Section 804 Importation Program

Colorado's Drug Importation Program

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Executive Summary

The Colorado Department of Health Care Policy & Financing (HCPF and SIP Sponsor) offers this amended Section 804 Importation Program (SIP) application to address the rising costs of prescription drugs, which total more than $5 billion per year in Colorado alone.[1] Nearly one in three Coloradans do not take their prescription drugs as directed because they simply cannot afford to.[2] Colorado's SIP can offer consumers in our state an estimated $46.2 million in cost savings over a three year period[3] by importing prescription drugs from Canada.

Colorado's SIP is authorized by state statute signed into law in 2019 (Senate Bill 19-005)[4] and is in full compliance with the Federal Food, Drug, and Cosmetic Act (FDCA)[5] Section 804 (21 USC § 384).[6] Since the passage of state legislation, HCPF has analyzed U.S. and Canadian prescription drug markets, met with stakeholders to develop a draft SIP proposal, responded to federal regulations outlining the detailed requirements for SIP sponsors, and released an Intent to Negotiate to secure supply chain partners. HCPF has secured the partners required in the Final Rule[7] including a Canadian licensed wholesaler (Foreign Seller), a U.S. licensed wholesaler (Importer) and U.S. licensed relabeler, and an FDA-approved laboratory. All supply chain partners, in both the U.S. and Canada, have been fully vetted by HCPF in collaboration with our hired, expert consultants. With these partners in place, Colorado is fully prepared to implement its SIP upon approval from FDA.

The SIP will achieve significant cost savings for the program through direct negotiation with manufacturers. Specifically, the state has identified twenty eligible drugs (individual drugs and dosages) that are high cost and/or high volume in Colorado and, if imported, could save an estimated $46.2 million for consumers, as well as employers and other self-funded plan sponsors, municipalities, or the Colorado Department of Corrections, depending on market adoption. The state's proposed drug list targets medications that treat a number of conditions including blood clots, cystic fibrosis, cancer, type 2 diabetes, HIV, psoriatic arthritis, and rheumatoid arthritis. At the request of FDA, this amended SIP includes a smaller list of drugs for importation than our previous application. The state has attempted negotiations with drug manufacturers in Canada; while we have faced resistance from those with whom we have conducted outreach, we are hopeful that a program approval will open up negotiations with these companies.

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[1] Center for Improving Value in Health Care. 2024. Affordability Dashboard. https://civhc.org/get-data/public-data/affordability-dashboard-2/

[2] Altarum Healthcare Value Hub. 2019. Colorado Residents Worried about High Drug Costs—Support a Range of Government Solutions. https://cohealthinitiative.org/wp-content/uploads/2019/11/Colorado-Altarum-Data-Brief-Drug-Costs.pdf

[3] 2025 - 2027

[4] Colorado General Assembly. 2019. 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

[5] Federal Food Drug & Cosmetic Act will be referred to as "FDCA" throughout the application.

[6] 21 U.S.C.§ 384. Importation of Prescription Drugs. https://www.govinfo.gov/content/pkg/USCODE-2011-title21/html/USCODE-2011-title21-chap9-subchapVIII-sec3 84.htm

[7] U.S. Food and Drug Administration. 2020. Importation of Prescription Drugs. U.S. Department of Health and Human Services. www.hhs.gov/sites/default/files/importation-final-rule.pdf

HCPF will oversee the SIP once approved and attests that the SIP will pose no additional risk to public health and safety, as required by federal law and regulation. The program's framework supports this through strong oversight and accountability in contracts with supply chain partners. All prescription drugs approved for importation through the Colorado SIP will be the same as the current FDA-approved versions, which are produced worldwide, as is the case in the U.S. market today.

Eligible drugs that have been negotiated with manufacturers and approved by FDA for importation will be subject to the same safety protocols conducted by Canadian oversight entities today. The Foreign Seller will purchase the drug directly from the manufacturer and will be held to standards in federal rule to ensure each drug can be tracked and traced back to the manufacturer. The Foreign Seller is contracted with HCPF's named Importer for purposes of importing and distributing the drug to Colorado. Before distribution can occur, the Importer must ensure that batch testing has occurred by HCPF's named FDA-approved laboratory. The Importer will contract with pharmacies that have agreed to stock and dispense drugs imported from Canada under the SIP.

While the state of Colorado has great hope for its drug importation program, barriers continue to make our effort challenging. A prompt SIP approval will help address some of these barriers by demonstrating progress and will help our state advance our goal of reducing drug costs for consumers, employers, and the state.

Introductory Statement & Overview of SIP Proposal

Per the Final Rule, including § 251.3 (d) 1-11, the Colorado Department of Health Care Policy & Financing (HCPF, or SIP Sponsor) is offering this amended SIP Proposal (named "Colorado's Drug Importation Program") to the Food and Drug Administration (FDA) for consideration. Detailed SIP Sponsor information is included in Appendix A. This introductory statement and SIP overview provides a brief history of Colorado's effort and process to bring prescription drug importation to the state.

Colorado Senate Bill 19-005

In 2019, the Colorado General Assembly passed Senate Bill 19-005, which requires HCPF to develop a Canadian prescription drug importation program and pursue approval for such a program from the federal government. Senate Bill 19-005 includes detailed requirements to ensure compliance with Section 804 of the Federal Food, Drug, and Cosmetic Act (FDCA)[8] which authorizes state-led wholesale importation programs. Our state legislation reinforces requirements that testing, labeling, and recordkeeping are of the utmost importance in administering an importation program.

Senate Bill 19-005 outlines requirements for any Importer and Canadian supplier participating in the program. The legislation also provides the state with oversight authority and monitoring responsibility to ensure compliance of the SIP with state and federal policy rules and standards. This includes oversight of any vendor(s), regular monitoring of the importation drug list and suspension of importation of any drug that is in violation of the state statute or federal rules. This SIP complies with all these aspects of state statute and the process and implementation approach are outlined in further detail below.

Our Process

Since the passage of Colorado's authorizing legislation, Senate Bill 19-005, HCPF has undergone a significant implementation effort to support submission of this SIP application. Launching a completely new health care initiative to establish an innovative, affordable and disruptive marketplace has been a significant investment. Over the last four years, the state has primarily focused on the areas below:

Evaluation of Market Dynamics
In order to create a new marketplace, it is critical to understand systemic issues within the current prescription drug market. This has informed HCPF's approach to partnerships both inside and outside of the supply chain, and the selection of drug list candidates. Through numerous engagements with stakeholders and supply chain participants and experts since the program's inception, we have grounded our SIP application in the following learnings:

[8] 21 U.S.C.§ 384. Importation of Prescription Drugs. https://www.govinfo.gov/content/pkg/USCODE-2011-title21/html/USCODE-2011-title21-chap9-subchapVIII-sec3 84.htm

1. **Supply chain innovators.**
   Smaller, nimble, innovative companies comprise our supply chain because they support developing new strategies to bring consumers safe and effective lower priced drugs.
2. **Importance of direct negotiation with manufacturers**.
   In general, manufacturer contracts with Canadian wholesalers include language that prevents exportation of their products to the U.S. This requires a direct negotiation with manufacturers to develop agreements without such language. Because the Final Rule did not contemplate this market reality, Colorado has been advocating for FDA guidance regarding how to operationalize the rule.
3. **Rebate challenges**.
   Because of the misaligned financial incentives to carriers and pharmacy benefit managers from rebates and the concurrent reduction of rebates through the importation process, carriers will likely create pushback on all state importation plans.
4. **Pharmacy Benefit Manager (PBM) dynamics**.
   Most PBMs rely on profit-oriented or market share growth processes and strategies that are rarely transparent, such as rebates, spread pricing, and complex fee structures; however, there are a growing number of sophisticated employer clients and responsive PBMs using pass-through, national average drug acquisition cost (NADAC) and cost-plus reimbursement approaches that provide discount transparency and direct savings to plan sponsors and their members. These are likely our best partners to bring imported drugs and their relative savings to Coloradans with coverage, the state, and our employers.

Policy Analysis
Since the launch of HCPF's work on this program, the state has completed many critical policy analysis steps. Initially, HCPF evaluated the Canadian market's framework for drug pricing to inform the development of a preliminary drug list and operating framework. Once FDA released its draft rule to implement Section 804 in December 2019, HCPF analyzed the rule and submitted a comment letter outlining concerns with its framework and highlighting the need for increased flexibility for states.

In developing and submitting a draft SIP application in early 2020, HCPF analyzed FDA's Notice of Proposed Rulemaking to assess its impact on the initial program framework and made adjustments to the proposed approach, as appropriate. Throughout these steps HCPF solicited public comments, held stakeholder engagement sessions, and made program adjustments. As the work progressed to secure supply chain partners, and FDA released a Final Rule in October 2020, HCPF continued to analyze the Final Rule and identified operational challenges associated with various aspects. HCPF has also worked diligently with other states to monitor and evaluate both state and federal policy activity to inform the application approach.

Since submission of the state's original SIP application, HCPF has appreciated its ongoing dialogue with FDA regarding the issues highlighted above and has raised additional concerns regarding rule implementation. In correspondence, the state has asked FDA to provide further clarifications of various regulatory challenges (see *Challenges and Opportunities* below), and has requested increased collaboration with FDA regarding sourcing challenges, which are seen as fundamental to implementing a successful importation program. We look forward to

learning more from FDA about how to resolve these issues, and we value FDA's continued partnership.

Stakeholder Engagement
In advance of submitting the draft SIP application in 2020, HCPF embarked on a significant stakeholder education and input gathering process to ensure the proposal would be responsive to the interests of our stakeholders. This process included issuance of two Requests for Information[9] to pharmacies and wholesale distributors, as well as targeted meetings with insurance carriers and PBMs in the state. HCPF held three well-attended public stakeholder meetings to solicit further input and released a consumer survey[10] to over 500 stakeholders asking for their views on Canadian drug importation generally, and costs, safety and access specifically.

In addition to these efforts, HCPF has continued an ongoing and open dialogue with the Canadian government through regular meetings with representatives from the Consulate General of Canada. The focus of these discussions has emphasized Colorado's commitment to not disrupting the Canadian drug supply or importing drugs on shortage in Canada. We will continue to prioritize these underlying principles.

HCPF paused stakeholder engagement starting in early 2021 to focus on identifying the best supply chain partners through an active state procurement process. After submitting our formal SIP on December 5, 2022, we held a public stakeholder meeting on January 10, 2023.[11] We will continue with stakeholder engagement upon this submission and expect to expand our outreach to promote the program should an approval be received.

Partner Identification
In January 2021, HCPF released an Invitation to Negotiate (ITN) to solicit supply chain partners. Through this process HCPF promoted the ITN, reviewed solicitation responses, conducted site visits, all while continuing to develop the infrastructure needed to effectively operate an importation program. Each partner has been carefully vetted throughout this process, including by supply chain experts. This effort included successful site visits in both Canada and the U.S., resulting in partnerships with the following vendors:

- AdiraMedica Inc. ("Adira Canada"), a Canadian wholesaler located in Mississauga, Ontario, Canada, will fulfill the role of Colorado's Foreign Seller. The Foreign Seller serves as the primary conduit with Canadian manufacturers, and AdiraMedica is FDA-registered as a SIP Foreign Seller.[12] AdiraMedica will purchase eligible drugs for Colorado's program and ensure they meet specifications for exportation to the United States. AdiraMedica has been in business for 15 years, specializing in supply chain management including import/export for global clinical trials. They are used to working with products that require the utmost care and attention to detail and are well-versed in navigating the exportation process into the United States.

[9] Can be found in Appendix I.

[10] Can be found in Appendix I.

[11] Can be found in Appendix I.

[12] https://dps.fda.gov/decrs/searchresult?type=adira

- AdiraMedica, LLC ("Adira U.S.")[13], based out of Clark, New Jersey, with a cGMP[14] facility in Aston, PA, will serve as Colorado's U.S.-based Importer and program relabeler. They will be the distributor of imported medications to participating Colorado pharmacies and are fully licensed in Colorado and FDA registered as a wholesaler.[15] They will assume program relabeling duties in-house as a cGMP and FDA registered relabeler. Lastly, Adira U.S. will manage the required statutory testing by partnering with a qualified laboratory.
- Q Laboratories[16] was selected by the program to be the Program's Qualified Laboratory. Located in Cincinnati, Ohio, Q Laboratories is registered with FDA for pharmaceutical testing, and is cGMP/GLP Compliant and ISO/IEC 17025 accredited. They are an independent laboratory with over 50 years of experience.
- Denver's Rocky Mountain Poison & Drug Safety (RMPDS), which has been serving the public since 1956, will be responsible for all FDA required adverse event reporting and will respond to consumer inquiries. RMPDS has decades of experience with handling medical information inquiries and safety reporting. RMPDS can fully integrate safety reporting intake processes with many different solutions for pharmacovigilance database management and reporting as required by the Final Rule. The Colorado team of pharmacists and nurses are rigorously trained to ensure they identify and capture appropriate information about any safety events or product quality complaints.

Overview of SIP Proposal

The Colorado Department of Health Care Policy and Financing (HCPF), as a governmental entity of the state of Colorado, will be the SIP Sponsor and will provide oversight of the importation of FDA-approved drugs from Canada to deliver lower cost prescription drugs to Colorado consumers. The program framework establishes a robust oversight process to ensure compliance with the FDCA, including Section 804 and the provisions added by the Drug Supply Chain Security Act (DSCSA). HCPF houses a Drug Importation Division (HCPF DID), which will manage the Canadian importation drug list and oversee the activities of all participants in the supply chain to ensure compliance with operational and safety requirements. The program's overarching dedication to compliance is documented within Colorado's Drug Importation Program Quality Manual, which can be found in Appendix A. The Quality Manual is distributed among all involved partners, and we ensure that all partners' SOPs adhere to the commitments the program has made to safety and quality standards.

Colorado's SIP will leverage the current U.S. drug distribution system, which already relies heavily on drugs manufactured abroad. For example, FDA estimates that 78% of active pharmaceutical ingredient (API) manufacturers are located outside the U.S.[17] Colorado's program will negotiate directly with manufacturers to arrange an agreed-to price for the purchase of prescription drugs from FDA-approved manufacturers through FDA-approved facilities. Prescription drugs approved for the program will be the same as the current FDA-

[13] Importer, AdiraMedica LLC, will be referenced as Adira U.S. throughout the document to differentiate from AdiraMedica or Adira Canada, the Foreign Seller

[14] cGMP = current Good Manufacturing Practices

[15] AdiraMedica LLC FDA WDD Registration, FDA WDD Annual Reporting January 1 - March 31 for each calendar year

[16] Q Labs, LLC. (DBA Q Laboratories)

[17] U.S. Food and Drug Administration. 2023 Fact Sheet: FDA at a Glance https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance

approved versions available for consumption in the U.S. Additionally, all eligible drugs imported through Colorado's program will be trackable and traceable and in compliance with the DSCSA.[18]

HCPF will work with Adira U.S. and Adira Canada entities to ensure all safety requirements are met, including ensuring that a Section 804 serial identifier (SSI) is assigned and affixed, if necessary.[19] Before entering the U.S., Adira U.S., the Importer, will arrange for the importation of eligible prescription drugs from Mississauga, Ontario, Canada to the United States, in compliance with the requirements of the Final Rule.

Imported medications will enter the U.S. at the U.S. Customs and Border Protection (CBP) port of entry in Detroit, Michigan, as authorized by FDA,[20] and be shipped to the Adira U.S.-contracted secure warehouse within 30 miles of the CBP port of entry[21] and held there for further processing. Adira U.S. will coordinate the sampling and testing of statistically valid samples with Q Laboratories to ensure that the drug is authentic and has not degraded. The Form results of those tests will be submitted to FDA for review and approval. During the testing process, the imported prescription drugs will remain in quarantine at the warehouse under a CBP importation bond in Detroit. Once the testing results have been approved by FDA, Adira U.S. will arrange for the in-bond transport of the imported eligible drugs to Adira U.S.' Aston, PA, warehouse to be relabeled in accordance with the Final Rule. Once they are relabeled, they will be transported in-bond back to the warehouse in Detroit for an FDA admissibility decision. Once the prescription drugs are approved for distribution by FDA and released by both FDA and CBP, Adira U.S. will transport the drugs to Adira U.S.' Aston, PA, warehouse for distribution to Colorado pharmacies.

Adira U.S. will contract with pharmacies in Colorado that have agreed to stock and dispense drugs imported from Canada under the approved SIP. Our importation program will provide consumers, carriers, PBMs, hospitals and doctors in Colorado with access to drugs imported from Canada through a variety of sources, including community pharmacies and mail order pharmacies.

Any drug imported under the importation program and available for purchase in the state of Colorado will fall under the jurisdiction of FDA. The Colorado State Board of Pharmacy will continue to regulate the receipt, storage, and proper dispensing of these drugs (like any other prescription drug) pursuant to valid, patient-specific orders once the drug is received by a Colorado-based, Board-registered pharmacy. In addition, as a wholesaler registered to distribute in Colorado, Adira U.S. will be subject to the same regulatory oversight as any other registered wholesaler in the state.

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[18] U.S. Food and Drug Administration. 2022. Drug Supply Chain Security Act (DSCSA). https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

[19] § 251.14 Supply chain security requirements for eligible prescription drugs (c) (4) (ii) "Assign an SSI to each package and homogenous case intended for sale to the Importer in the United States, **unless each such package and homogenous case displayed a manufacturer affixed or imprinted product identifier**, as such term is defined in section 581(14) of the Federal Food, Drug, and Cosmetic Act…"

[20] https://www.cbp.gov/document/guidance/fda-supplemental-guide (page 18)

[21] § 251.17 (b) "...The secured warehouse or other secure distribution facility must be within 30 miles of the authorized Port of Entry for examination."

