The Pros and Cons of State Prescription Drug Importation Programs

May 17, 2024

Panelists

Dr. Aaron Kesselheim

Professor

Harvard Medical School

Rachel Cottle Latham

Director of State Policy

Pharmaceutical and Research Manufacturers of America (PhRMA)

Kelly Swartzendruber

Drug Importation Program Manager

Colorado Department of Health Care Policy and Finance

D.D. Pickle

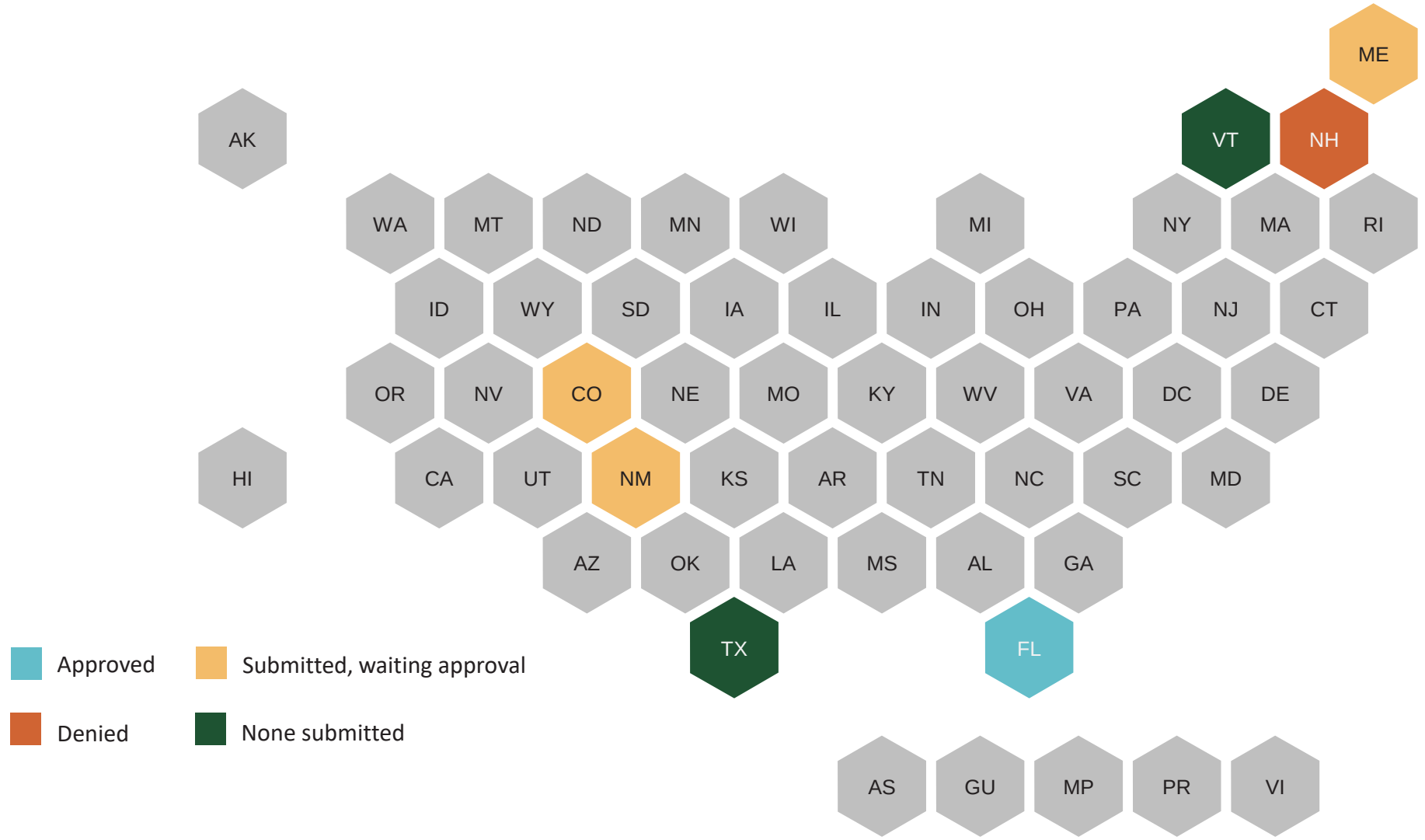
Program Director

Florida Agency for Health Care Administration

State Legislation

- Colorado (2019) SB 5 – Allows for the importation of drugs from Canada. (2021) SB 123 – Expands the importation program to include suppliers from other countries
- Florida (2019) HB 19– Allows for the importation of drugs from Canada and other countries as allowed by federal law.
- Maine (2019) LD 1272 – Allows for the importation of drugs from Canada.
- New Hampshire (2020) HB 1280 – Allows for the importation of drugs from Canada.
- New Mexico (2020) SB 1 – Allows for the importation of drugs from Canada and other countries as allowed by federal law.
- North Dakota (2021) SB 2212 – Established a workgroup to study to impact of a state importation program.
- Texas (2023) HB 25 – Allows for the importation of drugs from Canada and other countries as allowed by federal law.
- Vermont (2018) SB 175 – Allows for the importation of drugs from Canada.
- Virginia (2024) SB 186 – Newly passed legislation to establish a workgroup to examine the impact of a state importation program.

