
- Determine exact method for delivering savings to consumers at the point of purchase and through insurance premium rates
- Identify resources to administer and monitor program

Safe Importation Action Plan

- Request meeting with HHS to clarify proposal and advocate for pilot program prior to final rule
- Work with other states to provide comment on proposed rule

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