



COLORADO
Department of Health Care
Policy & Financing

1570 Grant Street
Denver, CO 80203

December 1, 2021

Governor Jared Polis
136 State Capitol
Denver, CO 80203

Dear Governor Polis:

Enclosed please find a legislative report from the Department of Health Care Policy and Financing on the implementation of the Prescription Drug Importation Program.

Pursuant to section 25.5-2.5-206, C.R.S., on or before December 1st 2021, and each year after, HCPF shall submit a report including: a list of the prescription drugs that were imported under the program, the number of participating Canadian suppliers and eligible importers, the number of prescriptions dispensed through the program, the estimated cost savings during the previous fiscal year and to date, a description of the methodology used to determine which prescription drugs should be included on the wholesale prescription drug importation list established pursuant to section 25.5-2.5-203 (2)(a); and documentation demonstrating how the program ensures that: (I) the vendor verifies that Canadian suppliers participating in the program are in full compliance with relevant Canadian federal and provincial laws and regulations, (II) Prescription drugs imported under the program are not shipped, sold, or dispenses outside of the state once in possession of the eligible importer, (III) Prescription drugs imported under the program are pure, unadulterated, potent and safe, (IV) The program does not put consumers at a higher health and safety risk than if the program did not exist, and, (V) the program provides cost savings to the state on imported prescription drugs.

Since the Program has not yet started to import prescription drugs, this year's report provides a program status update. Over the last year, the Department has largely focused on a procurement process to identify the supply chain partners necessary to carry out the importation of cheaper prescription drugs from Canada. The Department anticipates the Program will be operational by mid-2023, pending federal approval.

If you require further information or have additional questions, please contact the Department's Legislative Liaison, Jo Dolin at Jo.Dolin@state.co.us or 720-610-7795.



Sincerely,



Kim Bimestefer
Executive Director

KB/maq

Enclosure(s): HCPF 2021 Prescription Drug Importation Program Report

Cc: Legislative Council Library
State Library
Tracy Johnson, Medicaid Director, HCPF
Bonnie Silva, Community Living Interim Office Director, HCPF
Tom Massey, Policy, Communications, and Administration Office Director, HCPF
Anne Saumur, Cost Control Office Director, HCPF
Bettina Schneider, Finance Office Director, HCPF
Parrish Steinbrecher, Health Information Office Director, HCPF
Rachel Reiter, External Relations Division Director, HCPF
Jo Donlin, Legislative Liaison, HCPF





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Policy & Financing**

Department of Health Care Policy and Financing
1570 Grant Street
Denver, CO 80203

December 1, 2021

The Honorable Leroy Garcia, President of the Senate
Colorado General Assembly
200 E. Colfax Avenue
Denver, CO 80203

Dear President Garcia:

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Policy & Financing**

Department of Health Care Policy and Financing
1570 Grant Street
Denver, CO 80203

December 1, 2021

The Honorable Alec Garnett, Speaker of the House
Colorado General Assembly
200 E. Colfax Avenue
Denver, CO 80203

Dear Speaker Garnett:

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Colorado's Drug Importation Program

Annual Report

December 1, 2021



COLORADO
Department of Health Care
Policy & Financing

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I. Addressing the High Cost of Prescription Drugs

As the high cost of prescription drugs continues to plague the United States, Colorado is taking steps to address this issue, which is at the forefront of health care affordability. In January 2021, the Department released a comprehensive report¹ that explains the drivers of rising prescription drug costs and the federal and state-based solutions to address them. Importation is one solution to meaningfully reduce costs for consumers, employers and other payers in the state.

II. Federal Oversight of Drug Importation

Drug Importation from Canada was made legal in the United States in 2003 but it was not until recently that the federal government took steps to implement state-led importation programs. The United States Department of Health and Human Services (HHS), through the Food and Drug Administration (FDA), has oversight of all importation programs and constructed the regulatory framework that will guide implementation and operation. All state-led programs will apply to the FDA for approval prior to importing any prescription drugs from Canada. Once in operation, programs will report to the FDA on safety, quality, and savings. Colorado has engaged with our federal partners at the FDA to ensure successful program development and implementation.