2024 State Drug Importation Programs - FDA Application Status



Division of
Pharmacoepidemiology & Pharmacoeconomics
Department of Medicine, Brigham & Women's Hospital, Harvard Medical School

Prescription Drug Importation by US States: Policy Landscape

Aaron S. Kesselheim, M.D., J.D., M.P.H.
Professor of Medicine, Harvard Medical School
Director, Program On Regulation, Therapeutics, And Law (PORTAL)
May 17, 2024

PORTAL
Program On Regulation, Therapeutics, And Law

What is PORTAL?/Disclosures

- Embedded within Division of Pharmacoepidemiology/Department of Medicine at Brigham and Women's Hospital/Harvard Medical School

- We study medication use and outcomes in terms of the clinical, regulatory, legal, and economic aspects of such use
  - Faculty have expertise in medicine, law, epidemiology, ethics
  - Post-docs and numerous students from across Harvard campus and beyond

- One of the largest and most prolific non-industry funded research centers in the US focused on these areas
  - No one in our Division has personal financial relationships with any pharmaceutical company
  - Current research funding from Arnold Ventures, Elevance Public Policy Institute, Kaiser Permanente Institute of Health Policy, FDA, Greenwall Foundation, Commonwealth Fund, NIH (NHLBI, NIA)

Policy dilemma

- Drugs are among the most effective and cost-effective interventions in cancer care

- Drug industry plays important role in bringing products forward, which can require substantial resources

HOWEVER…

- High drug prices can make breakthroughs unaffordable for many patients and payors, leading to major fiscal burdens and bad clinical consequences

Prescription Drug Spending in the US

- **$634 billion in 2022**
  - 1 of every 7 health care dollars
  - Driven by brand-name drugs, which account for 10% of prescriptions but 80% of spending

- International per capita comparisons
  - US: **$858**; avg 19 industrialized countries: **$400**

Kesselheim, Hwang, Avorn, JAMA 2020

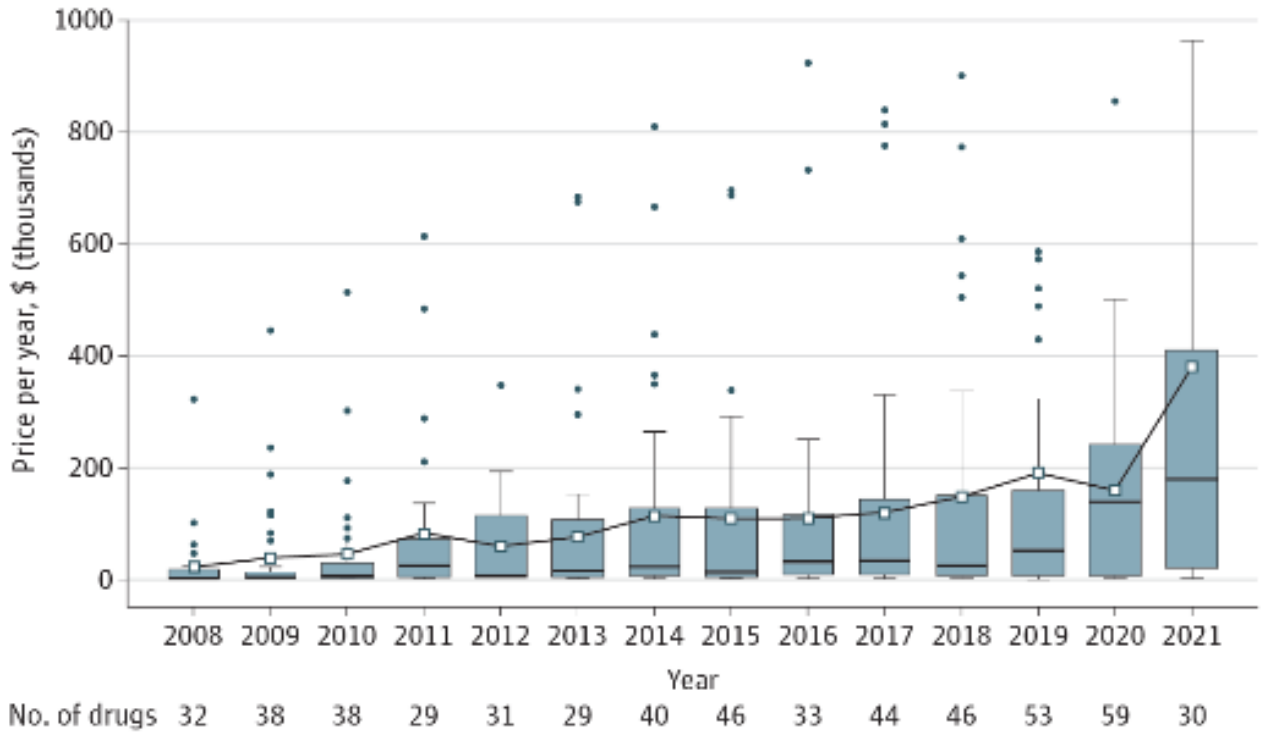
What has made drugs expensive in the US?

- Brand-name drug prices set freely by manufacturers at launch
  - Some payors have limitations on their ability to negotiate prices (e.g. Medicare prohibited by law from negotiating)
- After launch, brand-name manufacturers decide whether and how much to raise prices
- Once brand-name market exclusivity ends and generics/biosimilars enter the market, low prices are a function of adequate competition
  - Generic substitution estimated by IQVIA to save US health care system $1.67 trillion in the last decade
  - Shortages, other factors can lead to de facto monopolies and ability to raise prices

Kesselheim, Avorn, Sarpatwari, JAMA 2016

Brand-name launch prices increasing

- **↑20%/yr increase in launch prices**
- **↑ 11%/yr** after adjusting for rebates and drug characteristics (biologics, rare diseases, etc)
- **Median new drug cost**
  - 2008: $2,000/yr
  - 2021: $180,000/yr
  - 2023: $300,000/yr



Rome, Egilman, Kesselheim. JAMA. 2022.