RMPDS, as the program's regulatory compliance and reporting partner, will support meeting compliance-related obligations by ensuring all aspects of reporting and recordkeeping for adverse events and pharmacovigilance are maintained for the program and that adequate education is provided for employees. When each eligible drug is relabeled, that label will contain contact information that consumers can use to report a safety event.

HCPF will also work with Adira U.S. and RMPDS to conduct an educational outreach program to ensure pharmacists, health care providers, and patients are educated about the program. Upon SIP approval, HCPF's drug importation website will be expanded to include more detailed information about the program, including information specifically for health care professionals and consumers. Consumers and providers will be able to find the names and National Drug Codes (NDC) of all drugs imported from Canada as well as a list of all participating pharmacies. There will also be information on how to report safety events and a consumer support line, hosted by RMPDS, where consumers can call for additional information on the program. A section of the website for participating pharmacies will include a link to a secure online platform hosted by Adira U.S. where pharmacies can view available drugs and place orders.

Figure 1 below is a chart of the key players in Colorado's program:

Figure 1.

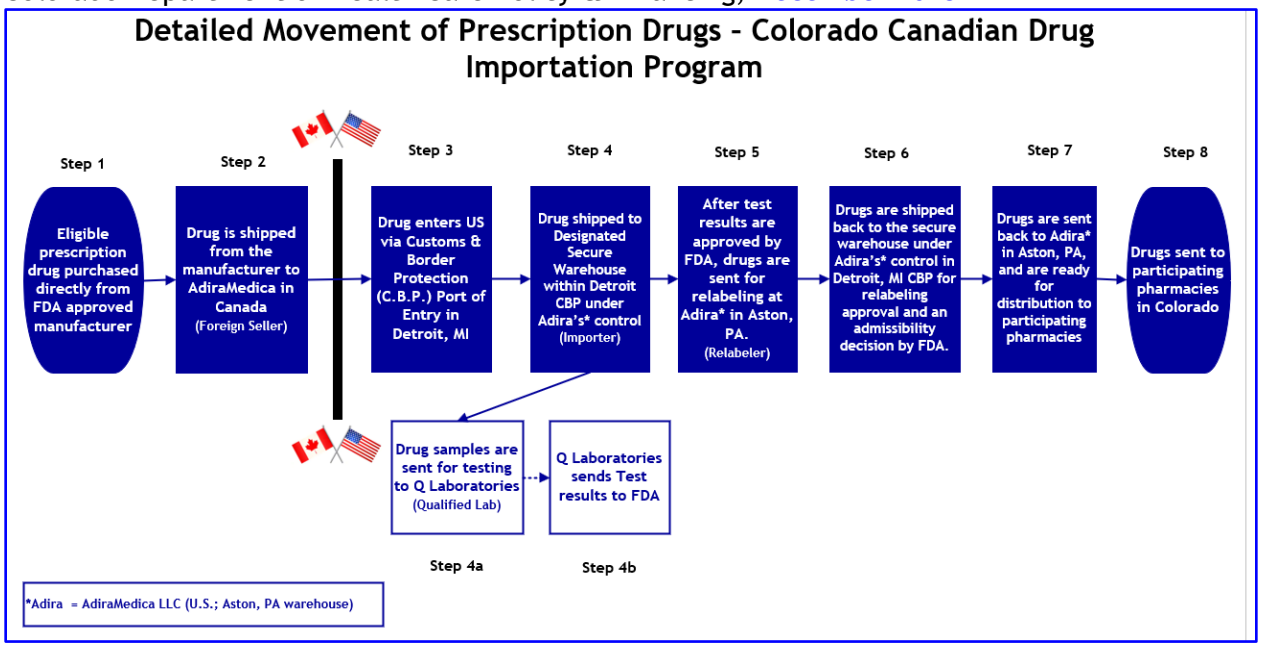
Name of the SIP	Colorado's Drug Importation Program
SIP Sponsor	Colorado Department of Health Care Policy & Financing Address: 303 E 17th Avenue Denver, CO 80203
Responsible Individual(s)	Kelly Swartzendruber Drug Importation Program Manager kelly.swartzendruber@state.co.us 720-483-4091 Vincent Giglierano Drug Importation Program Administrator vincent.giglierano@state.co.us Phone: 303-392-1735
Name and Address of Foreign Seller	AdiraMedica, Inc. Address: 2233 Argentia Rd. Suite 302, Unit# 306 Mississauga, Ontario, Canada L5N 2X7
Name and Address of Importer	AdiraMedica, LLC Address: 585 Turner Industrial Way Aston, PA 19014
Name and Address of Relabeler	AdiraMedica, LLC

	Address: 585 Turner Industrial Way Aston, PA 19014
Name and Address of Qualified Lab	Q Laboratories Address: 1930 Radcliff Drive Cincinnati, OH, 45204 513-471-1300

Colorado Department of Health Care Policy & Financing, December 2025

Figure 2 below provides a process map illustrating the life cycle of a prescription drug imported to Colorado:

Figure 2. Detailed Movement of Prescription Drugs through Colorado's Importation Program
Colorado Department of Health Care Policy & Financing, December 2025



Final Drug List

The drug list presented in this amended SIP is smaller than the list included in Colorado's initial SIP application. Per FDA guidance, we have a narrowed list of drugs and dosages. All drugs included are high cost or high volume drugs that Colorado consumers struggle to afford. Once we receive program approval, we will actively begin working to import these drugs while expanding the list of potential drugs to achieve the goals of the program.

The list of drugs Colorado intends to import and their associated percent savings is available at Table 3. A full drug list including all details specified in the Final Rule can be found in Appendix D. The Final Rule requires the manufacturer address for each finished dosage form and active ingredient(s). All reasonably known manufacturer headquarter addresses for the drugs on the list can be found in Appendix D. Until contracts with manufacturers to secure supply are completed, we are unable to provide the name and address of the manufacturer of

each imported finished dosage form and corresponding active pharmaceutical ingredient. This detail will be provided in the Pre-Import request as part of the next step in the importation process.

Cost Savings
HCPF commissioned an actuarial cost savings analysis to determine whether the SIP would result in a significant reduction in costs to the Colorado consumer for the eligible drugs. This analysis conservatively estimates $46.2 million in combined savings over the first three years of SIP implementation. Because full transparency into PBM rebates does not exist today, our analysis relied on the most conservative rebate savings pass-through assumption of 100 percent. While Colorado does not believe all PBMs are passing through the entirety of rebates, our actuarial study is sound and replicable with such an assumption. Should publicly available data be released that provides clarity around rebate pass-throughs, it is likely a portion of rebates would be proven to be held at the PBM or carrier level and therefore demonstrate even greater savings from the importation program. Appendix E details the assumptions, data, methodology, and conclusions of the cost savings analysis.

Challenges and Opportunities

While HCPF looks forward to receiving FDA approval for this amended SIP application, we are preparing to overcome market barriers to success. Some industry players that benefit from the status quo stand ready to litigate and push back on our program through policy and other mechanisms. Also, we recognize that the Final Rule's framework may limit our ability to achieve our cost savings goals. Key areas of concern are explained below:

Lack of Federal Approval Timeframes
The Final Rule does not provide clarity around the timeline or process for review and approval of a SIP application. HCPF requests an approval that will assist the state in negotiating with manufacturers and obtaining partnership commitments from carriers and PBMs.

Canadian Concerns
There is concern among various Canadian stakeholders regarding the potential for drug shortages in Canada resulting from an approved importation program. The state of Colorado commits to monitoring current and potential shortages and will not import any drug impacted by a shortage. That commitment and message has been communicated by HCPF a number of times directly to the Canadian Consulate in Denver. HCPF's contract with AdiraMedica, executed in 2022, includes a clause to maintain compliance with the Canadian exportation shortage regulation that has been in place since 2021. Our Foreign Seller is committed to complying with these Canadian exportation requirements and will procedurally review and document Health Canada's drug shortage report prior to ordering drug products intended to be exported under the SIP. In addition, the state has encouraged the federal government to embark on a diplomatic effort to bolster importation programs to ensure that Canadian officials are hearing directly from our federal partners about the importance of protecting the Canadian drug supply as a core, shared value of Canadian drug importation programs.

Potential for Retaliation in a Limited Supply Chain
Per the Final Rule, a SIP may only name one Canadian Foreign Seller and one U.S. Importer. Colorado has concerns that limiting the Foreign Seller to only one entity will not only limit the number of drugs states can access through manufacturer negotiations, but also open the

Foreign Seller to retaliation from non-participating manufacturers or wholesalers that oppose our program's success, and we hope for future opportunities to add additional Foreign Sellers and U.S. Importers, as appropriate.

Manufacturer Resistance
Due to manufacturer contracts with Canadian wholesalers that bar the exportation of drugs to the U.S., HCPF and the program's Foreign Seller have embarked on a negotiation process to identify manufacturers that agree to supply eligible drugs for Colorado's program. We have already met some initial resistance, particularly with brand name drugs. Importation programs offer a unique opportunity for pharmaceutical companies to address high costs for consumers while also sidestepping the veiled rebate and fee structure that is characteristic of the U.S. pharmaceutical market.

HCPF has taken active steps to engage with manufacturers and has been challenged with resistance. We outreached to 23 companies that manufacture prescription drugs, including those on our targeted importation list. Of these, nine companies declined to meet. Of the four that agreed to meet, all relayed that they would not participate in the program. Ten companies did not respond to our request to meet, despite multiple outreach attempts. A complete list of pharmaceutical manufacturers HCPF outreached to is available in Appendix H.

Wholesale Distribution and Pharmacy Participation
While we have received some interest in our program, there are concerns from pharmacies that participation in the importation program may negatively impact current primary wholesale contracts. In most cases, primary wholesalers have volume guarantee requirements attached to discounts. While we believe that the benefit of importation savings should outweigh these concerns, pharmacy hesitancy remains a variable concern. HCPF is also exploring a mail order pharmacy option as a potential solution to these issues.

Insurance Industry Hesitation
Carriers and PBMs have been open to conversations with HCPF about the opportunities presented by importation but have generally appeared hesitant to explore partnerships or the inclusion of imported drugs on their formularies. HCPF believes this is due to our importation program's ability to neutralize the perverse incentives in place through the sharing of rebates and other revenues between drug manufacturers, carriers and PBMs and that impact to carrier and PBM profits. HCPF has gained commitments from both the Colorado state employee health benefit program and the Colorado state employee PBM to support the inclusion of imported drugs on the formulary for Colorado state employees. This partnership is a promising first step to ensuring access to Colorado consumers through a pilot with one of the largest employers in the state. We hope carriers and PBMs will consider exploring innovative strategies with the state to achieve these lower cost options for consumers upon the program's approval by FDA.

Additional Challenges Raised Since 2022 SIP Submission

Since submission of the original application in 2022, Colorado has continued to evaluate market dynamics and the Final Rule and elevate newly identified program challenges to FDA. A copy of these correspondences are found in Appendix H. Several key concerns raised in discussions and in writing with FDA include:

- Sourcing absent direct negotiation - The Final Rule does not appear to contemplate a scenario in which states are able to source drugs absent manufacturer approval or agreement. Colorado continues to seek guidance from FDA regarding how such sourcing can occur given that the Final Rule prohibits sourcing from a secondary wholesaler.
- Sourcing and direct negotiation - The Final Rule does not appear to be structured in a way that allows for the operationalization of a partnership negotiated between a state and manufacturer. For example, the Final Rule requires an eligible drug label to include a statement implying that the manufacturer does not agree to the purchase.[22]

Addressing these fundamental issues in Section 804 importation programs will be critical to state success in implementing Canadian importation. The State of Colorado continues to be interested in ongoing dialogue and collaboration with FDA to address these challenges and would welcome detailed guidance and engagement by the Agency in these issues.

[22] § 251.13 (4)(iv) "[This drug was/These drugs were] imported from Canada without the authorization of [Name of Applicant] under the [Name of SIP Sponsor] Section 804 Importation Program."

Final Drug List

Colorado's final drug list contains 20 unique drugs and dosages, including medications that treat a number of conditions including blood clots, cystic fibrosis, cancer, type 2 diabetes, HIV, psoriatic arthritis, and rheumatoid arthritis. To secure drug supply for Colorado's SIP, the program's Foreign Seller, in collaboration with HCPF, will negotiate directly with manufacturers. The list presents high cost, high volume drugs using Colorado-specific data from our Colorado All Payer Claims Database (CO APCD). All of these medications have a significant impact on affordability to consumers in the state through employer health plans, state funded health care and benefit programs, individual health plans and to documented and uninsured individuals. These drugs are integral to the everyday lives of Coloradans, representing, in many cases, lifesaving solutions if lower prices can be achieved. This section complies with all Final Rule requirements regarding submission of a drug list, including §251.3(e)(1), (5)-(6).

Final Drug List Methodology

HCPF developed an extensive methodology to identify good drug candidates for importation, as well as evaluation of the estimated cost savings generated by Colorado's SIP. The drug list was created using data from the CO APCD,[23] which is made up of claims data submitted by payers in the state.

To identify a list of target drugs, HCPF evaluated the 2,000 most expensive brand name and generic drugs for 2022. The identified drugs were compiled into a master list and checked against the Final Rule requirements and the eligible prescription drug exclusions of Section 804 to create a final list of potential prescription drugs for importation. (Upon program approval and prior to initiating a pre-import request, the medications on our importation list will again be evaluated for active Canadian shortages.[24]) Once the drug list was finalized, HCPF compared the CO APCD pricing with Canadian pricing primarily using data from the August 16, 2023 Quebec Province's "List of Medications."[25] The prices reflected on the Quebec list are the "guaranteed selling price," which is defined as the price at which it is sold by an accredited manufacturer or wholesaler to pharmacies. When Quebec data was unavailable, HCPF used wholesale prices supplied by our Foreign Seller. HCPF then commissioned an actuarial cost analysis (described in the Cost Savings section below) to further narrow the drug list only to drugs that would result in cost savings if imported. The final list of eligible drugs, which represents the drugs we anticipate importing through the SIP, reflects the drugs that produced significant cost savings to the Colorado consumer when imported, applying these criteria.

Our complete list of eligible drugs is outlined below in Figure 3. In Appendix D, all drug list details are found including names, application numbers, Canadian Drug Identification

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

[24] Due to Canadian regulations and our process, drugs determined to be in shortage in Canada will be excluded from active importation.

[25] Quebec Formulary from 8/16/23, accessed September & October 2023. https://www.ramq.gouv.qc.ca/en/media/15271.

Numbers (DIN) and National Drug Codes (NDC), evidence the drug is commercially available in the U.S. (per FDA Orange Book), as well as other details required by the Final Rule. As previously stated, the Final Rule requires HCPF to include the manufacturer address for each finished dosage form and active pharmaceutical ingredient (API). All reasonably known manufacturer headquarter addresses for the drugs on the list can be found in Appendix D.

Until contracts with manufacturers to secure supply are completed, we are unable to provide the name and address of the manufacturer of each imported finished dosage form and corresponding active pharmaceutical ingredient. Most (if not all) drug manufacturers do not publish the locations of their actual manufacturing sites. This detail will be provided in the Pre-Import request as part of the next step in the importation process. Full expenditure, price, and quantity projections for each drug under Plan and Baseline Scenarios were calculated using CO APCD data and are available in the Cost Analysis at Tables A3–A4.

Figure 3. Savings By Drug

Drug Index	Drug Name	Strength	Category	2027 Baseline Scenario Price per Unit	2027 Plan Scenario Importation Price per Unit	Savings Percentage
1	Biktarvy	50-200-25mg	Specialty	$118.28	$55.81	53%
2	Eliquis	2.5mg	Brand	$7.20	$3.74	48%
3	Erleada	60mg	Specialty	$117.81	$42.90	64%
4	Janumet	50/500mg	Brand	$4.88	$3.93	19%
5	Janumet	50/1000mg	Brand	$4.86	$3.25	33%
6	Januvia	25mg	Brand	$9.97	$8.17	18%
7	Januvia	50mg	Brand	$9.56	$6.99	27%
8	Januvia	100mg	Brand	$10.15	$6.17	39%
9	Odefsey	200-25-25mg	Brand & Specialty	$95.94	$64.41	33%
10	Otezla	30mg	Brand & Specialty	$64.76	$35.39	45%
11	Ozempic	OZEMPIC MULTIDOSE PREFILLED PEN 0.25MG OR 0.5MG	Brand & Specialty	$502.59	$275.13	45%
12	Ozempic	OZEMPIC 1MG	Brand & Specialty	$268.00	$137.57	49%
13	Prezcobix	800/150	Brand & Specialty	$60.80	$49.12	19%
14	Rinvoq	ER 15	Brand & Specialty	$176.55	$76.73	57%
15	Sprycel	100mg	Specialty	$397.35	$127.36	68%
16	Symtuza	800/150/200/10	Brand & Specialty	$133.63	$98.49	26%
17	Tivicay	50mg	Brand & Specialty	$50.40	$36.02	29%
18	Trikafta	100/50/75 and ivacaftor 150 mg tablets	Specialty	$325.91	$268.37	18%
19	Triumeq	600-50-300mg	Brand & Specialty	$71.86	$55.79	22%
20	Victoza 3 PAK	18mg/3mL	Brand	$59.03	$48.68	18%

**Notes: From August to March amendment, we have finalized our drug list to exclude Ibrance and Spiriva drugs and dosages. No other changes were necessary.*

Cost Savings

HCPF's cost savings analysis provides evidence that the SIP will result in significant cost savings, showing that if approved the SIP can save an estimated $46.2 million over the first three years of the program (2025-2027) compared to costs absent a program.[26] This section complies with all Final Rule requirements regarding demonstration of cost savings, including § 251.3(e)(9), as well as informal guidance from the Assistant Secretary for Planning and Evaluation (ASPE) of Health and Human Services.[27] The costs included in this analysis are comprehensive and will allow for HHS to verify data sources to consider reasonableness of assumptions, and determine whether the analysis is consistent with other elements of the proposal and process outlined in law and rule. The full cost analysis is available at Appendix E. The assumptions are further discussed in detail below.