III. Progress Update

The Department of Health Care Policy & Financing (the Department) has been working to implement the Prescription Drug Importation Program since the passage of Senate Bill 19-005² at the end of the 2019 legislative session. The Department submitted a draft Section 804 Importation Plan (SIP)³ for federal consideration in March 2020 as part of a federal request for comments on rulemaking. In November 2020, the federal government issued a final rule,⁴ setting forth the framework for state-led importation programs. With that framework in hand, the Department embarked on a competitive procurement⁵ process in early 2021 to identify the necessary supply chain partners to make the importation program a reality for Colorado. Since April, the Department has been in negotiations with several candidates and intends to award contracts in early 2022. Colorado intends to submit a formal application to the FDA by mid-2022.

IV. Program Structure

Colorado's importation program will consist of multiple supply chain partners to bring high quality, lower cost prescription drugs into Colorado from Canada. The Department will be the

¹Department of Health Care Policy & Financing (2021), Reducing Prescription Drug Costs in Colorado, 2nd edition <https://hcpf.colorado.gov/sites/hcpf/files/Reducing%20Prescription%20Drug%20Costs%20in%20Colorado%20Second%20Edition.pdf>

² Colorado General Assembly (2019), Senate Bill 19-005 Concerning wholesale importation of prescription pharmaceutical products from Canada for resale to Colorado residents, https://leg.colorado.gov/sites/default/files/2019a_005_signed.pdf

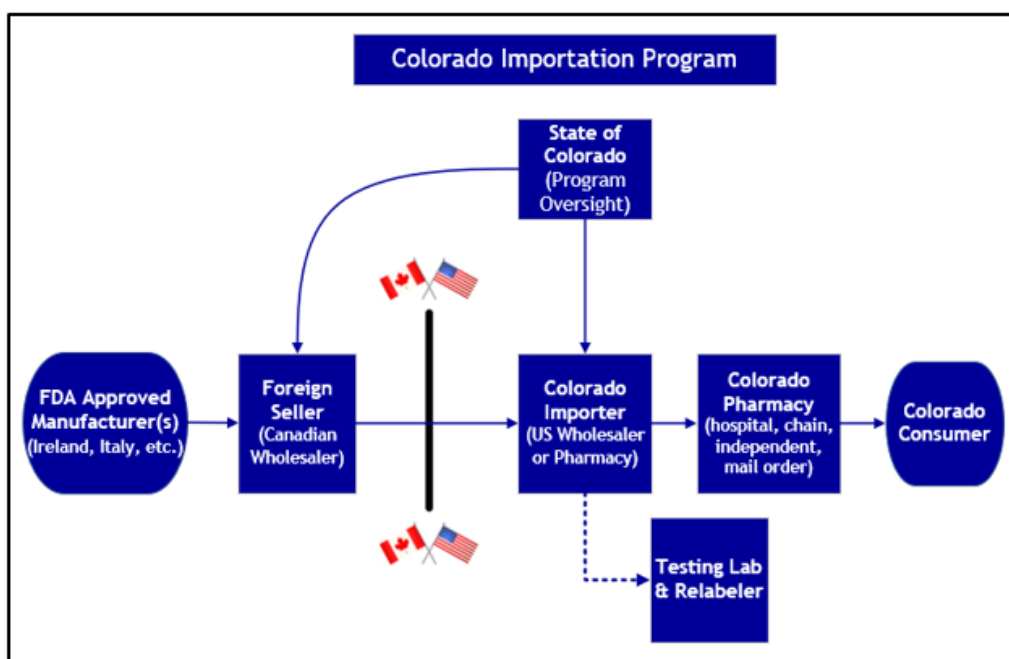
³ Department of Health Care Policy & Financing (2020), Draft Section 804 Importation Plan, <https://hcpf.colorado.gov/sites/hcpf/files/Colorado%20Draft%20SIP%20-%20-%20Version%203-9-2020.pdf>

⁴ US Department of Health and Human Services (2020), Importation of Prescription Drugs <https://www.hhs.gov/sites/default/files/importation-final-rule.pdf>

⁵ Department of Health Care Policy & Financing (2021), Invitation to Negotiate, <https://hcpf.colorado.gov/sites/hcpf/files/Drug%20Importation%20ITN%201-22-2021.pdf>

main oversight body and will hold contracts with the Foreign Seller and Importer, which are the two main roles for operating the program.