Importation as a solution?

- **High prices lead to patient harm …**
  - Patients prescribed a costly branded product rather than a more affordable generic alternative adhere less well
  - **About 3 in 10** report not filling prescriptions or skipping doses due to cost (KFF tracking poll, July 2023)

- **… and excess health care spending**:
  - Strain budgets of payors, like Medicaid programs, which have to cut back on other essential services or change eligibility requirements

- In other high-income countries, like Canada, drug prices are negotiated shortly after launch and there are restrictions on subsequent annual price increases beyond inflation
  - Brand-name drug prices 2-4 times lower than in the US

- According to FDA, about 40% of drug product and 80% of drug active ingredients are already imported, so safe importation is possible

Legislative & Regulatory Background

Medicine Equity and Drug Safety Act of 2000 (MEDS Act)

- Added Section 804 to the FDCA to allow pharmacists and wholesalers to import prescription drugs directly from certain industrialized countries, including Canada.

Medicare Modernization Act of 2003

- Amended Section 804 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

… Looooooooooooong wait…

Safe Importation Action Plan (2019)

- Executive Order directing FDA to create importation pathway

Final Rule (November 2020)

- States can begin applying to the FDA to operate state-led importation programs
- 2 criteria: (1) Result in a significant reduction in the cost of covered productsand (2) Pose no risk to the public's health and safety

Florida certification (Jan 2024)

Policy discussions

- In favor
  - Can be done safely
  - Drugs still being sold at a substantial profit, but at a price that is more fair based on negotiation tied to the drug's clinical benefits
  - US patients are struggling

- Opposed
  - Brand-name manufacturers will respond by making it administratively challenging
  - Other countries may not want to risk disruptions to its drug supply chain

Importation for generic drugs

- FDA already certifies importation of generic drugs to address shortages (e.g., varenicline in 2022-2023, cisplatin for cancer)

- More than half the off-patent drugs with no generic competition in the US had at least one independent manufacturer approved by a non-US peer regulatory agency

- Facilitating US patient access to such manufacturers could help sustain affordable access to essential off-patent drugs

Gupta et al.. BMJ. 2018;
Bollyky & Kesselheim,
Vanderbilt Law Review, 2020

Thank you!

PORTAL
Program On Regulation, Therapeutics, And Law

PhRMA

Prescription Drug Importation: Tradeoffs & Alternative Policies

Rachel Cottle Latham
PhRMA

NCSL Webinar: The Pros and Cons of Prescription Drug Importation
May 17, 2024

Importation Poses a Serious Risk to Public Health

Importation could harm patients by introducing counterfeit, substandard or diverted, repackaged and adulterated drugs into the United States' secure drug supply chain.

1 in 10

medicines in low- and middle-income countries are substandard or falsified.

95%

of internet drug outlets have been found to be operating out of compliance with federal and state pharmacy laws and practice standards.

9 million

fraudulent medical devices and illicit pharmaceuticals were seized by Interpol in June 2021.

PhRMA

Safety Concerns Are Not Minimized By Restricting Import Sources to Canada

Canadian law does not prohibit the transshipment of drugs from any country—including those in developing countries—into Canada and then into the U.S.

What You Think Happens in Canada	*What Actually Happens in Canada*
	

PhRMA

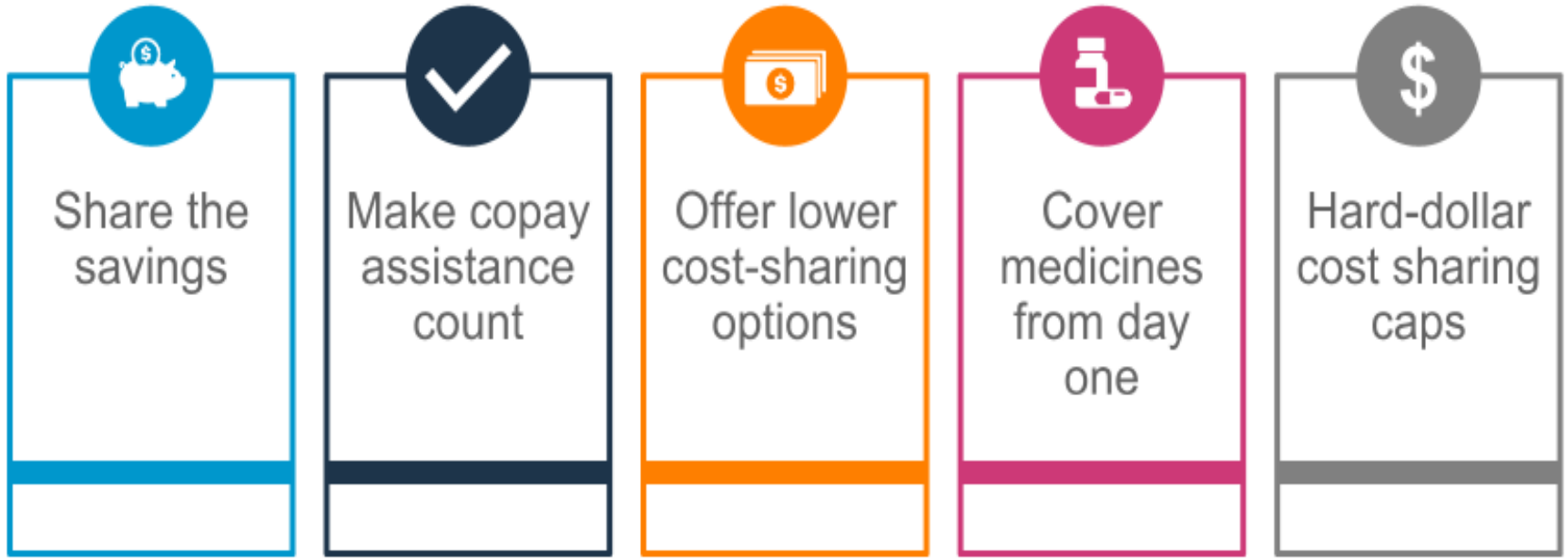
A State Importation Program is Unlikely to Produce Significant Cost Savings

Extensive state resources are required for the implementation and administration of an importation program.

