

# SB 1: Prescription Drug Importation Program Update

Interagency Pharmaceutical Purchasing Council

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# Goals of Senate Bill 1

## “Wholesale Drug Importation Act”

- Provide a state pathway to safe, effective, more affordable medications by importing them from countries that have lower-priced drugs
  - Reduce consumer costs, reduce state costs

## Types of medications

- High cost medications, but not biologics or controlled substances

## Safety and Effectiveness Safeguards

- State must meet FDA safety/efficacy standards
- State must comply with federal law on tracking and tracing
- Regular audits on program compliance

## Partner countries

- Canada
- Other countries if authorized by the FDA

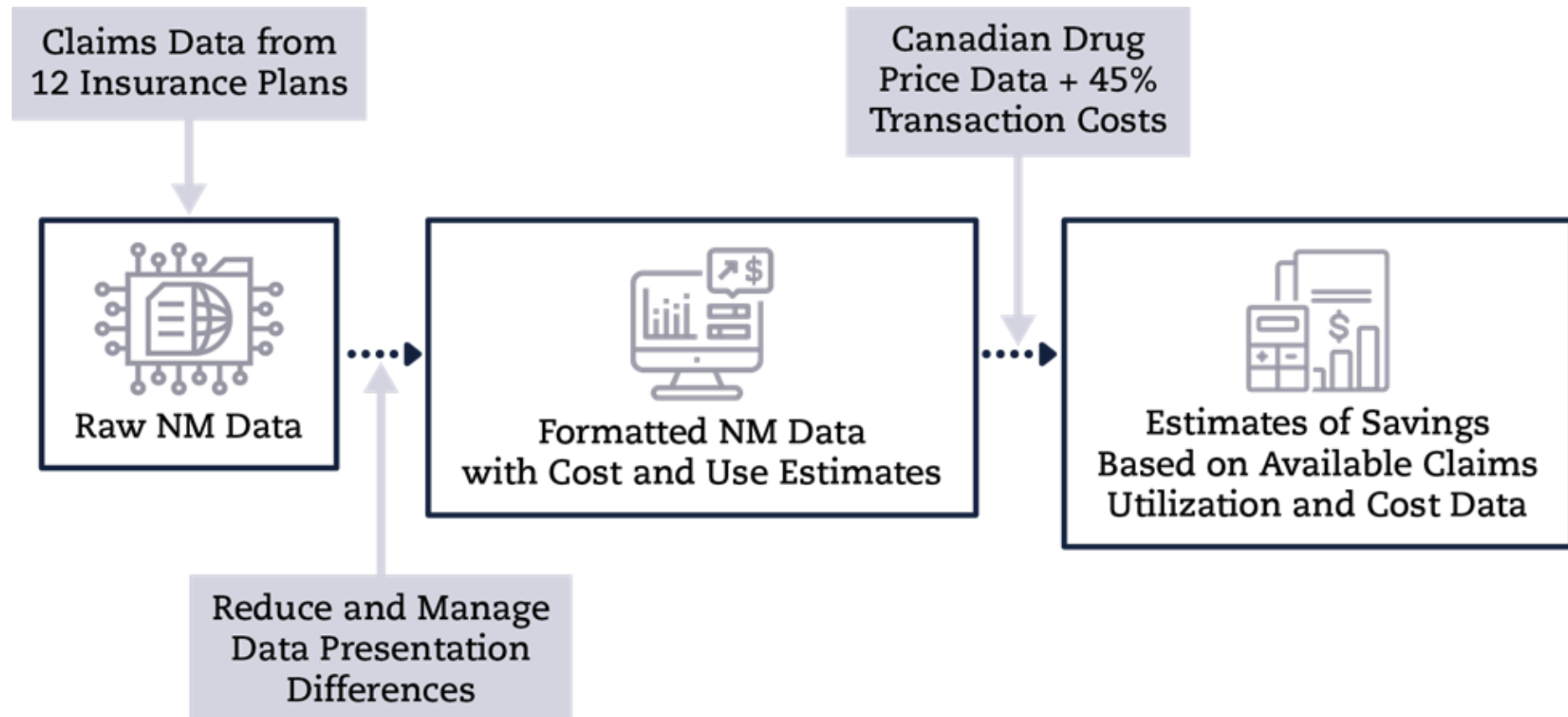
## Populations who may benefit

- Individuals with private insurance
- State employees and institutional purchasers
- Taxpayers
- The Uninsured

