

# Colorado's Drug Importation Program

March 12, 2024



# Agenda

- Program Background
- Federal Requirements
- Supply Chain Overview and Partners
- SIP Updates
- Sourcing
- Program Next Steps
- Q & A



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# 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.

# Why Importation?

**86%**

of adults agree that lowering out-of-pocket health care costs should be a top priority for policymakers.

*PhRMA, 2023*

Brand name drugs, even with rebates and other discounts, are

**3x**

more expensive in the U.S.

*Rand, 2024*

In 2021,

**9.7%**

of Coloradans were unable to fill a prescription due to cost.

*Colorado Health Institute, 2022*



# 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 – effective November 2020

- States can begin applying to the FDA to operate state-led importation programs



# Importation Pillars

Pose no risk  
to the  
public's  
health and  
safety

Result in a  
significant  
reduction in  
the cost of  
covered  
products

Obtain and maintain federal approval



# Application Requirements

**A SIP proposal must provide detailed information about:**

- All partners in the supply chain
- All drugs intended for importation
- Compliance with federal safety rules/standards
- Cost savings analysis

*SIP will be approved for 2 year terms, with the option to request extensions from 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:

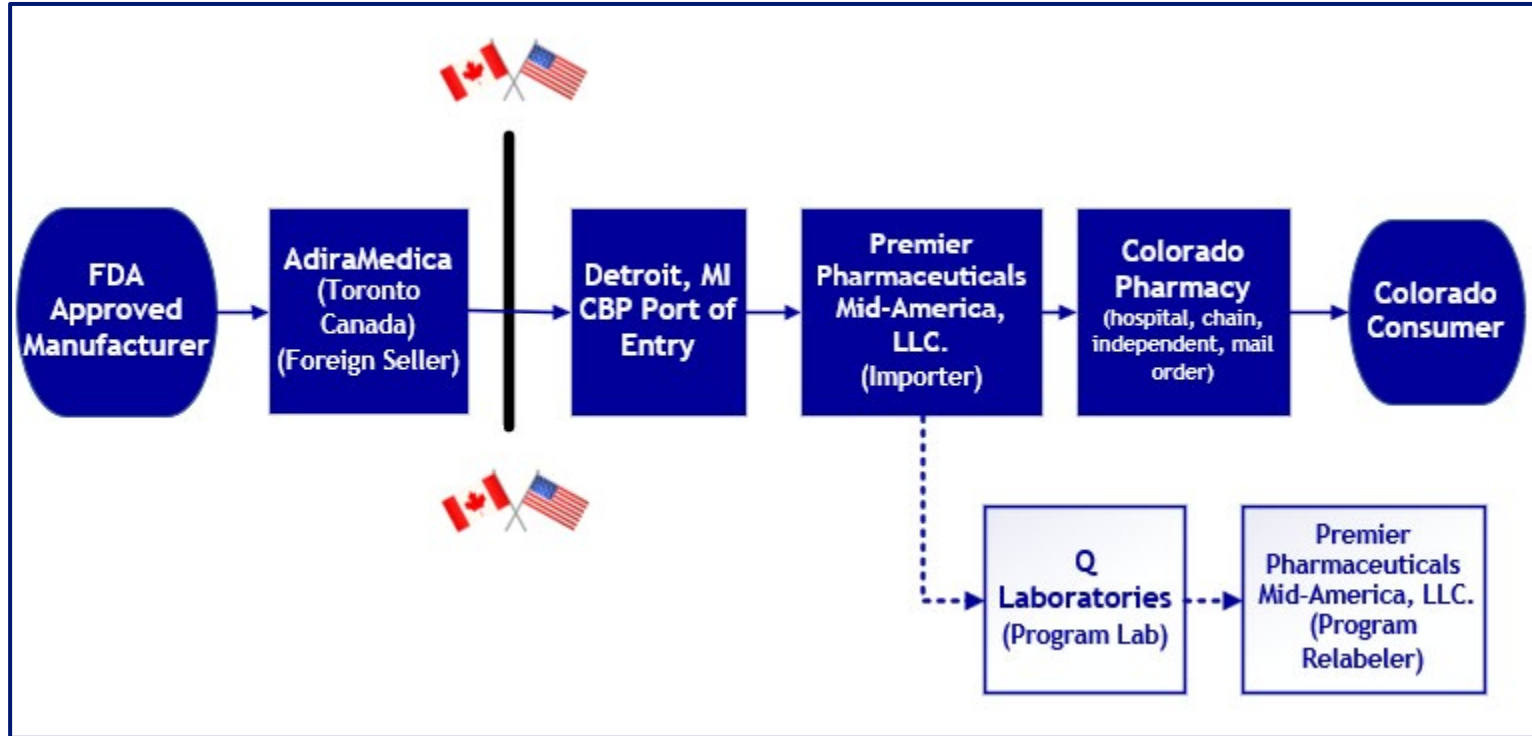
- FDCA: intravenous, infusion, controlled substances, biologics, drugs inhaled for surgery
- Importation Final Rule: REMS, intrathecal, and intraocular