- $ Startup Costs
- $ Ongoing Costs
- $ Compliance With Federal Law
- $ Law Enforcement Costs
- $ Public and Stakeholder Education

PhRMA

We Need to Take a Holistic Approach to Lowering Patient Costs While Supporting Medical Innovation



PhRMA

Thank You

Rachel Cottle Latham
RCottleLatham@phrma.org

Learn More at: PhRMA.org/Importation
PhRMA.org/BetterWay

PhRMA

Colorado's Drug Importation Program

May 17, 2024

COLORADO
Department of Health Care Policy & Financing

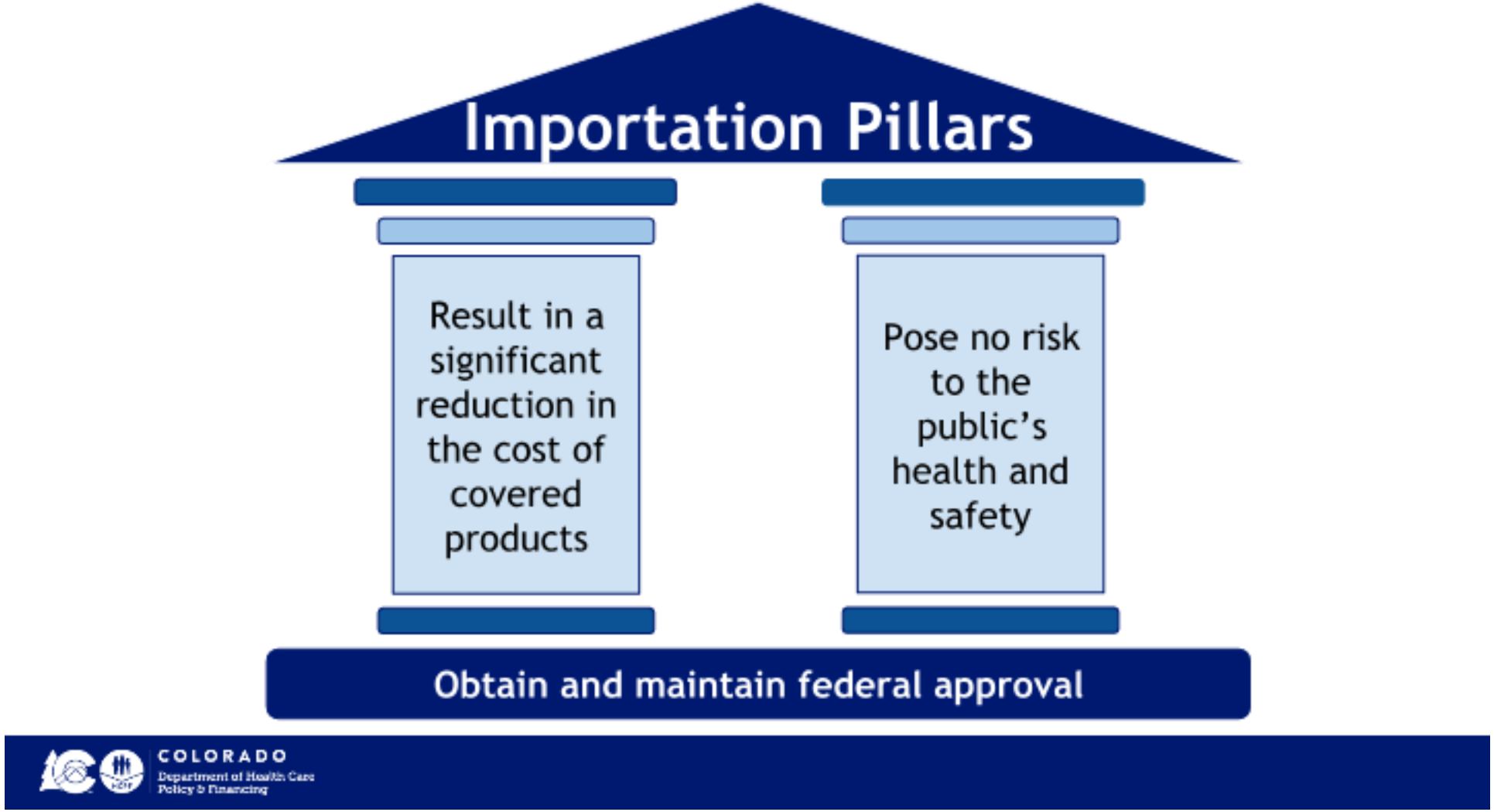
AGENCY FOR HEALTH CARE ADMINISTRATION
STATE OF FLORIDA

Agenda

- Market Population, Drug List & Savings
- Safety & Efficacy
- Supply Chain Overview and Partners
- Protecting Canada's Supply
- Legislative Advice - Other States
- Proposal Status (SIP) & Next Steps
- Importation References