Assumptions

To determine whether the SIP would result in a significant cost reduction, HCPF commissioned a team of actuaries to analyze the cost of eligible drugs in two scenarios: the Baseline Scenario and the Plan Scenario. The Baseline Scenario is a projection of the total expenditures for the eligible drugs if the SIP is not authorized and implemented. The Plan Scenario is a projection of the total expenditures of the eligible drugs if the SIP is authorized and implemented, beginning in 2025. The Plan Scenario cost savings are the difference between the total expenditures for the eligible drugs under the Baseline Scenario and the Plan Scenario.

Population Assumptions
This analysis assumes cost savings for individuals within the Colorado Commercial Insured Population, which is the population covered by commercial, private insurance and includes individuals covered by employer-sponsored insurance that may be insured and self-insured as well as individually purchased insurance.[28] In order to determine the number of individuals who would utilize eligible drugs, the analysis relied on 2022 utilization and cost data provided in the CO APCD, which is administered by the Center for Improving Value in Health Care (CIVHC).[29] The analysis assumes that the utilization and costs of the entire commercial market are similar to the population in the CO APCD. Therefore, the analysis extrapolated the population of the Colorado Commercial Insured Population from CO APCD data using a multiplier.

The Plan Scenario assumes participation only for the Plan Scenario Covered Individuals whose health insurance payers offer imported eligible drugs. This is an assumption selected by HCPF in discussion with the actuaries to estimate the level of participation in the SIP program. The conservative estimate is borne by the assumption that there will be modest initial uptake by insurers in program participation, growing by 2027.

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[26] Under FDA guidance, our cost analysis does not account for ongoing tariff negotiations. While our actuarial analysis assumes a three year sample period of 2025-2027, we assume similar savings in both direction and magnitude with a later implementation date.

[27] https://www.fda.gov/media/158564/download?attachment

[28] Appendix E (Cost Analysis Report), pages 7-8

[29] https://civhc.org/get-data/whats-in-the-co-apcd/

Cost and Utilization Assumptions

Allowed Cost and Utilization: This analysis also uses cost and utilization data from the CO APCD to determine the allowed cost, the number of units,[30] and the cost per unit of SIP Drugs. The analysis assumes that the utilization and cost of the entire market is similar to that for the population in the CO APCD, and uses the same multiplier as in the population assumptions.

Rebates: Pharmacy benefit managers (PBM) negotiate rebates with drug manufacturers to improve formulary position and consumer accessibility. These rebates and any pass-through arrangements to self-insured employers and fully insured plans are proprietary, making it challenging to estimate the true impact of rebates on the cost to the consumer. To address this issue impacting this cost analysis, the study relies on the conservative assumption that 100% of rebates are passed through in the baseline scenario, creating cost savings to consumers through lower premiums and cost sharing. While we are using this assumption to ensure that ASPE can replicate the actuarial findings, there is clear evidence that rebate pass-throughs are not consistently occurring. Colorado has been a leader in working to address this issue, including passing legislation to create more rebate transparency and pass-through standards impacting insured (with an opt-in provision for self-insured benefit plans) and expect increased consumer savings as a result in the coming years.[31]

Supply Chain Costs: In the Plan Scenario, supply chain costs include Importer price markups, transportation and logistical costs not captured by the Importer price markup, and costs associated with drug sampling, testing, and other requirements under Section 804 and the Importation of Prescription Drugs Final Rule. Because these costs apply only to the importation supply chain and not prescription drugs domestically sourced, the supply chain costs are only applied to the Plan Scenario, not the Baseline Scenario.

Patent Expirations: Patent expirations are assumed in the Plan Scenario and Baseline Scenario. When the patent for a brand drug expires, lower-cost generic drugs may enter the market, reducing costs due to both generic substitution and price cuts on the brand drug. The analysis projected reduced costs in the model due to the reduction in market price for certain drugs.

Exchange Rates: Canadian costs were converted to U.S. dollar costs at an exchange rate of USD$0.75 per CAN$1.00, as was in effect on August 1, 2023. As of March 7 2025, the exchange rate is $0.70[32], which could result in additional savings; however, to maintain a conservative estimate, the exchange rate was not updated in the March 2025 submission.

Trends: Once initial 2022 estimates for population, cost and utilization were calculated, these assumed values were trended to 2023-2027. The trend factors applied to the Colorado

[30] The analysis defines a **unit** as a dose of a drug (tablet, spray or injection).

[31] Colorado General Assembly, 2022. Coverage Requirements for Health Care Products. https://leg.colorado.gov/bills/hb22-1370

[32] Exchange rate verified 3/6/2025

Commercial Insured Population are the enrollment growth percentages from the CMS National Health Care Expenditure Table 17. Total drug trend and total pharmacy cost trends were also predicted.

Similar drug utilization in the Baseline Scenario and in the Plan Scenario were assumed. Specifically, the analysis does not assume any increase in utilization due to lower prices (induced utilization) on imported eligible drugs. Some induced utilization may be expected; however, the additional utilization would also provide some additional medical benefit, and this analysis does not quantify medical benefit.

Savings

Significant Savings
This SIP meets Final Rule requirements to demonstrate significant cost savings, providing details on uncertainties that may influence our success. Colorado has requested flexibility from FDA in the interpretation of significant savings given the need for state-led programs to begin with narrower lists of drugs and expand over time.

Estimated Savings
Our detailed evaluation finds that the Colorado SIP has the potential to provide an estimated $46.2 million in savings during the first three years of the program, if all 20 eligible drugs and dosages on the list were to be imported. The range of savings depends on the degree of adoption in the market.

Using the data and assumptions described above, the model was constructed for cost savings. In order to determine total cost and utilization in the Baseline Scenario, cost and utilization trends were applied, as well as rebates and the patent expiration effect. In order to determine total cost and utilization in the Plan Scenario, cost and utilization trends, as well as supply chain costs, the patent expiration effect, and exchange rates were applied. These costs were then trended forward through 2027.

The cost savings were calculated as the difference between the total cost in the Baseline Scenario and the total cost in the Plan Scenario (both Plan Scenario Covered Individuals and non-Plan Scenario Covered Individuals). This is illustrated below in Figure 4.

Most of these savings are expected to be passed on to the Colorado consumer in the form of (1) lower premiums and (2) lower out of pocket expenses, or "cost share." In 2022, Coloradans paid for 6.5% of the cost of these drugs in the form of co-pays, coinsurance, and deductibles while the plan paid for 93.5% of the total cost.[33] The last two rows of Figure 4 illustrate how the savings would be divided between cost share reductions and premium reductions, under the assumption that the total savings are allocated 6.5% to cost-sharing and 93.5% to premium.

[33] See Appendix E, Cost Analysis

Figure 4. Cost Savings (all figures in millions except packages)

Cohort	2022	2023	2024	2025	2026	2027
Baseline Scenario Units	3.0	3.1	3.2	3.3	3.3	3.4
Baseline Scenario Total Cost (Net Rebates)	$195.8	$212.0	$230.2	$245.9	$255.8	$266.9
Plan Scenario						
Units (SIP Participation)				0.2	0.6	0.8
Packages (SIP Participation)				8,289	23,185	30,804
Drug Cost				$6.1	$17.1	$22.8
Supply Chain Cost				$4.1	$10.1	$12.3
Total Cost (SIP Participation)				$10.2	$27.3	$35.0
Units (SIP Non-Participation)				3.1	2.7	2.6
Total Cost (SIP Non-Participation)				$230.7	$212.0	$207.3
Total Cost				$240.9	$239.2	$242.4
Plan Scenario Savings versus Baseline						
Total Savings				$5.0	$16.6	$24.5
Savings - Member Cost Share				$0.3	$1.1	$1.6
Savings - Premium				$4.7	$15.5	$22.9
**Notes: From August 2024 to March 2025 amendment, we have finalized our drug list to exclude Ibrance and Spiriva drugs and dosages. Cost savings reflect an updated drug list. No other changes were necessary.*						

Sources of Uncertainty

Major sources of uncertainty in the analysis include, but are not limited to, the following:

- The Plan Scenario Covered individuals, which is the SIP market share of the Colorado Commercial Insured Population, could be smaller or larger than assumed.
- The size of the Colorado Commercial Insured Population might be different than predicted; for example, this population may vary depending on federal action to extend ACA subsidies that are currently set to expire in 2026.
- The unit costs and utilization projected for eligible drugs might vary from the assumptions, due to changes in medical practice or other forces affecting pharmacy trends.
- The model assumes eligible drugs purchased under the SIP will be at current Canadian prices. If the SIP pays a higher or lower price, the savings would change.
- Actual rebates and pass-throughs may vary from the assumptions. If the rebates are higher the importation program will see lower savings, if rebates are lower, the importation program will achieve higher savings (see **Table 3.16 in Appendix E)**.
- Patent expiration dates and cost effects are hard to predict due to legal challenges and business decisions.

Technical Section 804 Importation Program

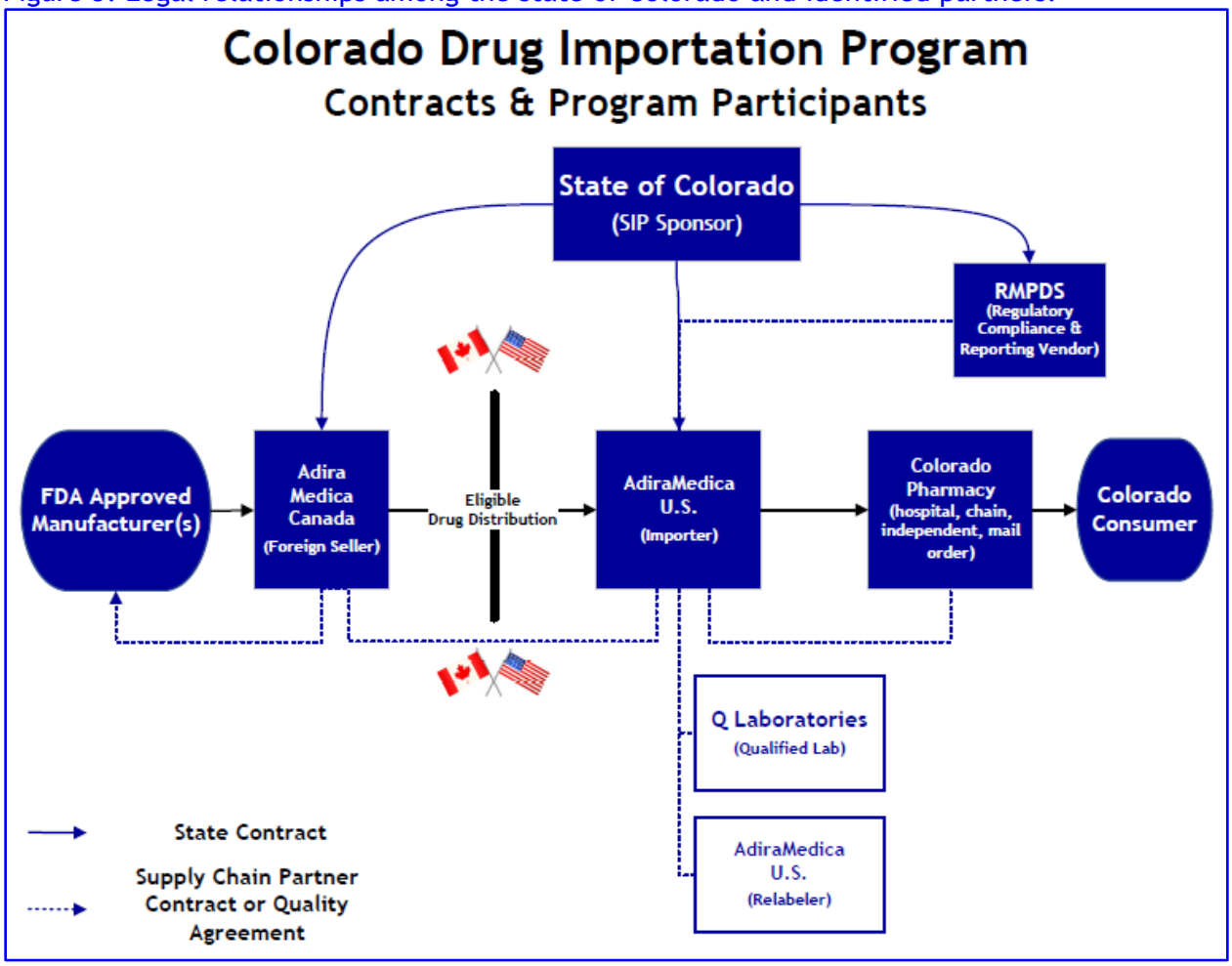
Below is Colorado's technical response to the regulatory standards set forth in the Final Rule.

Legal and Organizational Structure (§ 251.3 (e) 1-4)

The Colorado SIP is sponsored by the Colorado Department of Health Care Policy & Financing (HCPF), which is the state agency that administers Health First Colorado (Colorado's Medicaid program), and is authorized to submit this SIP application and oversee an approved program. The SIP is operated by HCPF's Drug Importation Division (HCPF DID), which has been fully operational since August 2019. It is important to note that Colorado's SIP is focused on the commercial market in Colorado but may explore an expansion to Health First Colorado in the future. Colorado's program does not have any co-sponsors.

HCPF has executed contracts with three primary entities that make up the supply chain for the program. These entities are: The Foreign Seller (AdiraMedica Inc./Adira Canada) is a Canadian-licensed wholesaler; its affiliated U.S. company, AdiraMedica, LLC (Adira U.S.), is a U.S.-licensed wholesaler serving as the Importer; the Importer (Adira U.S.), which is an FDA registered and Colorado licensed wholesaler in Aston, Pennsylvania; and the reporting partner (Rocky Mountain Poison and Drug Safety), which is a U.S.-based adverse event, pharmacovigilance, and poison control center in Denver, Colorado. Figure 5 demonstrates the legal relationships among supply chain and other partners required per the Final Rule.

Figure 5. Legal relationships among the state of Colorado and identified partners.



Colorado Department of Health Care Policy & Financing, December 2025

Aside from HCPF-executed contracts, Adira Canada and Adira U.S. have an executed quality agreement[34] that creates the framework for the purchase and exportation of eligible drugs. Adira Canada will also hold contracts with participating manufacturers that detail volume and price commitments. Adira U.S. maintains a quality agreement[35] with a qualified laboratory (Q Laboratories) and Adira U.S. will be the program relabeler. Adira U.S. will also execute contracts with participating pharmacies.

Colorado Department of Health Care Policy & Financing Drug Importation Division (HCPF DID)
HCPF DID is made up of two Full Time Equivalent (FTE) employees—a Program Manager (Pharmacist) and a Drug Importation Administrator. HCPF DID sits within HCPF's Pharmacy Office that is overseen by the Director and Deputy Director of the Office. HCPF's Executive Director is also actively engaged in program implementation from a strategic and oversight perspective. The team is listed in the table below in hierarchical order.

[34] Appendix C

[35] Appendix C

Figure 6. SIP Sponsor Leadership and Support Team

State of Colorado	Role
Kim Bimestefer, Executive Director of the Colorado Department of Health Care Policy & Financing	Strategic guidance, oversight, program advocacy
Tom Leahey, Director of Pharmacy Office	Management support and advisement
Jim Leonard, Deputy Director of Pharmacy Office	Management support and advisement
Kelly Swartzendruber, Drug Importation Program Manager	Program expertise and leadership, operations and communications, contract management, procurement and implementation, clinical analysis
Vincent Giglierano, Drug Importation Administrator	Program operations and communications, contract management, application writing, cost analysis

Contact information and attestations for Responsible Individuals is included in Appendix A.

Outside of this oversight framework, HCPF DID is supported by the communications and policy infrastructure within HCPF as well as a hired team of expert consultants. These consultants were carefully selected for their expertise in various areas of policy and operations integral in the development of the Importation Program.

Figure 7. Colorado's SIP Consultative Team

Consultative Subject Matter Experts	Role
AgoHealth LLC	Senior Advisor and Policy Consultant
FDA Imports.com LLC	FDA and CBP Regulatory Experts
RC Kennedy Consulting LLC	Supply Chain Security Experts
Koerber Pharma	Supply Chain Security Experts
Prompt Praxis Laboratories, LLC	Qualified Laboratory Experts
LDT Health Solutions, Inc.	Qualified Laboratory Capacity Experts
Rocky Mountain Poison & Drug Safety	Regulatory Compliance and Pharmacovigilance

To identify supply chain partners, HCPF conducted numerous interviews and negotiation sessions. These meetings included our consultants as well, to ensure HCPF received expert assessments of each candidate. HCPF also conducted site visits to Importer and Foreign Seller

candidates, and once selected, the qualified laboratory and relabeler.[36] Each site visit included members of the HCPF DID and consultants with expertise specific to the type of facility visited. Each facility was assessed for:

- Good Manufacturing Practice (GMP) compliance
- Robust standard operating procedures (SOPs) for their facilities, procedures, and systems
- Physical security
- Inventory management
- Relabeling Capabilities
- Employee training programs

The Foreign Seller
AdiraMedica Inc. (Adira Canada), a Canadian wholesaler located in Mississauga, Ontario, Canada, will fulfill the role of Colorado's Foreign Seller. Adira Canada has been in business for 15 years, specializing in supply chain management including import/export for global clinical trials.

