

Colorado's Drug Importation Program

January 10, 2023



Agenda

- Program background
- Federal requirements
- Cost savings analysis
- Supply chain overview and partners
- Oversight and compliance
- Consumer support and education
- Next steps



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.

Legislative & Regulatory Background

- Medicare Modernization Act of 2003
 - Amends 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 - 2019
 - Authorizes HCPF to apply to HHS to implement an importation program
- Final Rule went into effect November 2020
 - States can begin applying to the FDA to operate state-led importation programs



Colorado's Importation Program - General Timeline



- SB19-005 Signed
- HHS releases Draft Rule

2019



- CO provides Draft SIP & Comments
- Final Rule Becomes Effective

2020



- CO Releases Invitation to Negotiate
- CO negotiates with potential supply chain partners

2021



All supply chain partner contracts executed and announced.

August 2022



Formal SIP submitted to FDA for federal review and approval.

December 2022



Begin importing prescription drugs from Canada for fairer prices.

Targeting Late 2023



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Why Importation?

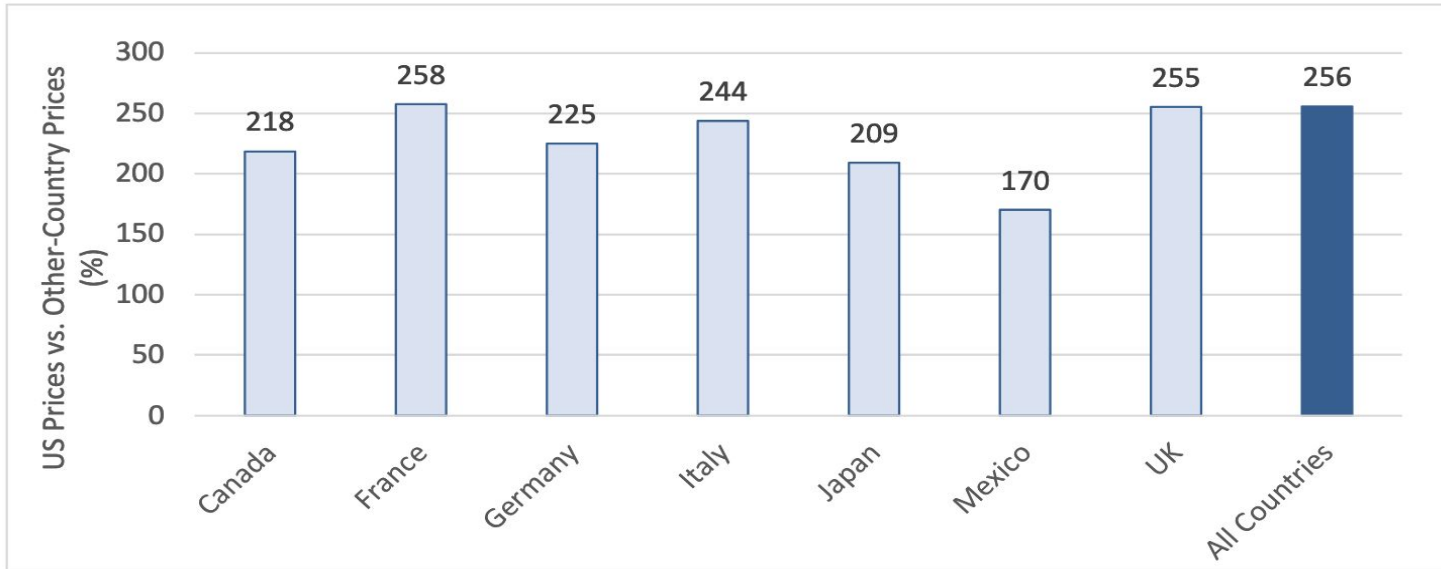
- Increasing health care affordability, including lowering drug costs, is a top priority for Governor Polis
- Retail drug spend totals \$5 billion in Colorado and prescription drugs account for 19% of total health care spending
- Nearly one in three Coloradans do not take their prescription drugs as directed because they simply cannot afford to.

Canadian importation is one lever that can help to address high drug costs in our state



Why Importation?

Figure S.1. U.S. Prescription Drug Prices as a Percentage of Prices in Selected Other Countries, All Drugs, 2018



Source: Rand Corporation, January 2021, <https://www.rand.org/news/press/2021/01/28.html>

Importation is an Opportunity

- Creation of a new marketplace
- Increase transparency for drug pricing
- Partnering with manufacturers, health plans and PBMs



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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,
 - List of drugs intended for importation (and related details)
 - Analysis of cost savings, and
 - Demonstration of compliance with federal safety rules/standards
- SIPs will be approved for 2 year terms, with the option to request extensions from the FDA.