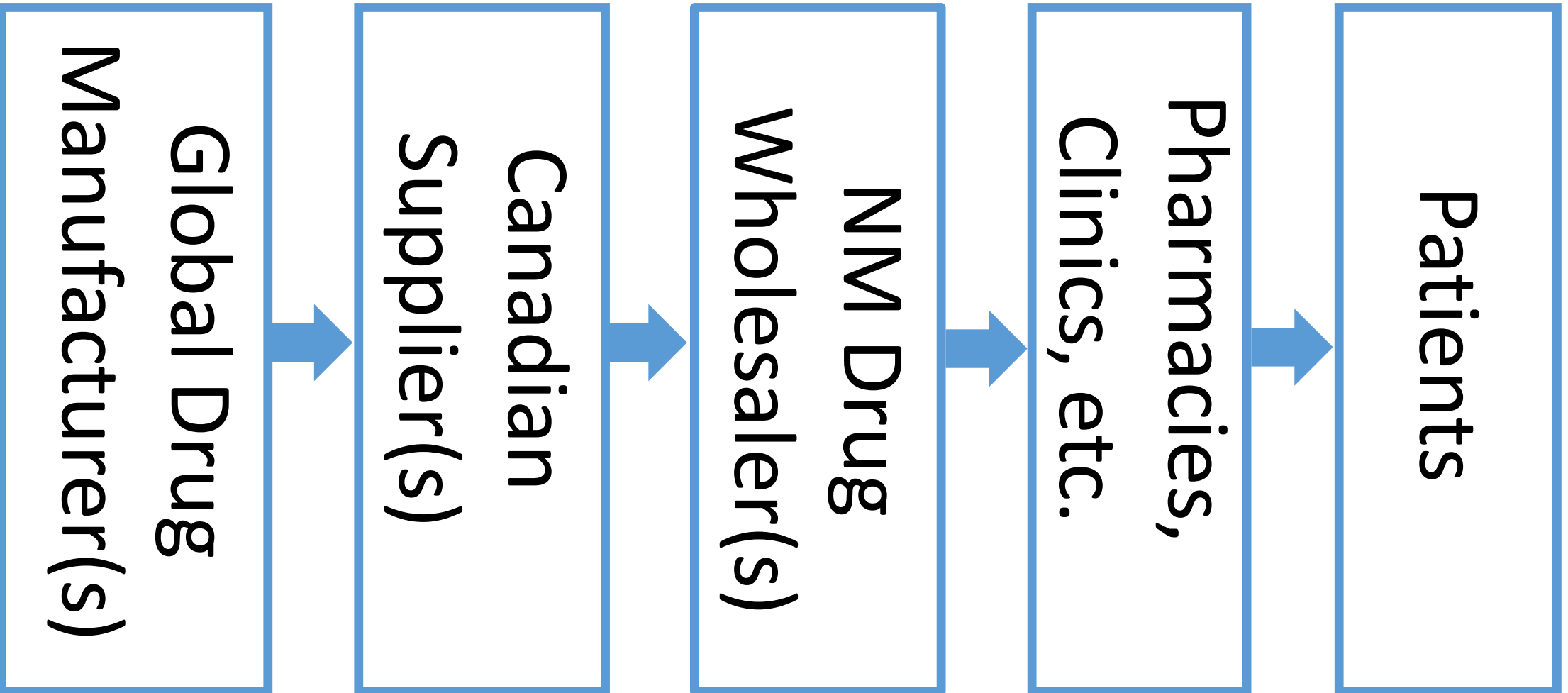
## State agencies involved

- DOH
- Advisory Committee: DOH, OSI, HSD, GSD, Board of Pharmacy

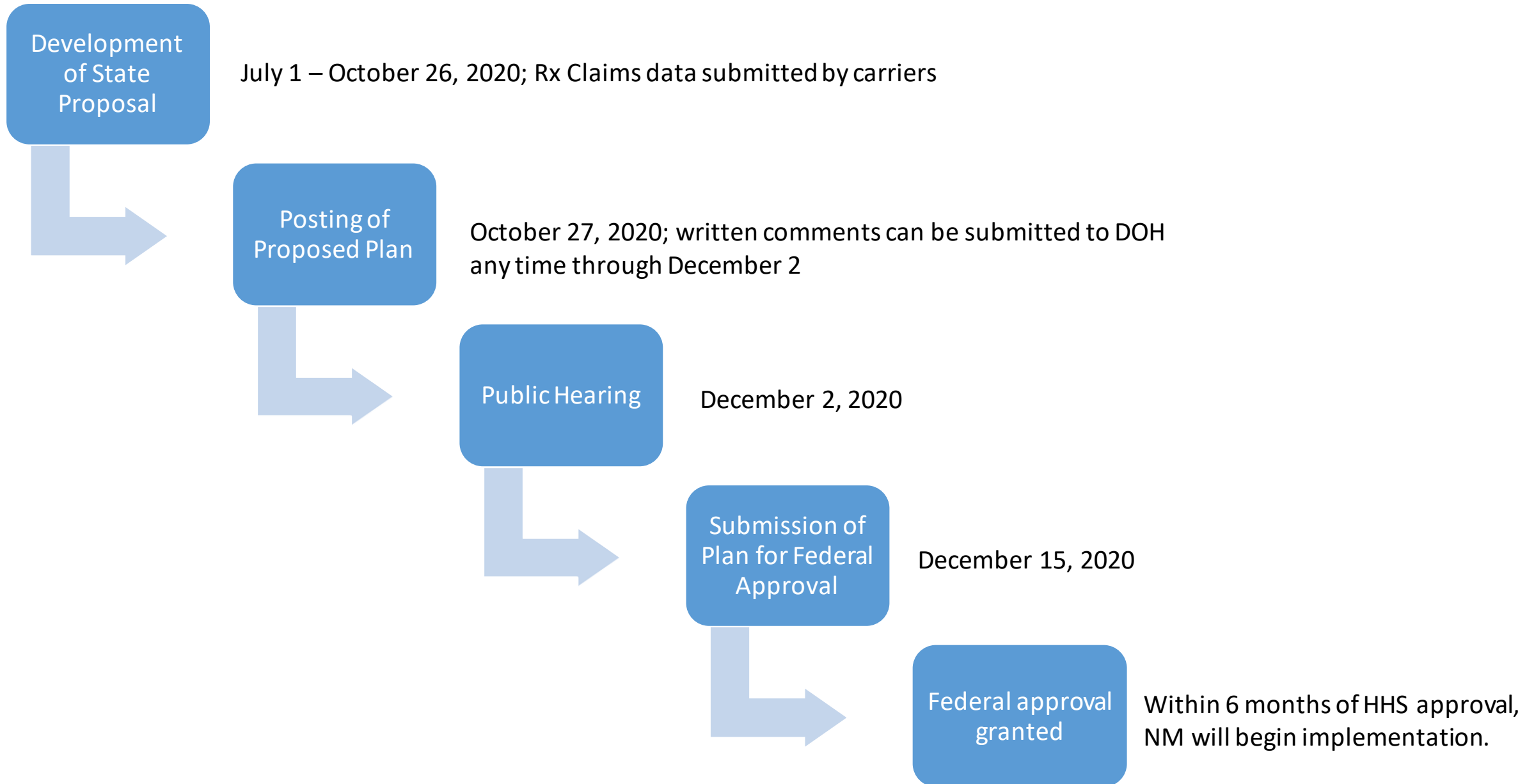
# Flow Diagram of Importation Cost-Savings Analysis



