

Drug Importation Program Update



October 15, 2020

Webinar Rules



Due to the large number of attendees, all lines will be muted for the duration of the webinar. If you have questions, please type them into the Q&A box. We'll read out loud and respond to as many questions as possible.

Agenda

- Background
- Program Requirements
- Colorado Oversight
- Drug Access/Sample Drug List
- Importation Process/Reimbursement
- Next Steps
- Q&A Session

Why Importation?

- Increasing health care affordability, including lowering drug costs, is a top priority for Governor Polis
- Retail drug spend totalled \$6 billion in Colorado in 2018
- Canadian importation is one lever, among many, that Colorado will pursue to address high drug prices in our state

Legislative/Regulatory Framework

- Medicare Modernization Act of 2003
 - Amended Section 804 of the Federal Food Drug and Cosmetic Act (FDCA) to:
 - Permit the importation and reimportation of prescription drugs from Canada by a pharmacist or wholesaler, provided the prescription drugs meet certain minimum safety and quality standards
- Colorado Senate Bill 19-005
 - Authorized HCPF to apply to HHS to implement an importation program
- Notice of Proposed Rulemaking (NPRM) Released December 2019
 - CO submitted comments on the Proposed Rule as well as a draft SIP proposal
- Final Rule released September 24. Effective November 30
 - Once in effect, states can submit applications to the federal government to operate a program

Program Timeline



How will Coloradans access imported products?

- Pharmacy counter/mail order
- Through insurance coverage or out of pocket

The State will publish information about available drugs and participating pharmacies

Estimating Cost Savings

- In our initial program proposal, we estimated \$36-60 million in annual savings, 61% average savings across all drugs
 - Includes a 45% mark up for the supply chain
 - Assumes a replacement or market shift of 15-25%
- Program will conduct an analysis of the final drug list, in the context of participating stakeholders, to develop this savings estimate for our final application
- Freedom in final rule to prove consumer savings