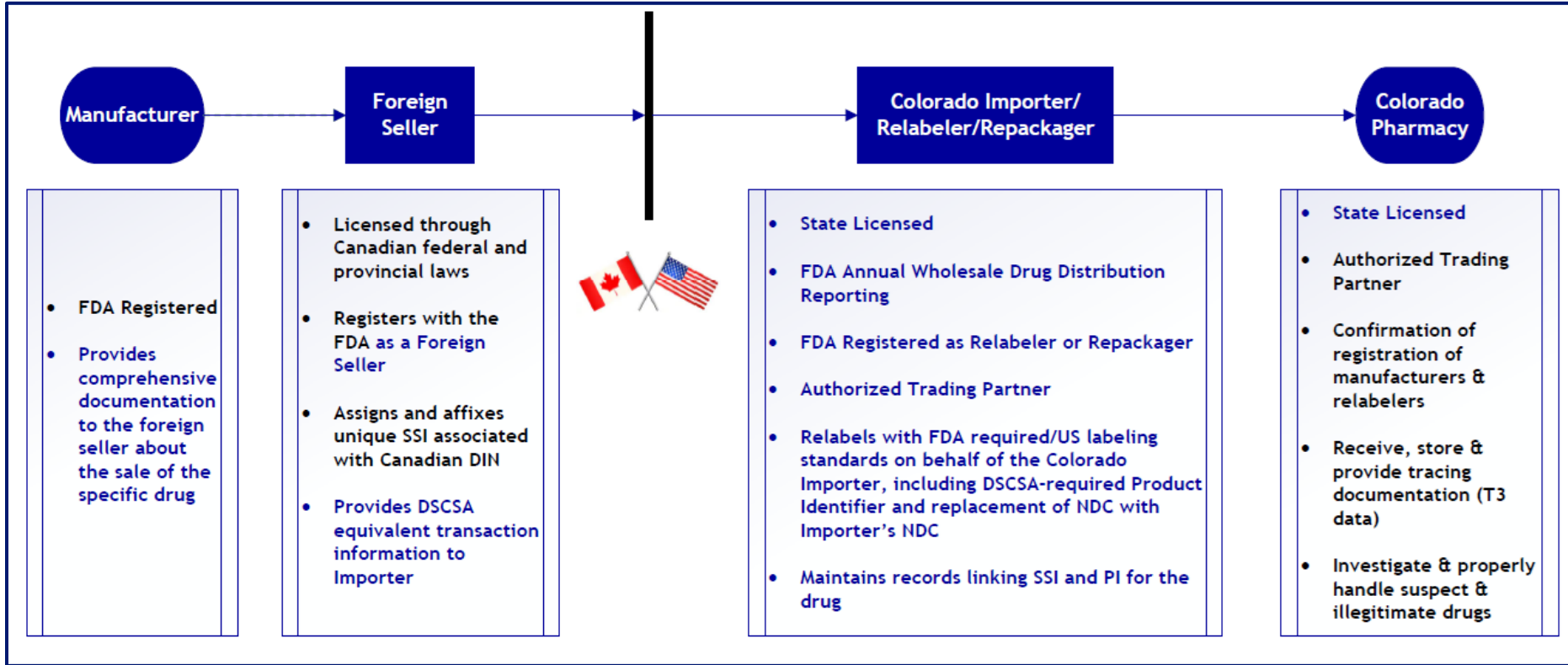
# Supply Chain Partners



# SIP Distribution Chain



# Supply Chain Security



# Oversight & Program Monitoring

- Regular reporting, audits, inspections
- Maintenance standards for physical space & security, SOPs, staff education and training
- Track and trace monitoring (DSCSA compliance)
- Return & Recall Detailed procedures
- 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

