

# Colorado's Drug Importation Program



Colorado Retail Council & National Association of  
Chain Drug Stores

September 2, 2020

# Agenda

- Introductions
- Overview of legislative/regulatory framework
- Program rationale
- Colorado's Draft Section 804 Importation Program (SIP) overview
- Process Flow
- Questions for you
- Next Steps

# 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
  - Provides detailed requirements for participating State Importation Program (SIP) sponsors
  - CO submitted comments on the Proposed Rule as well as a draft SIP proposal
- Final Rule Release - TBD

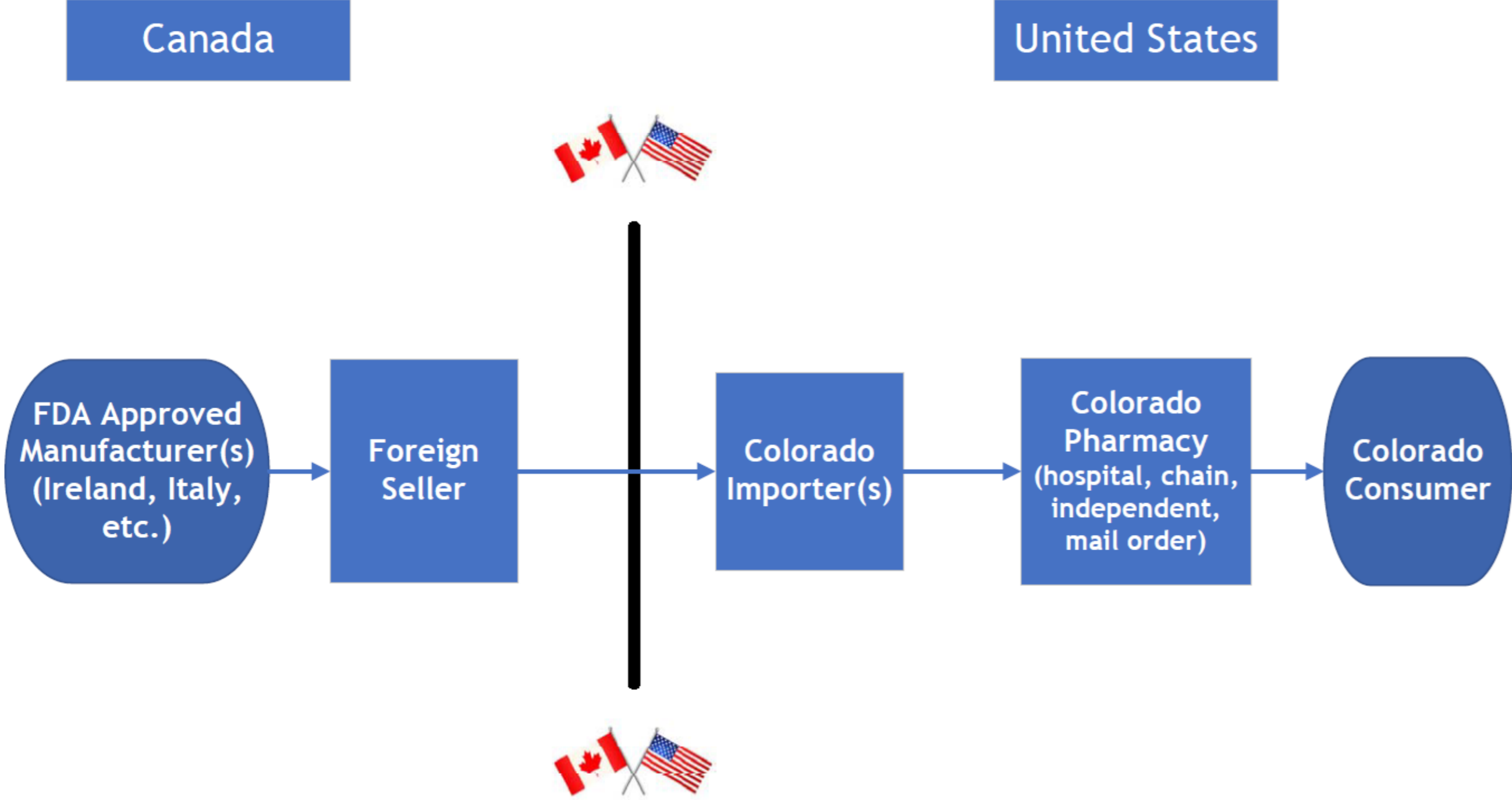
# Program Rationale

- Controlling drug costs is a major priority of the Polis Administration.
- Drug costs in CO total more than \$6 billion.
- Canadian importation is one lever among many that can change manufacturer behavior.

# Colorado's Draft SIP

- *Provides an estimated savings of \$36 to \$60 million per year for 167 imported prescription drugs--an average savings of 61% per drug.*
- *Leverages the existing regulatory framework in the U.S.*
- *Provides intensive state oversight across the distribution chain.*
- *Requests the final NPRM increase state flexibility to ensure significant cost savings.*