Figure 8. Foreign Seller Key Personnel

Key Personnel	Company	Expertise
Arvind Bhandari, Founder, President and CEO	AdiraMedica Inc., Canada	More than 25 years of pharmaceutical industry experience including, but not limited to, wholesale distribution, global supply chain management and global clinical trial supply services.
Cal Bains, Director of Business Development	AdiraMedica Inc., Canada	More than 15 years of pharmaceutical industry experience including, but not limited to, wholesale distribution, global supply chain management and global clinical trial supply services.
Arvind Bhandari, U.S. Agent	AdiraMedica LLC, U.S.	U.S. parent company of AdiraMedica Inc.

Adira Canada's attestations, licenses, full inspection history, FDA Foreign Seller registration, and disciplinary actions can be found in Appendix B.

The Importer
AdiraMedica, LLC (Adira U.S.), located in Aston, Pennsylvania, will serve as Colorado's

[36] Appendix F contains certification reports for all program participants.

Importer. Adira U.S., as the Importer, is responsible for the importation, testing, relabeling, and distribution of eligible prescription drugs to the Colorado market. Adira U.S. will complete the relabeling duties for Colorado's program. They are a fully FDA registered and GMP compliant relabeler.

Adira U.S. has a quality agreement with a qualified laboratory, Q Laboratories, to conduct the statutory testing required by the Final Rule. Q Laboratories, a qualified laboratory located in Cincinnati, Ohio, is registered with FDA for pharmaceutical testing, and is cGMP/GLP Compliant and ISO/IEC 17025 Accredited. Copies of all Q Laboratories' accreditations and inspection history are included in Appendix C.

Figure 9. Importer Key Personnel

Key Personnel	Company	Expertise & Job Duties
Arvind Bhandari, Founder, President, & CEO	AdiraMedica, LLC	Pharmacist and subject matter expert in distribution and drug importation
Doris Correa, Senior Director, Quality Assurance	AdiraMedica, LLC	Program Lead, Program Compliance and Quality Assurance
Sharon Johnson, Operations Manager	AdiraMedica, LLC	Day to Day Program Operations, Wholesale Distribution Management
Cathleen Owen, Director of Pharmaceutical and Personal Care Services	Q Laboratories	Thirty years of manufacturer industry, regulatory, and quality experience that she applied to laboratory and pharmaceutical analysis.

Adira U.S., attestations, licenses, full inspectional history, FDA registrations, and disciplinary actions can be found in Appendix C.

The Regulatory Compliance & Reporting Partner
Denver's Rocky Mountain Poison and Drug Safety (RMPDS), which has been serving the public since 1956, will be responsible for all FDA required adverse event reporting and respond to consumer inquiries, as well as supporting compliance for the Program. One of the premier poison control centers in the nation, RMPDS can fully integrate safety reporting intake processes with many different solutions for pharmacovigilance database management and reporting as required by the Final Rule. The Colorado team of pharmacists and nurses are rigorously trained to ensure they identify and capture appropriate information about any adverse events or product quality complaints. Additionally, RMPDS will aid HCPF in operationalizing a compliance framework and assist in training and record keeping needs as they pertain to the quality management of this program.

Figure 10. Regulatory Compliance & Reporting Partner Key Personnel

Key Personnel	Company	Expertise
Dr. Theresa Chua, Associate Director, Medical Information	Rocky Mountain Poison & Drug Safety	Dr. Theresa Chua handles day to day operations for multiple contracts regarding medical information and safety report intake. She develops and implements processes to ensure regulatory compliance in everyday case handling.
Dr. Kevin Nork, Associate Director, Pharmacovigilance	Rocky Mountain Poison & Drug Safety	Dr. Kevin Nork handles the operationalization of all pharmacovigilance activities to ensure audit-readiness and regulatory compliance.
Dr. Christopher Hoyte, Medical Director	Rocky Mountain Poison & Drug Safety	Dr. Christopher Hoyte is the Medical Director of the Rocky Mountain Poison Center. He is also the Fellowship Director of the Medical Toxicology Fellowship Program at RMPDS. He is an Associate Professor at the University of Colorado School of Medicine in Emergency Medicine and the Section of Medical Toxicology. He currently serves as the Medical Director of the Medical Toxicology Clinic at the University of Colorado Hospital.
Dr. Andrew Monte, Medical Director	Rocky Mountain Poison & Drug Safety	Dr. Andrew Monte specializes in medical toxicology, precision medicine, and genetic testing to improve medication effectiveness and safety. As an emergency physician and medical toxicologist, Dr. Monte is

		well positioned to examine efficacy and safety of drugs.
Brandon Ensign, Chief Operating Officer	Rocky Mountain Poison & Drug Safety	Brandon Ensign currently oversees the Drug Center, which offers services to the pharmaceutical and biopharmaceutical industries in support of FDA regulation. He is also the Operations Director within the Poison Center at RMPDS.

Compliance & Oversight Plan

As the SIP Sponsor, HCPF is responsible for oversight and implementation of the program compliance plan and the program more broadly once the SIP is approved. HCPF will be fully dedicated to SIP implementation including ensuring compliance with the requirements of Section 804 of the FDCA [21 U.S.C. 384], the Final Rule on Importation of Prescription drugs (as codified at 21 CFR and Part 251), the Drug Supply Chain and Security Act (DSCSA), other applicable provisions of the FDCA, its implementing regulations, and any applicable state regulations.

Program Compliance

HCPF will ensure compliance with the program compliance plan that includes SIP Sponsor requirements, through the state's authorizing legislation, program infrastructure, and partner contract requirements.

Program Compliance Plan

The program will take a comprehensive approach to compliance with the Section 804 requirements at every step. The Quality Manual and multiple SOPs in Appendix A detail the overall compliance plan for the program by HCPF. Oversight measures are summarized below.

SIP Sponsor Oversight Measures

As the sponsor of this SIP, HCPF maintains a Quality Management System that ensures compliance with all federal and state requirements, including 21 CFR 251.3(e)(11). Four primary SOPs govern HCPF's oversight activities:

1. Partner Qualification Audit SOP 5086
    a. Before contracting with any key participant (Importer, Foreign Seller, Laboratory, Relabeler, Subcontractor(s)), HCPF conducted a partner qualification process to assess regulatory compliance, DSCSA and cGMP adherence, and the partner's internal quality controls.
    b. Ongoing audits (at least every two years) verify that each partner continues to meet SIP requirements. Any critical findings prompt corrective actions or potential contract termination.
2. Management Review SOP 5088

a. At least annually, HCPF convenes a management review to evaluate overall SIP performance, including partner audit results, nonconformances, complaints, and corrective actions.
b. Leadership uses these reviews to make strategic decisions – such as updating drug lists, improving relabeling processes, or revising pharmacovigilance procedures – to ensure continuous compliance.

3. Internal Audit SOP 5080
    a. HCPF also audits its own processes, ensuring the sponsor's internal governance, documentation, and monitoring remain effective.
    b. Findings from internal audits feed into management reviews, helping HCPF quickly address any gaps or inconsistencies in how it oversees the SIP.
4. Corrective and Preventive Action (CAPA) SOP 5082
    a. Through the CAPA SOP, HCPF ensures that any nonconformance, complaint, or potential risk is promptly identified, investigated, and resolved – either by correcting existing problems or preventing future ones. HCPF staff or partners initiate a CAPA workflow when a nonconformance or potential issue is discovered which are then logged and tracked to ensure no issues are overlooked or left unresolved. HCPF's Quality Assurance Manager reviews each CAPA, approves the proposed action plan, and monitors progress.
    b. All CAPA activity is summarized and elevated to Management Review, where leadership can spot trends, make systemic improvements, and ensure broader program compliance.

Through these SOPs as well as additional supporting SOPs listed on page 15 of the Quality Manual, HCPF maintains an active oversight role in verifying compliance, detecting potential risks, and enforcing corrective measures across all aspects of the importation program among all contractors and subcontractors throughout the program.

At the time of this submission, all partners' standard operating procedures (SOPs)[37] were reviewed and approved for their adherence to Section 804 including storage, handling, transportation, and distribution practices. The Quality Policy for the program has been shared with all partners. Additionally, all partners have been evaluated for compliance for their specific responsibilities under the Section 804 on an annual basis and will be subject to a physical audit by HCPF or third-party organizations acting on behalf of HCPF at least every two years as referenced in HCPF SOP 5086 in Appendix A.

The responsibilities for each partner based on Section 804 requirements were incorporated into a respective partner compliance checklist. This checklist was then used to evaluate each partner's SOPs and ensure that all SOPs address the requirements laid out in Section 804 including processes for security, distribution, storage (including eligible drugs stored at room temperature and/or refrigeration), and handling of imported medications.[38] HCPF has assessed that partners' SOPs meet the requirements of the Final Rule and do not affect the quality or impinge on the security of the eligible prescription drugs. The checklist will be used

[37] Foreign Seller SOPs are in Appendix B; Importer SOPs are in Appendix C.

[38] Copies of partner compliance checklists used for evaluation are in Appendix A

in the future during annual check-ins and during on-site audits to ensure the compliance to the approved SOPs. In addition, all partners are required to complete Non-Conflict of Interest attestations and Disclosure agreements annually (see Appendix A for a blank copy). This attestation ensures parties have adopted procedures for conflicts of interest. Additionally, it clearly defines that the consequences of any non-compliance in these areas will be subject to termination. The Non-Conflict of Interest and Disclosure Agreement will be sent with the annual partner assessment forms and updated yearly as part of the annual partner assessment process as outlined in HCPF SOPs 5086 and 5082.

Legislative Requirements
The importation program's state legislation, SB 19-005, ensures there are strong state statutory requirements placed on supply chain partners in support of Section 804. SB 19-005 requires:

- Statistically sampled batch shipment testing.
- Certifications for marketing, FDA-approved labeling and ensuring no drugs are misbranded or adulterated.
- Verification that all entities participating in a SIP are in compliance with DSCSA, including track and trace rules, and
- Maintenance of qualified laboratory records, including all testing data and documentation that the testing was conducted by a qualified laboratory.

The state statute also provides the state with oversight authority and responsibility to ensure compliance with federal policy rules and standards. This includes oversight of any vendor(s), regular monitoring of the importation drug list, and suspension of importation of any drug that is in violation of state statute or federal rules. This oversight role is enforced by HCPF primarily through contractual relationships with supply chain partners.

Program Infrastructure & Contracting
HCPF holds direct contracts with supply chain partners, and these contracts outline specific requirements to ensure compliance with Section 804 of the Federal Food, Drug, and Cosmetic Act, 21 CFR part 205, and 21 CFR parts 210 and 211. The Importer/Foreign Seller contract requires that any subcontractor partners (such as transportation providers) also adhere to these standards.

To maintain oversight, HCPF regularly meets with each supply chain participant to review operational performance and ensure ongoing compliance with contractual obligations and applicable regulatory requirements. In addition, HCPF performs formal audits at least every two years – or more frequently as deemed necessary – to verify that storage, handling, distribution, and relabeling practices meet the required standards and do not compromise drug quality or security as outlined in HCPF SOP 5086. Any instance of noncompliance will be addressed through contractual remedies, such as corrective action plans, breach-of-contract findings, or contract termination, as appropriate. Certification reports for all partners can be found in Appendix F and procedures for partner audits can be found in HCPF SOP 5086 in Appendix A.

The state's contracts with Adira Canada and Adira U.S. are much the same in terms of standards, reporting procedures, maintenance of licensures in good standing, and audits:

Figure 11. Contract Requirements for Supply Chain Partners

Area of Compliance	Contract Requirements
Statute & rules	• Must comply with all applicable federal and state laws, rules, and regulations, regarding the development and operation of an Importation Program.
Maintenance	• Maintain proper Standard Operating Procedures (SOPs) for all processes and procedures relating to the operation of the Program. • Maintain proper physical security, storage systems and temperature controls. • Create an importation implementation work plan that outlines all steps and processes needed to successfully import drugs. • Develop education, training, and certification processes to ensure that employees and subcontractors engaged with the Program understand their compliance-related obligations that must be followed. • Develop a process for the handling of pre-import requests (Pre-Import Process). • Develop and implement a recall and return plan. • Develop and implement plans to ensure subcontractor compliance.
Inspection & Audit	• HCPF will inspect the facility that houses imported products for the Program at least every two years. • HCPF will complete site visits of subcontractors involved in integral parts of the Program at least every 2 years. • Provide all state/federal/Canadian inspection reports to HCPF upon request.
Security & Capacity	• Comply with security and capacity requirements to ensure the safe and efficient distribution of imported products.
Monitoring & Reporting	• Maintain all DSCSA records with applicable T3 data to track and trace the drug through the supply chain. • Meet regularly with HCPF during the first year of active importation. • Submit regular quarterly and annual reports. • Maintain a process to protect the anonymity of any complainants or whistleblowers regarding any Program concerns by contractor employees.

	• Include a clause in the Importer/Foreign Seller contract to ensure compliance with Canadian regulation regarding shortages for exported products as referenced in C.01.014.8, C.10.004 and C.01.014.13 to C.01.014.14 of the Canadian FDR.[39]
Qualified Personnel	• Provide qualified personnel as necessary to perform the work throughout the term of the contract.
Subcontractors	• HCPF reserves the right to review all contracts and subcontracts relevant to the Program. • HCPF will certify each subcontractor's ability to carry out the work of the Program.
Licensure	• Maintain all required licenses, permits, and/or registrations in good standing and provide documentation to HCPF.
Termination	• HCPF may terminate the contract based on any noncompliance with any requirements.
Continuity	• Must have an operational continuity plan in cases of emergency.

HCPF maintains a Quality Manual and Standard Operating Procedures that can be found in Appendix A that govern how the program operates. HCPF also approves all standard operating procedures submitted by the contracted supply chain vendors. HCPF is responsible for the following compliance functions, including, but not limited to:

- Ensuring HCPF and vendor staffing is adequately maintained to operate the SIP.
- Maintaining contracts with all supply chain vendors and holding these partners accountable to contract requirements.
    - Verifying at least annually that Foreign Seller and Importer state licenses and federal registrations are up to date and determining whether any FDA actions have been taken against partners.
    - Ensuring that all contracted entities respond to HCPF and FDA inquiries in a timely manner.
    - Completing regular audits of supply chain partners and additional audits as appropriate, such as for non-compliance.
    - Conducting site visits to all supply chain entities and additional parties, as identified, at least every 2 years.
    - Approving all subcontract partners, all standard operating procedures for the Program, and major staffing changes in the organizations, as they impact the

[39] **Guide to distributing drugs intended for the Canadian market for consumption or use outside Canada (GUI-0145)**
https://www.canada.ca/en/public-health/services/publications/drugs-health-products/guide-distributing-canadian-market-consumption-outside-canada.html#a3

Program.

- In conjunction with the Importer/Foreign Seller, maintaining, updating and consistently analyzing the importation drug list to ensure savings for Coloradans are prioritized and that importation never negatively impacts Canadian drug supply.
    - Monitoring price agreements among the Importer/Foreign Seller and manufacturers.
    - Maintaining the list of available medications through the Program on a public website.
    - Monitoring the cost savings of the program.
- Registering all entities participating in the program annually, including pharmacies, hospitals, carriers and PBMs, and listing participating entities on our public website.
    - Ensuring these entities are properly licensed to operate in Colorado and that they agree to only dispensing or reimbursing imported products for Colorado residents.
- Reviewing established written compliance policies, procedures, and protocols to ensure compliance with FDA-approved SIP and modify as regulatory changes occur.
- Utilizing established auditing procedures to evaluate compliance and addressing any noncompliance or misconduct. The Quality Manual contains the following SOPs that address these issues in Appendix A:
    - Partner Qualification Audit Procedure (HCPF SOP 5086) that informs the processes for confirming that the partners meet SIP requirements and selecting partners. This also regularly confirms compliance with all agreed upon standard processes.
    - Non Conformance Procedure and Corrective and Preventive Action Procedure (HCPF SOP 5082) outline how we address and investigate any noncompliance.
- Providing drug importation education and training for supply chain partners as referenced in HCPF SOP 5096, HCPF Training. Education will include, but is not limited to:
    - Overview of relevant state and federal statute and regulations regarding the program.
    - Partner specific processes and procedures relating to the operation of the program.
    - Key program updates as necessary.
    - Compliance obligations for mandatory reporting to FDA including adverse event reporting.
- Maintaining a SIP webpage with up-to-date information related to compliance and auditing as well as education for pharmacy partners.
- Staffing a helpline for compliance reporting (including tip line for whistleblowers) and to answer program questions and provide consumer support.
- In conjunction with the Importer/Foreign Seller and the Reporting Partner, developing and implementing a recall and return plan for medications imported through the SIP.
- Submitting required FDA reports in accordance with section 804 regulations, as well as state statutory reporting requirements.
- Responding to any FDA records requests.

Supply Chain Security and Adverse Events (§ 251.3 (e) 11)

A cornerstone of Section 804 is the requirement that a SIP may only be approved if it poses no additional risk to the United States' public health and safety. Section 804 and the Final Rule

provide a robust framework for the implementation of Colorado's SIP from a health and safety perspective. FDA's proven oversight and high standards for the drug supply chain help guarantee the safety and quality of the drugs that currently enter the United States from foreign sources. Further, the provisions set forth in the Drug Supply Chain Security Act (DSCSA), once fully implemented, ensure traceability of all products in the current U.S. supply chain.

