

# Colorado's Drug Importation Program

*Annual Report to the Colorado General Assembly*

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

# Contents

Contents	2
Executive Summary	3
Introduction & Background	4
Progress Update (2024 Q4-2025)	5
Next Steps	7
Conclusion	7

## Executive Summary

This report documents Colorado’s continued progress to stand up a safe, compliant Section 804 Drug Importation Program. HCPF continues to engage federal partners to ensure operational readiness so the state can import identified prescription drugs once authorized. The program remains focused on delivering lower prices on drugs while maintaining FDA’s safety and quality requirements.

Prescription drug prices remain a major affordability challenge for families, employers, and state programs. Colorado’s Section 804 effort - first authorized by SB 19-005<sup>1</sup> and in development with FDA oversight since 2019 - aims to provide a regulated pathway to import certain lower-priced drugs from Canada, subject to rigorous safety, labeling, testing, and pharmacovigilance controls.

On December 20, 2024, in response to Colorado’s Section 804 Importation Proposal (SIP),<sup>2</sup> FDA issued Colorado a Request for Information (RFI)<sup>3</sup>, requiring compliance resolution on relabeling and testing procedures. Following the issuance of the RFI, FDA sent Colorado a letter on January 10, 2025 re-affirming that, if Colorado addresses the previously stated deficiencies, the Agency will be positioned to authorize the SIP.<sup>4</sup> Colorado responded by updating standard operating procedures (SOPs) with an emphasis on relabeling and clarifying procedures. Colorado resubmitted the SIP in March 2025 and plans to resubmit again in December 2025. To reduce costs and increase efficiency, the Department initiated a consolidation of certain supply-chain functions later in the year and will reflect associated changes via SIP amendment. The Department plans to resubmit an amended SIP with updated importer information in early December.

Immediate next steps include: Resubmit amended SIP; Await further feedback from the FDA on our latest SIP application; File an additional potential SIP amendment capturing supply-chain updates; finalize RFI-responsive SOPs and labeling materials for rapid pre-import submissions post-authorization; and continue coordinated work with FDA’s Office of Drug Security, Integrity, and Response team.

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<sup>1</sup> [SB19-005: Import Prescription Drugs From Canada.](#)

<sup>2</sup> [Section 804 Importation Proposal.](#) The RFI was to the August 2024 application which has since been updated in March 2025.

<sup>3</sup> [December 2024 RFI](#)

<sup>4</sup> [Letter from FDA Commissioner Califf to Governor Jared Polis](#)

## Introduction & Background

As the high cost of prescription drugs continues to drive up the overall cost of health care in the United States, Colorado continues to implement strategies that address this critical affordability issue. HCPF released a comprehensive report identifying the drivers of rising prescription drug costs and the federal and state-based solutions to address them.<sup>5</sup> Drug importation from Canada is a central solution identified in the report designed to meaningfully reduce prescription drug costs for consumers, employers and other payers in the state.

Drug importation from Canada, as it stands today, was made legal in the United States in 2003, but it was not until recently that the federal government took steps to enable the implementation of state-led importation programs by releasing program necessary rules and regulations. In October 2020, the United States Department of Health and Human Services (HHS) promulgated a final rule<sup>6</sup> pursuant to Federal Food, Drug, and Cosmetic Act Section 804 to implement a program to allow states and other eligible sponsors to submit proposals to HHS' FDA to operate time-limited SIP. HHS, through FDA, oversees all drug importation programs, including Colorado's, under the regulatory framework outlined in the final rule. Any SIP proposal must be approved by FDA prior to importing prescription drugs from Canada. Once in operation, programs will report regularly to FDA on safety, quality, and savings.

HCPF has been implementing Colorado's Drug Importation Program since the passage of Senate Bill 19-005. Figure 1 outlines the timeline below:

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<sup>5</sup> Department of Health Care Policy & Financing (2021), Reducing Prescription Drug Costs in Colorado, 2<sup>nd</sup> edition. <https://hcpf.colorado.gov/sites/hcpf/files/Reducing%20Prescription%20Drug%20Costs%20in%20Colorado%20Second%20Edition.pdf>

<sup>6</sup> Importation of Prescription Drugs Final Rule. <https://www.hhs.gov/sites/default/files/importation-final-rule.pdf>

**Figure 1. Importation Timeline**



### Progress Update (2024 Q4-2025)

This update covers Colorado’s SIP development activities from December 2024 through late 2025. It begins with FDA’s December 20, 2024 RFI, continues through early-2025 FDA engagement, documents the State’s SIP resubmission in March 2025, and summarizes ongoing operational readiness while the application remains with FDA for approval. The program estimates \$46.2 million in cost-savings over a 3 year period by importing 19 unique drugs and dosages.