Eligible 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
- Excluded drugs include:
 - FDCA: intravenous, infusion, controlled substances, biologics, drugs inhaled for surgery
 - Importation Final Rule: REMS, intrathecal, and intraocular



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SIP Drug List Methodology

Top 2000
highest cost
drugs from
commercial
data from
CO APCD

Remove
drugs
ineligible for
importation
per the Final
Rule

Apply cost
comparison
methodology

Review for
significant
savings

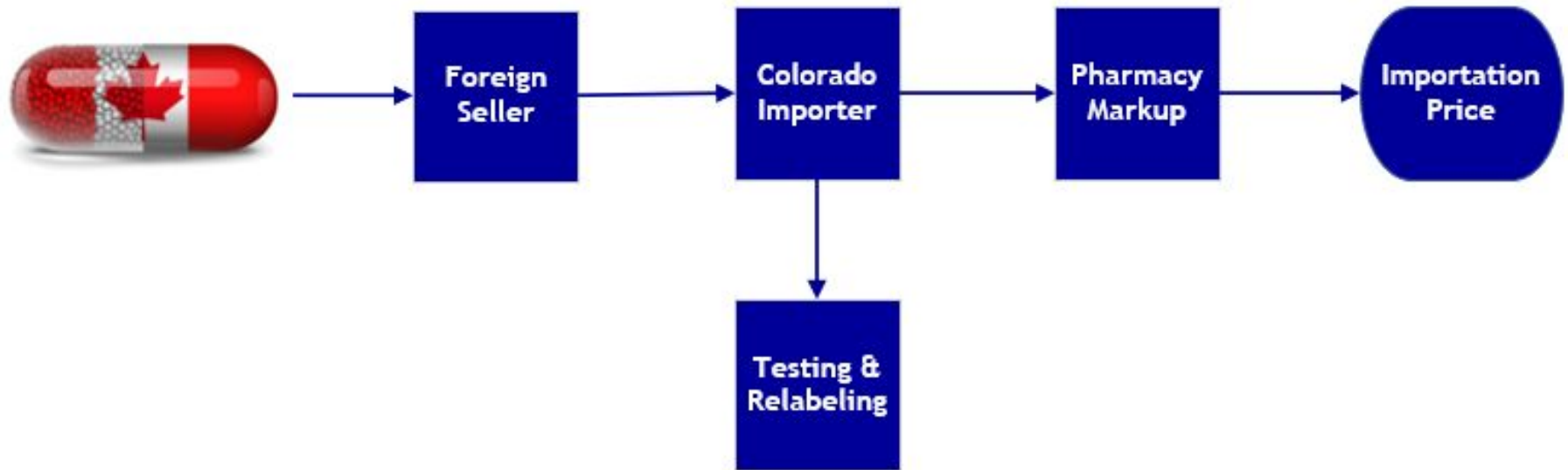
SIP
Drug
List



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Colorado Importation Price



SIP Drug List

- Wholesale importation program targeting the commercial market.
- **Aspirational** drug list and cost analysis for SIP includes:
 - 112 unique drugs and dosages
 - 80% brand, 20% generic



SIP Overview: Cost Savings

Colorado Drug List Savings Summary by With Market Replacement Estimates				
2022 Colorado SIP Drug List (112 Unique Drugs)				
Market Replacement Percentage	Colorado Annual Drug Spend in the Commercial Market	Estimated Annual Importation Spend	Difference in Price between Colorado Drug Spend & Importation Drug Spend	% Savings
100%	\$523,072,244	\$182,641,586	\$340,430,658	65%
25%	\$130,768,061	\$45,660,397	\$85,107,664	65%
15%	\$78,460,837	\$27,396,238	\$51,064,599	65%

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Cost Savings Summary

Drug Category	Number of Unique Drugs	% Savings
Anaphylaxis	4	24%
Antipsychotic	4	91%
Blood Thinners	6	73%
Cancer	18	56%
Dry eyes	3	59%
HIV	10	53%
Low Blood Sugar	3	54%
Multiple Sclerosis	6	64%
Respiratory	28	66%
Smoking Cessation	4	80%
Type 2 Diabetes	12	78%
Women's Health	6	62%
Miscellaneous Classes	8	69%