In all supply chain vendor contracts, the state requires safe storage, handling, distribution, and transportation practices, as well as robust visual screening procedures and reporting. The state ensures this by reviewing and approving partner SOPs to verify that the appropriate storage conditions (including sterile drugs or drugs that require special storage conditions such as temperature controls for refrigeration as referenced in Foreign Seller SOP SIP-018 in Appendix B and Importer SOP - 900, handling, distribution, and transportation (including transportation providers) for each drug are occurring from the manufacturer and are adhered to at every step of the process. Lastly, these contracts require supply chain partners to maintain required licenses, permits, and/or registrations in good standing and to provide documentation to HCPF, including compliance with Title 21 CFR § 205.50.

All of our partners and corresponding subcontractors are required to have approved, program specific standard operating procedures and systems in place, as well as program specific compliance training for all employees. These SOPs address all aspects of supply chain security and include processes for identifying, isolating and reporting suspect foreign products and illegitimate foreign products as defined by the Final Rule and can be found in the associated appendices for each partner. As a SIP Sponsor, we will leverage existing state, federal and international regulatory frameworks and agreements to ensure the drug supply is safe. Additionally, per the Final Rule and our vendor contracts, we will ensure that all eligible prescription drugs imported for distribution to Colorado are in compliance with DSCSA track and trace requirements through the use of SIP Sponsor Oversight Measures including, but not limited to, partner qualification audits, management reviews and corrective and preventive actions, as previously described in the SIP Sponsor Oversight Measures section. Our contracts ensure that all necessary data regarding the transactions and movement of eligible drugs through our program are documented, reported, and maintained for at least seven years.

Supply Chain Facilities, Standards & Reporting
All storage facilities and vehicles used to store and transport eligible prescription drugs for Colorado's Section 804 Importation program must comply with 21 CFR part 205 (guidelines for State Licensing of Wholesale Prescription Drug Distributors) and 21 CFR parts 210 and 211 (current Good Manufacturing Practice Requirements). This means that the Importer, Foreign Seller, and any subcontractors handling, relabeling or transporting prescription drugs must be properly licensed, maintain robust security controls, follow documented SOPs governing product storage and movements, and undergo routine audits to verify cGMP adherence. In addition to setting rigorous requirements, HCPF oversees partners' compliance through our Quality Management System and SIP Sponsor Oversight Measures which includes regularly scheduled reporting and site visits, as well as formal inspections every two years as referenced in HCPF SOP 5086. This oversight process includes review of operational records, temperature logs, SOPs, and security measures to ensure the quality and security of prescription drugs remain uncompromised.

In HCPF's contracts with Adira (Adira Canada and Adira U.S.), we have set forth standards as follows:

- The facility must have adequate space, security and environmental conditions necessary for proper storage of prescription drugs, including a designated space that is for the sole purpose of quarantining, storing, and staging eligible prescription drugs for the Program.
- The facility is maintained as referenced in Appendices B and C.
    - SOPs for all processes and procedures relating to the operation of the Program including, but not limited to: security, product handling, log books, adverse events, storage/environmental conditions, employee access to products, facility management, distribution processes and employee training programs.
    - Standard pharmaceutical wholesale security measures such as an alarm system, an internal and external security camera system, outdoor lighting, and a keycard or locking system.
    - Storage systems designed specifically for the Program that allows for eligible drugs to be kept separate from the rest of the facility's inventory.
    - Temperature control for all storage areas through an environmental monitoring system.
- To ensure these standards are consistently met, The SIP Sponsor has verified the Program's Importer/Foreign Seller compliance by completing multiple site visits to their facilities used for storing the program's eligible prescription drugs. The following items have been verified:
    - Adequate size, storage conditions, quarantine areas, cleanliness, and security.
    - Climate control (for sterile drugs or drugs that require special storage conditions such as temperature controls for refrigeration) and accurate instrumentation for measuring temperature and humidity.
    - Program policies and procedures that ensure the oldest approved stock is distributed first and for handling recalls and withdrawals.
    - Program policies, procedures, and systems that remove outdated prescription drugs from those designated for distribution.
    - Third Party expert consultants have reviewed all program facilities for compliance with current Good Manufacturing Practices and have ensured drugs requiring special storage conditions, such as cold chain drugs, are able to be stored to remain compliant as referenced in Appendix F, Certification Reports.
    - Adira U.S., the program's relabeler, has been inspected for compliance to 21 CFR parts 210 and 211.

Following successful contract negotiations, HCPF, supported by supply chain experts, attested that standards outlined above were evaluated and deemed in compliance during site visits with partners. The team has visited Adira Canada's Canadian headquarters and facility twice and recently visited Adira U.S.' Pennsylvania facility. Our third-party consultants have certified[40] that our partners have met the standards for storage, handling, transportation, and distribution defined above and in the Final Rule. All are verified to be in compliance with all aspects of the Final Rule.

[40] Certification reports are included in Appendix F.

HCPF approves the use of any subcontractors, such as transportation providers, for the Program and conducts any necessary site visits to ensure that they also meet all standards set forth in state and federal law and regulation. HCPF will approve the use of a secure warehouse within 30 miles of the Detroit, MI, CBP prior to submitting a Pre-Import request to FDA, per FDA guidance, after the program has been approved.[41]

Once operational, HCPF and supply chain partners will provide frequent reports as required. HCPF will evaluate these reports and follow up with partners if any information is incomplete or potentially out of compliance with the requirements and take corrective action, if necessary. Required reporting is outlined in our Communication Matrix in Appendix A and as outlined in Figure 12, below. This comprehensive reporting framework ensures that HCPF maintains active oversight, addressing issues promptly and preserving the integrity of the Program.

Figure 12. Required Reporting for Colorado's Importation Program

HCPF Communications Plan Matrix				
External				
What	**When**	**To Whom**	**How**	**Who**
Correspondence	As Needed	Colorado Consumers	Website	State of Colorado- HCPF
FDA Communications	Program Approval	US Agent (Foreign Seller)/Importer/ State of Colorado- HCPF	Email	FDA
	General Questions		Phone	
	Data Questions		FDA Website	
	Cease and Desist		Web Meetings	
Health Canada Communications	Health Canada Recall	Foreign Seller/State of Colorado HCPF	Email	Health Canada
	Shortage		Health Canada Website	
Program Disclosures (e.g. criminal convictions, disciplinary actions, etc.)	As necessary within 10 calendar days of occurrence	FDA	ESG	State of Colorado- HCPF
			Email	
Quarterly Importation Report	Quarterly per 251.19(a)	FDA	ESG	State of Colorado- HCPF
			Email	
Annual Report	Annually on December 1 per CO State Statute	Colorado General Assembly	Email	State of Colorado- HCPF
Quarterly Financial Report	Quarterly per CO State Statute	Colorado General Assembly	Email	State of Colorado- HCPF
Safety Reports	As necessary per ICSR outcome	FDA	E2B (R3) Safety Database	RMPDS on behalf of Importer
Reporting for Combination Products	As directed per 251.18(c)	FDA	E2B (R3) Safety Database	RMPDS on behalf of Importer
			Email	
		original manufacturer of SIP Medications	Email	
NDA Field Alert Reports	As necessary per complaint investigations and 251.18(b)	FDA	Form FDA 3331a via email	Importer
		original manufacturer of SIP Medications	Email	
Pre-Import Request	As necessary	FDA	ESG	Importer
			Email	

Colorado Department of Health Care Policy & Financing, March 2025

[41] FDA Request for Information (RFI) December 20, 2024, page 5

Pre-Import Requests and Importation of Eligible Drugs
Before importing an eligible drug, Adira U.S. will be required to collect and submit to HCPF and FDA a Pre-Import Request for each eligible drug, as required under the Final Rule. The Importer will submit the request to FDA via electronic format after HCPF has reviewed and approved a draft at least 30 calendar days prior to the scheduled date of entry for consumption. Once approved by FDA, Adira U.S. will submit a purchase order to Adira Canada to initiate the purchase of eligible drugs approved for importation directly from the manufacturer. The manufacturer will ship the eligible drugs to Adira Canada's warehouse in Mississauga, where Adira Canada staff will inspect and prepare the drugs for exportation.

Adira U.S. will facilitate the compliant importation of eligible drugs into the United States and their eventual transportation to Aston, PA. Adira U.S. will work with a customs-licensed customs broker to complete the required importation documentation. The customs broker, on behalf of Adira U.S., will make an entry for consumption at the Detroit CBP port of entry. Once the eligible drugs have cleared customs, the product will be stored under a CBP importation bond at a secure warehouse under control of Adira U.S. under appropriate environmental conditions to maintain the integrity of the products within 30 miles of the Detroit CBP. Adira U.S. will update FDA in the Pre-Import request with specific details of the secure warehouse to be used for the importation process. Adira U.S. will coordinate the sampling and testing of statistically valid samples with Q Laboratories to ensure that the drug is authentic and has not degraded. The results of those tests will be submitted to FDA for review and approval. During the testing process, the imported prescription drugs will remain in quarantine at the Adira U.S.-controlled warehouse under a CBP bond in Detroit. Once the testing results have been approved by FDA, Adira U.S. will arrange for the in-bond transport of the imported eligible drugs to the Adira U.S. relabeling facility to be relabeled in accordance with the Final Rule. Once they are relabeled, they will be transported back to the Adira U.S. contracted secure warehouse for an FDA admissibility decision. Once the prescription drugs are approved for distribution by FDA, they will go back to Adira U.S.' Ashton, PA warehouse and await distribution to Colorado pharmacies.

Compliance with the Drug Supply Chain Security Act
Colorado's SIP Sponsor has ensured all participants and imported drugs comply with the Drug Supply Chain Security Act (DSCSA),[42] and is allowed through Final Rule exemptions by multiple site visits as required by Partner Qualification Audits (HCPF SOP 5086). This includes HCPF's review of applicable registrations, licenses or permits from federal and/or state authorities, and to maintain certain records to verify the supply chain for each drug distributed so it can be traced back to the original manufacturer quickly and efficiently. HCPF maintains oversight over all participants and imported drugs through the use of SIP Sponsor Oversight Measures described above including, but not limited to, partner qualification audits, management review, internal audits and corrective and preventive action processes.

The state's Program leverages the Final Rule's equivalent set of transaction record standards and other flexibilities to ensure appropriate tracking and tracing of all imported medications. Key Final Rule exemption standards that the Colorado SIP and related supply chain partner contracts deployed include:

[42]The Drug Supply Chain and Security Act, 21 USC § 9(V)
https://uscode.house.gov/view.xhtml?path=/prelim@title21/chapter9/subchapter5/partH&edition=prelim

- Foreign Seller compliance with authorized trading partner (ATP) definitions equal to U.S. ATP standards where appropriate as well as Foreign Seller required registration with FDA.
- Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers as required by the DSCSA.[43]
    - See Appendix C for Adira U.S.' required annual reporting registrations
- Maintenance of transactional information for each eligible drug, meeting T3 data[44] requirements, including a statement that the product was purchased directly from a manufacturer.
- Permitting Importer to receive a product without:
    - A product identifier, as long as the Foreign Seller affixes a Section 804 Serial Identifier, or SSI, if necessary.[45]
    - A standardized numerical identifier (SNI)[46] within the product identifier as long as an SSI is affixed or imprinted by the Foreign Seller, if necessary.

In the Colorado Program, DSCSA compliance begins with the manufacturer. All eligible drugs in the Program will be purchased directly from manufacturers, as defined in the Final Rule. Adira Canada will ensure, through purchase agreements for each eligible drug, that manufacturers supply comprehensive documentation that includes all required information to appropriately track and trace an imported drug back to its origin. Additionally, Adira Canada will be responsible for the addition of a Section 804 serial identifier (SSI) if the product does not already have a standard product identifier (PI) affixed by the manufacturer. Should this SSI be necessary, it will be linked to the PI subsequently affixed by the Importer and it will be crosslinked to the transaction records (described below) to ensure the data being captured is equivalent to that of the PI under DSCSA.

Adira Canada will also be responsible for verifying that the drug is not a suspect or illegitimate foreign product and is required to supply various applicable certifications to affirm that they received the product from the manufacturer and that the Foreign Seller did not alter the transaction history. See Appendix B for SOP-SIP-005 that outlines these specifics.

Both Adira Canada and Adira U.S. will comply with detailed documentation requirements outlined in the Final Rule, including supplying data that is comparable to DSCSA-required T3 data, or Transaction History, Transaction Information and the Transaction Statement. Adira Canada will ensure the following data, which is equivalent to T3 data, is transferred electronically to Adira U.S. Figure 13 shows how the Final Rule requirements relate to their counterpart DSCSA provisions.

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[43] https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/annual-reporting-prescription-drug-wholesale-distributors-and-third-party-logistics-providers

[44] "T3 data" is a reference to an eligible drug's Transaction History, Transaction Information and the Transaction Statement.

[45] § 251.14 Supply chain security requirements for eligible prescription drugs (c) (4) (ii) "Assign an SSI to each package and homogenous case intended for sale to the Importer in the United States, **unless each such package and homogenous case displayed a manufacturer affixed or imprinted product identifier**, as such term is defined in section 581(14) of the Federal Food, Drug, and Cosmetic Act…"

[46] Title II of the Drug Quality and Security Act § 581(20) as part of the Product Identifier(14). https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act

Figure 13. Final Rule and DSCSA Counterpart Provisions Comparison

Information	Final Rule Requirement	DSCSA Counterpart
A statement from the Foreign Seller purchased directly from the manufacturer	251.14 (c), (6) (i)	TH 25
Proprietary name of the product	251.14 (c), (6) (ii)	TI 26 A
Strength & dosage form	251.14 (c), (6) (iii)	TI 26 B
Container size	251.14 (c), (6) (iv)	TI 26 D
Number of containers	251.14 (c), (6) (v)	TI 26 E
Lot number	251.14 (c), (6) (vi)	TI 26 F
Date of transaction	251.14 (c), (6) (vii)	TI 26 G
Date of shipment if more than 24 hours after the date of transaction	251.14 (c), (6) (viii)	TI 26 H
Business name and address of the person associated with the Foreign Seller from whom ownership is being transferred	251.14 (c), (6) (ix)	TI 26 I
Business name and address of person associated with the Importer to whom ownership is transferred	251.14 (c), (6) (x)	TI 26 J
SSI for each package or homogeneous case	251.14 (c), (6) (xi)	Final Rule Specific
Canadian DIN (Drug Identification Number)	251.14 (c), (6) (xii)	(replaces TI 26 C)/Final Rule Specific
Transaction Statement Equivalent	251.14 (d), (7)	Final Rule Specific

Colorado Department of Health Care Policy & Financing, 2022.

For the Program, Adira U.S. will use Warehouse Management (WMS) and serialization software to comply with the Supply Chain Security requirements defined in §251.14 and the enhanced DSCSA requirements. The systems will provide the following functionalities, which will be validated by Adira U.S. prior to their operational use:

- Receiving and internal status tracking of:
  - Product Identifiers (PIs) shipped by the Foreign Seller, but affixed by the manufacturer.
  - SSIs affixed or imprinted and then shipped by the Foreign Seller.
- Generation and tracking of serialization information, including unique product identifiers as defined under section 581(14) of the FDCA act for each individual product and homogenous case of imported products.

- Equipment and systems supporting the relabeling activities defined in SOP-905 Relabeling.
- Interfaces for verification requests and the interoperable, electronic exchange of transaction data to its business partners through industry standards like Electronic Product Code Information Services (EPCIS).
- Record retention, including the association between the Canadian SSIs/manufacturer PIs and their DIN and the Importer's NDC and UPI, as well as production of relevant reporting documents.

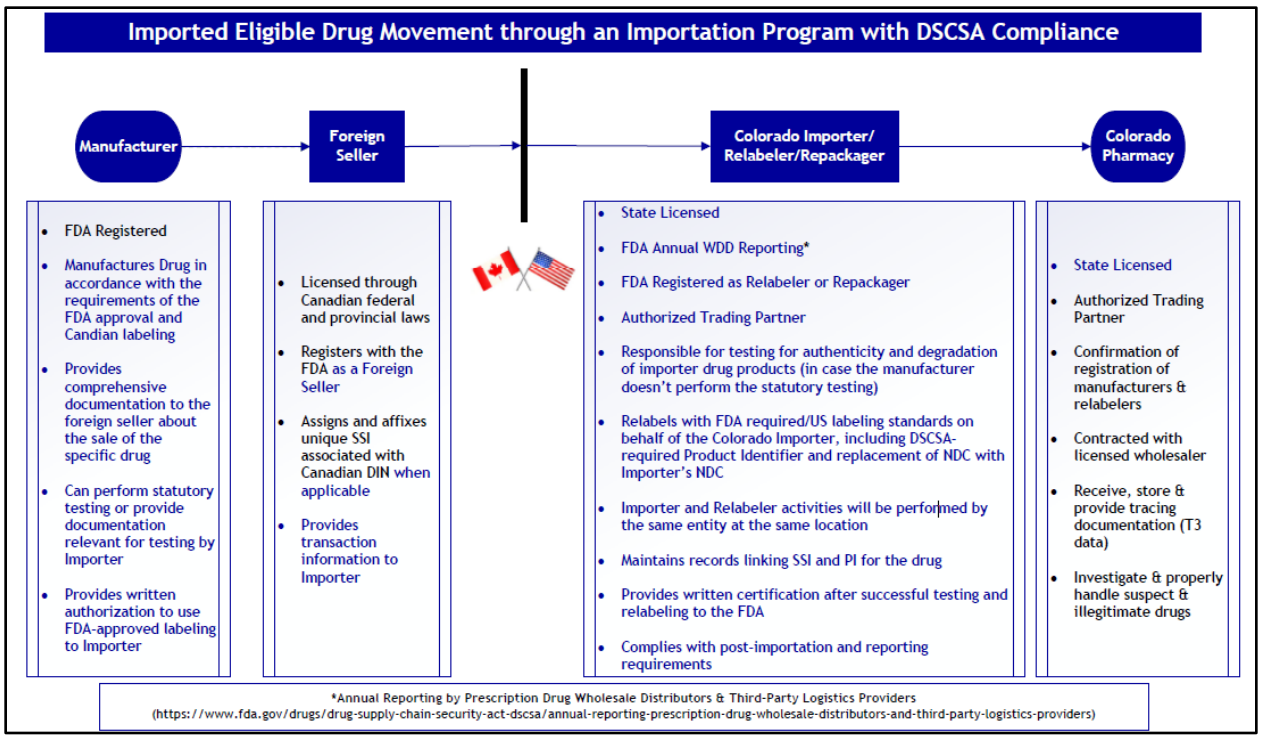
The deployed systems will support all policies and procedures defined within this SIP Application in order to prevent counterfeit, adulterated, or contaminated foreign prescription drugs from entering the U.S. drug supply chain and from reaching consumers. The SIP Sponsor and all SIP participants are committed to fulfilling their obligations to adhere and comply with the drug supply chain security requirements of the Final Rule and all applicable requirements of the DSCSA.

