

Colorado's Drug Importation Program

Annual Report to the Colorado General Assembly

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I. Executive Summary

As the high cost of prescription drugs continues to drive up the overall cost of health care in the United States, Colorado is taking steps to address this health care affordability issue. In January 2021, the Department of Health Care Policy and Financing (HCPF) released a comprehensive report¹ that explains the drivers of rising prescription drug costs and the federal and state-based solutions to address them. Drug importation is one solution identified in the report 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 more recently 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), oversees all drug importation programs and constructed the regulatory framework that guides implementation and operation. All state-led programs must apply to FDA, via a Section 804 Importation Program (SIP) application, and receive FDA approval prior to importing any prescription drugs from Canada. Once in operation, programs will report to FDA on safety, quality, and savings. HCPF engages regularly with our federal partners at FDA to ensure successful program development and implementation.

HCPF has been designing and implementing this program since 2019, including submitting the SIP application in December 2022,² identifying the necessary supply chain partners, and actively negotiating with interested vendors. Through this process, we have identified a few significant challenges, including: securing drug supply for the program, drug manufacturer resistance, and regulatory ambiguity. Colorado has taken care to fulfill the requirements laid out in the final rule; however, these challenges require further FDA and/or manufacturer action to be resolved.

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 Department of Health Care Policy & Financing (2022), Section 804 Importation Plan, <https://hcpf.colorado.gov/sites/hcpf/files/Colorado%27s%20Drug%20Importation%20Program%202022%20Formal%20SIP.pdf>

As part of the review process, Colorado regularly engages with federal partners at FDA to address questions and clarify parts of the SIP. In response to an FDA request for information (RFI), HCPF will submit an updated SIP to FDA in early 2024. This update will include a new cost savings analysis and a significant update to the program's compliance plan.

II. Progress Update

HCPF has been implementing Colorado's Drug Importation Program since the passage of Senate Bill 19-005³ at the end of the 2019 legislative session. Implementation has included in-depth research and stakeholder engagement as well as the design of a unique supply chain to bring lower cost imported prescription drugs to Colorado. HCPF submitted a draft Section 804 Importation Plan (SIP)⁴ in March 2020 as part of a federal request for comments on rulemaking. In November 2020, the federal government issued a final rule,⁵ setting forth the regulatory framework for state-led importation programs. With that framework in hand, HCPF embarked on a competitive procurement process⁶ in early 2021, to identify the necessary supply chain partners required by the final rule to make the importation program a reality for Colorado. HCPF negotiated with interested vendors, including a U.S. wholesaler and a Canadian wholesaler, and announced executed contracts in August 2022. On Dec. 5, 2022, HCPF formally submitted a SIP⁷ to FDA for review and approval. Since submitting the SIP, HCPF has continually and collaboratively communicated with FDA, and sought guidance on outstanding implementation questions. Additionally, HCPF is currently developing a substantial response to an FDA Request for Information (RFI)

³ 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

⁴ 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>

⁵ US Department of Health and Human Services (2020), Importation of Prescription Drugs <https://www.hhs.gov/sites/default/files/importation-final-rule.pdf>

⁶ Department of Health Care Policy & Financing (2021), Invitation to Negotiate, <https://hcpf.colorado.gov/sites/hcpf/files/Drug%20Importation%20ITN%201-22-2021.pdf>

⁷ Department of Health Care Policy & Financing (2022), Section 804 Importation Plan, <https://hcpf.colorado.gov/sites/hcpf/files/Colorado%27s%20Drug%20Importation%20Program%202022%20Formal%20SIP.pdf>

received by the state on March 2, 2023. Based on these discussions and information Colorado has received from FDA, we anticipate submitting an update to our SIP in early 2024.

This past year, we have focused on additional supply chain development and worked with FDA to advance our SIP. Once we have submitted our updated SIP, we will conduct further outreach to stakeholders in Colorado who are critical to the success of this program including: consumers, employers, pharmacists, health carriers, pharmacy benefit managers, and drug manufacturers.

III. Cost Savings

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, including medications that treat conditions such as respiratory disease, cancer, Type 2 diabetes, HIV, multiple sclerosis and more. The estimated savings from that analysis found that Colorado could achieve \$53 to \$88 million in annual savings, if all 112 drugs on the list were imported, with an average of 65% savings across all drugs.

Based on feedback from FDA on our December 2022 application, HCPF is updating this cost analysis 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 request of FDA and the HHS Assistant Secretary for Planning and Evaluation (ASPE) office, we are also narrowing our drug list cost analysis because ASPE wants the ability to duplicate our savings findings as part of its review and prefers a smaller data set. HCPF is working with Lewis & Ellis Inc., an actuarial firm, to assist with this study.

IV. Implementation Challenges

Over the last year, HCPF has identified several complex implementation challenges. We are working diligently to address these obstacles and continue to do everything within state authority to fully implement the program, including contracting with federally-required supply chain partners. Generally, the challenges that remain are outside state authority and rely on action by FDA and/or drug manufacturers. These challenges are outlined below:

1. **Securing drug supply:** Because drug manufacturers in Canada have contract terms with wholesalers, including any FDA-required foreign seller, 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 urged FDA to release further guidance regarding how states can operationalize the program with this in mind, but to date, no guidance has been released.
2. **Resistance by drug manufacturers:** HCPF has taken proactive steps to engage manufacturers to secure drug supply for the program over the last year. We have outreached 23 companies that manufacture prescription drugs that are on our target importation list. Of these, nine companies declined to meet and negotiate. Only four agreed to meet, but relayed they would not participate in the program. Ten companies did not respond at all to our request to meet after multiple attempts.
3. **Lack of regulatory clarity:** Because the rule did not contemplate the need to negotiate with manufacturers, there is a disconnect between the intended and 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 changes to our updated SIP accordingly.

V. Next Steps

While HCPF will continue to work diligently to advance the program, in order to be successful it is essential that FDA provide direction, through guidance, that is flexible and responsive to Colorado regulatory questions. Additionally, without regulatory changes, success is dependent on the willingness of brand drug manufacturers to be open to partnership with Colorado.

HCPF will be finalizing and submitting an updated SIP soon. The SIP will address any outstanding items raised by FDA in their RFI, as well as review information we have learned over the last year through discussions with our partners, consultants, FDA, and other states. We anticipate FDA will take 4-6 months to review our updated proposal. During this time, we may receive additional RFIs from FDA, which we will respond to in a timely manner.