COLORADO
Department of Health Care Policy & Financing

AGENCY FOR HEALTH CARE ADMINISTRATION
STATE OF FLORIDA


Importation Pillars
Result in a significant reduction in the cost of covered products
Pose no risk to the public's health and safety
Obtain and maintain federal approval
COLORADO
Department of Health Care Policy & Financing

Population, Drug List, Cost Savings

- **Market Population:** Commercial market with an emphasis on self-funded insured patients
- **Drug List Categories:** Brand name drugs treating conditions like blood clots, cystic fibrosis, COPD, cancer, type 2 diabetes, HIV, and arthritis
- **Actuarial cost analysis found $51 million in savings over the first 3 years**

COLORADO
Department of Health Care Policy & Financing

AGENCY FOR HEALTH CARE ADMINISTRATION
STATE OF FLORIDA

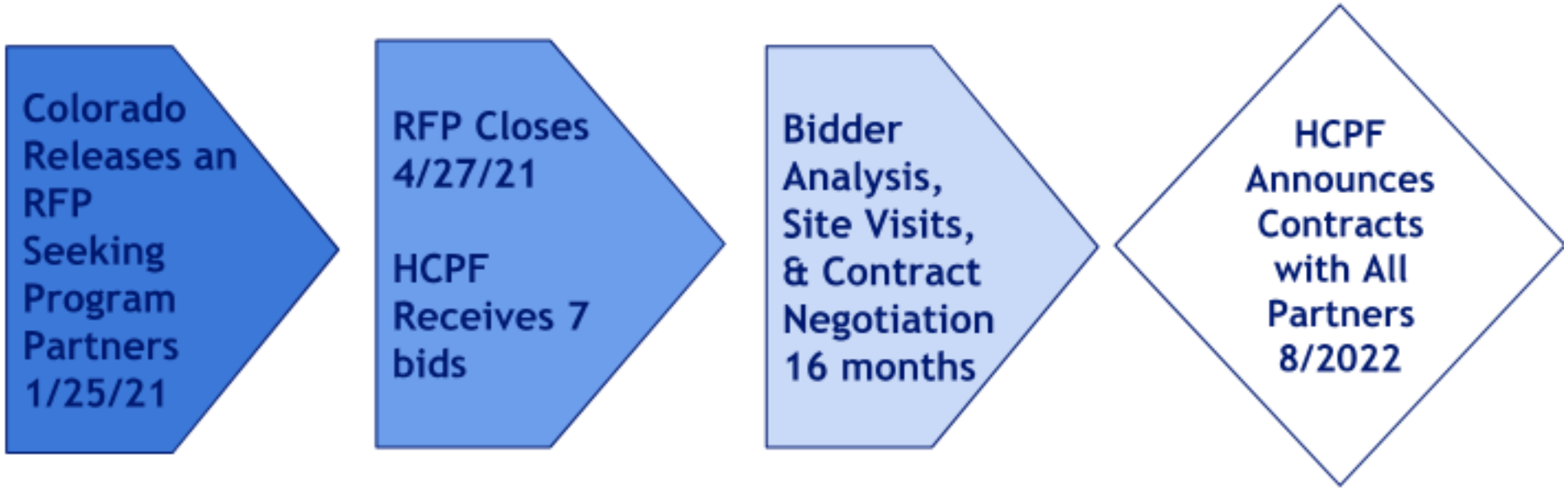
Safety: Oversight & Program Monitoring

- 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 Event Reporting

COLORADO
Department of Health Care Policy & Financing

AGENCY FOR HEALTH CARE ADMINISTRATION
STATE OF FLORIDA

Finding Partners: Colorado's Search



COLORADO
Department of Health Care Policy & Financing

AGENCY FOR HEALTH CARE ADMINISTRATION
STATE OF FLORIDA

Supply Chain Partners

AdiraMedica

Premier Mid-America

Q Laboratories

ROCKY MOUNTAIN POISON & DRUG SAFETY

Saving lives with answers.™

COLORADO
Department of Health Care Policy & Financing

AGENCY FOR HEALTH CARE ADMINISTRATION
STATE OF FLORIDA

Protecting Canada's Supply

Canadian Shortage Regulations

- 2021: Final shortage order
- 2024: Drug Establishment Licensing Bulletin

Colorado's Actions

- Advocating for federal diplomacy
- Regular contact with the Denver-based Canadian Consulate
- Program Foreign Seller Requirements

