



COLORADO

Department of Health Care
Policy & Financing

Section 804 Importation Program

*Colorado's Drug Importation Program -
Draft Application*

March 9, 2020

Table of Contents

Executive Summary	3
Program Justification	7
Federal Regulatory Landscape	7
Colorado Senate Bill 19-005	8
Canadian Price Negotiations and Safety Oversight	9
Our Process	10
Overall Program Framework	12
Oversight	15
Quality and Safety	16
Significant Cost Savings	29
Barriers, Risks and Opportunities	37
Conclusion	40

Appendices

- Appendix A - State of Colorado Comments on the FDA's Proposed Rulemaking
- Appendix B - Colorado Senate Bill 19-005
- Appendix C - Background Research on Canadian System prepared by AgoHealth
- Appendix D - State of Colorado Request for Information Questions
- Appendix E - State of Colorado Consumer Survey Findings
- Appendix F - Proposed Rule Pathway 1 Distribution Chain Process Map
- Appendix G - Proposed Rule Pathway 2 Distribution Chain Process Map
- Appendix H - Drug Recalls Process Map
- Appendix I - Adverse Events Reporting Process Map
- Appendix J - State of Colorado's Draft Importation Drug List
- Appendix K - State of Colorado's Biologic Drug Analysis
- Appendix L - Enlarged Figure Library

Executive Summary

Colorado consumers, like all Americans, face significant challenges as a result of continually rising pharmaceutical costs, which total more than \$6 billion per year in Colorado alone.¹ One in five Coloradans struggle to afford their prescription drugs, while nearly one in three Coloradans do not take their prescription drugs as directed because they simply cannot afford to.² Lowering the cost of prescription drugs through importation will directly and meaningfully improve access to prescription drug therapy for Coloradans, thereby improving the health and well-being of our population.

Governor Jared Polis has championed health care affordability, including supporting Canadian drug importation as a way to reduce Coloradans' prescription cost burden, address affordability and improve the health and well-being of Coloradans. The Department of Health Care Policy & Financing (the Department) is proud to present this initial Section 804 Importation Program (SIP) proposal, while the U.S. Department of Health and Human Services (HHS)/U.S. Food and Drug Administration (FDA) develops its Final Rule for Importation of Prescription Drugs. The Department hopes to inform final rulemaking and advance our efforts to establish a Canadian prescription drug importation program as outlined in Colorado Revised Statutes (CCR) 25.5-2.5-201-207.³

The Federal Food Drug and Cosmetic Act (FDCA) Section 804 (21 United States Code § 384)⁴ requires HHS/FDA to establish a program permitting importation of eligible prescription drugs from Canada by pharmacists and wholesale distributors under certain conditions, provided HHS certifies the program will pose no additional risk to public health and safety and will result in a significant reduction in costs to U.S. consumers.⁵ Colorado's draft SIP proposal is designed to both ensure the safety and quality of all imported prescription drugs and bring significant cost savings to Coloradans.

Through our initial analysis, the Department estimates a savings of \$36 million to \$60 million per year from 168 unique drugs and dosages, using a market replacement assumption of between 15 to 25 percent of those prescriptions analyzed. These savings represent a **61 percent average price reduction** compared to current U.S. prices for the drugs identified for importation. For the purposes of a robust analysis,

¹

<https://www.kff.org/health-costs/state-indicator/total-sales-for-retail-rx-drugs/?currentTimeframe=0&sortModel=%7B%22colld%22:%22Location%22,%22sort%22:%22asc%22%7D>

² <https://cohealthinitiative.org/wp-content/uploads/2019/11/Colorado-Altarum-Data-Brief-Drug-Costs.pdf>

³ https://leg.colorado.gov/sites/default/files/2019a_005_signed.pdf

⁴ <https://www.govinfo.gov/content/pkg/USCODE-2011-title21/html/USCODE-2011-title21-chap9-subchapVIII-sec384.htm>

⁵ [https://uscode.house.gov/view.xhtml?req=\(title:21%20section:384%20edition:prelim\)](https://uscode.house.gov/view.xhtml?req=(title:21%20section:384%20edition:prelim))

the Department included a broad pool of drugs. Going forward, the Department will monitor this drug importation list for future adjustments. Future analysis will rely on an objective scorecard to evaluate drugs for importation. This scorecard will evaluate cost savings, patent law and consideration of potential risks to the Canadian drug supply.

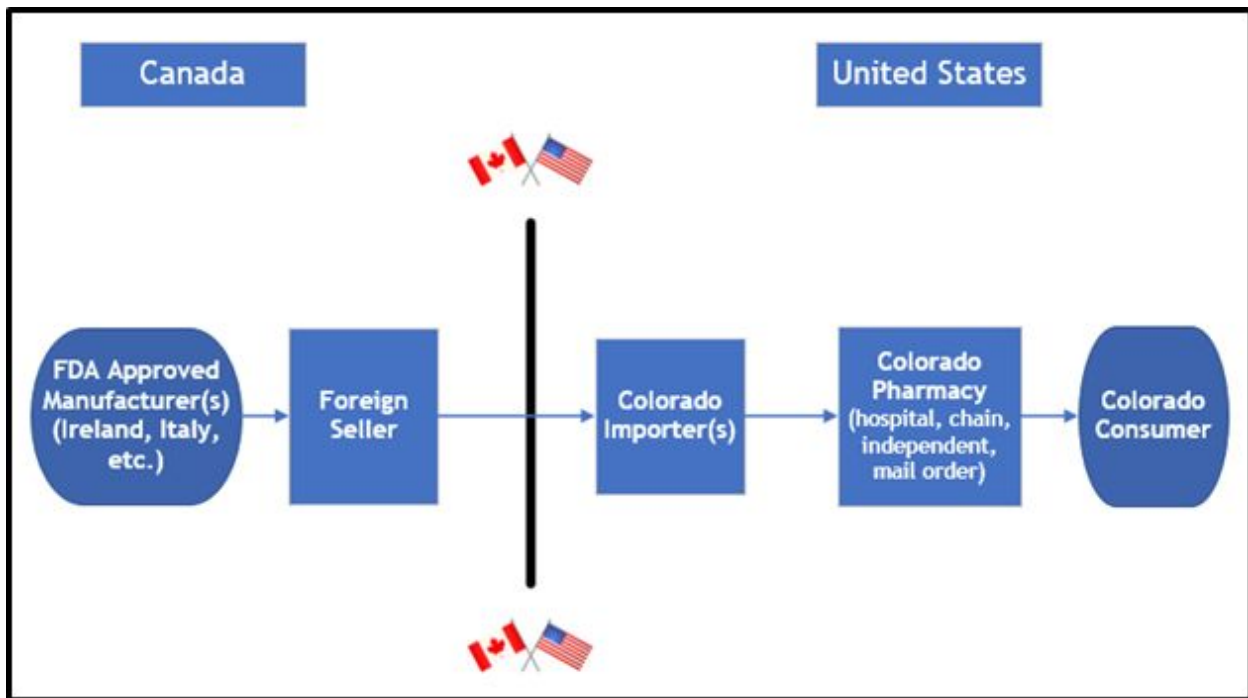
Additionally, our savings analysis conservatively estimates a 45 percent markup to cover the costs across the supply chain to import the drugs. It should be noted that the markup does not significantly or meaningfully affect the cost savings. In fact, our savings without the markup would only increase by 17 percent.

This clearly illustrates that the U.S. prescription drug cost challenge is not driven by the cost of getting drugs to the United States—or the distribution system—but rather, the price at which drugs are sold to the U.S. buyers.

When approved, Colorado’s drug importation program will provide all Colorado consumers with access to certain drugs imported from Canada, with a focus on high cost, high volume as well as specialty drugs where permissible. The state will ensure the safety of and cost savings realized by such drugs through a robust program that provides oversight through a newly created Drug Importation Division (DID). The DID would oversee all aspects of the supply chain to ensure compliance with state and federal safety requirements.

All prescription drugs approved for importation through the Colorado SIP will be the same as the current FDA-approved versions, which are produced world-wide as is the case in the U.S. market today. Once reaching Canada, the drugs will be subject to safety protocols conducted by Canadian oversight entities. Foreign Sellers, which are likely Canadian wholesalers registered and approved by both Canada and the United States, will purchase the drug for the Colorado market. These Foreign Sellers will be held to safety standards in federal rule to ensure each drug can be tracked and traced back to the original manufacturer. The Foreign Seller will contract with a U.S. Importer with a Colorado license (likely a wholesaler) for purposes of importing the drug to the state. Before that transaction can occur, the Importer must ensure each drug has been tested in an FDA-approved laboratory. Importers will contract with pharmacy providers that have agreed to stock and dispense drugs imported from Canada under the SIP. A high-level graphic of the program framework is provided in Figure 1.

Figure 1.



Colorado Department of Health Care Policy & Financing, 2020.

This application is in full compliance with Section 804 of the FDCA and addresses many of the provisions outlined in the FDA’s Notice of Proposed Rulemaking (NPRM) on the Importation of Prescription Drugs.⁶ However, certain provisions of the NPRM cannot be addressed in the draft SIP proposal, including the names and contact information of partners including Foreign Seller, Importer, Repackager/Relabeler and relevant background information as well as specific drug information including Canadian DIN (Drug Identification Number),⁷ name and address of NDA (New Drug Application)⁸ owner, name and address of manufacturer, drug labeling details, etc. Both of these items will be addressed in a final SIP proposal.

While we are pleased to see HHS/FDA take a significant step forward in advancing drug importation by releasing the NPRM, we are concerned that the proposed rule unnecessarily narrows the scope of Section 804, which will negatively impact Colorado’s ability to achieve and demonstrate significant cost savings to consumers. Colorado encourages HHS/FDA to prioritize four key areas in its final rulemaking to support state efforts in developing prescription drug importation programs:

⁶ 84 Fed. Reg. 70796 (December 23, 2019)

https://www.hhs.gov/sites/default/files/nprm-importation-of-prescription-drugs_12-18-2019.pdf

⁷ <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fact-sheets/drug-identification-number.html>

⁸ <https://www.fda.gov/drugs/types-applications/new-drug-application-nda>

1. Do not limit SIP Sponsorship to the state agency or “entity that regulates wholesale drug distribution and/or the practice of pharmacy”;
2. Allow for conditional approval of SIPs that do not specify Importers, Foreign Sellers, repackagers/relabelers and labs;
3. Allow a SIP to include multiple Foreign Sellers in Canada, both horizontally and vertically; and
4. Allow for relabeling to occur in Canada and prior to importation of the drug to provide financial benefits to the country and engender Canadian support.

These priorities are highlighted in this draft SIP proposal, as well as in our public NPRM comment letter, and are critical to achieving significant cost savings as required by Section 804 of the FDCA. The full comment letter can be found in Appendix A.

