Colorado's Drug Importation Program

Annual Report to the Colorado General Assembly

December 1, 2024

COLORADO
Department of Health Care Policy & Financing

Contents

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Department of Health Care Policy & Financing

I. Executive Summary

The Department of Health Care Policy and Financing (HCPF) has been implementing Colorado's Drug Importation Program since the passage of Senate Bill 19-005[1]. HCPF submitted its original Section 804 Importation Programs (SIP) application in December 2022 and has since engaged regularly with federal partners at the Food and Drug Administration (FDA) to ensure successful program development and implementation. In 2024, HCPF made significant progress by submitting an amendment to the SIP on February 27, 2024, followed by a second amendment on August 28, 2024. A new actuarial analysis of a narrowed list of 24 unique drugs and dosages found that the program would conservatively save an estimated $50.9 million from 2025 to 2027, should the program be fully implemented in 2025, compared to costs absent a program. HCPF remains focused on refining program operations, strengthening partnerships, and working to solicit drug manufacturers participation, despite resistance from drug manufacturers thus far.

II. 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. In January 2021, HCPF released a comprehensive report[2] identifying the drivers of rising prescription drug costs and the federal and state-based solutions to address them. 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. In October 2020, the United States Department of Health and Human Services (HHS) promulgated a

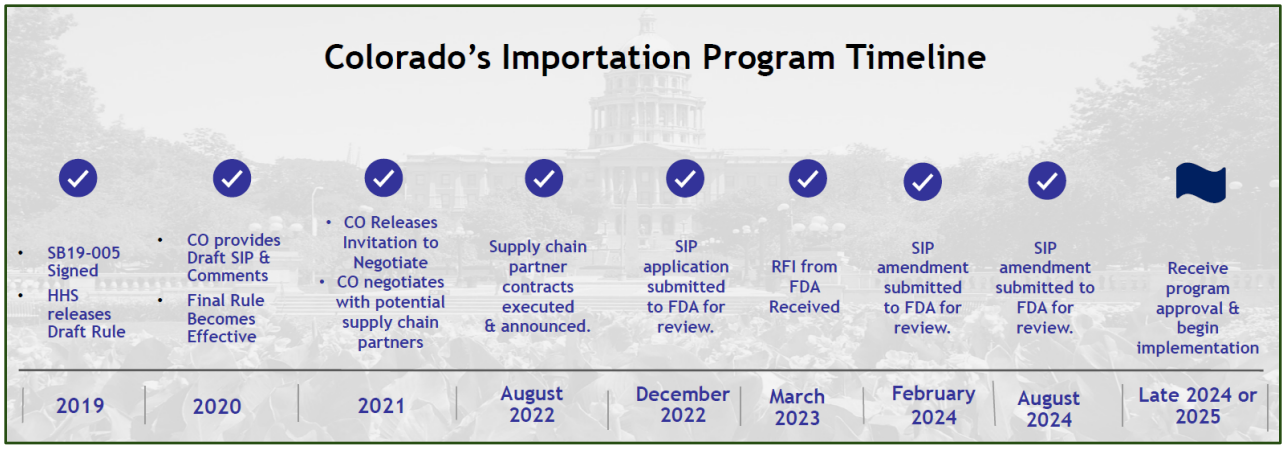
[1] Colorado General Assembly (2019), Senate Bill 19-005 Concerning wholesale importation of prescription pharmaceutical products from Canada for resale to Colorado residents, https://leg.colorado.gov/sites/default/files/2019a_005_signed.pdf

[2] 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

final rule[3] 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:

Figure 1. Importation Timeline



III. Progress Update

In 2024, HCPF made two key submissions to FDA, including a substantial amendment to the SIP on February 27, 2024, and a second, administrative amendment on August 28, 2024. The February 2024 amendment responded to all questions included in the FDA's March 3, 2023, Request for Information (RFI)[4] including, but not limited to, further refining the target eligible prescription drug list to 24 unique drugs and dosages, a new comprehensive and independent

[3] https://www.hhs.gov/sites/default/files/importation-final-rule.pdf

[4] https://hcpf.colorado.gov/sites/hcpf/files/Appendix%20H%20FDA%20Correspondence%20All%20files%202.23.24_accessible.pdf, page 8