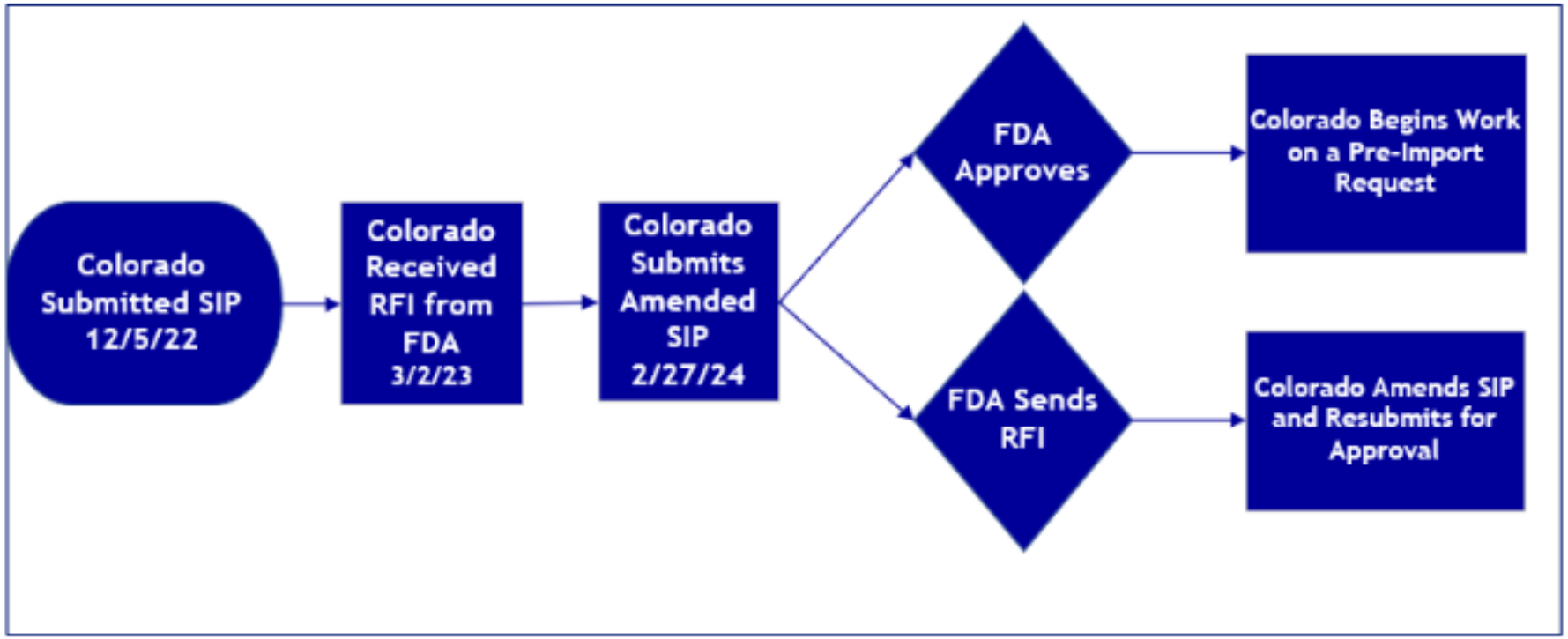
Legislative Lessons Learned

1. Flexible Procurement Process
    - Procurement rule exemptions
    - Soliciting Wholesalers
2. Ensuring Fiscal Support
    - Program FTE
    - SIP Development, Actuarial Cost Analysis, Expert Consultants, and other program needs

COLORADO
Department of Health Care Policy & Financing

AGENCY FOR HEALTH CARE ADMINISTRATION
STATE OF FLORIDA

Colorado's Program Status



Adapted from https://www.fda.gov/media/158068/download page 7

Next Steps

Await federal approval

Answer potential questions from FDA

Additional program planning with supply chain partners

COLORADO
Department of Health Care Policy & Financing

AGENCY FOR HEALTH CARE ADMINISTRATION
STATE OF FLORIDA

State Importation References

- Colorado Program Website: https://www.colorado.gov/hcpf/drug-importation
- Program Contact information: hcpf_005drugimportation@state.co.us

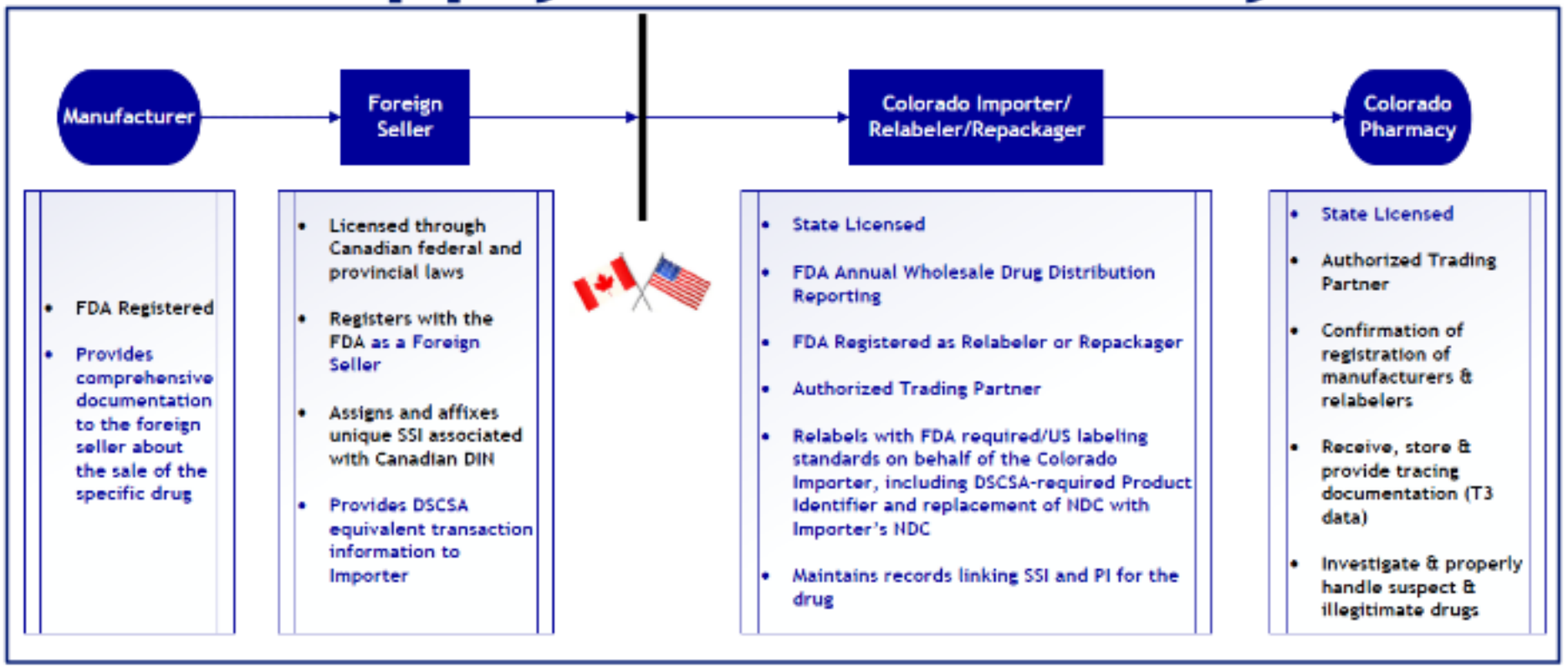
- Canadian Shortage Regulations
  - https://www.canada.ca/en/public-health/services/publications/drugs-health-products/guide-distributing-canadian-market-consumption-outside-canada.html
    - Finalized 11/28/2021
  - Drug Establishment Listing Bulletin Published 1/8/2024
    - https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/drug-establishment-licensing-bulletin/regulatory-requirements-prior-distributing-canadian-drugs-outside-canada.html