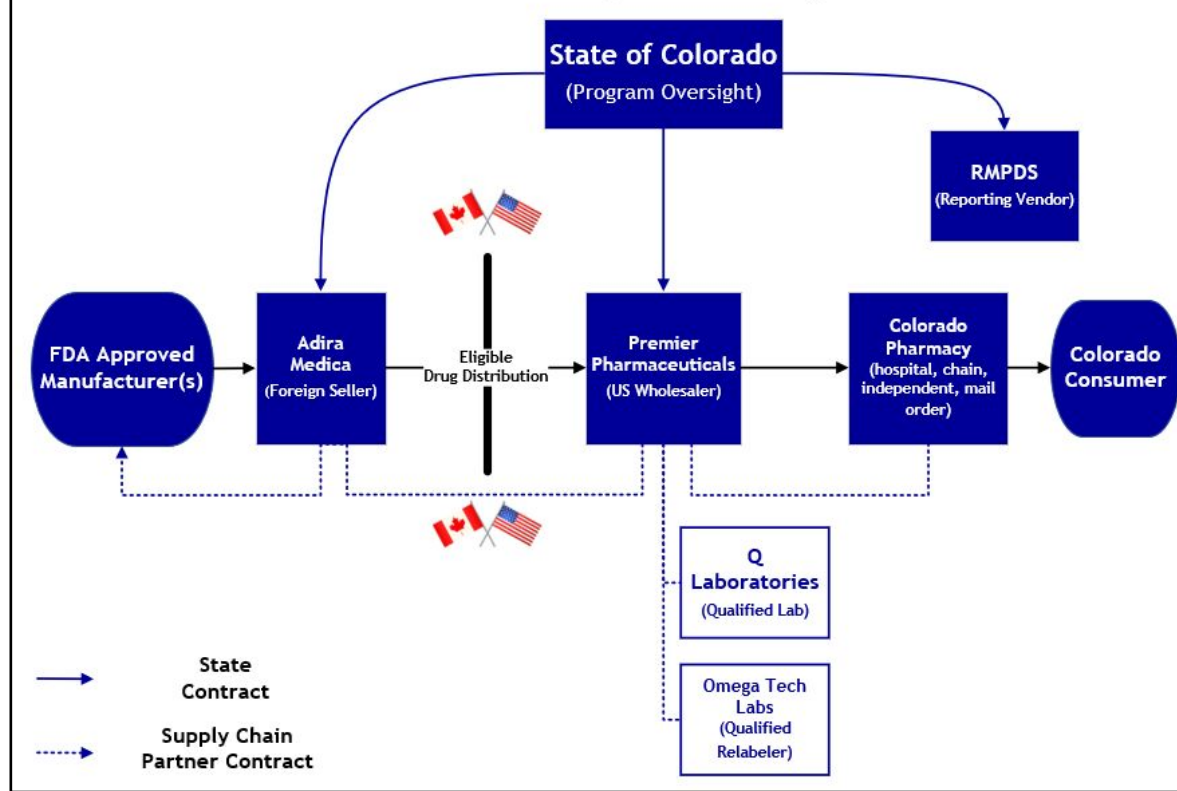
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Price Comparisons for U.S. and Canadian Brands and Generics				
Name	U.S. Brand	U.S. Generic	Imported Brand	Imported Generic
Nuvaring	\$142.71	\$92.01	\$14.11	\$14.11
Ventolin	\$54.00	\$25.97	\$6.75	\$5.63
Chantix	\$8.35	\$7.50	\$1.93	\$1.04

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Colorado Drug Importation Program Contracts & Program Participants



Supply Chain Partners



— **ROCKY MOUNTAIN** —
POISON & DRUG SAFETY

Saving lives with answers.™



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Supply Chain Partners

In addition our primary supply chain partners, Premier Pharmaceuticals has identified a qualified laboratory and a relabeler to fulfil those roles for the program.



Supply Chain Partners

Site visits to all supply chain partners to evaluate compliance with FDA Final Rule requirements including:

