



COLORADO

Department of Health Care
Policy & Financing

303 East 17th Avenue

Denver, CO 80203

Colorado's Drug Importation Program

Manufacturer Fact Sheet, February 2024

In Colorado, prescription drugs account for 19% of health care spending, totaling almost \$5 billion a year. In order to address these escalating costs, the Colorado Department of Health Care Policy & Financing (HCPF) is deploying a Canadian drug importation strategy to address the burden that high drug costs pose to the Colorado health care market. Partnerships with Canadian manufacturers are critical to the success of this program, and HCPF is currently seeking opportunities to engage with innovative drugmakers to ensure adequate drug supply for the program.

Program Background

In accordance with [Colorado Senate Bill 19-005](#), HCPF submitted an application to the U.S. Department of Health and Human Services (HHS) on December 5, 2022. In response to questions from the Food and Drug Agency (FDA), HCPF [amended](#) and resubmitted the application on February 26, 2024. If approved, this program will establish a Canadian prescription drug importation program, bringing significant reductions in the costs of prescription drugs to Colorado families and employers. The application names all required vendor partners, including a Canadian and a U.S. wholesaler, as well as a relabeler and a qualified laboratory. The application also includes an updated drug list and outlines implementation strategies to ensure compliance with the federal Final Rule.

Colorado's proposed program establishes a framework to allow a Colorado registered Importer (wholesaler or pharmacy) to contract with a registered Foreign Seller (Canadian wholesaler) to safely import eligible prescription drugs that have been approved by FDA for importation. HCPF's estimate finds that such a program could save Colorado families and employers an up to \$51 million over three years (2025-2027).

Section 804 Importation Program (SIP) Framework

HCPF's Drug Importation Division (DID) will oversee the SIP once approved, providing strong oversight and accountability. All prescription drugs approved for importation through the Colorado SIP will be the same as the current FDA-approved versions, which are produced worldwide.

Colorado will negotiate directly with manufacturers to arrange an agreed-to price for the purchase of prescription drugs from FDA-approved manufacturers through FDA-approved facilities. The Foreign Seller will purchase the drug directly from the manufacturer and will

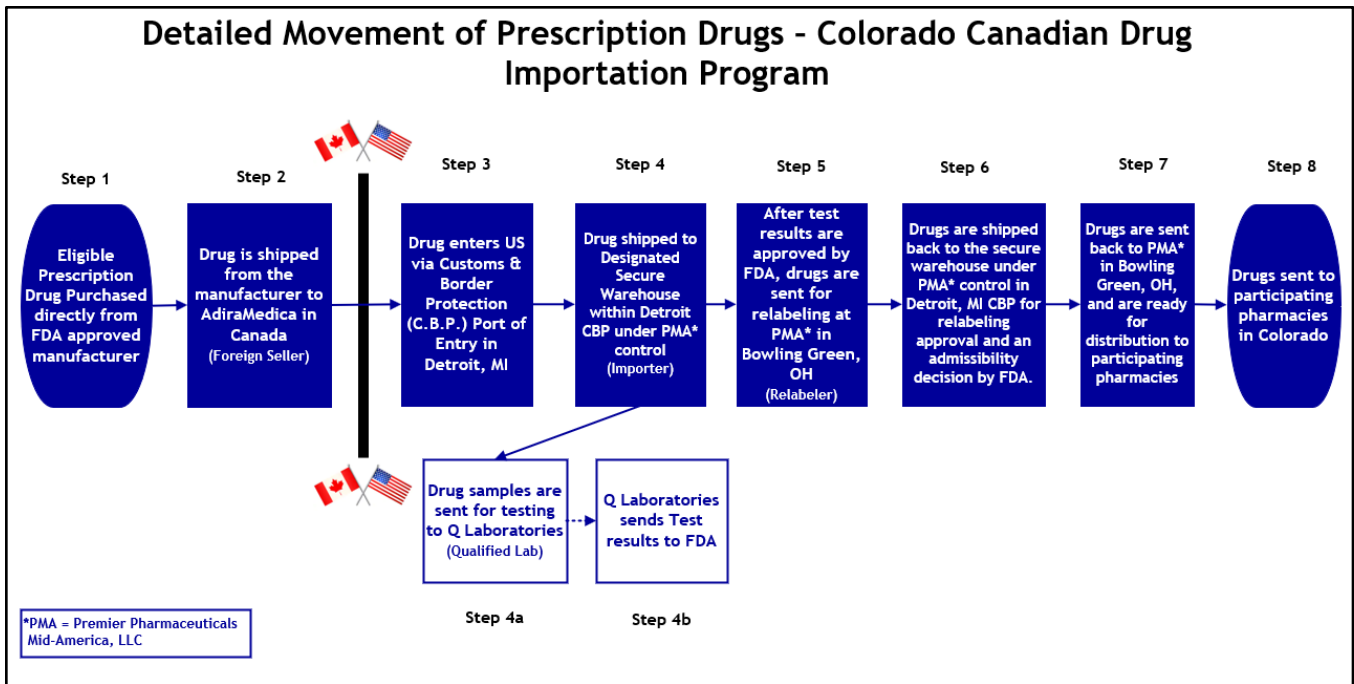
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saving Coloradans money on health care and driving value for Colorado.

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be held to standards in federal rule to ensure each drug can be tracked and traced back to the manufacturer. The Foreign Seller is contracted with HCPF’s named Importer for purposes of importing and distributing the drug to Colorado. Before distribution can occur, the Importer must ensure that batch testing has occurred by HCPF’s named FDA-approved laboratory. The Importer will contract with pharmacies that have agreed to stock and dispense drugs imported from Canada under the SIP.

Because HCPF will negotiate directly with manufacturers, in no way will a diversion scheme be used to import drugs to Colorado. Manufacturer partnerships will be key to our success, and we welcome them. The movement of approved imported drugs through the state’s program is outlined below:



We look forward to the opportunity to work with manufacturer partners to design a strategy that can best meet the needs of Coloradans.

For more information, contact:
[Colorado’s Drug Importation Division](#)