The imported eligible drugs will arrive at an Adira U.S.-controlled secure warehouse within 30 miles of the Detroit CBP and will be screened, according to written established SOPs, for any evidence that they may have been adulterated, are counterfeit, have been tampered with, are expired, or are a suspect foreign product or an illegitimate foreign product. If a shipment lacks adequate SSIs when required by the Final Rule, Adira U.S. will quarantine the prescription drugs immediately and ensure return of the shipment to Canada, as these drugs are not eligible for distribution in the U.S. as referenced in Adira U.S. SOP - 900 in Appendix C.

The drugs will remain in quarantine while a statistically valid sample is sent to the Program's qualified laboratory to undergo statutory testing. The test results, as well as three additional samples, will be sent to FDA field lab identified by FDA for approval. Once the test results have been approved by FDA, Adira U.S. will transport the eligible drugs to their Pennsylvania warehouse to be relabeled according to the Final Rule, including assigning FDA-approved NDC designated for Colorado's SIP and affixing a product identifier (PI). Adira U.S. will compile and maintain all records associated with the imported products that link the SSI or previous product identifier to the newly placed product identifier. The drugs will be shipped back to the Adira U.S.-controlled secure warehouse within 30 miles of the Detroit CBP. The drugs will remain under a CBP importation bond until released by FDA. Once FDA grants an admissibility decision, the drugs will be shipped back to Adira U.S.' Pennsylvania warehouse. At this point, the imported eligible drug is now ready for distribution to participating Colorado pharmacies.

Once the drug is purchased by a participating pharmacy, the pharmacy will receive, store, and provide T3 documentation on any imported drug, if requested. This is no different than the drugs purchased by pharmacies in Colorado today. A summary of DSCSA requirements and how they are handled for the Colorado program is illustrated below in Figure 14.

Figure 14. Imported Eligible Drug Movement through an Importation Program with DSCSA Compliance



Colorado Department of Health Care Policy & Financing, 2024

Between the DSCSA-equivalent transaction information, transaction statement and transaction history documentation, and the additional documentation and statutory testing required by Section 804, the documentation requirements for drugs imported under a SIP ensure the safety and transparency of the supply chain.

Adverse Events

Safety event reporting is fundamental to ensuring public safety, and industry standards for reporting were used in conjunction with the Final Rule to develop a comprehensive pharmacovigilance program which will be run by Rocky Mountain Poison and Drug Safety (RMPDS) on behalf of the Importer, Adira U.S. Adira U.S. and RMPDS have an executed Master Services Agreement (MSA) in Appendix C, outlining the working relationship. These procedures will include steps to ensure all responsibilities relating to submission of adverse events, field alerts and other reports as required by FDA relating to surveillance, receipt evaluation, FDA reporting, and record keeping of adverse events. A toll-free number and email address for safety reporting will be included in the new labeling and on the Colorado Drug Importation Program website. The line will be staffed with specialists trained in adverse event and special situation identification, collection, and documentation in preparation for timely submission to FDA and Market Authorization Holder (MAH). All suspected safety events will be submitted to RMPDS' pharmacovigilance group for medical confirmation of causality, severity and expectedness, execution of required follow-up, and appropriate submission to FDA per FDCA and part 251.3(e)(11)(iv) as described below.

All partners and individuals involved in the Section 804 program will be trained in identification and timely reporting of adverse events and special situations for all drugs imported. The requirements and timelines of partner safety event reporting are documented in SOPs and will be trained on by all partners annually and upon every new drug being

imported. The updated product packaging will also contain the safety reporting number where any pharmacists and consumers can call and report an adverse event. The reporting number will be staffed 24/7/365 with a live answer HCP[47] agent in order to facilitate timely reporting.

Upon report of a safety event, the RMPDS intake group agent will document a unique report for each patient. For each safety report, an attempt will be made to collect all information (as detailed in Section 20 of DC Case Handling in MIQ Work Instruction 2543) required for a valid Individual Case Safety Report (ICSR) as outlined in 251.18 (d) 7 including, but not limited to:

- Patient information: patient age at time of adverse event or year of birth, patient gender, pregnancy status, and patient weight.
    - Each patient will be assigned a unique code as reports to FDA will not include the name and address of the patient.
- Adverse event: outcome attributed to the event, date of adverse event, date of ICSR submission, description of adverse event (including a concise medical narrative), adverse event term(s), description of relevant tests, including dates and laboratory data, and other relevant patient history including preexisting medical conditions.
- Suspect medical product(s): Product name, product dose, route of administration and frequency, therapy dates, indication, whether the product is a combination product, whether adverse event abated after drug use stopped or dose reduced, whether adverse event reappeared after reintroduction of drug, lot number, expiration, NDC, and concomitant medical products and therapy dates.
- Reporter information: Reporter name, address and telephone, and whether the initial reporter is a health care professional and, if so, their occupation.
- Importer information: Name and contact office address, the date the report was received by the Importer, whether the ICSR is an expedited report, an initial report or follow-up report, and a unique case identification number that is the same as the initial report.

The RMPDS intake group will forward all intake reports described above to the pharmacovigilance group within 24 hours of receipt for the assessment and evaluation of each ICSR. The pharmacovigilance group will submit expedited safety reports to FDA via E2B(R3) within 15 days of awareness (unless FDA regulations specify otherwise) and will submit non-expedited reports to FDA within 90 calendar days of initial awareness. Subsequent to submission of each report to FDA, RMPDS PV group will forward each submitted ICSR to the manufacturer. Procedures completed by the pharmacovigilance group congruent with 251.18(d)(9) will include the following, as detailed in Pharmacovigilance Intake SOP 5107:

- Duplicate search of historic cases to ensure novelty of each ICSR, or need for follow-up to a previously reported case
- Data entry of intake form into ClinevoTech PV database, E2B(R3) reporting pathway through AS2 Gateway has been established for regulatory submissions to FDA.

[47] HCP = Health Care Professional

    - The ClinevoTech[48] PV database is a validated, cloud-based Drug Safety System designed to intake cases from MICC, Web Intake, Manual Entry, Email Intake, E2B file import, and literature intake.
    - 21 CR Part 11, GAMP 5, Annex 11 and GDPR compliant database.
    - Database allows for Safety Data Entry, Auto/Manual MedDRA coding of event terms, and development of Safety Narratives.
    - Dynamic workflows and timeline tracking/alerts ensure timely reporting
    - Inbuilt AS2 gateway for regulatory submissions with FDA compliant reporting rules
    - Line listing and periodic report generation for non-expedited case reporting
- Evaluation of all reports and classification of each report as an expedited ICSR, non-expedited ICSR, or a determination that no reportable event occurred.
- All ICSRs will be evaluated for completion of the minimum data set and all ICSR elements will include:
    - All items previously listed
    - Importer name and contact office
    - Whether the ICSR is expedited or non-expedited
    - Whether the ICSR is an initial report or follow-up report
    - All source and supporting documentation relevant to the ICSR, including if applicable:
        - Copy of the autopsy if the patient died
        - Copy of the hospital discharge paperwork if the patient was hospitalized
- Adverse event terms will be coded using standardized medical terminology (e.g., MedDRA).
- If any elements are missing from the report, attempts will be made to reach out to the reporter to gather missing information. Documentation of the attempts to gather missing information will be maintained within the case record. Follow-up procedures are governed by Work Instruction PV Outbound Communication Attempts (PV WI 5623).
- Seriousness, expectedness, and causality will be assessed based, minimally, on FDA-approved U.S.Prescribing Information and with any other product information available (i.e. Safety Data Sheet).
    - Per 21 CFR 314.80, a determination of seriousness will be made for any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency

[48] Clinovetch.com

room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.
    - Per 21 CFR 314.80, a determination of expectedness will be made for any adverse drug experience that is not listed in the current labeling for the drug product. This includes events that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differ from the event because of greater severity or specificity. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the labeling only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the labeling only listed cerebral vascular accidents. "Unexpected," as used in this definition, refers to an adverse drug experience that has not been previously observed (*i.e.*, included in the labeling) rather than from the perspective of such experience not being anticipated from the pharmacological properties of the pharmaceutical product.
    - In addition to considering the reporter's assessment of causality, causality will be systematically evaluated to determine the potential for a causal relationship between the administration of a drug or medical product and the occurrence of an adverse event or side effect. Structural tools, such as the Naranjo Scale and Hill Criteria, will be employed to aid in assessing the probability that an adverse reaction is actually due to the drug or medical product.
- Each ICSR will be Quality Reviewed for completeness and accuracy against all source documentation, and any additional follow-up will be performed as warranted.
- Medical review will be performed by RMPDS PV Medical Director for a final determination of causality, severity and expectedness/listedness, accuracy of MedDRA coding, and timeline of reporting.
- Any incomplete cases in which the minimum information required for a valid ICSR cannot be obtained after follow-up will be nullified. If additional information is received that would provide any elements required for a valid case, the case will be processed per aforementioned SOP.
- Cases, including follow-up reports, will be submitted electronically (E2B(R3)) within fifteen (15) calendar days for expedited reports and ninety (90) calendar days for non-expedited reports unless otherwise specified by FDA regulation.
- All serious, unexpected adverse events will be submitted as expedited ICSRs regardless of whether or not the Importer believes the events are related to the imported product.
- Specific to handling of ICSRs related to combination products, as defined by FDA under 21 CFR 3.2(e), reporting timelines will be determined by:
    - 21CFR 314.80 and 600.80 for 15-day reports of serious and unexpected (per 21 CFR 314.80(a) and 600.80(a)) adverse experiences related to combination products marketed under an ANDA, NDA or BLA.
    - 21CFR 4.102(c)(2)(ii) and (c)(3)(ii) If a combination product is marketed under a Device Application reporting timeline will be 30 calendar days from initial awareness.

- 21CFR 4.102(b)(1) and 4.102(c)(1)(i)) for combination products requiring 5 business-day reporting from initial awareness for reports that:
  - Necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health
  - Upon written request by FDA pursuant to 21 CFR 803.3(v)
- Malfunction reports of combination products that contain a device constituent part will be submitted within 30 calendar days of initial awareness if the report reasonably suggests the product malfunctioned (defined in 21CFR4.102(a) and 803.3(k) and would be likely to cause or contribute to the death or serious injury (defined in 21CFR803.3(w) if the malfunction were to recur.
  - Malfunction reports will be submitted within 15 calendar days of initial awareness for combination products containing a device constituent part and are marketed under an ANDA, NDA or BLA if the unexpected, serious event was caused by or contributed to by the malfunction.
- Follow-up of all 15-day, 5-day and Malfunction reports for combination products will be performed as required in 21 CFR 4.101.

All records of safety reports will be maintained by RMPDS and partners for 10 years. Records will be available to FDA upon written notice.

Sponsor Oversight of Adverse Event Reporting
As the SIP Sponsor, HCPF actively oversees adverse event reporting to ensure full compliance with section 251.3(e)(11)(iv) and 251.18(d)(9):

1. Partner Qualification & Audits
   a. Before approving any Importer or pharmacovigilance partner, HCPF applies its Partner Qualification Audit Procedure (HCPF-SOP-5086). This includes verifying that the partner has:
      i. Written procedures for individual case safety reports (ICSRS) consistent with 21 CFR 314.80/600.80 (for drug or biologic constituent parts) and 21 CFR 4.102(c) (for combination products).
      ii. A validated system for timely electronic submission of expedited or periodic ICSRs to FDA and manufacturers.
   b. HCPF will periodically re-audit the Importer and RMPDS to confirm ongoing compliance, reviewing ICSRT records, training logs, and any field alerts issued.
2. Management Review
   a. During annual Management Reviews, HCPF's executive team and QA staff evaluate adverse event trends, timelines for ICSRD submission, and any Corrective Action and Preventive Action (CAPA) related to missed or delayed reporting. This ensures oversight of RMPDS's performance and the Importer's responsibilities for adverse event reporting.
   b. If repeated adverse event reporting lapses are detected, HCPF can require corrective actions, impose contract remedies, or conduct follow-up audits.
3. Ensuring Label Access for Expectedness Assessment
   a. The Importer provides RMPDS with current FDA-authorized labeling as referenced in the MSA in Appendix C for all imported drugs, including combination products, so RMPDS can accurately determine expectedness of adverse events. HCPF monitors this handoff through routine check-ins and audits.

b. Label updates are tracked and reviewed in Management Reviews, ensuring RMPDS always has the latest product labeling for adverse event evaluation.

4. Monitoring Combination Products
    a. Because the program includes combination products, HCPF confirms the partner's SOPs incorporate 21 CFR 4.102(c) for device-related malfunctions or drug-device adverse event reporting. RMPDS must clearly document and report any device constituent part malfunctions within the 5-day or 30-day deadline as required.
    b. HCPF's internal audit processes periodically sample combination product ICSR files to verify timely, complete submission to FDA and the manufacturer.
5. Recordkeeping and FDA Access
    a. Per FDCA and 21 CFR 251.18(d)(9), RMPDS and the Importer keep all adverse event records for 10 years. HCPF ensures these records remain readily available for FDA inspection upon request.

Testing of Imported Medications

Qualified Laboratory (§ 251.3(e)(7) & 251.15)
Adira U.S. has a quality agreement with Q Laboratories, based in Cincinnati, Ohio, to conduct the statutory testing required by the Final Rule. Q Laboratories is registered with FDA for pharmaceutical testing, and is cGMP/GLP Compliant and ISO/IEC 17025 Accredited. They are compliant with the relevant sections within Title 21 Code of Federal Regulations Sections 210 and 211, including Sections 211.160 and 211.194. Copies of all Q Laboratories' accreditations and inspection history are included in Appendix C. HCPF and Adira U.S. have reviewed the master site file and HCPF has visited the site to review compliance as referenced in HCPF SOP 5086, Partner Qualification Audit Procedure. A summary of onsite compliance review is in Appendix F. HCPF has evaluated Q Laboratories for inclusion in Colorado's program. If an OAI (Official Action Indicated) classification is received or the ISO 17025 certification is revoked or expires, Colorado will evaluate new laboratories for the program and update FDA accordingly with a SIP amendment. Further, HCPF maintains oversight over all participants, including Q Laboratories, through the use of SIP Sponsor Oversight Measures described earlier including, but not limited to, partner qualification audits, management review, internal audits and corrective and preventive action processes.

Ensuring the purity and authenticity of imported eligible drugs is central to the design of Colorado's SIP. As required by federal and state laws and regulations, additional testing will be performed on drugs imported through Colorado's Program. Drugs imported through Colorado's Program are identical to those entering the marketplace through the traditional domestic supply chain except for their labeling. The testing described below is in accordance with the Final Rule requirements. The testing description below is high-level to the extent possible and will be updated specific to each eligible drug in the Pre-Import request once the detailed testing requirements are known from the original manufacturer.

Testing & Sampling Process (§ 251.3(e)(7))
Adira U.S. will send a statistically valid sample from the lot of imported eligible drugs, based on the size of the lot. The samples, selected at random, will be pulled directly from the shipment coming from Adira Canada. Adira U.S. will submit the sampling plan per batch of eligible drugs in a Pre-Import Request for FDA approval. Statistically valid sample sizes will be determined once the methods are known with the associated sample requirements from the

manufacturer. Twice the amount needed will be pulled for testing in addition to retention samples of the same quantity. If the manufacturer completes the statistically valid testing, they will complete the same sampling techniques and process and send all paperwork directly to FDA as described by the Final Rule.

Testing of drug products is designed to ensure the identity, strength, quality, purity and performance of the drug product throughout its shelf life and during the period of patient use. The testing often involves numerous orthogonal technologies that collectively demonstrate the drug product satisfies safety, efficacy, and performance attributes. As such, the nature of the drug product dictates the types of required testing. As the majority of drugs on the Colorado final drug list are oral dosage forms, the universal tests indicated in USP <2>, *Oral Drug Products – Product Quality Tests* must include an appearance assessment, a stability-indicating assay method, an identification method that ensures selectivity for the analyte of interest, and an impurity method. Liquid chromatography is an extremely useful tool in achieving potency, identification, and degradation assessments. This technology, based on separation science, is capable of quantifying each component of interest in a selective and specific manner; *i.e.*, each response is unique and specific to the analyte of interest regardless of other excipients and components within the composition. Multicomponent drug products may require multiple methods depending on the physicochemical attributes of each active pharmaceutical ingredient as chromatographic separations are based on the hydrophobicity or lipophilicity of each molecule under evaluation.