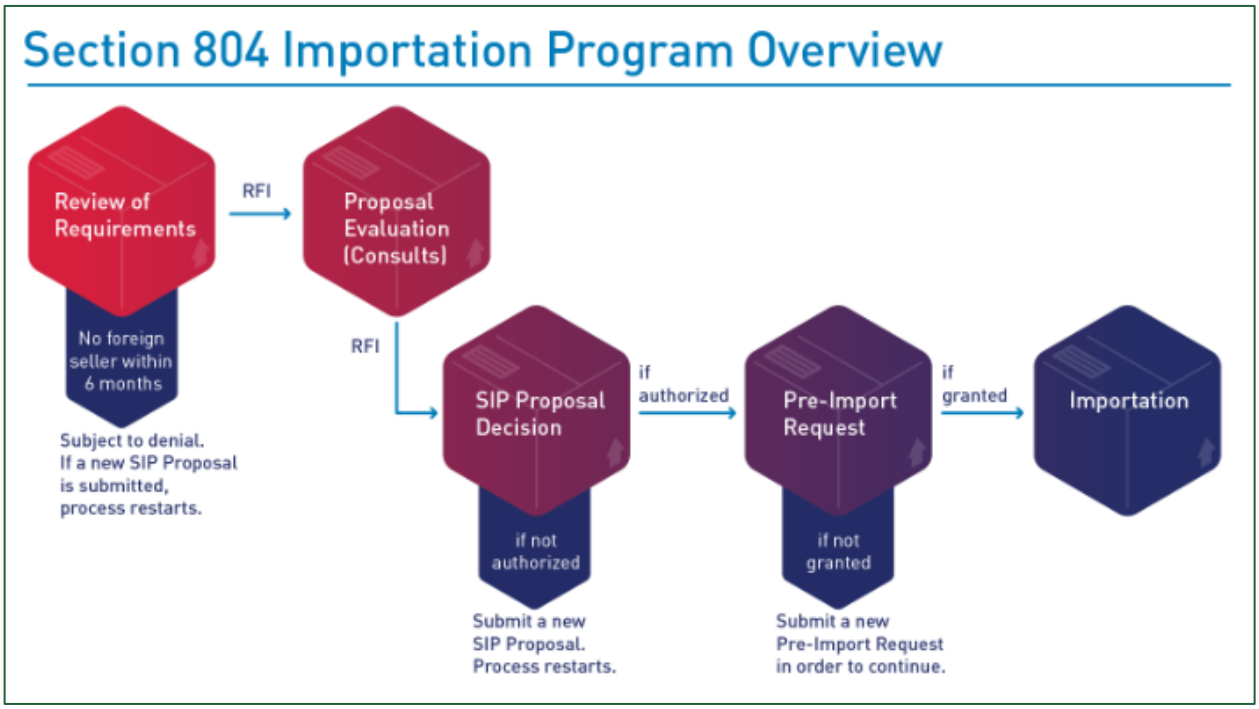
actuarial cost analysis of the program, details on FDA compliance and quality measures, additional laboratory testing information, and all required labeling changes. The second amendment reflects an administrative program change of the importer warehouse location from Ohio back to Idaho. There were no changes to the cost analysis in the second amendment. These submissions represent crucial milestones in Colorado's ongoing effort to establish a sustainable and compliant importation program under FDA's oversight.

HCPF has maintained communication with FDA throughout the year. HCPF has continued to engage with FDA representatives to discuss technical questions, raise concerns, and invite focused discussions to address challenges faced by state-led importation programs. Most importantly, HCPF has raised concerns with FDA about how importation programs should acquire drug supply. The FDA's final rule does not contemplate the need to seek permission from or negotiate with drug manufacturers to import their drugs to the U.S., which will be necessary to successfully operate a program. Despite this reality, HCPF remains committed to working alongside FDA to address this obstacle; illuminate drug manufacturers' defiant lack of engagement with HCPF on Canadian drug importation efforts to date in order to protect their U.S. prices and profits, which are multiples higher than all other nations; and concurrently seek drug manufacturers that will engage in an effort to be part of Colorado's Canadian drug importation solution in the best interest of Coloradans, employers and taxpayers. Further, HCPF also continues to request information and clarification from FDA on its expectations and timelines around the SIP submission process.

Per Figure 2 below, which is the five step process presented by FDA, the HCPF application is at the SIP Proposal Decision step (step 3) and awaiting final approval or receipt of another RFI from FDA. While waiting, HCPF is actively preparing the necessary details to submit pre-import requests (one per drug, step 4) as soon as the program is approved by FDA. This includes working with program contractors including AdiraMedica, LLC. and Premier Pharmaceuticals LLC., the Foreign Seller and Program Importer, respectively, to refine the logistical processes required to bring safe and affordable imported drugs into Colorado. In addition, HCPF is further developing the program's compliance and reporting requirements with Rocky Mountain Poison & Drug Safety (RMPDS), the program's third vendor. HCPF continues to certify program partners with site visits to each importation partner on

a regular basis, as per contract terms, to ensure partner compliance with FDA safety standards and program supply chain requirements. Lastly, HCPF continues to evaluate the drug list, advance its manufacturer outreach strategy, and respond to ongoing stakeholder requests.

Figure 2. FDA Importation Progress Diagram



from: https://www.fda.gov/about-fda/reports/importation-program-under-section-804-fdc-act

IV. Cost Analysis

Section 804 requires that a SIP include a cost savings analysis to demonstrate that the state's importation program will bring significant cost savings to consumers. Colorado's December 2022 application contained 112 unique high cost, high-volume drugs and dosages commonly used by Coloradans, including medications that treat conditions such as respiratory, cancer, Type 2 diabetes, HIV, multiple sclerosis and more.