With innovation, comes great opportunity. The Department recognizes that the next phase of successful drug importation programs will require additional support from our federal partners. First, the Department urges Congress to support a statutory change to the FDCA that would allow for the importation of biologics. In completing an initial analysis of the top ten biologic drugs in Colorado, we estimated we could save \$21 million to \$35 million applying a 15 to 25 percent market replacement assumption. Said another way, the savings on biologics is about ten times greater compared to the 168 more traditional brand name drugs evaluated. Given the industry’s focus on innovating high cost, specialty drugs, our ability to import biologics will generate critical savings for Coloradan consumers and employers now and going forward.

Second, the Department supports action by Congress to amend the FDCA to expand and implement importation from countries other than Canada, such as the United Kingdom, European Union member countries and Japan. This would increase our access to a broader array of lower priced, high quality prescription drugs. Ultimately, we urge the Administration to engage in a robust diplomatic effort with Canada that creates an upside for Canada, thereby ensuring the achievement of our ultimate importation objective.

We appreciate your consideration of the comments noted throughout this draft SIP proposal.

Program Justification

Governor Polis has made saving people money on health care a top priority of his administration. The development of a Canadian prescription drug importation program is one way states are taking the lead in reducing drug prices for American consumers. Colorado is proud to be one of the states pioneering this innovative solution.

In doing so, our intention is to reduce costs for consumers and thereby remove the biggest barrier to prescription drug access – *which is affordability*. By reducing the price of prescription drugs and therefore increasing access to prescription therapy, we can improve the health and well-being of Coloradans, which is a critical objective of our importation quest. A swift process to rule finalization and Colorado’s submission of our final SIP is paramount in achieving these shared goals—*reducing the prescription drug cost burden to Coloradan families while improving their health and well-being*.

Federal Regulatory Landscape

The possibility of importation of drugs from Canada has received significant attention at the federal level in recent years. The idea has gained enough traction recently to propel multiple states to pass legislation to operationalize importation programs.

The Federal Food Drug and Cosmetic Act (FDCA) Section 804 (21 U.S.C. § 384) (“Section 804”) requires HHS/FDA to establish a program permitting importation of eligible prescription drugs from Canada by pharmacists and wholesale distributors under certain conditions, provided HHS certifies that the program will pose no additional risk to public health and safety and will result in a significant reduction in costs to U.S. consumers.⁹ Section 804 outlines various requirements for importation to ensure drugs imported from Canada to the United States under Section 804 adhere to all FDA regulations and maintain the highest standard of safety and quality. However, Section 804 has never been implemented, despite the legality of importing prescription drugs into the United States and its current importance to the U.S. drug supply.

In July 2019, the Trump administration, in a significant change in federal policy on the issue of drug importation, released the Safe Importation Action Plan.¹⁰ The plan laid out two potential pathways for importation of drugs that cost less in other countries: Pathway One is for states, wholesale distributors and pharmacists. It would allow for importation of certain prescription drugs from Canada. Pathway Two is for

⁹ [https://uscode.house.gov/view.xhtml?req=\(title:21%20section:384%20edition:prelim\)](https://uscode.house.gov/view.xhtml?req=(title:21%20section:384%20edition:prelim))

¹⁰ <https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf>

manufacturers and is not as limited. Pathway One, which Colorado intends to seek approval to use, was advanced in late 2019 with the release of a Notice of Proposed Rulemaking (NPRM)¹¹ that outlines proposed processes and standards for SIPs, marking a significant step forward in advancing Section 804.

In 2013, Congress passed the Drug Supply Chain and Security Act (DSCSA), which amended the FDCA to give the FDA increased oversight of and increased authority to regulate drug supply chains. The DSCSA outlines steps to build an electronic, interoperable system by the year 2023 to identify and trace certain prescription drugs intended for sale in the United States. The Department is particularly aware of the requirements set forth in the DSCSA and is designing a program that is fully compliant.¹²

Colorado Senate Bill 19-005

In 2019, the Colorado General Assembly passed Senate Bill 19-005,¹³ which requires the state to develop a Canadian prescription drug importation program, if approved by the federal government. SB19-005 can be found in Appendix B. SB19-005 permits the Department to identify and contract with one or more vendors to act as the administering entity. For this draft SIP proposal, we assume the state will directly handle all oversight responsibilities. Should a vendor be selected, per SB 19-005, the entity would: 1) support development of an importation drug list; 2) identify and facilitate contracts with participating suppliers and importers that meet program safety requirements; and 3) conduct safety assurance measures and other oversight processes.

SB 19-005 required the following to ensure compliance with Section 804:

- 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
- Maintenance of qualified laboratory records, including all testing data and documentation that the testing was conducted by a qualified laboratory.

SB 19-005 outlines detailed requirements for importers and Canadian suppliers participating in the program. The Act also provides the state with oversight authority and 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

¹¹ 84 Fed. Reg. 70796 (December 23, 2019) (available at <https://www.federalregister.gov/documents/2019/12/23/2019-27474/importation-of-prescription-drugs>)

¹² Includes compliance with any necessary exemptions duly authorized by FDA under the DSCSA.

¹³ https://leg.colorado.gov/sites/default/files/2019a_005_signed.pdf

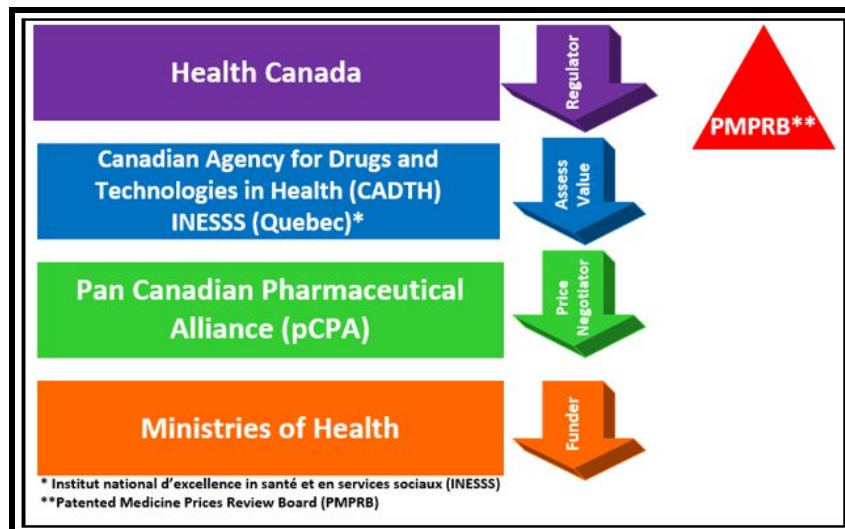
importation drug list and suspension of importation of any drug that is in violation of the state act or federal rules (Comment 1).

Comment 1: SB 19-005 places the authority and responsibility of developing and implementing a SIP on the Colorado Department of Health Care Policy & Financing. Accordingly, if the final rule keeps the proposed requirement that a state agency can only be a SIP Sponsor if it “regulates wholesale drug distribution and/or the practice of pharmacy” (see proposed § 251.2), Colorado will be unable to implement a SIP as required under SB 19-005. Furthermore, it is questionable whether the state agency that regulates wholesale drug distribution and the practice of pharmacy in Colorado (the Colorado Board of Pharmacy (BoP)) would be the appropriate entity to develop and implement a SIP. The Colorado BoP is a seven-member body that meets on a limited basis. As we note below, the Department would work with the appropriate state agencies to develop and administer the SIP.

Canadian Price Negotiations and Safety Oversight

Colorado’s prescription drug importation program seeks to leverage Canadian drug price negotiations to achieve significant savings for Colorado consumers. Canada has an extensive drug safety and effectiveness review process that is comparable to that of the United States.¹⁴ Drug price negotiation and safety oversight in Canada is conducted across numerous entities, including national and provincial governments:

Figure 2.



Myeloma Canada. [Understanding New Drug Development, Approval and Reimbursement Processed in Canada.](#) March, 29, 2017.

¹⁴ We also note there are some prescription drugs that are approved by the FDA but not by Health Canada, and vice versa, on the basis of safety and effectiveness concerns. Accordingly, importation under a SIP of only those prescription drugs that have been approved by both the FDA and Health Canada offers an additional assurance of the safety and effectiveness of drugs imported under a SIP.

The Canadian Patented Medicine Prices Review Board (PMPRB),¹⁵ which is an independent quasi-judicial tribunal, ensures that the prices of patented (brand name) medicines sold in Canada are not excessive. PMPRB primarily does this by setting limits on the prices that can be set by patentees for specific brand name medicines sold in Canada.

Canada is the only country with universal health care that does not have a national prescription drug coverage program. Therefore, most provinces have established supplemental drug coverage programs with local government-negotiated drug prices, for both brand name and generic drugs. These local negotiations are supported by analysis conducted by the PMPRB.¹⁶ The pan-Canadian Pharmaceutical Alliance (pCPA) represents local and some national governmental entities in joint negotiations with manufacturers for select drugs.¹⁷ Colorado's importation program will benefit from these price negotiations to help drive down costs for consumers in our state.

All drugs that would enter Colorado through the importation program would be manufactured in accordance with the key requirements of the corresponding FDA-approved New Drug Application (NDAs) for brand name drugs or Abbreviated NDA (ANDA) for generic drugs, including meeting safety and effectiveness requirements and being manufactured at the FDA-approved facilities. The versions of FDA-approved drugs would have already met U.S. safety and efficacy requirements and would also have been approved by Health Canada's Health Products and Food Branch (HPFB) Therapeutic Products Directorate (TPD), which is Canada's chief regulator of the safety, efficacy and quality of prescription drugs. In accordance with Health Canada requirements, the products would also be subject to post-market surveillance.¹⁸ Additional details regarding the Canadian drug oversight and distribution system can be found in Appendix C.

Our Process

Colorado values collaboration. The Department participated in a comprehensive stakeholder engagement process to ensure that Colorado's drug importation proposal is not only responsive to the interests of our stakeholders, but is also created in partnership with them. This process included our issuance of two Requests for Information (RFI) to pharmacies and wholesale distributors, as well as the release of a stakeholder survey. The Department also held three well-attended public stakeholder meetings to solicit further input. The Department also hosts a website where stakeholders can find resources on importation and submit questions and feedback to a monitored email inbox.¹⁹

¹⁵ <http://pmprb-cepmb.gc.ca/home>

¹⁶ Ibid.

