

Colorado's Drug Importation Program

Annual Report

Dec. 1, 2022



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Appendix
Colorado's SIP

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 of Health Care Policy and Financing (Department) released a comprehensive [report](#)¹ that explains the drivers of rising prescription drug costs and federal and state-based solutions to address them. Prescription drug Importation from Canada is one solution identified in the report that will reduce prescription drug costs for consumers, employers and other payers in the state.

II. Federal Oversight of Drug Importation

Drug Importation from Canada was authorized by Congress in the United States in 2003, but it was not until 2020 that the federal government took steps to enable the implementation of 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 must 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 has been implementing the Colorado's 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 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. The Department actively negotiated with interested vendors and announced executed contracts on August 18, 2022. Those partners are:

- [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

¹ Department 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-%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>

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.

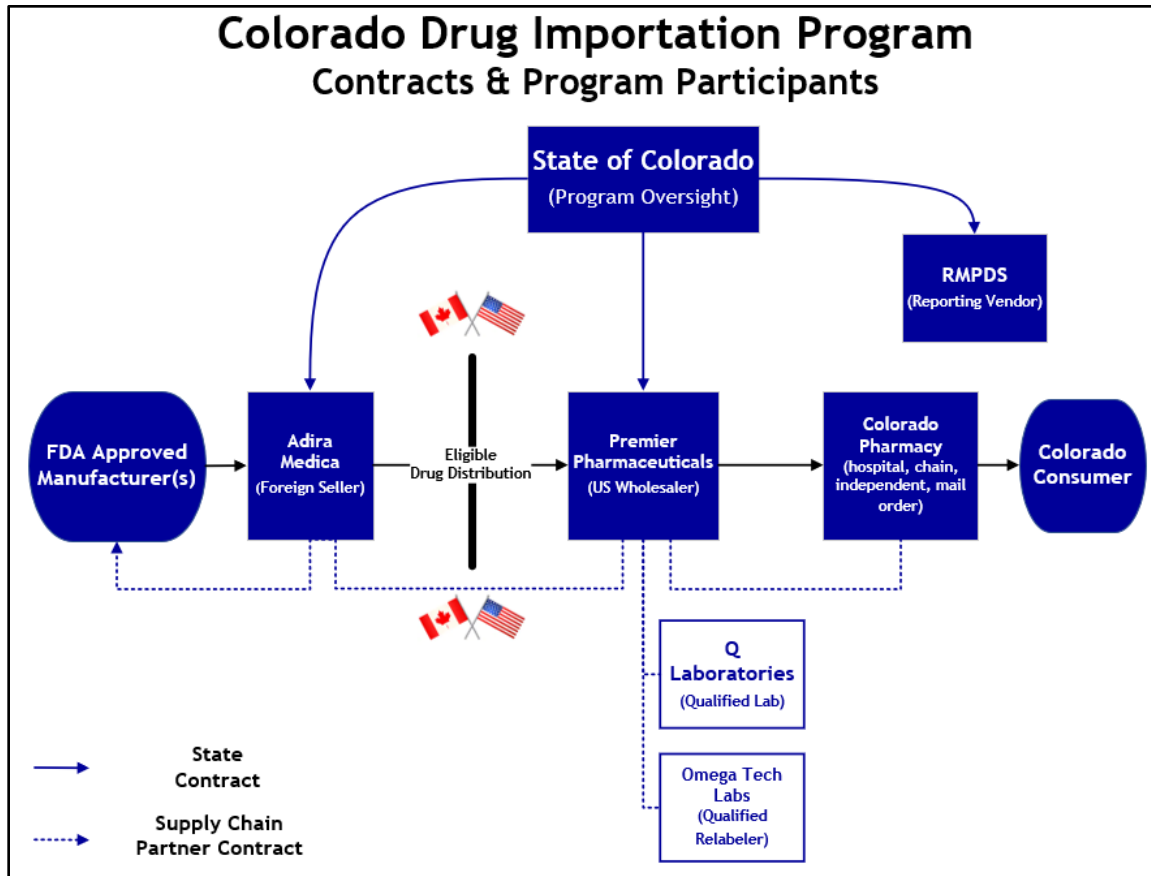
- Denver’s [Rocky Mountain Poison and Drug Safety](#) will be responsible for all FDA required adverse event reporting as well as responding to consumer inquiries.

The Department has also created a supportive network of consultants and supply chain experts to aid in the design and implementation of Colorado’s Importation Program.