# Updated SIP- What's New?

1 Drug List

2 Cost Analysis

3 Relabeling

4 Compliance

5 Supply Chain

6 Reporting

# Identifying SIP Updates

Colorado's final drug list contains 24 unique drugs and dosages, including medications that treat a number of conditions including blood clots, cystic fibrosis, respiratory illnesses (COPD), cancer, type 2 diabetes, HIV, psoriatic arthritis, and rheumatoid arthritis. To secure drug supply for Colorado's SIP, the program's Foreign Seller, in collaboration with HCPF, will negotiate directly with manufacturers. The list presents high cost, high volume drugs using Colorado-specific data from our Colorado All Payer Claims Database (CO APCD). All of these medications have a significant impact on affordability to consumers in the state through employer health plans, state funded health care and benefit programs, individual health plans and to documented and uninsured individuals. These drugs are integral to the everyday lives of Coloradans, representing, in many cases, lifesaving solutions if lower prices can be achieved. This section complies with all Final Rule requirements regarding submission of a drug list, including §251.3(e)(1), (5)-(6).



# SIP Update 1: Drug List

- 24 unique drugs and dosages
- Treating conditions like: blood clots, cystic fibrosis, COPD, cancer, type 2 diabetes, HIV, and arthritis

# SIP Update 2: Cost Analysis

*§ 251.3(e)(9): Explain how the SIP Sponsor will ensure that the SIP will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs that the SIP Sponsor seeks to import. The explanation must include any assumptions and uncertainty, and it must be sufficiently detailed to allow for a meaningful evaluation.*

- Baseline Scenario vs. Plan Scenario
- Population and Cost Assumptions
- \$51 million in savings over the first 3 years



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# SIP Update 3: Relabeling

- Updates to:
  - package inserts
  - carton and container labeling
- Consistent with US labeling

# Original Label

**Biktarvy tablets**  
Each tablet contains 50 mg of bicitegravir (equivalent to 52.5 mg of bicitegravir sodium), 200 mg of emtricitabine, and 25 mg of tenofovir alafenamide (equivalent to 28 mg of tenofovir alafenamide fumarate).  
Store below 30 °C (86 °F) (see insert).  
Keep container tightly closed. Dispense only in original container.  
See package insert for dosage and administration.  
**KEEP OUT OF THE REACH OF CHILDREN**  
Manufactured for: Gilead Sciences, Inc. Foster City, CA 94404  
Made in Germany

NDC 61958-2501-1 30 tablets

**Biktarvy®**  
(bicitegravir, emtricitabine, and tenofovir alafenamide) tablets  
50 mg /200 mg /25 mg

© 2019 Gilead Sciences, Inc.

**Rx only**

Note to pharmacist:  
Do not cover ALERT box with pharmacy label.  
**ALERT: Find out about medicines that should NOT be taken with Biktarvy**

1007E206

Importer NDC

Product Identifier

# Importation Label

**Biktarvy tablets**  
Each tablet contains 50 mg of bicitegravir (equivalent to 52.5 mg of bicitegravir sodium), 200 mg of emtricitabine, and 25 mg of tenofovir alafenamide (equivalent to 28mg of tenofovir alafenamide fumarate).  
Store below 30 °C (86 °F) (see insert).  
Keep container tightly closed. Dispense only in original container. See package insert for dosage and administration.  
**KEEP OUT OF REACH OF CHILDREN**  
This drug was imported from Canada without the authorization of Gilead Sciences, Inc under the state of Colorado Section 804 Importation Program.  
Imported by: Premier Mid-America Pharmaceuticals, LLC 2231 Venture Drive Bowling Green, OH 43402  
Manufactured for: Gilead Sciences, Inc. Foster City, CA 94404  
Made in Germany

NDC 84098-001-30 30 tablets

**Biktarvy®**  
(bicitegravir, emtricitabine, and tenofovir alafenamide) tablets  
50 mg /200 mg /25 mg

© 2019 Gilead Sciences, Inc.