# SB 1 Supply Chain To Mimic Existing Flow



# Timetable



# Implementation

- Within 6 months of HHS approval, NM DOH must begin implementation.
- SB 1 outlines the requirements that must be addressed on implementation.
- The Wholesale Prescription Drug Importation Fund will be created as a non-reverting fund in the state treasury.
- DOH must submit an annual report to the Governor and Legislature about the operation and impact of the program.

# Importation: Federal Law

- **In general**, importing Rx into the US is not legal except under the control of the original manufacturer, except as follows:
  - **Personal:** The FDA does not enforce the law for importation of drugs for individuals when quantity  $\leq 90$  pills
  - **Wholesale:** With Federal DHHS Secretarial approval, allows importation of wholesale quantities of drugs from Canada by wholesalers or pharmacies if safe and consumer savings are guaranteed
    - Biologics (including insulin and vaccines) excluded from importation by law
    - Imports only from Canada allowed
- In general, ~70% of US Rx supply is imported already by manufacturers. Federal law and regulation establish a safe, transparent, global supply chain that state wholesale import programs would use. Proposed regulation tries to add more requirements to wholesale importation that are not needed and make state importation very difficult on several levels.

# Importation: Final Regulation

- Federal Proposed Rule, 12/2019, Final Rule 9/24/2020.
  - Rule establishes requirements for federal approval of an import program
    - Program must be overseen by a state government – we are working with the BOP on a co-sponsored program
      - Two year approval periods
      - Program terminated for any infraction – no corrective action
    - Pharmaceuticals *licensed and labeled* for Canadian market
    - Foreign Seller (~Canadian wholesaler) registered with FDA
      - Only 1 foreign seller per state
    - Import packaged products (not bulk quantities)
    - Batch testing after purchase and before labeling for US market, on US soil, by lab with FDA testing history
    - Phased federal application approval – Foreign seller vendor can be identified within 6 months of conditional application approval. State application must name rest of supply chain
    - Program requires manufacturers to provide certain data and records to the State
    - Flexibility to calculate consumer savings

# The Basics of State Wholesale Importation

- Price through the supply chain based on imported price
- Imported price is publicly available
  - Consumers know what price to expect
  - Carriers know what to pay
- Import price should be basis of claims payment
- Import price should be basis of insured's cost sharing or out of pocket if uninsured
- Only prescription drugs with Canadian price that produce net savings should be imported

# The Basics

- Imports tested prior to distribution in NM
- Imports relabeled to FDA specifications
  - including NDC for billing and payment purposes
  - State will be the manufacturer/labeler of record
- Imports stay in NM for safety assurance
- There are no US manufacturer rebates on imported products

# Take- Away...

- Despite having developed a Drug Importation Program, we interpret the final rule to limit the implementation of these programs for states
- There is much uncertainty given the eventual shift in administrations and policy priorities
- We have joined several states in passing legislation to reduce the cost of prescriptions in light of the federal government taking no action. This momentum is valuable
- We have learned a great deal about our New Mexico population and ways to deliver these savings
- This a valuable and foundational step for any future proposals seeking to limit the cost of these drugs to NM consumers