



**COLORADO**

Department of Health Care  
Policy & Financing

1570 Grant Street  
Denver, CO 80203

# Colorado's Drug Importation Program

*Frequently Asked Questions February 2023*

Since the passage of [Senate Bill 19-005](#), the Department of Health Care Policy & Financing (HCPF) has been implementing the program to bring significant prescription drug cost savings to consumers, estimated to be a 65% average reduction in costs.

## Program Timeline and General FAQ

### When will the importation program be operational?

Based on the requirements of the final rule, HCPF estimates that an importation program in Colorado could be operational by late 2023 at the earliest and is dependent on how quickly the federal government approves Colorado's application.

### What has HCPF been working on since the program began in late 2019?

HCPF efforts have included:

- Engaging with stakeholders to shape the program. HCPF conducted focused stakeholder engagement with health plans, pharmacy benefit managers (PBMs), pharmacies, and employer groups.
- Developing a [draft program proposal](#) in March 2020.
- Providing [comments](#) on the [draft rule](#) released by the Department of Health and Human Services (HHS) in December 2019. The [final importation rule](#) went into effect Nov. 30, 2020, which gives Colorado the regulatory framework needed to move forward with the process of seeking vendors.
- Releasing an [Invitation to Negotiate \(ITN\)](#), seeking vendors for the program in January 2021. Over the next year, HCPF negotiated with potential partners and [announced all selected supply chain vendors](#) on Aug. 18, 2022.
- Analyzing drug pricing data to expand our list of identified drugs for importation. Most recently, on Dec. 5, 2022, HCPF formally submitted a Section 804 Importation Program (SIP) proposal to the Food and Drug Administration (FDA) for federal approval to operate a Canadian drug importation program.
- Educating Coloradans about the program through a public stakeholder meeting on Jan. 10, 2023.

### Is Canadian importation really something that can be sustainable in the long run to address drug pricing issues?

Importation is one strong lever in addressing the high costs of prescription drugs, putting downward pressure on manufacturers to modify their current practices. This isn't the only solution to our drug pricing challenges but does provide an opportunity to demonstrate how lower prices can be achieved. HCPF issued a report, [Reducing Prescription Drug Costs in Colorado Report - 2nd Edition](#), in January 2021, which outlines strategies and solutions, including drug importation, to address these challenges.



### Why is the Canadian price different?

Canadian provincial governments and an alliance of governmental entities negotiate drug prices with pharmaceutical companies, allowing for better ability to control prices.

### Has the state talked to Canada about the program?

HCPF has had conversations with the Canadian consulate in Denver. HCPF welcomes a continued dialogue with Canada about our program. We anticipate more communication down the road when the federal government approves a Colorado importation program.

## Program Partners

### How will Colorado establish partnerships to run its importation program?

HCPF released an Invitation to Negotiate (ITN) in January 2021, soliciting vendors to make up the importation program's supply chain. On Aug. 17, HCPF announced three critical partnerships that make up the supply chain for the program.

- [AdiraMedica LLC](#), a U.S. wholesaler and their subsidiary located in Ontario, Canada, will fulfill the role of Colorado's foreign seller, which serves as the primary conduit with Canadian manufacturers. They will purchase the products for Colorado's program and ensure they meet specifications for exportation to the United States.
- [Premier Pharmaceuticals LLC](#) is a U.S. wholesaler located in Boise, Idaho and will serve as Colorado's importer. They will be the primary distributor once medications come into the U.S. and will sell the medications to participating Colorado pharmacies. Additionally, Premier manages key aspects of the program including partnering with a qualified laboratory and relabeler to ready products for the Colorado market.
- Denver's Rocky Mountain Poison and Drug Safety will be responsible for all Food and Drug Administration (FDA) required adverse event reporting as well as responding to consumer inquiries.

## Drugs Eligible for Importation

### Which drugs can be imported under the Colorado program?

Prescription drugs eligible for importation are those that could be sold legally in either the Canadian or American market with the appropriate labeling. Per federal statute, Colorado state law, and the final importation rule, the following drugs are NOT eligible for importation:

- Controlled substances (such as Percocet, Vicodin)
- Biologic products (such as Humira, insulin)
- Infused and parenteral (drugs not taken by mouth, such as those given at an infusion center)
- Intravenously injected drugs, including those given at an infusion center
- Drugs inhaled during surgery
- Drugs administered intrathecally or intraocularly
- Drugs with a Risk Evaluation Mitigation Strategy (REMS)

Colorado plans to target expensive drugs in our state that are eligible for importation. HCPF supports changes to federal statute that would allow for the importation of biologics. Many



of these drugs are widely available at pharmacy counters, require no additional safety protocols, and are some of the most expensive drugs in the state.