IV. Colorado’s SIP

Colorado’s importation program consists of multiple partners that work together to form a unique supply chain to bring high quality, lower cost prescription drugs into Colorado from Canada. The Department will be the main oversight body for the program and holds active contracts with a Foreign Seller, an Importer and a reporting partner. Colorado will submit a formal application to FDA for review and approval on December 5, 2022, after which it will be available for review on our program [website](#).

Once the program is approved and operational, AdiraMedica will purchase the agreed-to prescription drugs from FDA-approved manufacturers. AdiraMedica 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 Importer, Premier Pharmaceuticals, 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, Premier will work with a local relabeler to relabel all imported drugs for use specifically in Colorado. Premier will then sell imported drugs to participating Colorado pharmacies. 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:



Additionally, the Department has continued to prioritize Colorado’s commitment to our Canadian neighbors to not disrupt the Canadian drug supply or import drugs on shortage in Canada. This will remain a central focus in our program.

V. Cost Savings

Per federal requirements, Colorado’s SIP includes a final proposed drug list and a cost savings analysis. To secure drug supply for Colorado’s SIP, the program’s Foreign Seller, in collaboration with the Department, will negotiate directly with manufacturers. These negotiations are ongoing and therefore, the list in the SIP is aspirational and will be amended as commitments are secured. As stated earlier, the Canadian drug supply is taken into account in our analysis—the program will never seek to import a drug if importation would negatively impact Canadians’ access to prescription drugs.

Colorado’s final drug list contains 112 unique drugs and dosages, including medications that treat conditions such as respiratory diseases, cancer, type 2 diabetes, HIV, multiple sclerosis and more, as outlined in the chart below. The list presents high cost and/or high-volume drugs using Colorado-specific data from the Colorado All Payer Claims Database (APCD), including both brands and generics.⁶ All of these medications have a significant impact on affordability in the state—from employers and health plans to consumers. These drugs are

⁶ Center for Improving Value in Health Care. (2022) Colorado All Payer Claims Database. <https://www.civhc.org/get-data/whats-in-the-co-apcd/>

integral to the everyday life of Coloradans, representing, in many cases, lifesaving solutions if lower prices can be achieved. A summary of the drug classes targeted in the Department’s most recent analysis and their associated percent savings from importation is below.

| Drug Category | Number of Unique Drugs | % Savings |
|---|------------------------|-----------|
| Anaphylaxis | 4 | 24% |
| Antipsychotic | 4 | 91% |
| Blood Thinners | 6 | 73% |
| Cancer | 18 | 56% |
| Dry eyes | 3 | 59% |
| HIV | 10 | 53% |
| Low Blood Sugar | 3 | 54% |
| Multiple Sclerosis | 6 | 64% |
| Respiratory | 28 | 66% |
| Smoking Cessation | 4 | 80% |
| Type 2 Diabetes | 12 | 78% |
| Women's Health | 6 | 62% |
| Miscellaneous Classes | 8 | 69% |
| Colorado Department of Health Care Policy & Financing, 2022 | | |

Latuda is a staggering example of savings from Colorado’s importation program with a 90% savings. For a month’s supply of this highly utilized drug used to treat schizophrenia, a Coloradan without insurance coverage could expect to pay nearly \$1,500. Colorado’s SIP could supply an imported version to close to \$120 per month. For those with insurance coverage, cost varies depending on how the drug is covered on benefit formularies, but this would account for a significant savings to the plan and could result in potential significant savings for consumers if plans were to pass the savings on to patients in the form of a zero-dollar co-pay.

Our detailed evaluation finds that the Colorado SIP has the potential to provide an estimated \$53 to \$88 million in annual savings in the commercial market, if all 112 drugs on the list were to be imported. The analysis shows an average of 65% savings across all drugs. The range of savings depends on the degree of adoption in the market. Rather than assume a 100% adoption of imported drugs across the market, Colorado conservatively estimates a 15-25% replacement within the market, as illustrated in the chart, below.



| Colorado Drug Spend and Potential Savings for Complete SIP Drug List | | | |
|--|------------------------------------|-------------------|----------------------------|
| Annual Drug Spend (Commercial Market) | Estimated Annual Importation Spend | Potential Savings | Market Replacement Percent |
| \$134,639,802 | \$47,012,296 | \$87,627,506 | 25% |
| \$80,783,881 | \$28,207,378 | \$52,576,504 | 15% |
| Colorado Department of Health Care Policy & Financing, 2022 | | | |

VI. Next Steps

Once submitted, the Department will await FDA approval of Colorado’s SIP. The FDA has set forth a timeline of six months for review, so the Department estimates that a Colorado program could be operational by late 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.