State Importation References Cont.

- Safe Importation Action Plan - 2019
  - https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf

- HHS/FDA References:
  - FDA Drug Importation Websites: https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-imports
  - https://www.fda.gov/about-fda/reports/importation-program-under-section-804-fdc-act
  - Importation Final Rule: https://www.hhs.gov/sites/default/files/importation-final-rule.pdf
  - FDA Final Rule Overview Presentation from NASHP All State Meeting 3/31/2022: https://www.fda.gov/media/158068/download
  - HHS Cost Savings Presentation from NASHP All State Meeting 3/31/2022: https://www.fda.gov/media/158564/download

Supply Chain Security



COLORADO
Department of Health Care Policy & Financing

AGENCY FOR HEALTH CARE ADMINISTRATION
STATE OF FLORIDA

Colorado's Drug List

- Biktarvy- HIV
- Eliquis 2.5mg - blood thinner
- Erleada - cancer
- Ibrance - cancer
- Janumet - type 2 diabetes
- Januvia - type 2 diabetes
- Odefsey - HIV
- Otezla - psoriasis
- Ozempic - type 2 diabetes
- Prezcobix - HIV
- Rinvoq ER 15mg - RA
- Spiriva Respimat 2.5 - respiratory
- Sprycel 100mg - cancer
- Symtuza - HIV
- Tivicay - HIV
- Trikafta - cystic fibrosis
- Triumeq - HIV
- Victoza - type 2 diabetes

Florida's Canadian Prescription Drug Importation Program

National Conference of State Legislatures

Devona "D.D." Pickle, Program Director

May 17, 2024

FLORIDA'S CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM

- In 2020, Florida developed a Section 804 Importation Program (SIP) proposal to import prescription medications from Canada for use in Florida.
  - Agency for Health Care Administration (AHCA) serves as the SIP sponsor. AHCA licenses and oversees health care facilities, administers the Medicaid program, and empowers consumers through health care transparency initiatives.
  - Department of Business and Professional Regulation (DBPR) serves as SIP co-sponsor. DBPR licenses and regulates businesses and professionals in the State of Florida.

WHO WILL RECEIVE IMPORTED DRUGS IN FLORIDA?

- Florida's Canadian Prescription Drug Importation Program (Program) will provide prescription medications to Floridians.