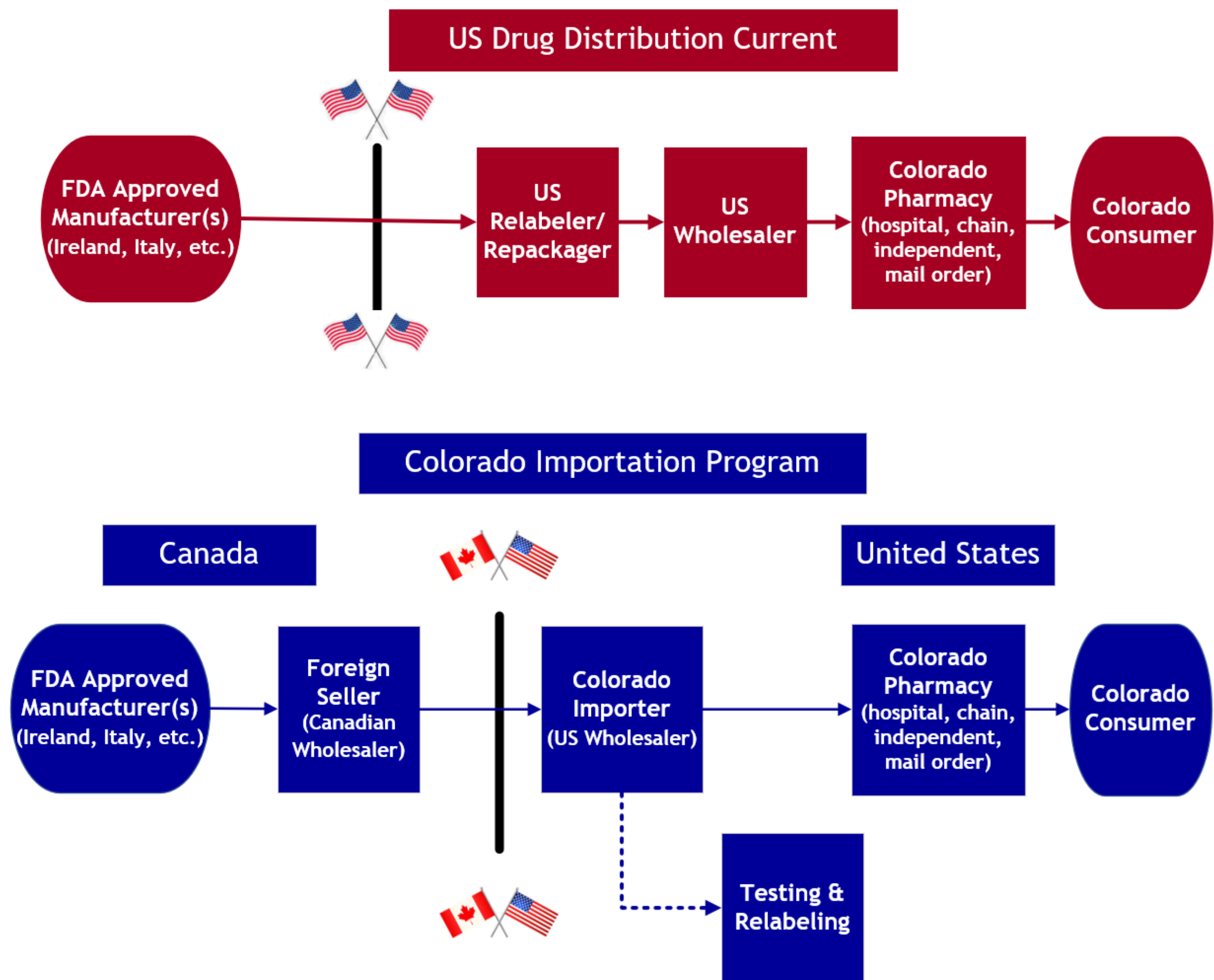
Program Requirements

- State Importation Plan (SIP) Sponsors must obtain federal approval to operate a Canadian prescription drug importation program
- A SIP sponsor's detailed application to FDA must include:
 - Names/details of all partners in the supply chain,
 - Demonstration of compliance with federal safety rules/standards,
 - List of drugs intended for importation, and
 - Analysis of cost savings for consumers
- SIPs will be approved for 2 year terms, with the option to request extensions from the FDA
- Colorado's statute requires:
 - Regular monitoring of the imported drug list, and
 - Setting a maximum profit margin to ensure consumer savings

State of CO Oversight

- Oversee/approve imported drug list
- Manage oversight of supply chain partners/verify all licensing/registration requirements
- Ensure compliance of partners with federal statute/regulation
- Develop a compliance plan to be approved by FDA
- Collaborate with stakeholders to promote the program
- Develop a communications plan to ensure all participating entities and the public know importation details

What Will Drug Importation Look Like?



Safety and Quality Standards

- Drug Quality Security Act (DQSA) - 2013
 - Title II - Drug Supply Chain Security Act (DSCSA)
 - Placement of identifiers on all products, and
 - Inclusion of transaction data to permit track/trace
 - Registration & license requirements
- Colorado's program will be in full compliance and ensure that every imported drug can be tracked/traced back to the original manufacturer



Product Identifier Example

Supply Chain Requirements

Foreign Seller - the Canadian supplier/wholesaler must:

- Be licensed by Health Canada
- Be registered with the FDA
- Affix an 804 serial identifier (SSI)

Importer - a U.S. wholesaler must:

- Be licensed to operate in the US
- Ensure that a product identifier is affixed
- Arrange for all statutorily required testing and relabeling
- Submit a Pre-import Request to FDA 30 days prior to arrival of shipment
- Submit adverse event information to FDA

Both are subject to all FDA supply chain and security requirements

Imported Drug Requirements

- Drugs must be:
 - Approved by Health Canada's Health Products and Food Branch
 - The same as an FDA-approved drug in the United States
- Each drug must be tested and approved by a lab and reviewed/approved by the FDA before entering the CO market
- Excluded drugs include:
 - intravenous, infusion, controlled substances, biologics, drugs inhaled for surgery, REMS, intrathecal, and intraocular
 - Excluded drugs cannot be imported unless federal statute or rule is changed