### **Does Colorado have a final list of drugs that will be imported?**

HCPF has analyzed hundreds of drugs eligible for importation to understand the potential for cost savings. We will be working with our selected supply chain vendors and drug manufacturers in Canada to identify the final list of drugs. However, in our analysis we have identified drug categories that may be ready for importation:

- Certain drug classes, such as medications that treat type 2 diabetes, cardiac conditions, multiple sclerosis, cancer, or HIV
- Both brand name and generic drugs
- High cost drugs that have a high unit cost
- Specialty drugs
- High volume drugs that may be a lower cost per unit, but the price difference is so significant they are worth considering (such as thyroid tablets)

In our [SIP proposal](#), submitted to the FDA in December of 2022, we analyzed over 2,000 National Drug Codes (NDCs) and our submitted list contains 112 unique drugs and dosages. This list is not yet final, pending negotiations with drug manufacturers to secure agreements to access supply.

## **Access to Imported Medications**

### **Will Health First Colorado (Colorado's Medicaid program) benefit from the importation program?**

In our initial analyses, Health First Colorado would not see significant savings from importation due to the deep discounts afforded by the Medicaid Rebate Program. That said, we may explore importing specific drugs for Health First Colorado in the future. HCPF's focus, currently, is bringing savings to the commercial market through importation.

### **Who will be able to access prescription drugs imported from Canada through the program?**

Colorado consumers may purchase Canadian imported drugs once the program is approved by the federal government. Consumers, including Medicare beneficiaries, should check to see which pharmacies are participating in the program and determine whether their health plan also covers such drugs. In some cases, it may be more affordable to purchase an imported drug not covered by your insurance. Consumers should evaluate their options.

### **Will insurers participate in the program?**

HCPF has met with health carriers and encouraged their participation in the program. However, SB 19-005, the authorizing legislation, does not mandate that plans cover imported drugs. Plans will decide whether to participate in the program and we hope they do.



**If I have insurance and go to my pharmacy, how will I know whether the imported drug would be my best option to save money? Will plan design pricing be tied to imported drug pricing?**

HCPF has been working with stakeholder partners in the pharmacy and insurance industries to promote access to transparent information to help consumers evaluate their best options for obtaining affordable drugs. Health plans will decide whether to include imported drugs in their benefit designs. Health plans will not be obligated to cover imported drugs, but if they do, they could reduce cost sharing for imported drugs. Consumers should evaluate their pricing options through their plan coverage to determine whether the imported drug is a better savings.

**Does the Importation Program take prescription drug rebates into consideration?**

Employers and plan sponsors rely on pharmacy benefit managers (PBMs) to negotiate drug discounts with a network of pharmacies, adjudicate claim transactions according to a benefit design, and secure rebates from pharmaceutical manufacturers on brand and specialty medications. Due to the volume of stakeholders in the pharmacy supply chain, PBMs capitalize on the complexity and opacity of the system to maximize gross margin on drugs. Colorado's program will not engage in the rebate structure but will instead provide prescription drugs at a "true" market value.

## Federal and State Oversight

**How is the federal government regulating the Colorado program?**

The FDA will be HCPF's main federal partner in the administration of the program. The FDA will approve the structure of the program and give the state of Colorado permission to fully implement its SIP and begin importing drugs from Canada. The state will also have an oversight role to ensure the safety and quality of the drugs imported and will be responsible for reporting this information to the FDA.

**How will imported drugs be regulated in Colorado pharmacies?**

Each state has a "board of pharmacy" which regulates the pharmacies in that state. As such, any drug imported under the importation program and available for purchase in the state of Colorado will fall under the jurisdiction of the FDA. The Colorado State Board of Pharmacy will continue to regulate the receipt, storage and proper dispensing of these drugs (like any other prescription drug) pursuant to valid, patient-specific orders once the drug is received by a Colorado-based, Board-registered pharmacy.

**Once Colorado's application is approved by the federal government, can it be taken away if the cost savings and safety promised are not achieved?**

Federal law permits the Secretary of Health and Human Services to terminate the program if the Secretary believes that the program's benefits do not outweigh any risks. That said, it is of utmost priority to HCPF that we implement a program that provides significant consumer savings while ensuring safety.