County Health Departments

State Prisons

State Mental Hospitals

Community & Forensic Programs for Persons with Disabilities

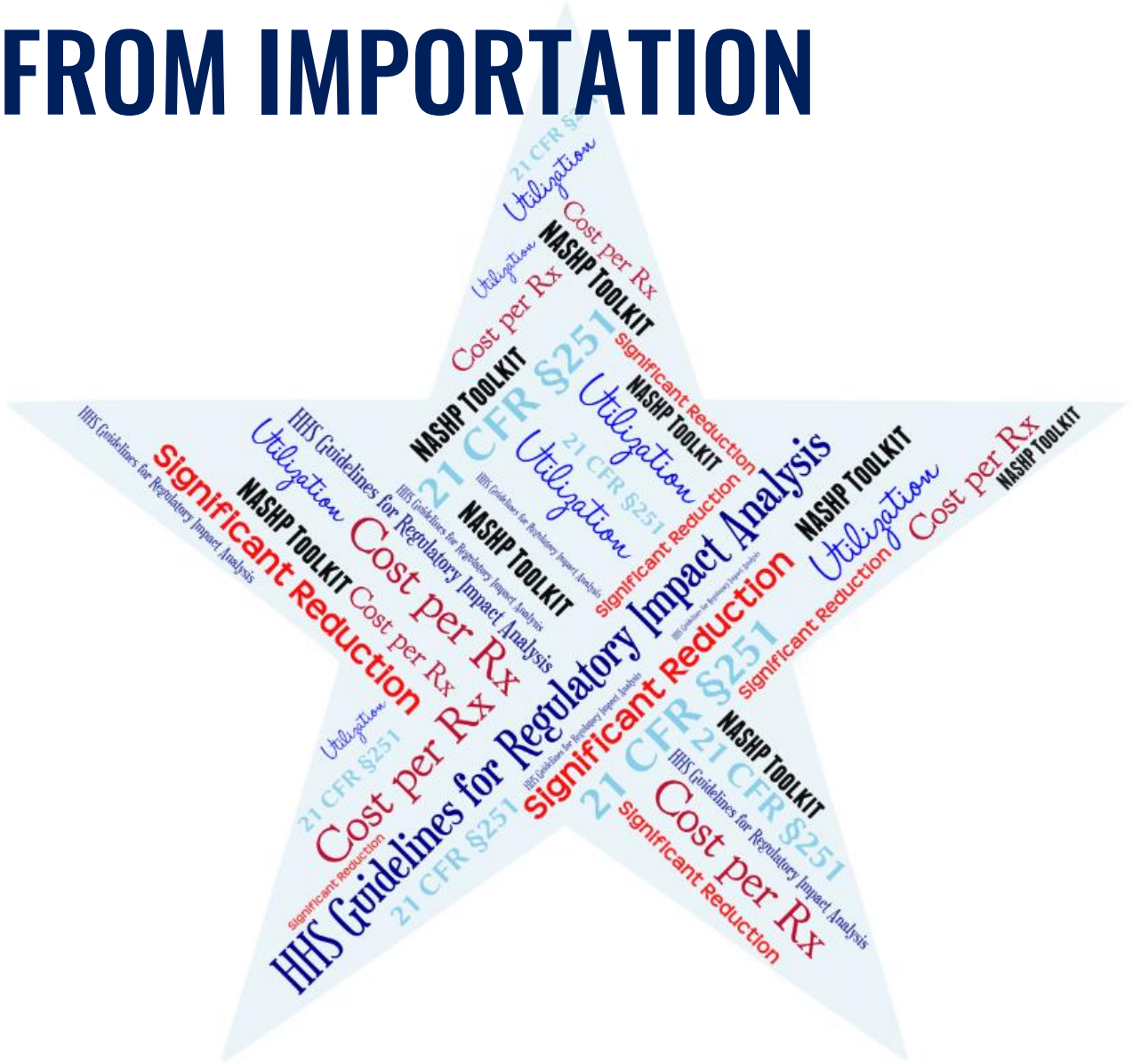
Medicaid Recipients

DRUGS FLORIDA SEEKS TO IMPORT

- Florida received authorization to import specific drugs in the following categories:
  - HIV/AIDS
  - Mental health
  - Cancer and metabolic disorders
- The State selected drugs from these categories because of their present utilization and the anticipated savings that can be attained by purchasing them at Canadian prices.

ANTICIPATED SAVINGS FROM IMPORTATION

- Florida could save up to $183 million in the first full year of implementation alone.
- This estimate is based on factors such as utilization, cost per prescription, and any rebates/discounts currently being received.



Resources:

https://wwwfda.gov/about-fda/reports/tips-sips

https://nashp.org/model-legislation-and-contracts-prescription-drug-pricing/

ENSURING DRUG SAFETY

- Prior to distribution in Florida, imported drugs will undergo laboratory testing and inspection to ensure safety and authenticity.
  - Every shipment must have samples tested by a qualified lab and the results verified by the U.S. Food & Drug Administration (FDA).
- Following FDA's admissibility decision, Florida must distribute the drugs in accordance with the Drug Supply Chain Security Act (DSCSA).
- Florida law requires that imported drugs must be stored in a dedicated Florida warehouse and may not leave the state.
- Florida has a monitoring plan that includes monthly and quarterly reviews, on-site monitoring, adverse event reporting, and a complaint monitoring and resolution process.
- Florida's sponsor and participating agencies will maintain open lines of communication supported by written interagency agreements.

Answers to Stakeholder Concerns About Drug Importation, Part 1

STAKEHOLDER CONCERNS	PROGRAM FACTS
X Counterfeit, substandard, or adulterated products will infiltrate the U.S. pharmaceutical supply chain.	✓ Each batch of imported Canadian drugs is **tested** in the U.S. by an FDA approved laboratory for **purity**, **potency**, and **authenticity**. The FDA must review and approve the test results before the imported drugs can enter the market.
X Imported medicines have no traceability and could be sourced online from anywhere.	✓ All SIP trade partners must comply with the U.S. **DSCSA**. A SIP U.S. importer will buy drugs **only** from the Canadian manufacturer.

Answers to Stakeholder Concerns About Drug Importation, Part 2

STAKEHOLDER CONCERNS	PROGRAM FACTS
X A majority of internet drug outlets have been found to be operating out of compliance with federal and state pharmacy laws and practice standards.	✓ The FDA reviews and approves credentials, disciplinary actions, and inspection histories for the foreign seller and importer to ensure all participants in the supply chain have a **history of compliance** with U.S. and Canadian regulations.
X Counterfeit drugs could contain dangerous impurities and differ from the real medicine in dosage, strength, or potency.	✓ Each batch of imported Canadian drugs is **tested** in the U.S. by an FDA approved laboratory for **purity**, **potency**, and **authenticity**.

FLORIDA'S NEXT STEPS AND FUTURE GOALS

- In January 2024, Florida received FDA approval of its Section 804 Importation Program (SIP) proposal.
- Florida is currently working to engage Canadian manufacturers and purchase drugs approved under the SIP proposal.
- Following implementation, the State will continue to explore importing additional prescription drugs that will yield savings and potentially expand the Program.

ADVICE FOR OTHER STATES

- Implementing a program requires both legislation authorizing its creation AND a recurring appropriation sufficient to meet all operating costs.
- To receive FDA approval of a SIP proposal, a state must have an importer and a foreign seller (i.e., Canadian wholesaler) under contract.
- The FDA's review process is time intensive. A complete SIP proposal is a tremendous document that has myriad components.

LOWER PRESCRIPTION COSTS

FOR FLORIDA

NCSL Resources

- State Drug Wholesale Importation Programs
- Prescription Drug Legislation Database
- Prescription Drug Policy Resource Center

Slides and a recording of this webinar will be available on the registration webpage after the webinar.

Thank you!

Colleen Becker

Project Manager

NCSL Health Program

Colleen.Becker@ncsl.org | **720-713-0298**