#### What We Did

HCPF worked closely with program supply chain partners and consultants to address the RFI topics and close any identified deficiencies. This included clarifying the Drug Supply Chain Security Act (DSCSA)<sup>7</sup> product-identifier procedures in relabeling SOPs; detailing pharmacovigilance responsibilities, describing the level of testing that will be provided in pre-import requests consistent with 21 CFR 251.16(d); and documenting distribution logistics and facility specifics. In parallel, the team corrected the 20 drug labels to align fully with the final rule requirements. These steps together support timely SIP authorization, protect potential consumer savings, and ensure end-to-end program feasibility once operating.

On March 10, 2025, Colorado’s Drug Importation program filed an updated SIP, responsive to the RFI. FDA acknowledged receipt of the resubmission, and we are

<sup>7</sup> [Drug Supply Chain Security Act](#)

awaiting their response. Colorado’s Drug Importation program has continued program development so the program can move quickly upon FDA approval.

HCPF also engaged the federal government on broader policy matters that could affect program viability by submitting comments urging tariff exclusions for pharmaceuticals to avoid eroding projected savings and recommending pragmatic regulatory adjustments to reduce reliance on manufacturer cooperation and to increase supply-chain flexibility.<sup>8</sup> Later in 2025, the Department consolidated select supply-chain functions by naming AdiraMedica - the program’s Foreign Seller - as Importer, replacing Premier Pharmaceuticals. Aligning the Foreign Seller and Importer reduces one transfer in the distribution chain, which simplifies handling, lowers administrative cost, and decreases opportunities for handling error or temperature excursions, while all DSCSA, cGMP, and Part 251 controls remain in place. As steward of the program, the Department’s role is to design the strongest, safest, and most cost-effective supply chain possible. As of the drafting of this report, a corresponding SIP amendment is planned in November to reflect role changes and associated operational controls.

### Why We Took This Approach

Colorado’s recommended practical adjustments to Parts 1 and 251—tools to mitigate manufacturer non-cooperation (e.g., restoring NPRM-style fallback authority for FDA to provide needed information), flexibility to allow multiple foreign sellers, and options to reduce redundant shipping/testing steps while maintaining statutory testing in the U.S. Federal comments were filed to mitigate external cost pressures (tariffs) and to streamline rules that limit supply-chain flexibility or rely on manufacturer cooperation, thereby protecting potential consumer savings. In addition to Colorado’s May comment letters, national policy signals—an April 15th Executive

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<sup>8</sup> Colorado OMB Deregulation Request for Information Final Rule.

<https://hcpf.colorado.gov/sites/hcpf/files/Colorado%20Comment%20Letter%20OMB%20Deregulation%205-5-2025.pdf>

Colorado Response for Section 232 Investigations of Pharmaceutical Tariffs.

<https://hcpf.colorado.gov/sites/hcpf/files/Colorado%20Comment%20Letter%20Tariff%20Section%20232%205-5-25.pdf>

Colorado Response for MAHA AHRQ Request for Information.

<https://hcpf.colorado.gov/sites/hcpf/files/Colorado%20Response%20for%20MAHA%20AHRQ%20RFI.pdf>

Order directing Section 804 streamlining<sup>9</sup> and a May 21st FDA announcement describing program enhancements<sup>10</sup>—reinforced the focus on procedural readiness.

## Next Steps

Colorado will maintain a narrow focus on procedural readiness and targeted federal engagement while FDA completes its review. Specifically, HCPF will: finalize and submit the SIP amendment and continue implementation readiness work so that priority drugs can move quickly post approval. HCPF will proceed on two tracks: (1) responding to FDA-identified items to secure program approval; and (2) preserving program savings and resilience through measured federal engagement and negotiations with manufacturers.

Colorado will maintain participation in federal processes to advance targeted regulatory updates that reduce dependence on manufacturer cooperation, allow multiple Foreign Sellers, and minimize redundant U.S. shipping/testing legs while preserving statutory testing in the United States.

## Conclusion

Colorado’s Drug Importation Program continues to prioritize safe, compliant implementation as a practical lever to lower prescription drug costs for Coloradans, within the federal framework governing Section 804 programs. The State’s approach centers on a tightly managed, compliant importation pathway that preserves safety and quality while maximizing savings for consumers, employers and other purchasers. HCPF looks forward to an approval from the FDA.

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<sup>9</sup> Lowering Drug Pricing by Once Again Putting Americans First.  
<https://www.whitehouse.gov/presidential-actions/2025/04/lowering-drug-prices-by-once-again-putting-americans-first/>

<sup>10</sup> Delivering Most-Favored-Nation Prescription Drug Pricing To American Patients.  
<https://www.whitehouse.gov/presidential-actions/2025/05/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients/>