**Rx only**

Note to pharmacist:  
Do not cover ALERT box with pharmacy label.  
**ALERT: Find out about medicines that should NOT be taken with Biktarvy**

GTIN:  
EXP:  
LOT:  
S/N:  
90231001

Barcode

Statement regarding importation and address of importer



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# Additional SIP Updates

4 Compliance

5 Supply Chain

6 Reporting

# Sourcing Medications



Canadian Contract  
Clauses



Limited Supply  
Chain



Regulation Silence  
on Sourcing

# Next Steps



Await federal  
approval



Seek additional  
guidance on sourcing  
eligible drugs



Additional program  
planning with supply  
chain partners

# Questions?

Contact us as at:

[hcpf\\_005drugimportation@state.co.us](mailto:hcpf_005drugimportation@state.co.us)

For more information, please visit our website:

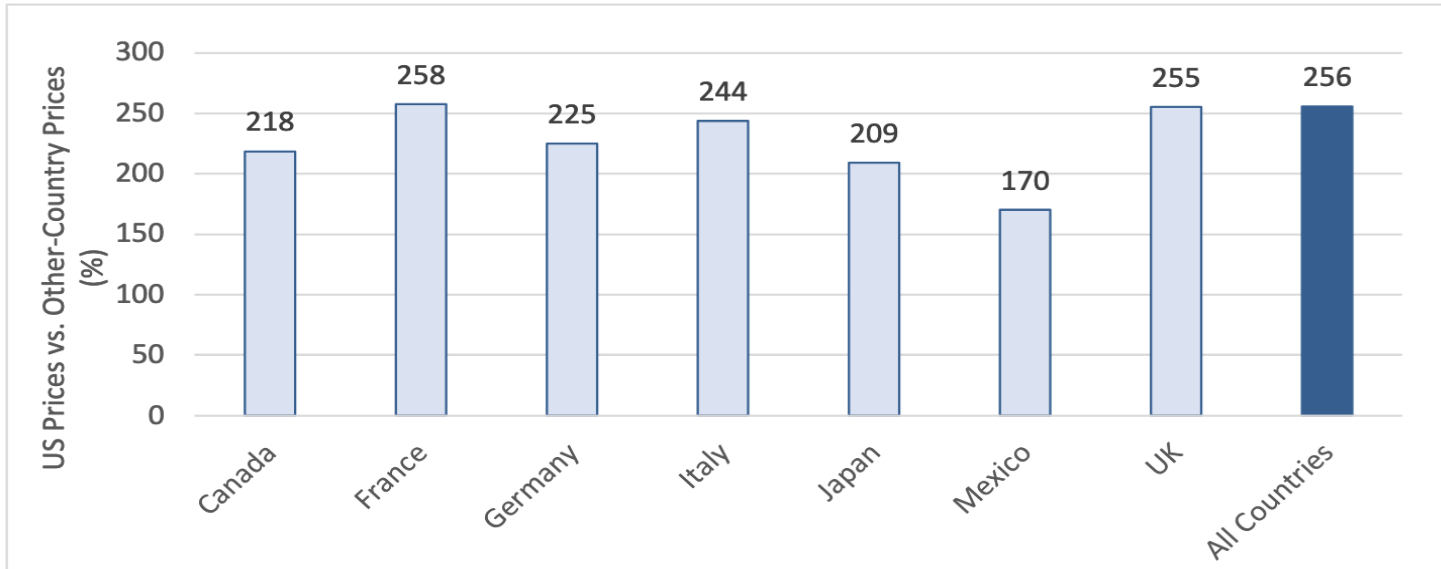
<https://www.colorado.gov/hcpf/drug-importation>



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# 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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# 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



# 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

# 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%
Colorado Department of Health Care Policy & Financing, 2022		

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
Colorado Department of Health Care Policy & Financing, 2022.				