¹⁷ <https://www.canadaspremiers.ca/pan-canadian-pharmaceutical-alliance/>

¹⁸ <https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/therapeutic-products-directorate.html>

¹⁹ <https://www.colorado.gov/hcpf/drug-importation>

The Department, through its RFIs, solicited feedback on the proposed framework for a prescription drug importation program, and included questions regarding the impact to pharmacies and wholesale distributors (see Appendix D for the questions included in the RFIs). The RFIs included key questions about what would encourage or discourage participation and asked for stakeholder perspectives on meeting federal safety requirements. The state received seven responses, which included a variety of perspectives. Specifically, wholesale distributor feedback encouraged the state to establish a program that minimizes burden and costs for participation. Pharmacies were generally open to the idea of an importation program as long as it would not favor any single pharmacy or create dual systems that could negatively impact their operations.

The Department released a consumer survey to over 500 stakeholders that was active from Nov. 5 through Nov. 30, 2019. Respondents were asked for their views on Canadian drug importation generally, and specifically with regards to costs, safety and access. The findings include:

- Sixty-eight percent of respondents indicated that they believe imported drugs would be as safe or safer than the current U.S. drug supply
- Fifty-five percent of respondents indicated they would be willing to use a mail order pharmacy for Canadian drugs if it meant lower costs
- Sixty-five percent of respondents indicated that they believe current drug pricing is a problem and that the current system needs improvement

Some survey respondents indicated the importance of addressing drug safety, which is addressed in detail in the application. The complete survey findings are found in Appendix E.

The Department hosted three stakeholder meetings, each targeted to a specific stakeholder subgroup, including: pharmacies, manufacturers and consumers/providers. A total of 82 individuals participated in these sessions either in-person or by webinar. The Department also met with health insurance carriers twice and solicited their feedback on key issues, including development of the initial importation drug list used in our analysis of cost savings. Stakeholders provided extensive feedback in these discussions and were also encouraged to submit additional feedback in writing.

It is also important to the state that we have an open dialogue—coordinated with our federal partners—with the Canadian government and other potential Canadian partners regarding our proposed program. The goal of this dialogue is to ensure the ultimate success of our importation program by proactively addressing their voiced concerns. To this end, the Department’s Executive Director Kim Bimestefer met November 18, 2019, at his request, with a representative from the Consulate General of Canada after approving that meeting agenda with HHS. The purpose of this initial meeting was to respond to their request for an ongoing dialogue. During this meeting,

the Department shared an initial draft list of prescription drugs under consideration for potential importation. We illustrated our identification of those drugs in short supply in Canada, underscored our intention to not drive shortages in Canada, and discussed with the Consulate our intent to exclude from our importation list any drugs at risk of shortage in Canada. The Department agreed to the Consulate's request for continued discussions with Canadian officials, as well as to share this document, which is a matter of public record, after its submission.

The Department is appreciative of the robust stakeholder engagement and for its generous and helpful feedback during this initial process. We have scheduled a stakeholder meeting for March 19 to discuss our draft SIP proposal and NPRM comments and anticipate ongoing discussions as we refine the program framework based on the final rule.

Overall Program Framework

The Department, as a governmental entity of the state of Colorado, will be the SIP Sponsor and will provide for the importation of FDA-approved drugs from Canada to deliver lower cost prescription drugs to Colorado consumers. The program framework would establish a robust oversight process to ensure compliance with the FDCA, including Section 804 and the provisions added by the DSCSA. The Department will house a Drug Importation Division (DID or Division), which will act in an oversight capacity to guide the development of the Canadian importation drug list and oversee the activities of all participants in the supply chain to ensure compliance with safety requirements. For purposes of this draft SIP proposal, the DID will be directly responsible for all day-to-day oversight activities; however, the DID intends to leave the option open for a contracted vendor to handle such activities in the future.

Colorado's SIP would leverage the current U.S. drug distribution system. Prescription drugs approved for the program will be the same as the current FDA-approved versions. Like the current U.S. drug supply chain, the state will rely on the current global drug distribution system. For example, the FDA estimates that, as of 2018, 88 percent of facilities making active pharmaceutical ingredients (APIs) and 63 percent of facilities making finished drugs sold in the United States are located overseas.²⁰

Once an FDA-approved version of the drug has entered Canada, it would be eligible for inclusion in the Colorado program if it is included on Colorado's importation drug list, which will be regularly evaluated and updated. Our draft SIP proposal leverages multiple Foreign Sellers to ensure the lowest costs for consumers, while ensuring the safety of the supply chain (**Comment 2**).

²⁰ (Congressional Research Service, In Focus: Prescription Drug Importation (Updated November 21, 2019) available at <https://crsreports.congress.gov/product/pdf/IF/IF11056>)

Comment 2: While the NPRM suggests that a SIP may only initially designate a single Foreign Seller and single Importer, we recommend that SIP Sponsors be permitted to specify multiple established Foreign Sellers both vertically and horizontally to ensure there is adequate supply to ensure consumer savings. These Foreign Sellers will be registered with the FDA to ensure the safety of the supply chain. This will also allow for the wide variety of supply chains that currently exist for drugs. Additionally, permitting only one Foreign Seller would allow drug manufacturers to discriminate against that one Seller, preventing the SIP from demonstrating to the FDA that they can consistently and successfully import prescription drugs.

The Department will work with eligible and participating Canadian Foreign Sellers to ensure all safety requirements are met and the DID will be responsible for ensuring that a Section 804 serial identifier (SSI) is assigned and affixed by the Foreign Seller. FDA-registered and FDCA-compliant repackagers and relabelers (hereinafter referred to collectively as “repackagers”) will label drugs for Colorado importation in compliance with FDCA requirements.²¹ Repackagers are regularly used without incidence in manufacturing and distribution chains in both the United States and Canada (**Comment 3**).

Comment 3: While the NPRM requires the relabeling to occur in the U.S., we are encouraging HHS to finalize the rule to allow for relabeling in Canada immediately prior to drug exportation to minimize program costs and create an additional market incentive for Canadian partners.

The Importer will contract with a qualified laboratory in the United States to conduct the required testing to ensure the drug is authentic and has not degraded. These test results would then be submitted to the FDA for review and approval. Once testing and relabeling is complete, a Colorado Importer may arrange for the drug’s entry into the Colorado supply chain. While the U.S. Importer will likely be a wholesale distributor, for purposes of this draft SIP, we are keeping all options available including an Importer that is a wholesale distributor, a pharmacy or an all-in-one wholesale distributor/mail order pharmacy.

Eligible Importers will contract with pharmacy providers that have agreed to stock and dispense drugs imported from Canada under the SIP. Our proposed importation program will provide consumers, carriers, pharmacy benefit managers (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. The Department is currently evaluating how best to collaborate with relevant state agencies to ensure proper oversight and compliance with state pharmacy rules.

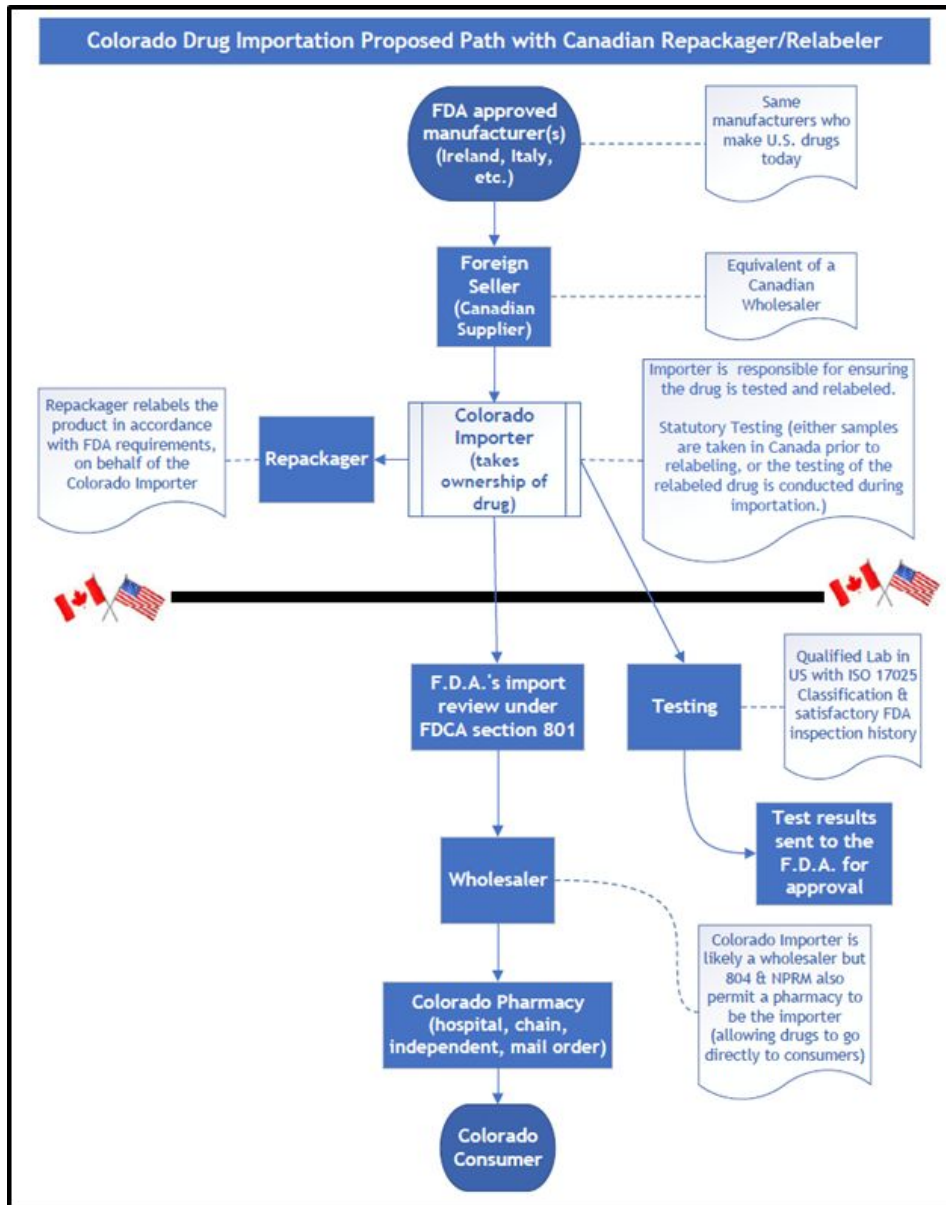
²¹ For the purposes of this draft SIP when we refer to a repackager, unless otherwise noted, we refer to only the act of relabeling except for any limited repackaging necessary to relabel the drug in accordance with FDA requirements.

The DID would also work with the Importer and others in the distribution chain to conduct an educational outreach program to ensure pharmacists, health care providers and patients are educated about SIP importation and pricing. Upon SIP approval, the Department's drug importation website would be expanded to include more detailed information about the program, including information specifically for health care professionals and consumers. Consumers would be able to find the names and National Drug Code (NDC) numbers of all drugs imported from Canada. The website would also publish a list of participating pharmacies. The section of the website for participating pharmacies would include similar details with drug names and NDC numbers, and also information on adverse drug event reporting and drug recalls.