Colorado's Foreign Seller (a Canadian wholesaler) will acquire agreed-to prescription drugs from FDA approved manufacturers. This vendor will be responsible for readying the drugs for exportation by affixing a Section 804 Serial Identifier, or SSI, which provides the transactional records from the Foreign Seller in a serialized electronic form. This SSI allows drugs imported through the program to be tracked and traced in full compliance with the Drug Supply Chain Security Act (DSCSA). Colorado's chosen Importer will have a contracted relationship with the Foreign Seller and purchase the drugs intended for Colorado. Once in the United States, the Importer will coordinate the required testing of imported drugs, through a subcontract with a qualified laboratory, to ensure that these drugs are the same as the drugs in the traditional supply chain. Once the test results are approved by FDA, the Importer will coordinate the relabeling of all imported drugs for use specifically in Colorado, through a subcontract with the relabeler/repackager. The Importer will then sell imported drugs to participating Colorado pharmacies, or other eligible Colorado buyers. Coloradans will be able to access imported drugs at a lower cost at the pharmacy counters they know and trust. The following graphic illustrates the process:



V. Identified Drugs for Importation

In 2020, the Department conducted extensive analysis to identify an initial list of drugs eligible for importation. As a result and as part of our SIP, the Department released a list of 167 drugs that could be imported into Colorado at a significant savings. Since the development of this initial list, the Department continues to refine the methodology for identifying drugs for importation. This methodology includes an in-depth analysis of pricing in Colorado and Canada, consideration of rebates in the Colorado commercial market, and an analysis of drug shortages in Canada. Colorado will never seek to import any drugs from

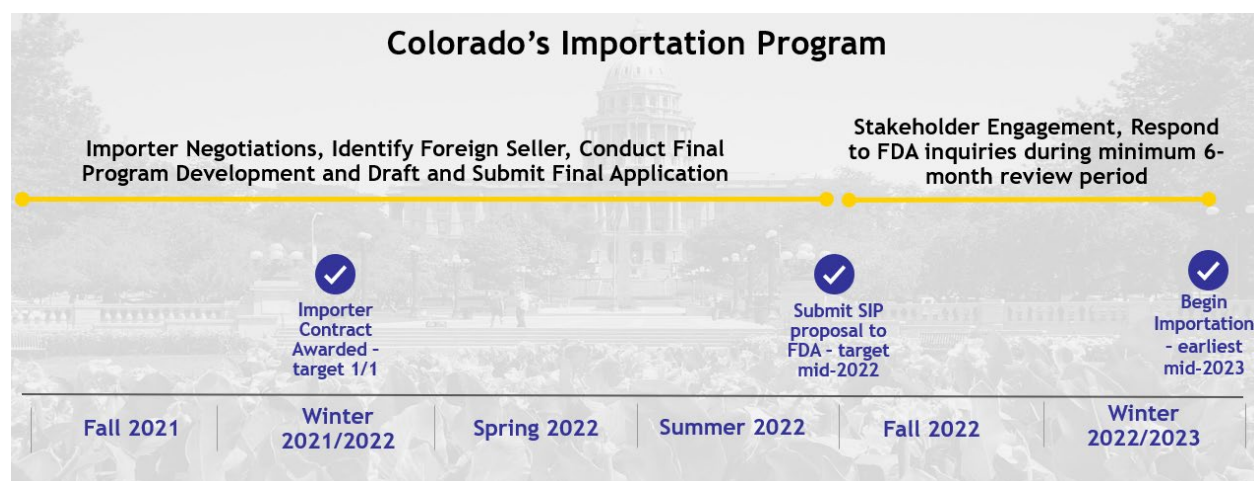
Canada that are experiencing a shortage. The resulting list will be very targeted, but, as of this reporting, has not been finalized.

However, the Department has identified categories of prescription drugs as potential candidates for importation. These categories include:

- Certain drug classes that include diabetes, cardiac, multiple sclerosis, HIV
- Brand name
- Select generics
- High cost
- Specialty
- High tiered drugs
- High volume

VI. Next Steps

The Department will announce supply chain partners in the first half of 2022 as contracts are executed and the drug list is finalized. Once these pieces are in place, the Department will finalize and submit a SIP application to the FDA by mid-2022. The FDA has set forth a timeline of six months for review and approval, so the Department estimates that a Colorado program could be operational by mid-2023, at the earliest. Throughout this process, the Department intends to hold targeted stakeholder engagements to ensure partners in Colorado are aware of progress and opportunities for engagement and participation.



Contact information:

Our team can be reached at: HCPF_005DrugImportation@state.co.us.

Please see our [program website](#) for additional information.