Drug Importation Stakeholder Update
Senate Bill 19-005

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Agenda

- Why Drug Importation?
- Legislative Framework for Drug Importation
- Importation timeline
- Program Feedback Process and Actions Taken
- Overview of the Process
- Key Proposal points
  - Program Costs/Profits
  - Consumer Savings
  - Quality and Safety
- Key Questions for stakeholders
- Next steps
- Final Questions

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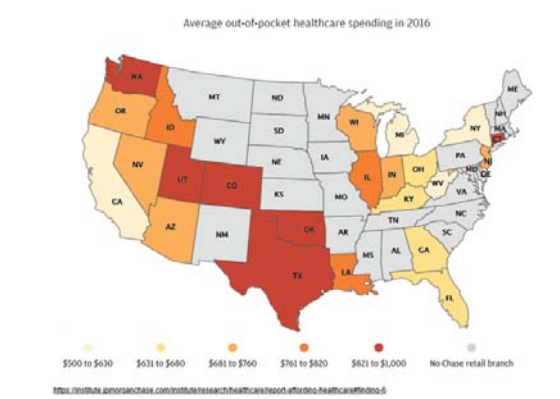
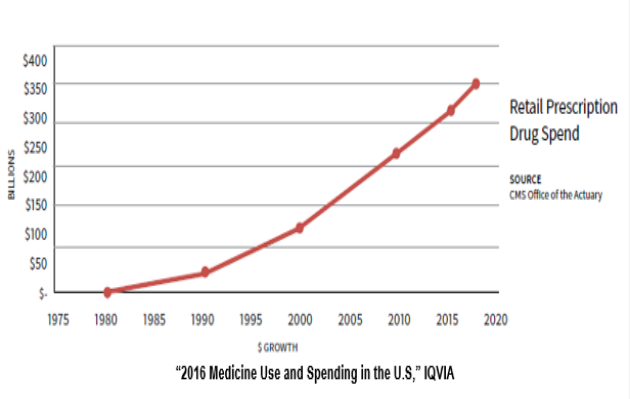
Why Drug Importation?





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Legislative Framework for Drug Importation

Federal Food Drug and Cosmetic Act (FDCA)

- Section 804 permits importation and reimportation of prescription drugs from Canada by a pharmacist or wholesaler, provided the drugs meet certain minimum standards. The Program must:
  - Pose no additional risk to the public's health and safety
  - Results in a significant reduction in costs to consumers
  - HHS must certify/approve a program to proceed

Senate Bill 19-005

Identify and contract with one/more vendors to develop a drug list, identify/facilitate contracts with participating suppliers and importers that meet safety and quality requirements and conduct safety assurance measures and other oversight processes

Several States looking at this:

- Colorado, Florida, Maine, Vermont, Utah

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Importation Project Timeline

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Process overview

- **Program Framework**
  - Positive consumer impact
  - Ensures safety
- **HCPF Oversight**
  - Division of Drug Importation within Pharmacy Office
  - Drug List development, profit margins, program costs
  - Ultimate responsibility for the program
  - Vendor contract
    - Program Oversight
    - RFP Process

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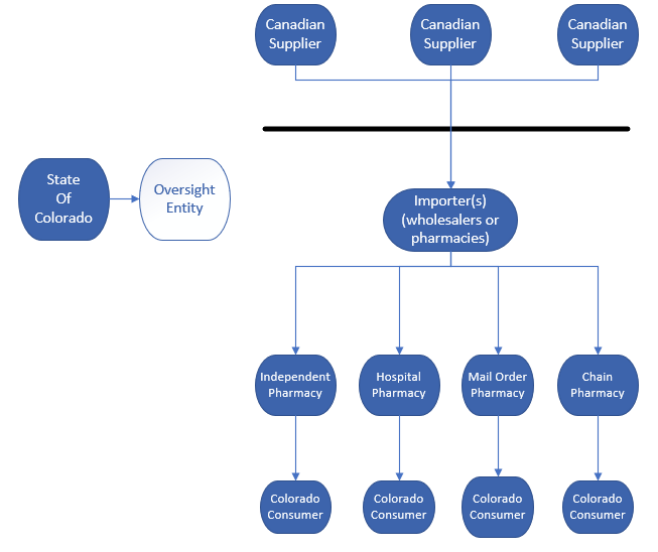
Overview of the Process