Figure 3 provides a proposed process map illustrating the life cycle of a prescription drug imported to Colorado from Canada with the option for a Canadian repackager to conduct relabeling. While the NPRM outlines two pathways for the drugs to come into the United States from Canada – through a Foreign Trade Zone (FTZ) with later consumption and filing, or filing early and bringing the drugs into compliance under FDCA 801(b) at a designated secure warehouse – Colorado's draft SIP proposes the inclusion of a Canadian repackager as an option for SIPs.²² We urge HHS to amend the Final Rule to allow for the option to have drugs relabeled in Canada. For Colorado's program, we propose Figure 3, a process map that includes a Canadian repackager.

²² See Appendices F and G of this report which demonstrate NPRM pathways one and two with the repackager in the United States.

Figure 3.



Oversight

Colorado’s draft SIP proposal establishes a robust oversight framework to ensure the program is in full compliance with all federal rules and regulations. The Department will house a Drug Importation Division (DID or Division) that would act in an oversight capacity, guide the development of the imported drug list, and oversee the activities of all participants in the supply chain.

The DID would oversee the development of an initial wholesale drug importation list, and make ongoing revisions to it as appropriate, establish reasonable profit margins to ensure active industry engagement and determine program costs.

The Department is currently evaluating how best to collaborate with relevant state agencies to ensure proper oversight and compliance with state pharmacy rules. The Department, through the DID, would also have responsibility for suspending the importation and distribution of any drug that is in violation of state or federal law, and communicate the suspension to those in the distribution system (**Comment 4**). The DID would partner with the appropriate state agencies to oversee the development of protocols to ensure drugs imported from Canada are not sold outside of Colorado's borders.

Comment 4: The NPRM suggests a cease of all importation activities should any element of the supply chain not meet all requirements in statute and regulation. This overly broad requirement is vague and likely unenforceable. We recommend the policy be targeted only to those drugs affected directly by a specific supply chain failure.

The DID would establish standards for participation by Canadian Foreign Sellers and Importers in Colorado and identify eligible Canadian Foreign Sellers that may have an interest in participating in the program. The DID would then evaluate their compliance with Canadian federal and provincial laws and their ability to provide cost savings. Before execution of a contract between a Canadian Foreign Seller and an Importer, the DID would be required to verify the Foreign Seller has submitted an attestation that they have registered with the FDA and have a registered agent in the United States. Similar to how it evaluates Foreign Sellers, the DID would verify that any interested Importer is eligible for the program based on state and federal requirements. The DID would also be responsible for providing support to pharmacies and consumers as questions arise, including addressing supply questions and developing effective adverse event communication strategies.

The DID would also use a draft objective scorecard, as described in the Cost Savings section of this report, to identify drugs for importation that have the highest potential for cost savings to the state and consumers. The list would be reevaluated and updated every three months, as required by state law.

Quality and Safety

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 NPRM provide a robust framework for the implementation of Colorado's SIP

from a health and safety perspective. The FDA's proven oversight and high standards for the drug supply chain help guarantee the safety and quality of the drugs that currently enter into the United States from foreign sources.

The Colorado draft SIP proposal ensures that the versions of FDA-approved drugs made by FDA-approved manufacturers distributed to Canada are as safe and effective as the versions that were originally intended for the U.S. market. The supply and distribution chains under Colorado's SIP for receiving drugs from Canada would look much like the existing U.S. drug supply chain. The major difference is that, because the drugs would originally have been intended for the Canadian market, the prescription drugs would have been originally labeled for the Canadian market. Accordingly, under a SIP, the drug would have to be relabeled in accordance with the requirements of the FDCA and the FDA-approved NDA or ANDA before the drug could be sold in the United States. Our draft SIP proposal relies on the measures already in place and also outlines additional safety protocols and standards specific to the Colorado program. As a SIP Sponsor, we would leverage existing state and international regulatory frameworks and agreements to ensure the drug supply is safe.

Supporting Framework: Agreement of Cooperation with Canada and Good Manufacturing Practices

The Colorado importation program will leverage existing international agreements and standards of best practice in the drug manufacturing industry to ensure the program meets federal safety requirements. Colorado's program will be supported by an existing international agreement between the FDA and the Canadian Department of National Health and Welfare. This agreement has been in place since 1973 and supports mutual cooperation through the exchange of drug establishment inspection information (including repackagers and relabelers).²³ The Canadian government has similar agreements with counterpart regulatory agencies around the world to advance the regulation and oversight of health products and promote access to new drugs.²⁴

The program would also rely on the FDA's inspection of manufacturers and repackagers of FDA-approved drugs – which would include all drugs imported under the SIP and their manufacturers and repackagers – to ensure they comply with all applicable DCSA provisions and regulations, including current good manufacturing practices (cGMPs).²⁵ The cGMP regulations provide requirements for the methods, facilities and controls used in the manufacturing, processing, packaging, labeling, testing and quality control of drugs.²⁶ These regulations make sure the drugs are not

²³

<https://www.fda.gov/international-programs/cooperative-arrangements/fda-canadian-department-national-health-and-welfare-agreement-cooperation>

²⁴ <https://www.canada.ca/en/health-canada/services/drugs-health-products/international-activities/international-collaborative-arrangements.html>

²⁵ <https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations>

²⁶ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211>

adulterated or misbranded, and that the drugs and their components all meet the applicable standards for identity, strength, quality and purity. As drug manufacturers are located all over the world, the FDA inspects more foreign drug facilities than it does domestic drug facilities. The FDA completed approximately 1,000 foreign drug facility inspections in 2019.²⁷ Furthermore, the FDA's inspections focus on manufacturers in higher risk countries rather than on countries that have highly effective drug regulatory systems (such as Canada and the countries of the European Union).

Compliance with the Drug Supply Chain Security Act

Colorado's SIP would ensure all participants and imported drugs comply with the Drug Supply Chain Security Act (DSCSA).

The DSCSA amended the FDCA to give the FDA increased oversight and authority over the drug supply chain, from the manufacturer of the drug to the pharmacy that dispenses the drug to the consumer. The DSCSA establishes various requirements for all parties in the prescription drug distribution chain, such as requirements to hold certain registrations, licenses or permits from federal and/or state authorities and to maintain certain records that can be used to verify the supply chain for each drug distributed, or intended for distribution, in the U.S. This extensive record of transactions allows a drug or set of drugs to be traced back to the original manufacturer quickly and efficiently.

The intent of the DSCSA was never to add a series of inspections along the supply chain; instead, if inspections or investigations were needed, they could be completed quickly and efficiently due to the sophisticated transaction record associated with the supply chain of any DSCSA-compliant drug. The NPRM lays the groundwork for an equivalent sophisticated transaction record for drugs imported under Section 804 and for participating Canadian suppliers (Foreign Sellers), foreign manufacturers and repackagers. In addition, the NPRM adds additional layers of safety that will be discussed in greater detail below.

In some circumstances (as the FDA notes in the NPRM), the FDA would allow for certain necessary exemptions from DSCSA rules for drugs imported under a SIP, as permitted by the DSCSA (**Comment 5**).²⁸ Some DSCSA provisions could not apply to drugs imported under a SIP because they only apply to drugs originally intended for the U.S. market. However, the Colorado SIP

Comment 5: The Department supports the use of exemptions under the DSCSA given there are other mechanisms in place across the distribution chain to ensure a drug and all of its components can be traced back to the original manufacturer.

²⁷ <https://www.fda.gov/news-events/congressional-testimony/securing-us-drug-supply-chain-oversight-fdas-foreign-inspection-program-12102019>

²⁸ 582(a)(3)(iii) <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act>

would provide the same level of oversight and traceability as required in the DSCSA through alternative methods (as outlined under the section below discussing Foreign Seller and Importer requirements). The supply chain information of drugs imported under the SIP will be readily available, comprehensive and can be verified. Accordingly, the intent and practical effect of the DSCSA requirements are fulfilled, ensuring the authenticity and transparency of the medication imported under the SIP.

The FDA would exempt SIPs from the DSCSA requirement that the SIP Importer only accept prescription drugs if the manufacturer affixed a unique product identifier (PI) to it and provides the Importer with certain specific information about the drug. However, the drug manufacturer would not comply with these requirements because it intends the drugs to be sold in the Canadian rather than U.S. market. Below, in our discussion of Foreign Supplier obligations, we discuss how these two requirements would be addressed under our SIP.