Q Laboratories will work with the manufacturer of record to transfer the validated methods to the laboratory. Once these transfers are successfully completed, the laboratory will support ongoing release testing. Once the appropriate set of methods has been established at Q Laboratories, the associated acceptance criteria will be very similar to that presented from a USP monograph.

MINIMUM TESTING	PROCEDURE	ACCEPTANCE CRITERIA
IDENTIFICATION	Chromatographic Analysis per validated conditions	The retention time of the major peak of the *Sample solution* corresponds to the analyte peak of the *Standard solution*, as obtained in the *Assay*
ASSAY	Chromatographic Analysis per validated conditions	Typically, NLT 90.0% and NMT 110.0% of the labeled amount of active pharmaceutical ingredient
IMPURITIES	Chromatographic Analysis per validated conditions	Impurity limits based on knowledge of the drug product
MICROBIAL INTEGRITY	USP Monograph testing	Per manufacturer's specifications

Evaluating for Authenticity

Authenticity testing discerns whether the prescription drug meets purity requirements by checking for the presence of unknown substances/toxins. Program testing will mirror the

authenticity testing established by the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA). This will provide confirmation that the Canadian Health Products and Food Branch (HPFB)-approved drug meets FDA-approved drug's specifications and standards. When assessing the authenticity of a prescription drug, Q Laboratories will conduct a visual inspection as well as the required laboratory tests per drug that may include chromatography and/or spectrometry. Authenticity testing will be completed using an adequate number of tests required by the drug based on the results of multiple tests. These tests can vary by drug based on its complexity. While no single technique delivers the universal results needed for verification, there are tests that will be used on multiple drugs that will leverage the guidelines for the appropriate dosage form described within the general U.S. Pharmacopeia (USP)[49] chapters, e.g., USP <2> *Oral Drug Products, USP* <1> *Injections and Implanted Drug Products*, and USP <5>, *Inhalation and Nasal Drug Products*.

Imported medications that fail the visual inspection or laboratory test will be removed from the supply chain and dispositioned in the U.S. Imported drugs that are not consistent with the U.S. counterpart, as required by the Final Rule, and/or not approved by FDA, will be dispositioned immediately and not undergo further testing.

Q Laboratories has or can obtain the necessary equipment to perform detailed testing on the samples using spectroscopic and high-performance liquid chromatography, as applicable, based upon the methods specified by the manufacturer. They already regularly test pharmaceutical products for authenticity, degradation, and other required tests as requested by their manufacturer customers. Q Laboratories will work directly with the manufacturer to identify the proper equipment and ensure that it is used for each test required.

Testing for Degradation
As required by the Final Rule, testing for degradation must include a stability-indicating assay provided by the manufacturer. Q Laboratories regularly tests pharmaceutical products for stability and either has or can obtain the equipment to perform the necessary stability-indicating tests on samples based on the manufacturer defined methods. Prescription drugs that have expired or will expire before being able to be safely consumed will be designated for disposition in the U.S.

Microbial integrity is only necessary for certain dosage forms (refer to USP <1111>) and not solid oral dosage forms. To evaluate whether a batch poses microbial or bioburden hazards, Q Laboratories will test for harmful microorganisms by following the appropriate USP monograph, e.g. USP <51>, <60>, <61> and / or <62> per the manufacturers' specifications. Testing results will follow the allowances described in USP <1111>. If a sample presents evidence of microbial contamination, Q Laboratories will ensure Adira U.S. is aware, and the originating batch will be quarantined and dispositioned in the U.S.

Submission of Testing Data to FDA
All data that has been generated and collected will be submitted through FDA electronic submission gateway (ESG) by Adira U.S. as required by the Final Rule.

[49] United States Pharmacopeia (2022). Other USP-NF General Chapters for Compounding. https://www.usp.org/compounding/compounding-general-chapters

Manufacturer Confidentiality for Required Testing (§ 251.3 (e) 16)
The qualified laboratory and the manufacturer will create and agree to a confidentiality agreement to establish levels of permission and authorization to all sensitive information such that it is used on a "need to know" basis with appropriate document timeouts, inability to print, inability to copy, and any other necessary mechanisms to restrict access and ability to distribute the proprietary information. Each page should contain, at minimum, the following statement: "Confidential and Proprietary Information of the Manufacturer. Do not distribute." Additionally, Q Laboratories will take steps internally to ensure security of a manufacturer's confidential information through the use of secure networks, firewalls, and Virtual Private Networks (VPN) when needed to access information. A Confidentiality Agreement has been drafted by Adira U.S. and Q Laboratories and an NDA agreement between both parties has been signed (Appendix C). These documents or similar versions can be used between the manufacturer, Q Laboratories, and Adira U.S. in the future.

§251.16 (e) Laboratory Testing Requirements - Manufacturer Testing
The manufacturer is the most knowledgeable party regarding the product and has a vested interest in ensuring that the brand is well supported in the marketplace. The manufacturer would want to ensure the health and safety of the patient population that could benefit from this program. If participating manufacturers would prefer to coordinate testing per the option in the Final Rule, Adira U.S. and the manufacturer will adhere to all Final Rule requirements.

Relabeling (§ 251.3 (e) 8)

The relabeler, Adira U.S., will relabel each eligible drug in compliance with the FDCA (e.g., FDCA Sections 502, 505, 804), and applicable regulations (e.g., 21 CFR 201 and the final drug importation rule). Adira U.S. implements a documented Relabeling SOP (SOP - 905) detailing each step in the relabeling process, including product intake, labeling material preparation, DSCSA product identifier assignment, and final release. The Importer (Adira U.S.) will ensure that a DSCSA-compliant product identifier (PI) is affixed or imprinted to every package and homogeneous case of each eligible prescription drug prior to their certification and distribution. The PI will include (a) NDC, (b) a unique alphanumeric serial number (≤ 20 characters), (c) lot number, and (d) expiration date, in both human-readable and machine-readable (2D Data Matrix) formats. Adira U.S. will commission each serial in its validated serialization system, associate the new PI with the Foreign Seller's Section 804 Serial Identifier (SSI) or manufacturer affixed or imprinted product identifier[50], and exchange transactions with authorized trading partners. All label stock, printing, scanning, and verification steps are validated; records retained for 6 years or longer. A Quality Assurance Director at Adira U.S. will oversee day-to-day relabeling operations and ensure that label content will meet all federal requirements (e.g., inclusion of NDC, warnings, and statements). The QA Manager will verify the final label accuracy before products are distributed. All personnel involved will be required to complete initial and ongoing training in areas such as product label design, handling of sterile and temperature-sensitive products, and adverse event reporting awareness. Specific steps to the relabeling process include, but are not limited to:

[50] § 251.14 Supply chain security requirements for eligible prescription drugs (c) (4) (ii) "Assign an SSI to each package and homogenous case intended for sale to the Importer in the United States, **unless each such package and homogenous case displayed a manufacturer affixed or imprinted product identifier**, as such term is defined in section 581(14) of the Federal Food, Drug, and Cosmetic Act…"

1. Label Content and Format
    - All wording is displayed prominently and is not false or misleading.
    - An NDC has been assigned to the drug and is affixed to the label.
    - The labeling features all labeling elements required by the approved NDA/ANDA and 21 CFR 201, including:
        - The proprietary and established name of the drug,
        - Strength, lot number, and expiration date
        - Name of the original manufacturer and name/place of business of Adira U.S. (the Importer)
        - All required warnings, indications, dosage, and use instructions etc.,
        - The statement: “"This drug was imported from Canada without the authorization of (insert A/NDA holder name) under the state of Colorado's Section 804 Importation Program. For more information, please visit https://hcpf.colorado.gov/drug-importation.”
        - A statement describing which package sizes or dosages of a drug, if any, are not being imported, if applicable
        - Uniformity between the imported label design and FDA-approved design, other than the mandatory additions or substitutions (e.g., new NDC) under the Section 804 Final Rule.
2. Affixing DSCSA-Compliant Product Identifiers
    - Adira U.S. follows SOP - 905 (Relabeling) to ensure each imported drug has a DSCSA-compliant product identifier in both human-readable and machine readable-(2D Data Matrix) formats, consistent with FDCA 581(14)[51]
    - Each product identifier includes the DSCSA-defined standardized graphic, the standardized numerical identifier (SNI)[52] (which includes FDA-assigned NDC and a unique serial number (up to 20 alphanumeric characters)), the lot number, and the expiration date.
    - Adira U.S. will use serialization system software to generate, track, and associate each new DSCSA product identifier with the original Section 804 Serial Identifier (SSI) affixed by the Foreign Seller. Any invalid or unscannable labels are automatically decommissioned.
    - These processes ensure full DSCSA track-and-trace compliance for all imported prescription drugs.
3. Container Closure Systems & Repackaging Limitations
    - Per 21 CFR 251.13(c) and stated in SOP - 905, Relabeling for U.S. Distribution (SIP), no relabeling activity may breach or compromise the primary container closure system. If a blister pack, cartridge, pen, or other primary container cannot be relabeled without physically opening or altering the sealed container or device function, that product will be excluded from the importation list.
        - For example, Trikafta has been confirmed to meet this criterion and can be relabeled without breaking the foil seal and has thus been included in our Final Drug List.

[51] https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act (581(14))

[52] https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act (581(20))

- Combination products (including drug/device products) will be removed from importation consideration if the label cannot be applied without affecting the product's sterility, device mechanism, or dose markings.
- The relabeling process for Trikafta (internal wallet packaging) is described in further detail in SOP - 905.

4. Cold-Chain and Sterile Product Handling
   - Adira U.S. relabels temperature-controlled or sterile products (e.g., injection pens) under cGMP conditions (21 CFR parts 210 and 211), with continuous temperature monitoring.
   - SOP- 905 describes how these products are handled in small batches and never left outside the validated temperature range beyond the maximum time allowed by the manufacturer.
     - For cold chain products like Ozempic and Victoza, Adira U.S. will relabel the product in small batches. The product will be outside of the recommended storage temperature, at room temperature, well within the manufacturer-permitted excursion period.[53] More details can be found in SOP - 905.
   - Sterile injection pens remain sealed during labeling; no internal components or drug reservoirs are exposed. If labeling placement risks breaching sterility or device function, the product is excluded from importation.
   - SIP Sponsor Oversight of Cold-Chain and Sterile Products:
     - To address the unique requirements of temperature-controlled and sterile drugs, Colorado will ensure ongoing compliance with 21 CFR parts 210, 211, and 205 through routine audits and management reviews, as outlined below:
       - Partner Qualification and Periodic Audits: Before engaging any partner who handles cold-chain or sterile products, HCPF, conducts a Partner Qualification Audit (see HCPF SOP-5086) to confirm they have validated temperature controls, cGMP-trained staff, and robust SOPs for sterile handling. HCPF's periodic audits (at least every two years or more frequently if needed) verify that the Importer and any subcontractors maintain continuous temperature monitoring, proper quarantine areas, and strict aseptic conditions for sterile injection pens. Audit teams review temperature logs, employee training records, and any deviations or CAPAs related to cold-chain handling.
       - Small-Batch Relabeling Under cGMP: Adira U.S.' relabeling SOPs for sterile or refrigerated products (SOP - 905) require small-batch processing to minimize exposure time outside the validated temperature range. Any product that cannot be relabeled without breaching the container closure or compromising sterility is excluded from the SIP.
       - Management Review of Cold-Chain Controls: HCPF's Management Review SOP ensures that senior leadership reviews cold-chain performance indicators – such as temperature excursion

[53] For example, www.novocalc.com. Adira U.S. will adhere to all current and future manufacturer temperature excursion guidelines.

incidents, audit findings, and any related CAPAs – on at least an annual basis. If significant risks or repeated issues are identified, HCPF leadership can require immediate corrective actions or suspend specific products from importation.

- Ensuring Stability and Mitigating Contamination: All facilities handling cold-chain or sterile products must pass Partner Qualification that confirms they have dedicated, temperature-controlled areas with validated environmental monitoring systems. The Importer must demonstrate aseptic handling practices through on-site inspection, ensuring no risk of contamination or compromise to the device's functionality. HCPF reserves the right to conduct spot checks or unannounced audits if concerns arise regarding cold-chain integrity.

5. SIP Sponsor Oversight Ensuring Drug Supply Chain Security
   - Partner Qualification & Audits
     - HCPF requires every key supply chain partner (Importer, Foreign Seller, Relabeler, Laboratory) to undergo Partner Qualification before contracting. This process follows our Partner Qualification Audit Procedure (HCPF SOP-5086).
     - HCPF performs ongoing audits at least every two years (or more frequently if concerns arise). Audits evaluate storage, handling, distribution, security, and DSCSA track-and-trace compliance (in line with 21 CFR part 205).
     - Audit findings are documented; noncompliance triggers corrective actions or potential contract termination.
   - Management Review & Internal Oversight
     - HCPF conducts Management Reviews at least annually (see Management Review SOP-5088), examining supply chain KPIs, contract compliance, security incidents, and CAPA status.
     - Internal Audits (SOP-5080) verify HCPFs own monitoring processes are effective. If issues are discovered (e.g., repeated temperature excursions, shipping security breaches), HCPF intervenes immediately.
   - Collaboration with Transportation Providers
     - Any transportation subcontractor must meet 21 CFR part 205 guidelines (licensing, secure vehicles, validated shipping practices). HCPF reviews their SOPs, requires proof of compliance, and reserves the right to do unannounced inspections or request shipping logs.
6. Post-SIP Approval and Ongoing Monitoring
   - Following SIP approval, Colorado will coordinate with Adira U.S. to update or finalize any labeling supplements before submitting Pre-Import Requests for specific drugs.
   - Any subsequent labeling updates – such as changes to FDA-approved prescribing information – will be tracked per SOP - 905 and submitted to FDA as needed.
   - HCPF will continuously monitor compliance with all DSCSA and 21 CFR part 251 requirements.

Additional details can be found in SOP - 905, Relabeling, in Appendix C outlining the program's relabeling process for every drug on the SIP list. A side-by-side comparison of FDA approved labeling for the source drug and the proposed patient labeling for the imported drug with differences annotated and explained, ensuring all changes proposed can be found in Appendix D. Once the SIP is authorized, HCPF will provide the updated final versions of labels to be submitted in the Pre-Import request.

Drug Recall Plan (§ 251.3 (e) 13 and § 251.18 (e) and 21 CFR Part 7.40-7.55[54])

Eligible prescription drugs imported under Colorado's SIP will adhere to domestic and Canadian recall policy standards already in place today. Colorado, as the SIP Sponsor, will ensure that all supply chain partners are informed when recalls must occur. Prescription drug recalls in the traditional market are initiated by the manufacturer. Manufacturers work with FDA to conduct a recall and are responsible for notifying their customers, including participating wholesalers. In a state-led importation program there are additional ways a recall can be initiated, due to the unique nature of these programs. A recall can be mandated by FDA, or requested by FDA, a SIP Sponsor, the Foreign Seller, Importer, or the manufacturer.

Recall Plan
Per the Final Rule, HCPF and all SIP participants have established recall plans and processes to ensure that all parties are monitoring both Canadian and FDA recall alerts. See Appendix B for SOP-901 and Appendix C, SOP - 902. All supply chain partners already participate in monitoring activities including:

- HCPF, Importer and Foreign Seller engage in regular monitoring of FDA recall and market withdrawal webpage.
- HCPF, Importer, and Foreign Seller subscribe to all FDA drug recall announcements and FDA's MedWatch announcements.
- HCPF, Importer, and Foreign Seller subscribe to the Canadian drug recall website notifications.
- Once the program is actively importing, participating manufacturers will be required to notify the Foreign Seller if an imported drug needs to be recalled.

This recall plan ensures that HCPF will effectuate any recall, whether it is required by FDA or initiated by any supply chain partner. The following individuals will be responsible for Drug Recall Monitoring for each SIP entity:

- HCPF Drug Importation Program Manager.
- The Director of Operations at Adira U.S.
- The Director of Quality Assurance and Regulatory Affairs at AdiraMedica, Inc or Adira Canada.

The Quality Manual Communication Plan requires all supply chain partners to provide regular communication regarding recalls, affirming that they have monitored and evaluated information from all sources.

[54] Title 21 CFR § 7.40-7.55 - Drug Recalls

If at any time, HCPF or Adira U.S. determines that an issue is present in the SIP that warrants a recall, they can issue their own recall and halt the importation of a SIP drug. The Agency and Importer will conduct all recalls in accordance with Title 21 CFR Part 7 and Title 21 CFR § 251.

HCPF will initiate a recall under the following scenarios:

- The HPFB of Canada issues a recall of an imported prescription drug.
- FDA issues a recall of a domestic prescription drug that is produced in the same facility as the imported prescription drug. (Note: this type will not apply to recalls implemented due to labeling or other issues that do not apply to the manufacturing of the prescription drug.)
- The Importer identifies an issue in the supply chain, labeling, or storage conditions of the imported prescription drug.