# What Will Drug Importation Look Like?

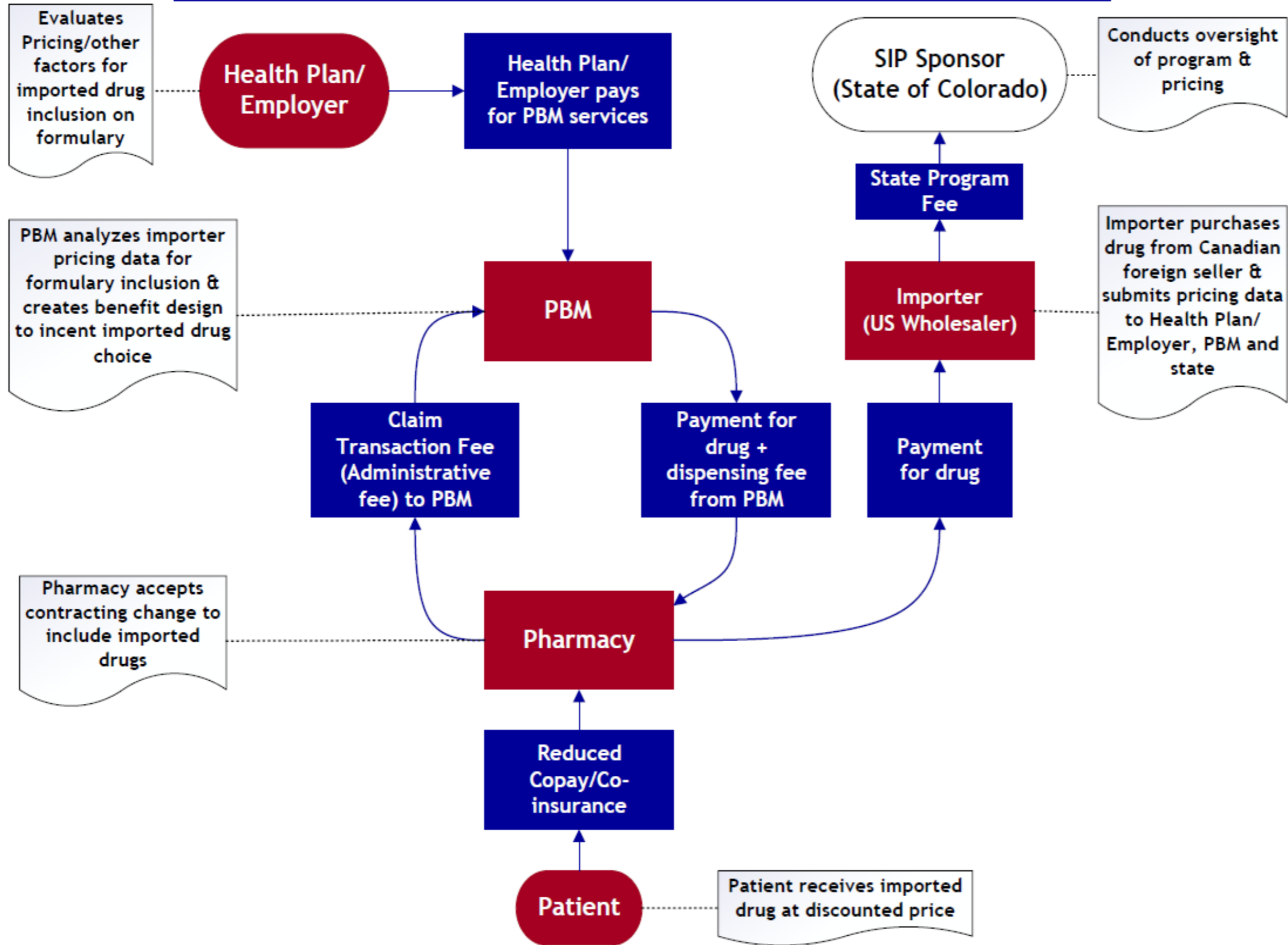


# Importation Savings Example: HIV

Drug Name	2019 CO Estimated Spend	% Difference
Biktarvy	\$29M	56%
Genvoya	\$33.5M	49%
Triumeq	\$13M	50%
Truvada*	\$31M	47%

Case Study: Truvada	
Brand Truvada	\$53.87/tablet (2019 in US) \$19.58/tablet in Canada (5/2020)
Generic Truvada	\$7.94/tablet in Canada (5/2020) 2019 CO total cost with CAN Generic: \$4.6M

**DRAFT: Colorado Drug Importation Proposed Process & Reimbursement Flow**





# Questions for Pharmacies

- How do your pharmacies get the best discount from their wholesaler?
  - Is it percent of generics purchased?
  - Is it total dollars spent/volume?
  - Both? Other?
- Your pharmacies may not have an existing contract with the importation wholesaler. How do your pharmacies manage new/secondary wholesaler contracts?
  - Is there a penalty? What can we do to ensure your pharmacies are protected from this issue?
- Would pharmacies need to adjust contracts with PBMs?

# Questions for Pharmacies, Cont.

- What systems/processes do your pharmacies to verify track/trace items from the DSCSA? Is there anything we need to consider for our program regarding this process?
- We have heard concern about double stocking. What is your perspective?
  - What could be done to mitigate the risk?
- What percent of patients pay out of pocket/cash for their prescriptions?

# Next Steps

- Our internal work:
  - Further refine the drug list
  - Further refine the supply chain mark-up
  - Analyze possible savings for state agencies
  - Evaluate Final Rule once released, make changes as needed
- With partners:
  - Continue stakeholder discussions to inform final SIP
    - Continue employer, plan, PBM, pharmacy conversations to refine, build support
  - Host public forums in line with COVID-19 guidelines

# Contact Info:

**Drug Importation Team**

[Lauren.Reveley@state.co.us](mailto:Lauren.Reveley@state.co.us)

[Kelly.Swartzendruber@state.co.us](mailto:Kelly.Swartzendruber@state.co.us)

[Mara@agohealth.com](mailto:Mara@agohealth.com)

Please visit our website:

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