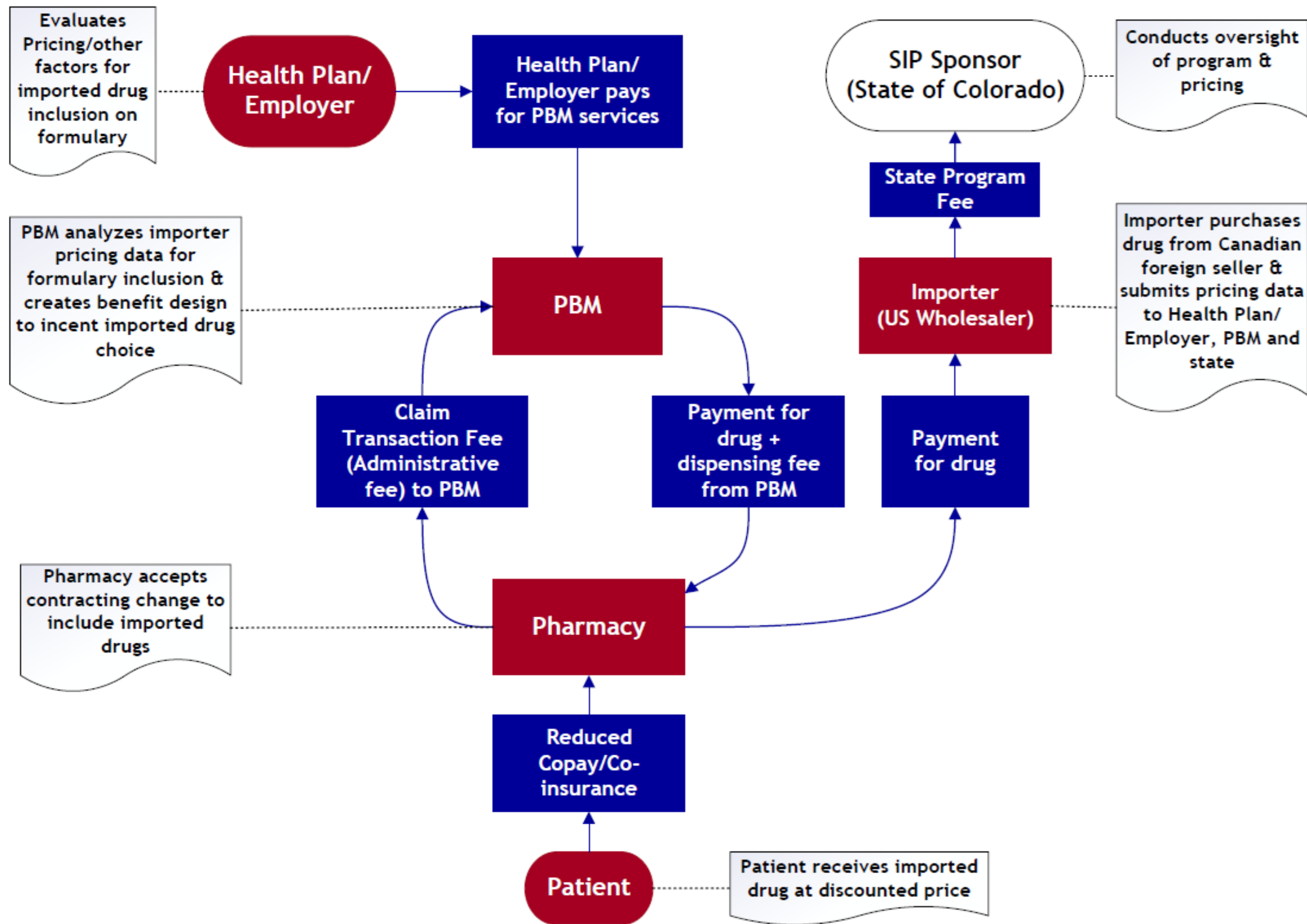
Drugs that are ripe for importation

- Certain drug classes
 - Diabetes, cardiac, multiple sclerosis, HIV
- Brand Name
- Generic
- High Cost
- Specialty
- High tiered drugs
- High volume

Sample Importation List

Drugs Eligible for Importation in Canada				
Drug Name	Broad Drug Category	2020 Colorado Cost*	Importation Price** from Canada	Percent Savings Canada
Brilinta	Cardiac	\$6.47	\$1.61	75%
Farxiga	Diabetes	\$16.10	\$2.66	83%
Generic Truvada***	HIV	\$48.51	\$7.94	84%
Gilenya	Multiple Sclerosis	\$275.71	\$92.62	66%
Ibrance	Cancer	\$629.00	\$276.13	56%
Spiriva Respimat	Respiratory	\$10.03	\$0.94	91%
<p>*Colorado's 2020 cost per unit is the 2019 Colorado cost per unit increased by 4.8% to account for annual average increase in drug prices, as estimated by the Centers for Medicare and Medicaid Services.</p> <p>**The Importation price is the unit cost of the drug in Canada, converted to US Dollar, with a 45% markup for the supply chain.</p> <p>***Generic Truvada's published Wholesale Acquisition Price as of October 2nd, 2020</p>				

Colorado Drug Importation Proposed Process & Reimbursement Flow with Health Plan/PBMs



Opportunities for Federal Action

- Expansion of importation from countries other than Canada
 - Access to even lower prescription drug prices for Coloradans
- Importation of Biologics
 - Increased cost savings

Next Steps

- Release of competitive solicitation for importation program vendors
- Continued stakeholder engagement
- Prepare for a final application to the federal government to operationalize Colorado's Importation Program
- Begin importing drugs safely at a cheaper price!



Questions?

Contact Information

For information regarding our solicitation:

To receive our solicitation announcement,
please email:

HCPF_005DrugImportation@state.co.us

To find information about the bidding process,
please visit our Vendor Support Services

Website:

[Colorado.gov/vss](https://colorado.gov/vss)

For all general questions and
comments:

Please email us at:

HCPF_005DrugImportation@state.co.us

Please visit our website to join our mailing list!

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

Thank You!