



**COLORADO**  
Department of Health Care  
Policy & Financing

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# Colorado's Canadian Drug Importation Program

*Frequently Asked Questions*

*Fall 2020*

Since the passage of [Senate Bill 19-005](#), the Department of Health Care Policy and Financing (the Department) has been working to implement a Canadian prescription drug importation program to bring significant drug cost savings to consumers. Efforts have included: stakeholder engagement to shape the program, development of a [draft program proposal](#) (March 2020), and providing [comments](#) on the [draft rule](#) released by the Department of Health and Human Services (HHS) in December 2019. The [final importation rule](#) was released on September 24, which gives Colorado the regulatory framework needed to move forward with implementation.

## Program Timeline and General FAQ

### When will the Importation Program be operational?

The federal government released the final importation rule on September 24, which will go into effect on November 30, 2020. Based on the requirements of the rule, we estimate that an importation program in Colorado could be operational by mid 2022, at the earliest.

### Has the timeline been impacted by COVID-19? And what has the Department been working on since March?

The implementation timeline has not been directly impacted by the COVID-19 pandemic and public health emergency. Since March, the importation team has been conducting very focused stakeholder engagement on the operational aspects of the program. For example, we have met with health plans, pharmacy benefit managers (PBMs), pharmacies, and employer groups. In addition, The Department has continued to analyze drug pricing data to expand our list of identified drugs for importation. Now that we have a final rule, we can begin concentrating on program implementation.



## **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. The Department issued a report, *Reducing Prescription Drug Costs in Colorado*, in December 2019, which outlines some potential 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?**

The Department has had conversations with the Canadian consulate in Denver. The Department 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. However, the Department encourages the U.S. federal government, which has jurisdiction over international affairs, to engage in a robust diplomatic effort with the Canadians on this topic.

## **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)
- Biological 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 the most expensive drugs in our state that are eligible for importation. The Department 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?**

The Department has analyzed hundreds of drugs eligible for importation to understand the potential for cost savings. A final list of drugs will not be available until we have identified our different vendors, including a Canadian supplier. Our vendors will help us identify the exact drugs available to import. However, in our analysis we have identified drug categories that may be ripe for importation:

- Certain drug classes, such as medications that treat type 2 diabetes, cardiac medications, multiple sclerosis, cancer, or HIV.
- Both brand and generic drugs.
- High cost drugs that have a high unit cost.
- Specialty drugs.
- High tiered drugs. For example, if a prescription drug coverage plan has five tiers of drugs, those drugs covered at tier four or tier five are usually brand name and covered with a higher copay.
- High volume drugs that may be a lower cost per unit but the price difference is so significant they are worth considering (ex: thyroid tablets).

## **Access to Imported Medications**

### **Will Medicaid benefit from the importation program?**

In our initial analyses, the Medicaid program will 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 Medicaid in the future. The Department's focus, at this time, is bringing savings to the commercial market through importation.

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

Anyone in Colorado may purchase Canadian imported drugs once the program is approved by the federal government. Consumers 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?**

The Department 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.

### **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?**

The Department 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.

## **Federal and State Oversight**

### **Since this program would require federal approval, is the state engaged in conversations with the federal government?**

Yes, the state is in ongoing discussions with the Department of Health and Human Services (HHS) regarding our application development and will continue this engagement.

### **How is the federal government regulating the Colorado Program?**

The Food and Drug Administration (FDA) will be the Department's main federal partner in the administration of the program. The FDA will approve the structure and intent of the program and give the state of Colorado permission to fully implement and begin importing drugs from Canada. Since drugs imported through the Colorado program may only be FDA-approved drugs made in FDA-approved facilities, the FDA has oversight of such drugs. In addition, 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 located in that state. For the most part, U.S. pharmacy boards do not register or monitor pharmacies or prescription drug wholesalers in other countries. 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 Federal Food and Drug Administration (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 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 the Department 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. An [estimated 70%](#) of the brand-name medications sold in your local U.S. pharmacy are manufactured elsewhere.

## Drug Distribution System

**Have any wholesalers expressed interest in your program from either Canada or the United States?**

The Department will release an Invitation to Negotiate (ITN) at the end of 2020 for interested vendors to respond to. An ITN is a more flexible type of solicitation that will allow vendors to respond to areas of the solicitation in which they have expertise. To sign up for information about the ITN release please visit [Colorado’s Vendor Self Service Portal](#).

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

The Department will have a scorecard for selecting drugs to be included in the importation program. An evaluation of supply issues in Canada will be part of that scorecard. If a drug is at risk of a shortage in Canada, it will not be included in our drug distribution list.

**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 identify 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.

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

The FDA has estimated [40% of finished drugs](#) on the market in the US today are made in a foreign country and about [80% of active pharmaceutical ingredients](#) (the ingredients used to make the finished product) are produced overseas. Colorado's importation program will be using the same FDA approved manufacturers as the drugs in the current US system today. The drugs will be relabeled to comply with US standards and distribution in Colorado. The risk of counterfeit drugs entering the US 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.

### **How does your program affect 340(b)?**

The 340B Drug Pricing Program is a US 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 340(b) and the two programs will not interact.

### **What is personal importation? Did that just get approved?**

Section 804 of the FDCA, in addition to permitting state-led importation programs, contains a pathway for personal importation. Personal importation has never been fully implemented, but the FDA is currently pursuing a way to formalize that process. Colorado's program is separate and seeks to bring imported drugs from Canada to multiple pharmacies across the state for all Coloradans.

### **Will imported drugs have new 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.

**For more information contact**

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<https://www.colorado.gov/hcpf/drug-importation>