If FDA mandates a recall, or FDA or SIP Sponsor partner suggests an imported drug recall is necessary, HCPF will conduct a meeting with all SIP supply chain partners, including the Foreign Seller, Importer, and reporting vendor to immediately halt the importation of the affected medication. If a supply chain partner indicates a recall may be necessary, they will immediately inform HCPF via phone and in writing of the determination with the factors supporting a recall. If HCPF determines a recall is necessary, HCPF will conduct a meeting to update the remaining partners to immediately halt importation. The recall shall be classified based on the standard definitions of drug recalls as defined by the United States[55] and Canada,[56] which use the same levels of classification:

- Tier 1: Recalled prescription drugs pose severe risks to individuals that can result in serious health complications or death.
- Tier 2: Recalled prescription drugs may cause a temporary health problem or have a slight chance of posing a serious health complication.
- Tier 3: Recalled prescription drugs in violation of labeling or manufacturing laws and do not pose a significant risk to individuals' health.

Based on the classification and specific reason for the recall, the depth of the recall (wholesale, retail, consumer level) will be determined and a distinct recall plan will be implemented, while coordinating with FDA.

The Importer and Foreign Seller will initiate their recall plans immediately after the need for a recall has been mandated or determined. Both entities will sequester the remaining SIP drug supply in the quarantine area of their warehouse specific to the storage of program medications. They will also ensure the drug is made ineligible in the WMS for further distribution. Adira U.S. will communicate with all participating pharmacies via email with instructions for quarantining the drug and returning it to Adira U.S. for further processing.[57] Depending on the next steps for the recall, Adira U.S. will work with a registered or

[55] U.S. Food and Drug Administration. (2022) Recalls Background and Definitions. https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions

[56] Health Canada. (2022) What is a Recall? https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/recalls/definitions.html

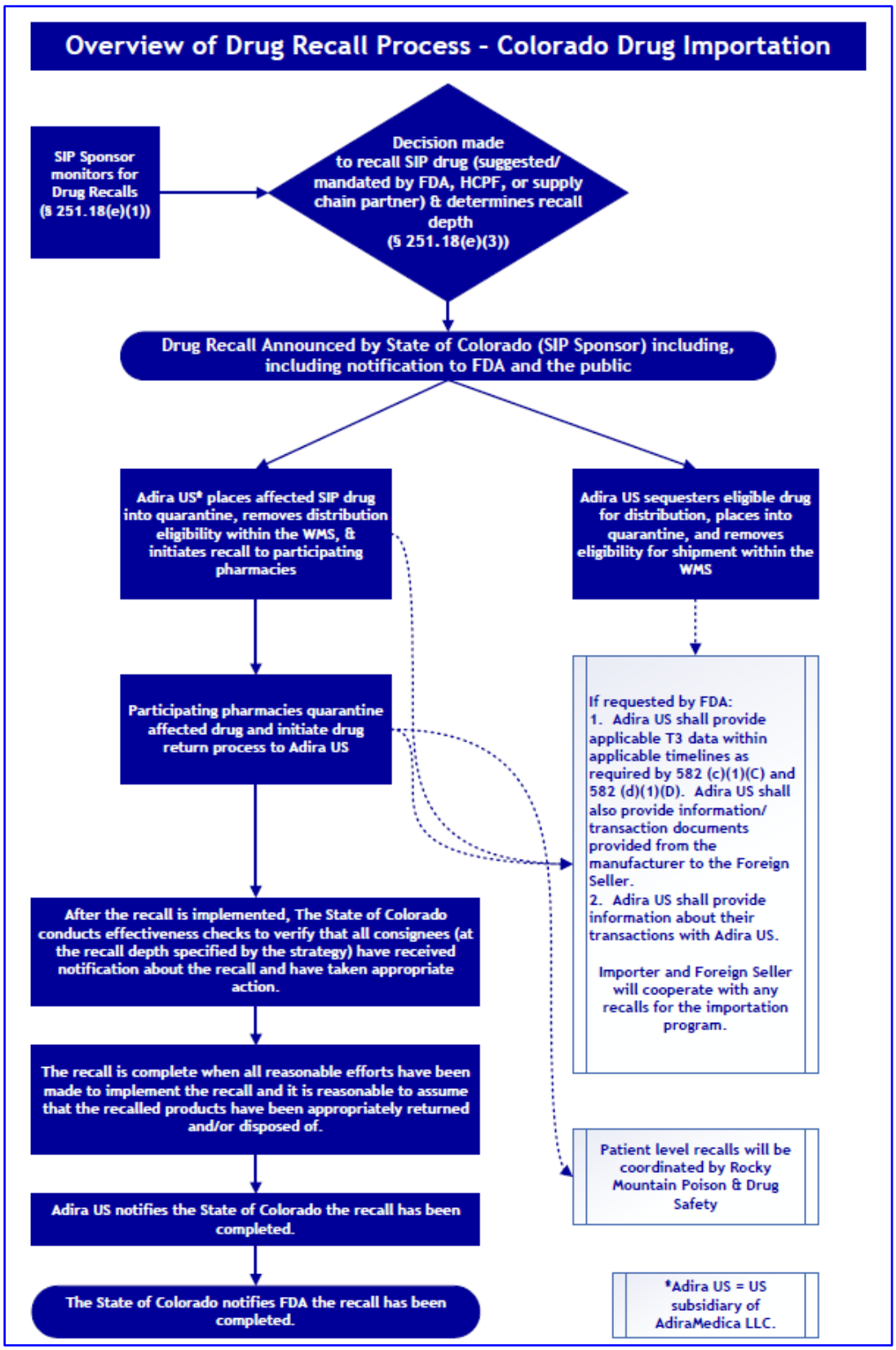
[57] Both the Importer and Foreign Seller have SOPs regarding the handling and communications of program recalls.

authorized reverse distributor to ensure that all recalled drugs are appropriately dispositioned in the U.S, and that the recalled medications do not get discarded in the trash or possibly contaminate a water supply. In addition, the destruction process needs to ensure the recalled products are physically destroyed or rendered as non-retrievable. Following disposition, Adira U.S. shall submit a summary report to HCPF.

To support effectiveness checks on the recall process and to abide by DSCSA reporting requirements, within one business day of the recall initiation, Adira U.S. will submit a report to HCPF with the following information:

- Quantity of drug recovered, including NDC, Section 804 serial identifier (SSI) if applicable, DIN, lot, and expiration;
- Number and size of containers distributed;
- Dates of transaction and shipments between the manufacturer, Adira Canada, and Adira U.S. and other applicable T3 data;
- The dates and quantities of the recovery;
- Unaccounted drug (if applicable);
- The expected amount of remaining drug to be recovered; and
- If it is a patient level recall, the date Adira U.S. notified RMPDS and the expected completion date by RMPDS.

HCPF will then ensure timely periodic reporting of the recall information to FDA.
Figure 15 shows the program's recall process:



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Recall Communications
In the event of a SIP drug recall, HCPF shall immediately notify FDA in writing of the recall initiation and steps that will be followed and ensure compliance with Title 21 CFR § 7.42 (b) based on the tier of the recall. HCPF will publish recall information on the program website.

Tier 1 and 2 Communication

- HCPF will immediately notify the public about any hazard(s) presented by the recalled drug by utilizing HCPF's Importation website, receiving support from RMPDS, and notifying state and local media outlets and newspapers.
- HCPF and Adira U.S. will inform additional stakeholders, including participating pharmacies, health plans, hospitals, or state-run facilities (e.g. prisons, clinics) with detailed return instructions to Adira U.S. for disposition.
- These entities in receipt of suspect product will assume the responsibility for preventing individuals from receiving the suspect product by following their existing procedures for the collecting and removal of recalled medications.
- Communications to program participants (pharmacies, health plans, hospitals, state-run facilities) will include the recalled prescription drug's name, NDC, lot number, and expiration date and other relevant information as required by Title 21 CFR § 7.49. The communications will also instruct staff and personnel to return the imported prescription drugs to the Adira U.S. warehouse for disposition.
- Communications to the public by state and local media will include:
    - the recalled prescription drug's name, NDC, lot number, and expiration date,
    - other relevant information as required by Title 21 CFR § 7.42 (b),
    - labeling specifying the recalled drug is imported from Canada, and
    - Adira U.S.' contact information and instructions on returning the recalled medications to the dispensing pharmacy.

Tier 3 Communication

- Because a Tier 3 recall does not pose significant adverse health effects on consumers, HCPF and Adira U.S. will extend the depth of the recall to the retail level as specified in Title 21 CFR § 7.42(b).
- HCPF will notify the public about any hazard(s) presented by the recalled drug, utilizing HCPF's Importation website and support from RMPDS.
- HCPF and Adira U.S. will inform additional stakeholders, including participating pharmacies, health plans, hospitals, or state-run facilities (e.g. prisons, clinics) with detailed return instructions to Adira U.S. for disposition.
- These entities in receipt of suspect product will assume the responsibility for preventing individuals from receiving the suspect product by following their existing procedures for the collecting and removal of recalled medications.
- Communications to program participants (pharmacies, health plans, hospitals, state-run facilities) will include the recalled prescription drug's name, NDC, lot number, and expiration date and other relevant information as required by Title 21 CFR § 7.49. The communications will also instruct staff and personnel to return the imported prescription drugs to the Adira U.S. warehouse for disposition.

Recall Reporting
If requested by FDA, Adira U.S. shall provide applicable T3 data as defined in the DSCSA, to FDA, every two weeks or other requested timeline of the recall initiation in accordance with the requirements of Title 21 CFR § 7.53 until FDA terminates the recall. The biweekly report will consist of the following components that are also specified in federal rule:

- Number of participating pharmacies, health plans, hospitals, or state-run facilities (e.g., prisons, clinics), and consumers that received the recalled imported prescription drug.
- Number of pharmacies, health plans, hospitals, or state-run facilities (e.g., prisons, clinics), and consumers who responded to the notification and the amounts of the recalled imported prescription drugs they have in their possession.
- Number participating pharmacies, health plans, hospitals, or state-run facilities (e.g., prisons, clinics), and consumers who did not respond to the notification.
- Numbers of recalled imported prescription drugs returned by participating pharmacies, health plans, hospitals, or state-run facilities (e.g., prisons, clinics).
- Numbers of effectiveness checks made and the estimated time for completion of the recall.

Adira Canada shall provide HCPF information about its transactions of the recalled drug with the manufacturer and Adira U.S. Additional details about partners' recall processes can be found in Appendix B, SOP - 901 and Appendix C, SOP - 902.

Patient Level Recall Plan
In the event that a recalled imported drug has been dispensed to patients, HCPF will work with its reporting partner, RMPDS to facilitate a patient level recall. This process is standard in the market today. First, RMPDS will work with HCPF to compile a list of affected lot numbers and identify which pharmacies received them. RMPDS will then work with the identified pharmacies to compile a list of patients, including their contact information, who have received recalled medication. RMPDS will send communication(s), either via phone or email, to the identified patients notifying them that a recall has been issued for a product they purchased. This communication will also include details of any potential concerns presented by the recalled drug. Once contact is made, RMPDS will provide patients with instructions on how to return the recalled product for proper disposal. As part of this process, RMPDS will document all communications with the identified patients and submit records to HCPF and the Importer. RMPDS will also maintain all documentation pertaining to the recall for a minimum of six years, as required by the DSCSA and the Final Rule. Any reportable safety events that are discovered during this process will be captured and reported as outlined in the Adverse Event Reporting Section.

Return Plan (§ 251.3 (e) 14)

HCPF has established a robust return plan, following standard industry practices, establishing a clear return process and ensuring the safe handling of such drugs, including preventing non-saleable products from re-entering any market. The plan also provides clear standards for the assessment of medications to determine if they are saleable. For pharmacy returns or recalled medications that must go through a return process, HCPF will require Adira U.S., through its contract, to ensure that all returned products remain in the original supply chain (i.e., using existing contracted transporters, including program participating pharmacies, and

stored in the Colorado program designated storage area within the Adira U.S. warehouse.) Adira U.S. will also ensure returned imported drugs remain separated from other returned Adira U.S. products.

If a participating pharmacy needs to return an imported product, they will initiate the standard return process as directed by Adira U.S. Once the drug has been received at Adira U.S., staff will inspect the drug for evidence of tampering or damage based on a 15 point inspection process to determine whether the product is re-saleable. As part of this inspection process, Adira U.S. will ensure each participating pharmacy completed an Ongoing Assurance Form which verifies that the entity has handled the product appropriately in accordance with state and federal regulations.

A previously recalled product may be eligible to be returned to the market for sale in a participating Colorado pharmacy if it was classified as a Tier 3 recall, such as a mistake in labeling or other minor issue that does not have clinical impact. In this case, HCPF will work with Adira U.S. to have the affected batch relabeled. If retesting is deemed necessary, Adira U.S. will randomly select new samples for testing at Q Laboratories to evaluate for authenticity and degradation. Once such testing is completed, if it is determined the product can be resold to a Colorado pharmacy, its T3 data will be updated with the additional information required and it will be returned to the saleable Colorado product section of the Adira U.S. warehouse. If it is determined that the imported drug is not eligible for resale, it will be placed in the designated quarantine area, proceed as ineligible for resale in the inventory/WMS system, and be sent for dispositioning by a reverse distributor in the U.S.

HCPF will regularly review Adira U.S.' recall and return reports to assess whether imported prescription drugs are missing from the list of received return shipments. HCPF will work with Adira U.S. to resolve any discrepancies. If a discrepancy can't be resolved, HCPF and Adira U.S. will communicate to all affected parties and contact law enforcement if theft is suspected. Additional details about Adira U.S.' return process can be found in Appendix C, SOP - 914.

Education and Communications Plan (§ 251.3 (e) 12)

HCPF has maintained a website to educate interested stakeholders and connect stakeholders with resources during the early phases of program implementation. Once operational, the nature of this website will change to allow for stakeholders to review the importation drug list, identify participating pharmacies, access other informational resources, and connect with the Program's call center. The website will also direct pharmacies to the Importer's website where orders for imported drugs under the Program can be placed. As new drugs are approved and added to the negotiated FDA-approved list, HCPF will share this information on the website and via email with interested parties. HCPF will also maintain an email inbox for stakeholders to share program input.

HCPF will also support several targeted initiatives to educate stakeholders in the state about the opportunities associated with the Program once the SIP application is approved:

Purchaser Road Show & Outreach
In order to ensure equitable access to imported drugs throughout Colorado, HCPF will host a series of informational sessions across the state to educate pharmacists, hospitals, and other

providers that may have an interest in purchasing drugs through the program. The focus of this outreach will be to: educate about the program framework, share information about specific drugs selected for importation and their pricing, and answer any questions about safety and compliance protocols. Urban, rural and frontier regions will all be targeted for these education sessions. Adira U.S. will also participate to answer questions about the purchasing process.

Adira U.S. will also be responsible for conducting outreach and marketing to Colorado pharmacies to increase program participation and ensure a favorable geographic spread for access. Adira U.S. will develop a Memorandum of Understanding (MOU), specific to the Importation Program, that participating pharmacies will need to review and agree to. This MOU will lay out requirements for participation, such as

- Ensuring a good faith effort is made to dispense imported prescription drugs only to Coloradans.
- Ensuring basic annual reporting to help the program track volume and consumer savings.
- Including program-specific adverse event reporting in their employee training regimens.

Ensuring Access to Imported Prescription Drugs
While HCPF has conducted outreach to health plans and PBMs earlier in our program development, many indicated that until there is a clear approval from FDA they are not able to focus attention on state partnerships to cover imported drugs. Once FDA has provided an approval (or provisional approval) for our SIP application, HCPF will work in earnest with these potential partners to obtain coverage for drugs approved under the SIP. As we await approval, HCPF will offer continued opportunities for health plans, PBMs and their trade associations to meet and learn about our program and its benefits. As mentioned earlier, we do believe that smaller, more nimble PBMs that use carve-out strategies to reduce drug prices are likely our best initial partners, so we will continue to outreach these PBMs.

HCPF will seek to pilot programs with specific stakeholders in the Colorado market such as the Colorado State Employee Health Benefits Program.

Consumer Outreach & Support
Once approved, HCPF will host several consumer-focused sessions, both virtually and in person, to reach as many people in the state as possible. The focus of these sessions will be to educate consumers on the choices available to them, direct them to resources and answer any questions they have about the Importation Program.

Once the Colorado program is actively importing prescription drugs from Canada, HCPF has contracted with Rocky Mountain Poison & Drug Safety to implement a patient education and support call center. Additionally, there will be an opportunity for patients to submit questions and concerns via email and a web portal. The support center will provide information about the program, such as:

- A list of all drugs imported from Canada, along with their NDCs and prices
- A list of participating pharmacies
- Information for consumers, including:

    - Overview of the drug importation program
    - Overview of the measures taken to ensure health and safety
    - Information regarding the recall process including additional information on any active recall
    - Information about state and federal program regulations
- Information for health care professionals, including:
    - Overview of the drug importation program
    - Overview of the measures taken to ensure health and safety
    - Information regarding the recall process including additional information on any active recall
    - Information on how to become a program participant
      Information about state and federal program regulations

Additionally, callers' inquiries will be screened for any possible reportable events (e.g., adverse events, product quality complaints, etc.) and if a reportable event is identified during the call, information will be collected and shared as appropriate with HCPF and FDA.

Conclusion

As FDA reviews the state of Colorado's amended SIP application, HCPF will continue its work to prepare the market to fully implement the program once approved, with a focus on addressing the challenges and barriers outlined throughout this document. HCPF will hold a stakeholder meeting soon after this submission to educate interested parties regarding the changes made to our application. We will continue to seek partnership with drug manufacturers; yet given the challenges faced thus far, we would welcome additional guidance from FDA regarding how best to operationalize Section 804 absent manufacturer engagement. Finally, our work with supply chain partners will continue to move forward so that we may quickly advance the program once FDA approves the SIP application. Colorado looks forward to continued work with all parties in the coming months and stands ready to collaborate with FDA to make this program a reality to the benefit of Colorado consumers and employers, as soon as possible.