



**COLORADO**

Department of Health Care  
Policy & Financing

1570 Grant Street  
Denver, CO 80203

# Colorado's Drug Importation Program

*Manufacturer Fact Sheet December 2022*

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 (Department) 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 the Department 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](#), the Department submitted a [final application](#) to the U.S. Department of Health and Human Services (HHS) on December 5th, 2022, to establish a Canadian prescription drug importation program, which will bring 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 aspirational drug list and outlines implementation strategies to ensure compliance with the federal Final Rule. While the Department awaits a response from the Food and Drug Administration (FDA) regarding the application, we are turning our energies to further engagement with partners, including employers, health plans, and manufacturers.

Colorado's proposed program establishes a framework to allow a Colorado registered Importer (wholesaler or pharmacy) to contract with a registered Foreign Seller (a Canadian wholesaler) to safely import eligible prescription drugs that have been approved by the FDA for importation. The Department's estimate finds that such a program could save Colorado families and employers an average of 65%.

## Section 804 Importation Program (SIP) Framework

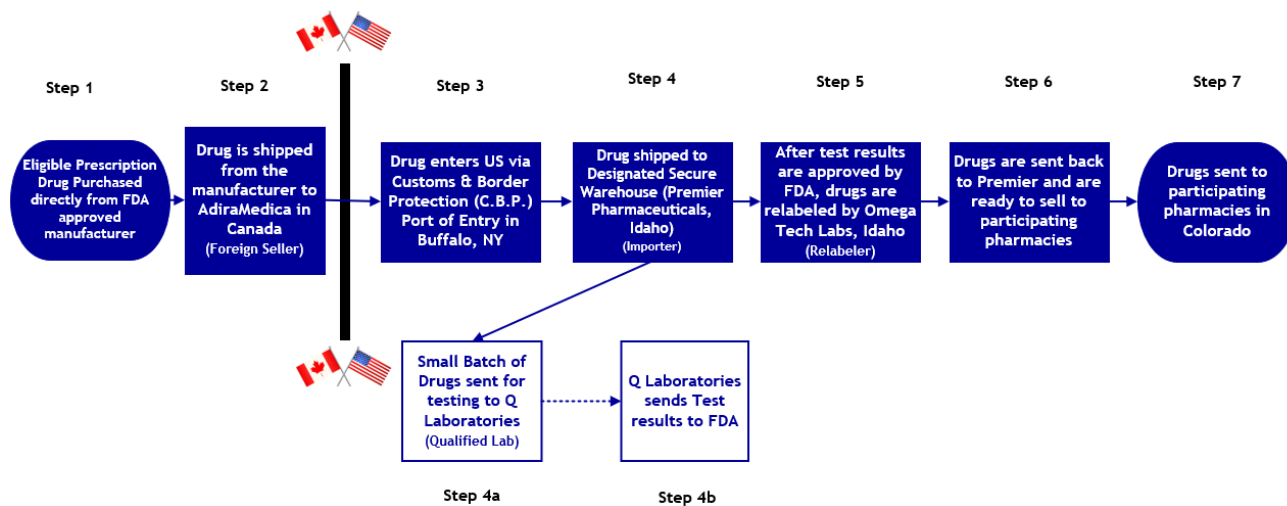
The Department's Drug Importation Division (DID) will oversee the SIP once approved, providing strong oversight and accountability. All prescription drugs approved for importation through the Colorado SIP will be the same as the current FDA-approved versions, which are produced worldwide, as is the case in the U.S. market today.



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 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 the Department’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 the Department’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 the DID 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:

### Detailed Movement of Prescription Drugs - Colorado Canadian Drug Importation Program



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](#)