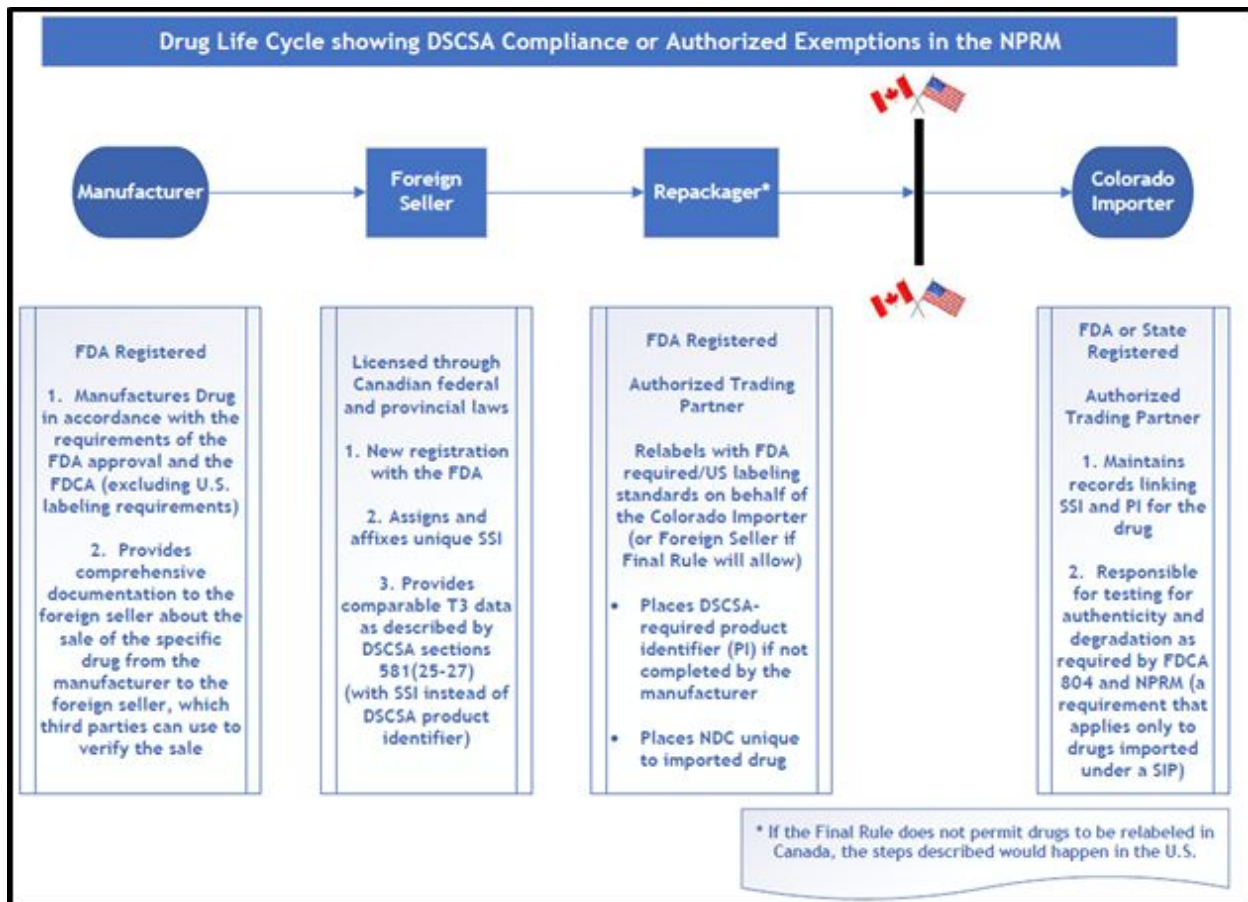
The FDA would also exempt SIP Importers from the DSCSA requirement to only purchase drugs in the drug distribution chain to what the DSCSA calls “authorized trading partners” (ATPs). A Foreign (Canadian) Seller would typically not qualify as an ATP because they are not located in the United States and would, therefore, likely not have a wholesaler license issued by a U.S. state.²⁹ The NPRM addresses this issue by proposing to allow Canadian Foreign Sellers to participate in a SIP if they meet certain requirements similar to the requirements for ATPs. For example, Canadian Foreign suppliers, like ATPs, would have to be registered with the FDA, be appropriately licensed (Foreign Suppliers would have to be located in Canada and licensed under Canadian federal and provincial laws), and report certain information to the FDA on an annual basis.

Figure 4 shows a summary of the DSCSA requirements and how they will be applied under the Colorado program. Of note, this graph shows our Canadian repackager option for consistency with this draft SIP proposal. If the final rule does not allow for a Canadian repackager, these requirements can be completed by a repackager in the United States.

²⁹ 581 (2),(3)

<https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act>

Figure 4.



Colorado Department of Health Care Policy & Financing, 2020.

Foreign Seller, Importer and Repackager Oversight and Requirements

Colorado, as SIP Sponsor, would have primary responsibility for ensuring all entities in the drug importation supply chain comply with applicable FDCA provisions and regulations, including Section 804, the final drug importation rule, and the DSCSA. As required under SB19-005, the Department would be required to oversee compliance with DSCSA track and trace requirements, as well as to ensure all statutory testing and laboratory records are properly maintained. The Department would also be responsible for helping ensure that each drug is approved by the FDA, is not adulterated or misbranded and is appropriately labeled. These functions would be overseen by the Department's DID.

Although this draft SIP proposal does not include a compliance plan as would be required by the NPRM, our final proposal will include a compliance plan for the FDA's review and authorization. Our compliance plan will include a written compliance

strategy that outlines training and qualification standards for supply chain participants, overall compliance communication plans and guidelines to address noncompliance or misconduct.

Foreign Sellers

The DID would evaluate interested Canadian Foreign Sellers to assess eligibility for the program, including assessing their compliance with Canadian federal and provincial laws and regulations. Foreign Sellers would be required to hold an active drug establishment license as a wholesale distributor from Health Canada, and a registration with a provincial pharmacy regulatory authority qualifying it to distribute HPFB-approved drugs. Foreign Sellers would also be required to register with the FDA as required by Section 804.

At this point, all entities involved in the supply chain of the drug would be FDA registered and DSCSA compliant, either strictly or by an FDA-authorized exemption as defined in the NPRM. Key activities of the Foreign Seller would include:

1. ensuring that a Section 804 serial identifier (SSI) is affixed or imprinted to each package or homogeneous case of the drugs and that it maintains records of its affixation or imprinting;
2. maintaining records regarding its process for developing and implementing SSIs;
3. separating drugs intended for the U.S. in its supply chain from drugs intended for Canada;
4. conducting due diligence to ensure the drugs are authentic and promptly responding to any associated information requests; and
5. providing the Importer with comprehensive information about the drug and its supply chain history.

Drugs imported through FDCA Section 804 are intended for Canada and will likely not have a product identifier (PI) attached to the drug because this is not a requirement of Canadian labeling. When a PI is not present, the NPRM would require the Foreign Seller to affix to the drugs an identifier called a Section 804 serial identifier (SSI), which is defined as “an alphanumeric serial number unique to each package or homogeneous case that is affixed or imprinted to each package or homogeneous case of the drugs.

Under the Colorado SIP, the drug manufacturer would sell the drug directly to the Canadian Foreign Seller. This direct transaction would be comprehensively documented, and the Canadian Foreign Seller would affix or imprint an SSI to the drug that would be linked with the PI subsequently affixed by the Importer. The SSI will be crosslinked to the transaction records (described in the following sections) to ensure the data being captured is equivalent to that of the PI under DSCSA. Accordingly, the supply chain of the drug is no less safe and transparent under a SIP than if the manufacturer had affixed a PI to the drugs.

As outlined in the NPRM, the Foreign Seller must also provide to the importer the below documentation regarding the drug, which is generally equivalent³⁰ to the required transaction information and transaction statement documents required by the DSCSA.³¹ In some instances, the documentation goes above and beyond DSCSA requirements. In a SIP with multiple vertical Foreign Sellers, each Foreign Seller would have to provide the below information to the subsequent foreign seller, and that documentation would become part of the transaction history that the Foreign Supplier provides to the Importer:

- Proprietary name of the product
- Strength and dosage form
- Container size
- Number of containers
- Lot number
- Quantity of each lot that the Foreign Seller originally received from the manufacturer (*this requirement is specific to drugs imported under a SIP, in addition to documentation required by DSCSA*)
- Date of transaction and shipment (if more than 24 hours after the transaction)
- Business name and address of the person associated with the Foreign Seller from whom ownership is being transferred
- Business name and address of person associated with the Importer to whom ownership is transferred
- SSI for each package or homogeneous case
- Canadian DIN
- Documentation specifying the original source of the drug (i.e., the original manufacturer) (*this requirement is specific to drugs imported under a SIP, in addition to documentation required by the DSCSA*)
- Verification that the drug is not a suspect or illegitimate foreign product
- Various applicable certifications required by the DSCSA, such as that the Foreign Seller received the product from an authorized trading partner and that, to the best of its knowledge, the Foreign Seller did not alter the transaction history.

Of note, the transaction history would not necessarily include the above transaction information and transaction statement documentation for the single transaction between the Foreign Seller and the manufacturer. However, information about the transaction would be fully documented under Canadian law, the transaction information and transaction statement for that transaction can be verified with the manufacturer by the Importer prior to statutory testing and relabeling. Accordingly,

³⁰ Under the default DSCSA requirements, the Foreign Supplier would have to include the below information that the manufacturer provided to the Foreign Supplier, in addition to including the below information for the transaction between the Foreign Seller and the Importer. However, under a SIP the manufacturer may not have supplied all that information to the Foreign Seller because the transaction would have been subject to Canadian documentation requirements rather than U.S. documentation requirements. The information might also not include the labeler and package size portions of the NDC number, as the Importer would be responsible for the relabeling.

³¹ 581 (25) (26) (27) <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act>

the DSCSA transaction history requirement for the single transaction between the Foreign Seller and the manufacturer would essentially be met under the SIP.

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, in certain respects above and beyond that of drugs being imported today. As discussed above, under these requirements and multiple layers of safeguards (e.g., documentation, verification requests and testing), multiple foreign sellers in Canada can be utilized in order to ensure an adequate drug supply and keep costs low, without imposing any additional risk to public health and safety. The requirements described above can be easily duplicated with additional Canadian Foreign Suppliers and Canadian repackagers/relabelers under contract with the Importer without compromising the safety and integrity of the program.

Importers

Eligible U.S. Importers must be registered and licensed as either a pharmacist or wholesale distributor in good standing. Importers would be permitted to import covered drugs from a Foreign Seller if the drug meets federal standards for safety, effectiveness, marketing, misbranding and adulteration, and complies with all DSCSA rules not exempted by the FDA. Documentation regarding compliance with these rules must be submitted to the DID and to the FDA as required under the FDCA. The Importer will be responsible for ensuring the drug is properly relabeled by an FDA-registered and FDCA-compliant relabeler, and that a fully DSCSA-compliant product identifier, which includes the National Drug Code (NDC) number and a unique alphanumeric serial number is affixed or imprinted on each package or homogeneous case and linked to the SSI assigned by the Foreign Seller. The Importer is also responsible for screening imported shipments to verify that labeling is consistent with that of an HPFB-approved drug and has a valid SSI. This would include a visual screening comparing a sample of the received drug to a sample of the HPFB-approved drug, as recommended by the NPRM.

The Department would use the following criteria to guide selection of Importer partners:

- Their current record keeping practices are stable and robust;
- Records demonstrate drugs they currently distribute are DSCSA-compliant and can be traced to the original manufacturer;
- All their policies and procedures are well documented, robust, current and being followed;
- They have detailed screening process for evaluation of drugs they receive, to ensure the drugs are not adulterated, counterfeit, damaged, tampered with or expired; and,
- Their drug storage policies, including climate and temperature control policies, are clear, sufficient and followed.

Before importing a drug under the SIP, Importers selected for the program would also be required to collect and submit to the DID and the FDA important information about each drug, as required under the Final Rule (see proposed section § 251.5, “Pre-Import Request”). For example, such information would include comprehensive information about the supply chain and supply chain participants (e.g., the manufacturer, foreign seller, importer, repackager and statutory testing laboratory) and about the drug (e.g., the applicable Approved NDA or ANDA number, NDC number, API, amount of API, strength, dosage form, route of administration, batch number and expiration date), about the manufacturer and about the supply chain.

Repackagers/Relabelers

As mentioned previously, we recommend the Final Rule allow for drugs imported under the SIP to be relabeled by repackagers/relabelers in Canada for the U.S. market. The NPRM lays out two options for U.S. relabeling: (1) admission to a Foreign Trade Zone where the drug can be relabeled before formal entry into the United States, or (2) the drug can be imported through an authorized U.S. port and tested and relabeled during the importation process under FDCA Section 801(a) and (b), prior to being admitted into the United States. These NPRM pathways are shown in process maps in Appendix F and G. The Department’s proposed third option would allow Importers (or Foreign Sellers, if permitted by the FDA) to complete the relabeling step in Canada.

