

Vermont's Canadian Wholesale Importation Program for Prescription Drugs

Describing Vermont's Concept Paper

November 26, 2019

Why is Vermont Submitting 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 explains that Vermont is updating its estimates of savings from a Canadian wholesale importation of prescription drugs.