Drug Importation Stakeholder Update
Senate Bill 19-005

Presented by:
Kelly Swartzendruber, PharmD, Drug Importation, Health Care Policy & Finance

Agenda

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

**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
Overview of the Process

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

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
Key Proposal Points: Consumer Savings
Drug List Details

• Excluded drugs from Importation include:
  o Generic products that would violate U.S. patent laws
  o Controlled substances
  o Biologics (will include insulin starting in March 2020)
  o Infused drugs
  o Intravenously injected drugs
  o Drugs inhaled during surgery
  o Parenteral drug

• Suggested drugs types for importation include:
  o High cost brand name drugs
  o High volume drugs
  o Drugs with US shortages

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

• Initial Drug List Parameters
  o Total cost of the drug (copay and plan)
    ■ Total charge for ages 19-64
  o Total member liability (all ages)
  o Volume of Prescriptions number of patients
  o Patent law rules

• Drug List Examples - DRAFT
  o Asthma (Breo Ellipta, Dulera, Advair Diskus, Ventolin HFA)
  o HIV (Atripla, Triumeq, Truvada)
  o Epi-Pen & Epi-Pen Jr.
  o Hormones (Estring, Premarin Cream, Synthroid)
  o Misc.: Invokana, Ibrance, Gilenya
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

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

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://www.accessdata.fda.gov/cder/sb-drls/topic2/topic2/da_01_02_0050.htm
• https://www.gao.gov/assets/690/681689.pdf
• http://www.worldstopexports.com/international-markets-for-imported-drugs-by-country/
• https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance
• FDAimports.com
• NASHP (National Academy of Health State Policy)