- Importer or importers
- Patients could receive CAN drugs from a choice of pharmacies



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Key Proposal Points: Program Costs/Profits

- SB19-005 Requirements:
  - Profit margin on imported drugs can't be more than profit margin of the US versions of the same drugs
  - Program costs can include a fee but that fee can't significantly reduce consumer savings
- Supply chain mark-up of 45% (from Canadian acquisition costs)
  - Repackaging/Relabeling
  - Testing
  - Records/Recall Management/Profit to supply chain
    - Wholesalers
    - Pharmacies

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Key Proposal Points: Consumer Savings
Drug List Details

- Excluded drugs from Importation include:
  - Generic products that would violate U.S. patent laws
  - Controlled substances
  - Biologics (will include insulin starting in March 2020)
  - Infused drugs
  - Intravenously injected drugs
  - Drugs inhaled during surgery
  - Parenteral drug
- Suggested drugs types for importation include:
  - High cost brand name drugs
  - High volume drugs
  - Drugs with US shortages

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Key Proposal Points: Consumer Savings
Drug List Details, Cont.

- Initial Drug List Parameters
  - Total cost of the drug (copay and plan)
    - Total charge for ages 19-64
  - Total member liability (all ages)
  - Volume of Prescriptions number of patients
  - Patent law rules
- Drug List **Examples** - **DRAFT**
  - Asthma (Breo Ellipta, Dulera, Advair Diskus, Ventolin HFA)
  - HIV (Atripla, Triumeq, Truvada)
  - Epi-Pen & Epi-Pen Jr.
  - Hormones (Estring, Premarin Cream, Synthroid)
  - Misc.: Invokana, Ibrance, Gilenya

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Key Proposal Points: Quality & Safety
Program Requirements

- Compliance with DSCSA
  - Track and Trace requirements from manufacturer to dispenser of the medication
  - Requires serialization once enacted
- Private Label Distributor Concept
  - State of Colorado to become a Private Label Distributor
  - No manufacturing/processing
  - Markets and Distributes under it's own trade name
  - Labels drug to be compliant with FDA requirements
  - Can be state OR a contractor hired by the state

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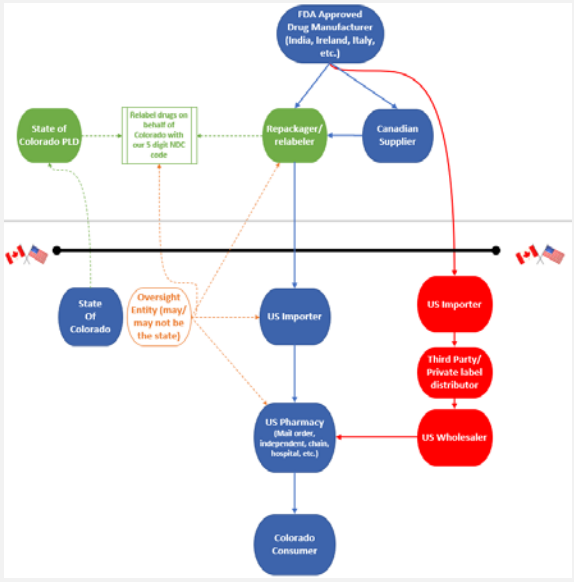
Key Proposal Points: Quality & Safety, Cont.
Private Label Distributor



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Next Steps: Drug Importation

- Collate feedback
- Use feedback to add detail to the program at all levels
- Create Initial Application to HHS
  - Send to HHS by 1/15/20
- For more information:
  - https://www.colorado.gov/hcpf/drug-importation
    - In-box for questions
    - Sign-up form for updates about the program

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References

- https://institute.jpmorganchase.com/institute/research/healthcare/report-affording-healthcare#finding-6
- "2016 Medicine Use and Spending in the U.S.," IQVIA
- Federal Food Drug and Cosmetic Act (FDCA), Section 804
- Colorado Senate Bill 19-005 https://leg.colorado.gov/sites/default/files/2019a_005_signed.pdf
- https://uscode.house.gov/view.xhtml?req=(title:21%20section:384%20edition:prelim)
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- NASHP (National Academy of Health State Policy)

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