The Canadian repackager would be required to adhere to all repackager responsibilities as defined in the FDCA and the FDA Current Good Manufacturing Practices (cGMP) regulations and the applicable provisions added by the DSCSA. Keeping this option available would allow the Importer and SIP to negotiate the best price for relabeling by receiving competitive bids from a variety of eligible and qualified U.S. and Canadian companies. Multiple options allow for market competition and lead to lower prices with the potential to increase quality. Further, allowing repackagers to label the drug in Canada would provide incentives for Canada to support SIPs by creating economic opportunities for Canadian businesses. The Canadian repackager option does not add any steps to the short supply chain but only changes where the drugs are relabeled, which is consistent with the intent of the tight supply chain described in the NPRM.

The Colorado SIP would require Canadian repackagers to be registered with the FDA and to be licensed with federal and provincial authorities in Canada, similar to the requirements for the Foreign Seller, while maintaining the safety and security standards discussed in the NPRM. Per the NPRM, a representative sample of the drug would be sent to a qualified laboratory in the United States to comply with statutory testing requirements. While samples are being tested, the remainder of the supply intended for the United States, per the NPRM, would be stored in a designated secure warehouse.

Labeling Requirements

Regardless of who completes the relabeling step, the same requirements would apply to the relabeling. These requirements include the affixation of product identifiers (PI), adherence to cGMPs and compliance with all FDA labeling requirements for the drug. The SIP would also require detailed recording and reporting of relabeling activities.

A key requirement of the DSCSA is the affixation of a product identifier (PI), defined under Section 581(14)³² of the DSCSA, as a standardized human- and machine-readable graphic that contains a standardized numerical identifier, lot number and expiration date. The intent of the PI is to ensure the ability of interested parties to electronically (and manually, if necessary) trace each drug back to the original manufacturer. Because the drugs in Colorado's importation program would originally have been intended for Canada, however, the manufacturer is unlikely to affix the PI because a PI is not a requirement of Canadian labeling. However, the SIP would account for this by requiring the original manufacturer to sell the drug directly to the Canadian Foreign Seller, and by requiring comprehensive documentation of that transaction. Under the SIP, the SSI would then be affixed to the drug by the Foreign Supplier, subsequent Foreign Suppliers (as permitted) would treat the SSI like a standardized numerical identifier for DSCSA purposes, and the PI would be affixed to the drug by the Importer at the relabeling stage.

The National Drug Code (NDC) number applied to each drug under the SIP would indicate the drug is specific to the state's importation program. Colorado may use a Private Label Distributor (PLD) under the SIP if the Final Rule allows multiple U.S. Importers under a SIP, in order to ensure consistency across NDCs. The PLD registrant would be determined at a later date and specified in Colorado's SIP proposal under the Final Rule.

The repackager, either in the United States or Canada, and under contract with the Importer, would relabel the 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), including ensuring that:

- All wording is displayed prominently and is not false or misleading in any particular
- The PI is affixed
- The NDC has been assigned to the drug and is affixed to the label
- The labeling features all labeling required by the approved NDA or ANDA and 21 CFR 201, including:
 - the proprietary and established name of the drug,
 - product strength,
 - lot number,
 - name of the manufacturer and the Importer,

³² 581(14)<https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act>

- o all warnings, indications, etc., and
- o the statement, “This drug was imported from Canada under the Colorado Section 804 Importation Program to reduce its cost to the American consumer.”

Statutory Testing

Drugs covered under Colorado’s importation program will only include versions of FDA-approved prescription drugs that comply with all applicable U.S. laws. For example, the drugs will contain only the required active pharmaceutical ingredients (API), at the required amounts, manufactured at the facilities that manufacture the APIs for the version of the drug originally intended for the U.S. market. Colorado’s program would ensure these requirements are met by establishing standards for the required testing of the drugs for authenticity and degradation.

As required by federal and state laws and regulations, testing of the drugs for authenticity and degradation will be required, above and beyond any testing currently required of drugs intended for sale in the United States. The Importer will be responsible for arranging for the required testing at a Qualified Laboratory in the United States (if the manufacturer does not conduct the testing) and maintaining documentation of the required testing. For purposes of this draft SIP we are not naming specific laboratories, but we will do so in our final SIP proposal. Drugs imported from Canada to Colorado will be subject to testing for authenticity and degradation as would be required by Section 804 and the final rule. This statutory testing will provide additional verification that all Canadian imported drugs are the same formulation as existing FDA-approved products manufactured by the FDA-approved manufacturer in the FDA-approved facility and that the drug has not degraded.

The Colorado SIP will require any participating laboratory to meet the applicable cGMP requirements of 21 CFR 211. In addition, the Program’s laboratory will have ISO 17025 accreditation as required by the NPRM.³³ ISO 17025 accreditation demonstrates the laboratory operates competently and generates valid results (**Comment 6**).³⁴

³³ <https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html>

³⁴ <https://www.iso.org/about-us.html>

Comment 6: The NPRM suggests requiring the qualified lab have an FDA inspection history, though the FDA does not generally inspect third party laboratories. It should generally be sufficient that a Qualifying Laboratory is accredited to ISO 17025 for the appropriate method or tests. Laboratories that are accredited to ISO 17025 are overseen by highly sophisticated accreditation bodies, they are subject to biannual inspection by those accreditation bodies, and they risk losing their ISO 17025 accreditation if they do not continue to meet the requirements of ISO 17025. Further, the requirements of ISO 17025 are generally either equivalent to or exceed the requirements of 21 CFR § 211.160 and 194.

Colorado’s DID will also develop a framework to ensure that any information provided by manufacturers for the purposes of statutory testing is kept confidential and secure and used only for the purposes of testing and compliance with the FDCA. Our final SIP will include detailed policy regarding this framework.

Post Importation Requirements

The NPRM and SB19-005 would require Colorado to demonstrate how post-importation requirements would be addressed, such as adverse event reporting and procedures to facilitate recalls. Because the drugs will have NDCs and have come from FDA-registered manufacturers, and because the Importer would typically be listed on the package as a packager or distributor, Colorado’s SIP would be able to rely on the processes in place today to fulfill recall and adverse event requirements.³⁵ Graphical illustrations of the recall and adverse event reporting workflows are available in Appendices H and I. The DID would establish additional procedures as required in the final published rule.

Drug Recalls

U.S. wholesalers currently have robust recall policies and procedures. In many cases, recalls are handled by a team of individuals with specific recall roles and responsibilities. The Colorado importation recall program would leverage the existing recall framework, while also delegating these responsibilities to importation supply chain partners. The Importer would have primary responsibility for recall processing with some responsibilities delegated to the Foreign Seller to process drugs still located in Canada at the time of the recall. We suggest the Importer have a primary employee and designated back-up employee assigned to SIP-specific drug recalls. The Importer would also be required to have an established written procedure and communication plan to follow when it recalls products under a SIP.

In the event of a recall, as proposed in the NPRM at § 251.18(e), the SIP Importer, in cooperation with the Foreign Seller, the FDA and the DID, would be required to:

³⁵ Unless otherwise required by the Final Rule. However, we believe many of the proposed rule’s provisions on event reporting would be unduly burdensome (such as those provisions that would require monitoring and reporting of “medication errors”, which go far beyond current definitions and reporting requirements for adverse event reports).

- Immediately cease distribution of the drug(s) affected by the recall;
- Directly notify consignees of the drug(s) included in the recall, including how to return or dispose of the recalled drugs;
- Notify the FDA and DID of the recall;
- Specify the depth to which the recall will extend;
- Notify the public about any hazards presented by the recalled drug(s) when appropriate to protect the public health;
- Conduct recall effectiveness checks to verify that all consignees at the specified recall depth have received notification about the recall and have taken appropriate action;
- Appropriately dispose of recalled product; and,
- Upon request by the FDA, provide the transaction history, information and statement of the recalled drug(s), as those terms are defined in sections 581(25), 581(26) and 581(27) of the FDCA, respectively.

Importers and Foreign Sellers under a SIP would be required to cooperate with the recalling entity (e.g., the Importer, the manufacturer, the FDA). The DID would expect SIP participants to effectuate the recall, as necessary, in coordination with the FDA.

The DID would function in an oversight capacity by regularly reviewing processed drug recalls and conducting, at least annually, a review of related policies and procedures of the Importer and Foreign Seller. Colorado’s final SIP proposal will include a comprehensive recall plan that assigns recall responsibilities to SIP participants as these processes happen today.

Comment 7: The Final Rule should allow SIP Sponsors to delegate recall monitoring tasks in accordance with established recall procedures in place today.

We have concerns that some of the proposed rule requirements regarding recalls are unnecessarily duplicative based on the drug recall process used today for all U.S.-distributed drugs (Comment 7).

Adverse Event Reporting

The Department plans to make use of the FDA’s current standard reporting structure for adverse event reports as these are established procedures in the distribution chain. If it is determined the imported drug’s label contributed to the adverse event, we suggest using the FDA’s standard reporting mechanism using the MedWatch form FDA3500 for Healthcare Professionals.³⁶ Additionally, the SIP would provide the link to the Patient voluntary reporting form, Medwatch form FDA3500B.³⁷ The FDA also provides an [online version of each MedWatch form through this portal](#). The DID would publicize this portal as part of its SIP outreach efforts to wholesalers, pharmacists, healthcare providers and patients. Further, the label or labeling of all drugs imported

³⁶ https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting_home

³⁷ <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=consumer.reporting1>

under a SIP, in accordance with 21 CFR § 209.2, would feature a phone number consumers could use to report any perceived drug side effects to the FDA (Comment 8).

In the event the Final Rule includes mandatory adverse event reporting for specific labeling issues as a result of a SIP drug, our final proposal will include reporting procedures created in conjunction with stakeholder feedback about the best mechanism to do so. Potential options for reporting include a web form (separate from the FDA MedWatch forms) or phone number (separate from the 21 CFR § 209.2 requirement) available on the Colorado Importation Program website that would come to the DID for follow up.

Comment 8: The Final Rule should eliminate the NPRM’s broad and vague adverse event reporting requirements as SIP participants do not have control over the development, manufacturing, and the labeling content of drugs which are central to evaluating the benefits and risks of a product.

All other adverse events and errors, regardless of whether it involves an imported drug, should be reported through the distribution chain participant’s normal error reporting procedure, not through a special SIP program reporting system.