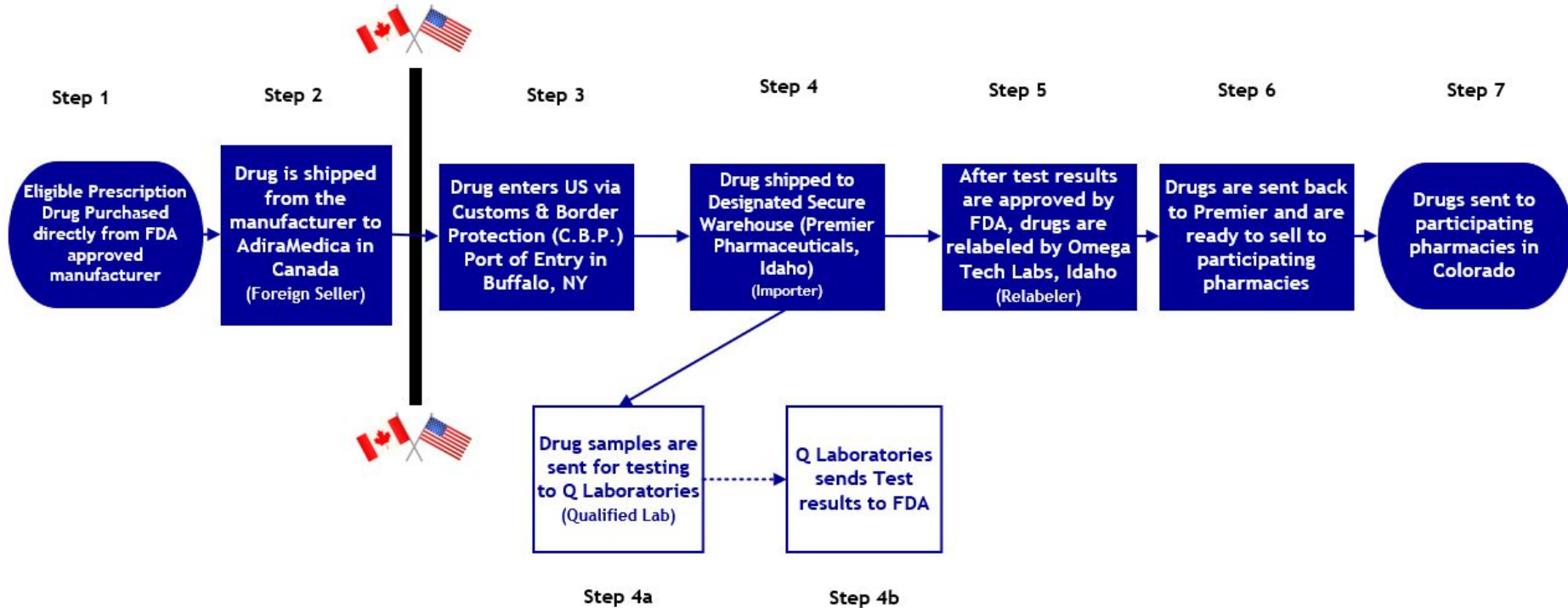
- Good Manufacturing Practice (GMP) compliance
- Robust standard operating procedures (SOPs) for their facilities, procedures, and systems
- Physical security
- Inventory management
- Employee training programs



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SIP Distribution Chain



HCPF Oversight

Compliance with federal safety requirements is operationalized through partner contracts which include compliance requirements for:

- Statutory/regulatory rules including licensure and regular reporting
- Maintenance standards for physical space & security, SOPs, staff education and training
- Track and trace monitoring
- Regular auditing and inspections

HCPF will have ongoing oversight of these terms



DSCSA Compliance

CO's SIP includes extensive safety and security requirements supported by the Final Rule and the Drug Supply Chain Security Act (DSCSA).

Compliance by:

- Placement of product identifiers on all products
- Inclusion of transaction data to permit track/trace.
- Registration & license requirements (state and federal level)



Product Identifier Example



Testing & Relabeling

- Testing - Statistically valid sampling for authenticity and degradation
 - Test results submitted to FDA for review/approval
- Relabeling - All eligible drugs, once tested and FDA-approved will be relabeled according to the Final Rule.



Supply Chain Monitoring

- Returns - Premier is required to follow standard return protocols within the original supply chain
- Recalls - All supply chain partners are required to monitor, report, and suggest drug recalls
- Adverse Events - RMPDS, our critical reporting partner, will:
 - Maintain reporting and recordkeeping requirements for adverse events and pharmacovigilance
 - Manage a consumer reporting hotline to report any safety events
 - Support on consumer level recalls



Consumer Support & Education

- Educational outreach to engage
 - Consumers
 - Pharmacists
- SIP website expansion including (upon application approval):
 - Approved imported drugs' National Drug Codes (NDCs)
 - List of participating pharmacies
 - Access to consumer support hotline, including adverse event reporting
 - Access for pharmacies to Premier's secure online portal for placing orders



Next Steps

- Awaiting federal approval
- Negotiations with drug manufacturers
- Outreach to CO stakeholders
 - Pharmacy commitments to offer imported products
 - Partnership with plans for coverage
 - Others: State employee program, Department of Corrections
- Additional programmatic planning with supply chain partners



QUESTIONS?

Contact us as at:

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For more information, please visit our
website:

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

