

Wholesale Prescription Drug Importation from Canada: State of Vermont and Federal Efforts

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Agenda

- Background: Federal Law and Vermont Law
- United States Food and Drug Administration Safe Importation Action Plan
- Vermont Concept Paper Submission
- Federal Notice of Proposed Rulemaking
- Next Steps

Background: 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

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

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

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

United States Food and Drug Administration Safe Importation Action Plan: Released July 31, 2019

- 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

November 26, 2019: Vermont Submitted a Concept Paper for Importation of Prescription Drugs

1. To aid federal partners in the process of developing regulations for a wholesale importation program.
2. To differentiate Vermont's importation program from the concept submitted to the Department of Health and Human Services and the U.S. Food and Drug Administration (FDA) in August 2019 by Florida.

Background

- July 2019: the U.S. Department of Health and Human Services (DHHS) and the U.S. Food and Drug Administration (FDA) released the *Safe Importation Action Plan*, including a notice of proposed rulemaking to promulgate regulations enabling importation of prescription drugs.
- August 2019: Florida submitted a concept paper to DHHS outlining its approach detailing its importation program concept to aid in the process of developing regulations.

How does Vermont's Importation Program Differ from Florida's?

- Payer participation is the primary difference between the two programs.
- Vermont's program is based on commercial insurer participation but is open to public payer participation.
- Florida's program is limited to public payers.
- Vermont's program will allow savings to be passed directly to consumers through these possible mechanisms:
 - lowering premiums
 - lowering deductibles
 - reducing or eliminating co-pays for prescription drugs

How are Vermont and Florida's approaches alike?

- Both states share similar approaches to fulfilling the safety requirements outlined in Section 804 of the Food, Drug and Cosmetic Act (FDCA). Examples include:
 - Manufacturers must be FDA-approved
 - Systems are required for verification and handling of suspect or illegitimate product
 - Drugs subject to FDA-Examination at the border
 - Licensure is required for eligible participants

Is there anything new in Vermont's concept paper that hasn't been shared before?

- Vermont's concept paper describes the same approach to meeting the safety requirements of Section 804 of the Food, Drug, and Cosmetic Act (FDCA) as was described in the Agency of Human Services' 2019 report to the Legislature.
- The concept paper makes clear Vermont's position that insulin should be included in a program of drug importation from Canada.

Notice of Proposed Rulemaking for Importation of Prescription Drugs: December 23, 2019

- The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend its regulations to implement a provision of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to allow importation of certain prescription drugs from Canada.
- If the rule is finalized as proposed, States or certain other non-federal governmental entities would be able to submit importation program proposals to FDA for review and authorization.
- An importation program could be co-sponsored by a pharmacist, a wholesaler, or another State or non-federal governmental entity. The rule, when finalized, would contain all requirements necessary for a State or other non-federal governmental entity and its co-sponsors, if any, to demonstrate that their importation program will pose no additional risk to the public's health and safety.
- In addition, the proposed rule would require that the State or non-federal governmental entity and its co-sponsors, if any, explain why their program would be expected to result in a significant reduction in the cost of covered products to the American consumer.
- Comment Period Deadline: March 9, 2020

<https://www.federalregister.gov/documents/2019/12/23/2019-27474/importation-of-prescription-drugs>

Next Steps

- Submit comment on proposed rules
- Continue convening with NASHP states group
- The Office of Professional Regulation recommends that the General Assembly could amend 26 V.S.A. § 2061 to provide that The Board of Pharmacy, *may, with or without the adoption of rules, issue wholesale-distributor- exporter and wholesale-distributor-importer licenses to drug outlets that comply with Federal, State, and Board requirements to import prescription drugs through a program approved by the Secretary of Human Services.*