Significant Cost Savings

The primary goal of the draft SIP proposal is to provide significant cost savings for Colorado consumers while ensuring no additional risk to public health and safety. This cost savings enables Coloradans to more readily afford their prescription drug therapy, thereby reducing the biggest barrier to care—and *that is affordability*. By achieving this affordability goal, we can also improve the health and well-being of Coloradans. In addition to these achievements, importation reduces costs for employers, providers, hospitals and carriers.

This proposal is focused on meeting the needs of Coloradans by importing specialty, high-cost, and high-volume prescription drugs.

Cost Savings Estimate

The purpose of an importation program is not to replace every drug in the state with an imported drug, but rather to provide more affordable options for those who need them. Therefore, the cost savings estimate represents savings gained by replacing 15 to 25 percent of the drugs evaluated and purchased by Coloradans covered by private, commercial insurance. Our estimates are based on 2018-2019 utilization data collected from Colorado’s All Payer Claims Database (CO APCD). This includes savings to both the fully-insured and self-funded markets. The cost savings is expected to be \$36 million to \$60 million annually, including a 45 percent markup to account for the

costs of maintaining a secure supply chain and ensuring all partners maintain profitability.

Initial estimates in this draft SIP proposal emphasize savings to the privately insured market and do not include the Medicaid population. The Department found no savings for Medicaid, upon initial analysis, due to already deep drug discounts in the program. The Department also did not find savings by importing generic drugs; savings were only on brand name drugs. The Department will be conducting further research to estimate savings to other populations and entities, including, the uninsured, the Colorado Department of Corrections, and other relevant state agencies.

The state will work with carriers, the Commissioner of Insurance, and supply chain stakeholders to ensure that the savings generated through the importation program are passed along to consumers in the form of reduced premiums, as well as lower enrollee cost sharing and spending in the deductible period. Drug importation can favorably impact all levels of the prescription drug marketplace – for both the insured and uninsured populations in Colorado.

Ultimately, the Department is confident that the average 60+ percent savings per drug analyzed will be significant to consumers and therefore meets the requirements for achieving cost savings as discussed in the NPRM (**Comment 9**).

Comment 9: The NPRM seeks comment on the factors that should be considered in determining whether a reduction in costs is significant. The Department would prefer it to be left to the states to decide on what is significant. Using a specific cost savings number, such as a required 50% savings on each imported drug, could greatly limit the savings generated by the Colorado SIP. The savings may also be passed on to the consumer through different mechanisms including direct prescription costs, lower insurance premiums, or reduced co-pays. It should be left to the states to determine the mechanism of cost savings that is most beneficial for their consumers.

Our estimate represents a snapshot in time and will change as drug prices evolve, new drugs enter the market, and with the timing of SIP approval and program implementation. The estimate will also be impacted by any drug patent expirations (or anticipated expirations) at the time of SIP approval. The cost estimate assumes multiple Foreign Sellers will participate in the program in order to generate the greatest cost savings and the Department urges the FDA to address this in final rulemaking.

Cost Savings Methodology

Colorado's initial drug list contains 168 unique drugs and dosages, including medications that treat a number of conditions including asthma, cancer, diabetes, HIV

and multiple sclerosis. In many cases, multiple doses of one drug were analyzed for cost savings. The Canadian drugs included in our analysis, on average, are priced 61 percent less than the same drug currently sold in the United States. (See Appendix J for the complete draft drug list). As previously stated, we recognize that importing all the drugs on our draft list may not initially be possible, but for the purposes of a robust analysis wanted to include a broad pool of drugs.

The Department developed an extensive methodology to evaluate the potential cost savings of Colorado's draft SIP using data from a variety of sources. While this preliminary analysis provides a solid foundation for evaluating cost savings, the fact that imported drugs will vary based on which manufacturers and wholesale distributors participate in the program does provide some limitations to our findings.

The draft drug list was created using data from the CO All Payer Claims Database (CO APCD).³⁸ The CO APCD is made up of claims data submitted by payers in the state. More than 33 commercial payers currently submit claims data to the CO APCD, representing about 1.5 million individuals across the state.³⁹ The Department recognizes that the CO APCD does not represent all Coloradans served by the private or commercial market. In fact, we estimate that the CO APCD does not include data for about 35 percent of Coloradans who are largely covered by self-funded, employer-sponsored programs.⁴⁰ The estimates for coverage were drawn from the "2019 Colorado Health Access Survey: Health Insurance Coverage" published by the Colorado Health Institute.⁴¹

As part of our savings analysis, the Department evaluated the 500 most expensive brand name drugs both from a payer and an out-of-pocket cost perspective for Calendar Year (CY) 2017-2018 and CY 2018-2019. The list includes drug utilization data from CY 2018-2019 that was applied to the cost savings in order to estimate the amount of each drug used annually in the state. The Department also received from the Colorado Association of Health Plans (CAHP) an aggregated list of carrier highest cost brand prescription drugs, as well as drugs that pose the highest out-of-pocket costs for their members. Any drugs from CAHP not on the 500 most expensive brand name drug list were assessed for eligibility and added to the master list. Additionally, the Department included drugs and drug classes requested by stakeholders. The identified drugs were compiled into a master list and checked against the NPRM requirements and the eligible prescription drug exclusions of Section 804 to create a final list of potential prescription drugs for importation. Ultimately, the drugs included in the evaluation must be approved by both the FDA and by the Canadian HPFB, be currently marketed in the U.S., and not fall into any of the exclusions from

³⁸ <https://www.civhc.org/get-data/co-apcd-overview/>

³⁹ <https://www.civhc.org/get-data/co-apcd-overview/data-submission/>

⁴⁰ CIVHC data includes 100 percent of fully-insured and 65 percent of self-funded lives (according to CIVHC and other sources- Ibid). In order to derive a cost savings estimate for the self-funded lives not included in CIVHC data, we assumed similar utilization rates to CIVHC claims but a lower cost per claim of 10 percent to account for the stronger negotiating power of larger self-funded employers. These assumptions are embedded in our methodology.

⁴¹ <https://www.coloradohealthinstitute.org/research/2019-colorado-health-access-survey-health-insurance-coverage>

the eligible prescription drug definition. The following types of drugs are excluded from the eligible prescription drug definition:

- Controlled substances
- Biological products
- Infused and parenteral (drugs administered by a non-gastrointestinal tract route)
- Intravenously injected drugs
- Drugs inhaled during surgery
- Drugs with a Risk Evaluation Mitigation Strategy (REMS) (**Comment 10**)

Comment 10: While the FDA may require REMS safety programs for certain drugs to address safety concerns, such programs are not affected by the source of the drug. Given this, we recommend any SIP proposed drug subject to a REMS be evaluated by the FDA on a case-by-case basis.

Any drug on this list that was also found to have a current Canadian shortage was excluded from further analysis. Using these guidelines, about 250 drugs were found to be eligible for importation from Canada.

In a final application, the Department will address additional drug list details that cannot be provided until partners are identified. These details include:

- Name and DIN of each eligible prescription drug that the Sponsor seeks to include in the SIP;
- Name and address of the applicant that owns the approved NDA or ANDA for each eligible prescription drugs FDA-approved counterpart, and the NDA or ANDA number;
- Name and address of the manufacturer of the finished dosage form of the drug, if available; and
- Name and address of the manufacturer of the active ingredient(s) of the drug(s), if available.

Once the draft drug list was finalized, the Department compared all U.S. pricing with Canadian pricing primarily using data from the February 2020 Quebec Province’s “List of Medications.”⁴² 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 pharmacists. When Quebec data was unavailable, the Department used Ontario and Saskatchewan pricing. Drugs for which no reliable pricing information could be found were removed from the list, resulting in 168 unique drugs on the final draft drug list.

All Canadian prices were then converted to U.S. dollars and a 45 percent markup was applied to each unit price to cover costs of the supply chain. The Department decided to use the 45 percent markup at the advice of industry consultants,⁴³ who have determined through supply chain cost research that this was adequate to cover the

⁴² http://www.ramq.gouv.qc.ca/SiteCollectionDocuments/liste_med/2020/liste_med_2020_02_05_en.pdf

⁴³ FDA Imports.com, LLC, and the National Academy for State Health Policy (NASHP)

costs of the supply chain and dispensing. The Department estimates that the 45 percent would be divided in the following manner:

- Repackaging/relabeling (10 percent to 15 percent)
- Testing (5 percent)
- Record keeping and recall management (5 percent)
- Other commercial entities within the supply chain (20 percent to 25 percent) such as foreign sellers, importers, pharmacies and PBMs.

The Department sees this markup estimate as a starting point that may be higher than necessary to ensure costs are accounted for across the supply chain. With additional research and through our eventual partnerships throughout the supply chain, the Department hopes to refine these estimates further. For example, the estimate of 20 percent to 25 percent for other commercial entities would become more granular as the state enters into partnerships and can participate in contractual conversations.

Finally, the cost savings estimate within this draft SIP proposal assumes that all drugs identified by the Department would be available for importation and that the data collected for both U.S. and Canadian drug pricing is accurate. Since the Department is not currently contracted with any potential partners, this estimate is not final and will continue to be refined and analyzed.

The Drug List

Using the above methodology, a list of 168 drugs including variation based on dosage, were analyzed for cost savings. Figure 5 shows a summary of the different drug categories included in our draft drug list:

Figure 5.

Colorado Draft Drug List	
Drug Category	Number of Unique Drugs
Cancer	19
Cardiac	4
Diabetes	12
HIV	11
Multiple Sclerosis	4
Respiratory	8
Women's Health	10
Misc. Classes	46

Colorado Department of Health Care Policy & Financing, 2020.

Even if only 15 percent of these drugs were replaced by drugs imported from Canada, savings estimates are still significant for the following drug categories:

Figure 6.

Drug Category	Annual Colorado Spend by Drug Category	Estimated Annual Importation Price by Drug Category	Percent Savings
Cancer	\$8,362,944	\$3,843,969	54%
Cardiac	\$3,857,070	\$979,762	75%
Diabetes	\$5,116,966	\$1,815,582	65%
HIV	\$14,128,493	\$7,414,589	48%
Multiple Sclerosis	\$8,085,249	\$2,376,944	71%
Respiratory	\$5,534,964	\$2,256,086	59%
Women's Health	\$2,601,466	\$370,351	86%

Colorado Department of Health Care Policy & Financing, 2020.