**As a drug regulator, does the FDA regulate drugs sold outside the U.S.?**

The FDA doesn't regulate drugs that are sold in pharmacies located outside the United States. However, the FDA does regulate medication that is manufactured abroad that is sold in the U.S. Those same drugs are also sold in foreign pharmacies. In fact, [68%](#) of the top 100 drugs, based on expenditures in Medicare Part D, are not made in the United States.

## Drug Distribution System

### **Aren't there concerns that our program will negatively impact the drug supply in Canada?**

Colorado fully supports protecting Canada's supply chain and access to drugs for the Canadian population. While the Canadian government has released an order barring the exportation of any prescription drug that would create or exacerbate a drug shortage, we have always taken Canadian drug shortages into account when analyzing drugs for importation and will continue to do so in the future.

### **How are drugs tracked in the United States?**

In 2013, Congress passed the Drug Supply Chain and Security Act (DSCSA), which amended the Food, Drug and Cosmetic Act (FDCA) to give the FDA increased authority to regulate drug supply chains. The DSCSA outlines steps to build an electronic system by the year 2023 to track and trace certain prescription drugs intended for sale in the United States. It requires that manufacturers, wholesale distributors, packagers, and third-party logistics providers (distributors of drugs) meet certain standards and register with the FDA. This process is meant to prevent counterfeit medication from entering the U.S. Per a series of exceptions provided by the Final Rule, Colorado's program will be fully compliant with the DSCSA.

### **Won't the importation of Canadian drugs introduce the threat of counterfeit drugs?**

The FDA indicates [78% of active pharmaceutical ingredient manufacturers](#) are located outside of the United States. Colorado's importation program will be using the same FDA approved manufacturers as the drugs in the current U.S. system today. The drugs will be relabeled to comply with U.S. standards and distribution in Colorado. The risk of counterfeit drugs entering the U.S. distribution chain would be no greater risk in an importation program than it is today.

### **Will pharmacies have the burden of a dual inventory system under this program?**

Colorado's program will not require a dual inventory system. Each imported drug will come into the state with a unique National Drug Code (NDC) identifier, indicating that the drug is specific to the state's importation program. These drugs will be like any other on a pharmacy's shelf.

### **Will pharmacies/pharmacists still be covered under their professional liability coverage if they choose to participate in Colorado's program and dispense imported medications?**

Pharmacies and pharmacists will need to check with their liability insurance providers to ensure they are covered under their specific policy. The Colorado State Board of Pharmacy will continue to regulate the proper dispensing of these drugs (like any other prescription drug dispensed in the state) pursuant to valid, patient-specific orders once the drug is



received by a Colorado-based, Board-registered pharmacy. In the course of HCPF's research on this topic, some liability coverage providers have indicated that as long as the Colorado State Board of Pharmacy allows the use of these medications to fill prescriptions and the drugs are legal to fill in Colorado, pharmacists and pharmacies would be covered under their professional liability policy for dispensing imported medications.

### **How does your program affect 340B?**

The 340B Drug Pricing Program is a U.S. federal government program that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. Colorado's importation program will operate separately from 340B and the two programs will not interact.

### **Will imported drugs have new National Drug Codes (NDCs)?**

Imported drugs through Colorado's importation program will have new NDCs as laid out in the final rule. The importer is responsible for requesting the new NDC numbers through the FDA. New NDCs come to the market all the time; therefore, a new NDC for Canadian imported drugs will not be a unique process and will not be a burden for pharmacies. The FDA transmits NDCs once a new listing occurs and sends them to Medispan, First Data Bank, and other data banks. Pharmacy computer systems receive NDCs from these data banks, allowing the drug to be dispensed just like other medications.

### **What is personal importation? Is that what Colorado is doing?**

No. Personal importation is when an individual purchases prescription drugs from a pharmacy in another country and has the drug sent to their residence. For more information on personal importation please visit the [FDA's website](#). Colorado is developing a wholesale importation program which will rely on pharmacies in Colorado to dispense to patients.

## **For more information contact**

[hcpf\\_005drugimportation@state.co.us](mailto:hcpf_005drugimportation@state.co.us)

[Colorado.gov/hcpf/drug-importation](https://colorado.gov/hcpf/drug-importation)