Based on feedback from FDA on our December 2022 application, HCPF updated this cost analysis for our February 2024 submission by providing greater detail to evaluate cost savings for program medications included in the SIP compared to costs for these same medications absent a program. At the suggestion of FDA and the HHS Assistant Secretary for Planning and Evaluation (ASPE) office, HCPF narrowed the drug list. The actuarial analysis from Lewis & Ellis Inc. found that the

updated list of 24 unique drugs and dosages will result in significant cost savings, showing that if approved, the SIP can conservatively save an estimated $50.9 million (2025-2027) compared to costs absent a program.[5] Table 1 below details the cost savings projected for each individual SIP Selected Drug in 2027.

Table 1. Savings by Drug

Drug Name	Strength	Category	2027 Baseline Scenario Price per Unit	2027 Plan Scenario Importation Price per Unit	Savings Percentage
Biktarvy	50/200/25 mg	Specialty	$118.28	$55.81	53%
Eliquis	2.5 mg	Brand	$7.20	$3.74	48%
Erleada	60 mg	Brand	$117.81	$42.90	64%
Ibrance	75 mg	Specialty	$521.99	$258.54	50%
Ibrance	100 mg	Specialty	$523.65	$246.82	53%
Ibrance	125 mg	Specialty	$498.41	$235.09	53%
Janumet	50/500 mg	Specialty	$4.88	$3.93	19%
Janumet	50/1000 mg	Brand	$4.86	$3.25	33%
Januvia	25 mg	Brand	$9.97	$8.17	18%
Januvia	50 mg	Brand	$9.56	$6.99	27%
Januvia	100 mg	Brand	$10.15	$6.17	39%
Odefsey	200/25/25 mg	Brand	$95.94	$64.41	33%
Otezla	30 mg	Brand	$64.76	$35.39	45%
Ozempic	0.25/0.5 mg	Brand	$502.59	$275.13	45%
Ozempic	1 mg	Brand	$268.00	$137.57	49%
Prezcobix	800/150 mg	Brand	$60.80	$49.12	19%
Rinvoq	15 mg	Brand	$176.55	$76.73	57%
Spiriva Respimat	2.5 mcg	Brand	$53.25	$20.51	61%
Sprycel	100 mg	Brand	$397.35	$127.36	68%
Symtuza	800/150/200/10 mg	Brand & Specialty	$133.63	$98.49	26%
Tivicay	50 mg	Brand & Specialty	$50.40	$36.02	29%
Trikafta	100/50/75 mg co-packaged with 150 mg	Brand & Specialty	$325.91	$268.37	18%
Triumeq	600/50/300 mg	Brand & Specialty	$71.86	$55.79	22%

[5] https://hcpf.colorado.gov/sites/hcpf/files/Appendix%20E%20Cost%20Savings%20Analysis%20All%20files%20combined%202.23.24_accessible.pdf

Victoza 3 PAK	18 mg/3 mL	Brand & Specialty	$59.03	$48.68	18%

V. Implementation Challenges

As illustrated in our 2023 annual report[6] HCPF identified several complex implementation challenges facing importation programs. These challenges are reiterated below:

I. **Securing drug supply:** Because drug manufacturers in Canada have contract terms with wholesalers that prohibit the exportation of drugs to the U.S., Colorado is unable to secure drug supply absent direct negotiation, and ultimately a contractual agreement, with manufacturers. As the federal Final Rule did not contemplate the need for this negotiation step, we have continued to urge FDA to release further guidance regarding how states can operationalize the program with this in mind, but to date, no guidance has been released. We also continue to advance our manufacturer outreach strategy in an effort to seek their active program engagement and negotiations to the betterment of Coloradans, employers and taxpayers.

II. **Resistance by drug manufacturers:**

A. HCPF has taken proactive steps to engage manufacturers to secure drug supply for the program. In 2023, we outreached 23 companies that manufacture prescription drugs that are on our target importation list. Of these, nine companies declined to meet and negotiate. Four agreed to meet, but indicated they would not participate in the program. Ten companies did not respond at all to our request to meet after multiple attempts.

B. The industry's continued resistance was verified by a recent Citizen Petition amendment filed June 17, 2024, in which multiple pharmaceutical companies and other organizations asked FDA to refrain from authorizing Colorado's SIP application.[7] HCPF responded to the petition on July 30, 2024.[8]

III. **Lack of regulatory clarity:** Because the rule did not contemplate the need to negotiate with manufacturers, there is a disconnect between the intended and

[6] https://hcpf.colorado.gov/sites/hcpf/files/HCPF%20Drug%20Importation%20Annual%20Report%202023.pdf
[7] https://www.regulations.gov/document/FDA-2023-P-1773-0004
[8] https://hcpf.colorado.gov/sites/hcpf/files/Colorado%20Citizen%20Petition%20Response%20Docket%20No.%20FDA-2023-P-1773-004%207.30.24.pdf

actual implementation of the rule, including around manufacturer attestation and labeling requirements.

We have provided FDA with detailed information regarding these concerns. If FDA provides further guidance on these concerns, we will make additional changes to our current SIP accordingly.

VI. Next Steps

HCPF will continue to request collaboration with FDA and other stakeholders to ensure a successful program launch, once FDA authorizes Colorado's program. Once authorized, program success will depend on regulatory clarity and the willingness of drug manufacturers to engage with the program, both of which are critical to achieving the state's goal of making prescription drugs more affordable for Coloradans.