To understand the significance of the estimated cost savings, it is important to consider the impact of importation for individual consumers across Colorado. Importation could lower costs for patients on drugs that are not fully covered by insurance plans, for vulnerable populations such as children and seniors, and for those paying out-of-pocket for their medications. Importation would greatly benefit consumers across the state through a variety of mechanisms, regardless of how they currently pay for their prescription drugs. Cost savings examples include:

- **Jardiance** is a non-insulin drug used to treat Type II diabetes. It can cost more than \$400 out-of-pocket for a one-month supply in the United States. For a patient who does not have insurance or who has a high deductible health plan, purchasing the same drug through the Colorado importation program would cost around \$85 for a one month supply, a savings of more than 80 percent or around \$315 per month.
- The drug with the highest utilization included in our analysis is **Advair Diskus**, an inhaler used to treat asthma and COPD. The out-of-pocket cost for an Advair Diskus 250mcg/50mcg dose inhaler is around \$270 for a one-month supply in the United States. The same drug would cost less than \$100 if imported from Canada. Importation could reduce the annual cost of this life-changing drug by more than 60 percent, or more than \$170 per month.
- **Gleevec** is a tyrosine kinase inhibitor used to treat various forms of cancer. The total monthly cost for this drug is close to \$10,000. On average, insured

patients pay for about 10 percent of the total cost of the 400mg dose of Gleevec out-of-pocket. The same exact drug sold in Canada is 66 percent less expensive and could provide significant savings for a potentially life-saving treatment. With that same health insurance coverage, a patient could save more than \$600 per month in out-of-pocket costs, as shown in Figure 7.

Figure 7.

	Monthly Colorado Cost	Cost Through Importation	Total Monthly Savings
Self-Pay (100 percent out of pocket)	\$10,000	\$3,400	\$6,600
Insurance (Based on a 10 percent co-pay)	\$1,000	\$340	\$660

Colorado Department of Health Care Policy & Financing, 2020.

Continued Drug List Evaluation and Oversight

The Department’s DID would have responsibility to oversee the drug list to ensure ongoing significant cost savings to consumers, including overseeing any changes to the drug list and regular review of the drug list every three months to ensure it meets all program requirements. Additionally, per Senate Bill 19-005, the DID would set a maximum profit margin on all levels of the drug distribution system for imported drugs, and determine a method for covering the costs of the program.

The Department would also use a scorecard tool to create the final drug list for Colorado’s final SIP application. All eligible drugs would be scored using a set of objective weighted measures. Drugs with a high score would be eligible for importation and drugs with a low score would not be considered. The measures included are designed to remove bias and would be scored by impact to the Colorado consumer. For example, consumers and health plans can suggest a drug for addition to the list, but if the drug doesn’t meet the minimum score, it will typically not be considered for importation. While this scorecard has not been used to prioritize our current list of potential drugs for importation, it will be an important tool as we refine and implement our program. Figure 8 shows our suggested measures and their proposed weights for scoring.

Figure 8.

Draft Measure	Background	Suggested Measure Weight (total 100%)
Recent U.S. Shortage?	Statutory	10%
Is it high volume?	Statutory	10%
Is it a specialty drug?	Statutory	5%
How much are potential savings?	Cost Reduction	25%
Is it a high cost drug? Does it have high out of pocket costs for consumers?	Cost Reduction	20%
Will the importation of this drug have savings for state agencies?	Cost Reduction	5%
When does the brand name patent expire?	Patents	15%
Drug Class: -Is the drug a maintenance drug or for emergency use? -Does the drug have a single indication? -Are there multiple drugs for the same indication?	Drug Class	10%

Colorado Department of Health Care Policy & Financing, 2020.

As additional data and patent research is completed and stakeholders are engaged, the measures will continue to be refined to ensure the final measures meet the criteria per the Final Rule.

Barriers, Risks and Opportunities

Although the Department has developed a robust draft SIP framework in alignment with current law and the NPRM, there are some challenges to overcome in order to implement a successful SIP. The Department has outlined below potential barriers and risks to our SIP and highlighted some potential strategies to address these issues. As we proceed with further development of our SIP, we will continue to evaluate these challenges and work to address them.

Our International Partners

The Department seeks a continued partnership with HHS to collaborate with Canadian representatives to ensure the ultimate achievement of our importation goals. Colorado has introduced a bill, Senate Bill 20-119,⁴⁴ in this year's legislative session that would allow for expansion from other foreign partners, should such an expansion be approved by the federal government. Colorado would support expanding importation from countries such as the European Union member countries, the United Kingdom or Japan – all of which have a version of an international arrangement.⁴⁵ Specifically, the United States has a Mutual Recognition Agreement with the European Union and the United Kingdom that allows drug inspectors to rely on information from drug inspections conducted within each other's borders.^{46 47} The United States has a cooperative arrangement with Japan regarding the exchange of information on pharmaceutical products.⁴⁸ Current action in the Congress to advance a drug pricing package provides a unique opportunity for the Administration to advance such a proposal and we encourage leadership on this issue in support of states.

The Department has explored several different avenues to provide economic incentives for Canadian participation in a SIP. First, as previously mentioned, we suggest the final rule allow repackaging and relabeling to occur in Canada. We are also supportive of any measures Canada would be interested in pursuing, including a Canadian fee on any exported drug. We do not believe this would have a meaningful impact on our projection of 61 percent average cost savings per prescription. The Department has also begun to analyze potential opportunities to export lower cost U.S. generics to Canada, and we would support the Administration's engagement in further exploring such a strategy with our Canadian neighbors.

⁴⁴ <https://leg.colorado.gov/bills/sb20-119>

⁴⁵ <https://www.fda.gov/international-programs/international-arrangements>

⁴⁶ <https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreement-mra>

⁴⁷ <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2019/february/ustr-signs-mutual-recognition>

⁴⁸ <https://www.fda.gov/international-programs/cooperative-arrangements/fda-japan-letter-regarding-exchange-information-pharmaceutical-products>

Supply Chain Participation

The Department will need to engage partners at all levels of the drug distribution supply chain to implement a successful drug importation program. To that end, the state will need to develop strong partnerships with drug manufacturers, Canadian Foreign Sellers and Importers. During our stakeholder engagement sessions, the Department heard from manufacturers that they did not view themselves as voluntary participants in importation programs. As such, wholesalers are seeking support from interested parties—Colorado, other states, HHS, and the Administration—in their negotiations with manufacturers should they choose to engage in a drug importation program.

In response to these concerns, the Department supports changes to the NPRM that allow for increased competition between members of the supply chain to support the achievement of the importation goals. Most importantly, we feel that allowing states to pursue partnerships with multiple Foreign Sellers and Importers will lessen the likelihood of manufacturer backlash and lead to a healthier supply of prescription drugs available to state importation programs.

FDA Resources

The Department acknowledges the challenges and resource intensity of setting up new programs and we understand that the oversight of drug importation programs will be no different. The proposed rule states that the FDA may not approve an otherwise compliant SIP due to a lack of resources. The Department urges the Administration to include in future budget requests additional funds for the FDA to dedicate to the successful implementation of drug importation programs.

Opportunities for Federal Expansion

As mentioned in earlier sections, the Department supports the exploration of two specific areas of expansion that would allow for additional significant cost savings for consumers and bolster the feasibility of a successful importation program.

Importation of Biologics

The Department supports a change to statute to the FDCA to allow for the importation of biologics, such as insulin and Humira. We support Secretary Azar's comments on February 26 about his openness to importing insulin from Canada.⁴⁹ Insulin costs create a significant hardship to hundreds of thousands of Coloradans who depend on the drug every day, often for their very survival.⁵⁰ In a limited analysis of

⁴⁹ <https://insidehealthpolicy.com/inside-drug-pricing-daily-news/azar-open-allowing-imports-insulin-despite-being-biologic>

⁵⁰ https://www.colorado.gov/pacific/sites/default/files/DC_Factsheet_Facts_For_Action_Diabetes_In_Colorado_November_2015.pdf

five commonly used insulins, Canadian prices would drive an 81 percent reduction in costs if the state was able to import insulin from Canada, as shown in Figure 9 (Appendix K). We urge HHS to seriously consider the importation of insulin.

Figure 9.

Drug Name	Dose	Annual Colorado Spend by Drug	Estimated Annual Importation Price by Drug	Percent Savings
Humalog	100U/mL	\$23,896,173	\$3,524,986	85%
Humalog KwikPen	100U/mL	\$10,394,228	\$1,355,973	87%
Lantus	100U/mL	\$4,464,525	\$1,424,809	68%
Lantus Solostar	100U/mL	\$6,256,829	\$1,689,547	73%
Levemir	100U/mL	\$7,048,920	\$1,845,686	74%

Colorado Department of Health Care Policy & Financing, 2020.

Further, the Department conducted a brief analysis of the top ten highest cost biologics using the state’s All Payer Claim Database data. The Department estimates Coloradans could save an additional \$21 million to \$35 million annually assuming the same 45 percent supply chain markup and a market replacement of 15 to 25 percent. It is important to note that the potential savings from importing just these ten biologics are ten times greater than the savings the Department found in our analysis of the 168 traditional brand name drugs. Removing biologics from the ineligible drug list under Section 804 could significantly increase cost savings for states. For example, Humira, the United States’ number one selling drug, has prices far in excess of Canada’s and other countries, as shown in Figure 10. Through importation, Colorado consumers could save up to 65 percent on Humira, or just under \$1,500 per dose.

United States (from CIVHC data)	\$2,233.88
United Kingdom	\$479.10
Japan	\$259.05
Canada (Quebec formulary)	\$535.68
Australia	\$444.36
Portugal	\$577.62
France	\$329.94
Netherlands	\$310.32
Germany	\$427.34
Denmark	\$787.10
Sweden	\$650.98
Switzerland	\$567.81

https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf

Expansion to Additional Countries

The Department supports an amendment to the FDCA to allow for the expansion of importation from countries other than Canada. This statutory change would allow for additional price competition between countries and incentivize states to partner with countries that can offer its residents the most savings. Additionally, this change could relieve any potential pressure on our Canadian partners.

Conclusion

As HHS and the FDA work to finalize rulemaking for Canadian prescription drug importation, we encourage the review of Colorado's draft SIP proposal to inform its development. The Department, in consultation with the stakeholder community, has taken extensive efforts to develop a meaningful proposal that is in compliance with federal law and in alignment with the NPRM. As the Administration pursues a Final Rule, Colorado will continue its efforts to advance a Canadian importation program so we may act with a sense of urgency that recognizes that one in five Coloradans are struggling to afford their medications, making affordability the leading barrier to health and well-being.

While we await final rulemaking, the Department will continue to assess and refine our drug list for importation; including conducting a more in depth analysis on the benefits of importing biologics, like insulin. The Department will meet with stakeholders and industry experts to gain input on this draft SIP proposal and identify emerging trends in the market. As part of our program development, the Department intends to engage potential partners and prioritize collaboration with other states to meet our shared goals of creating successful drug importation programs. We hope this draft SIP will be instrumental in informing the Final Rule as we work towards our shared goal of reducing prescription drug prices for consumers. We stand ready to offer our support, leadership, and insights.