# SB 1: Prescription Drug Importation Program

10/13/2020

# Goals of SB 1

- Provide a path 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

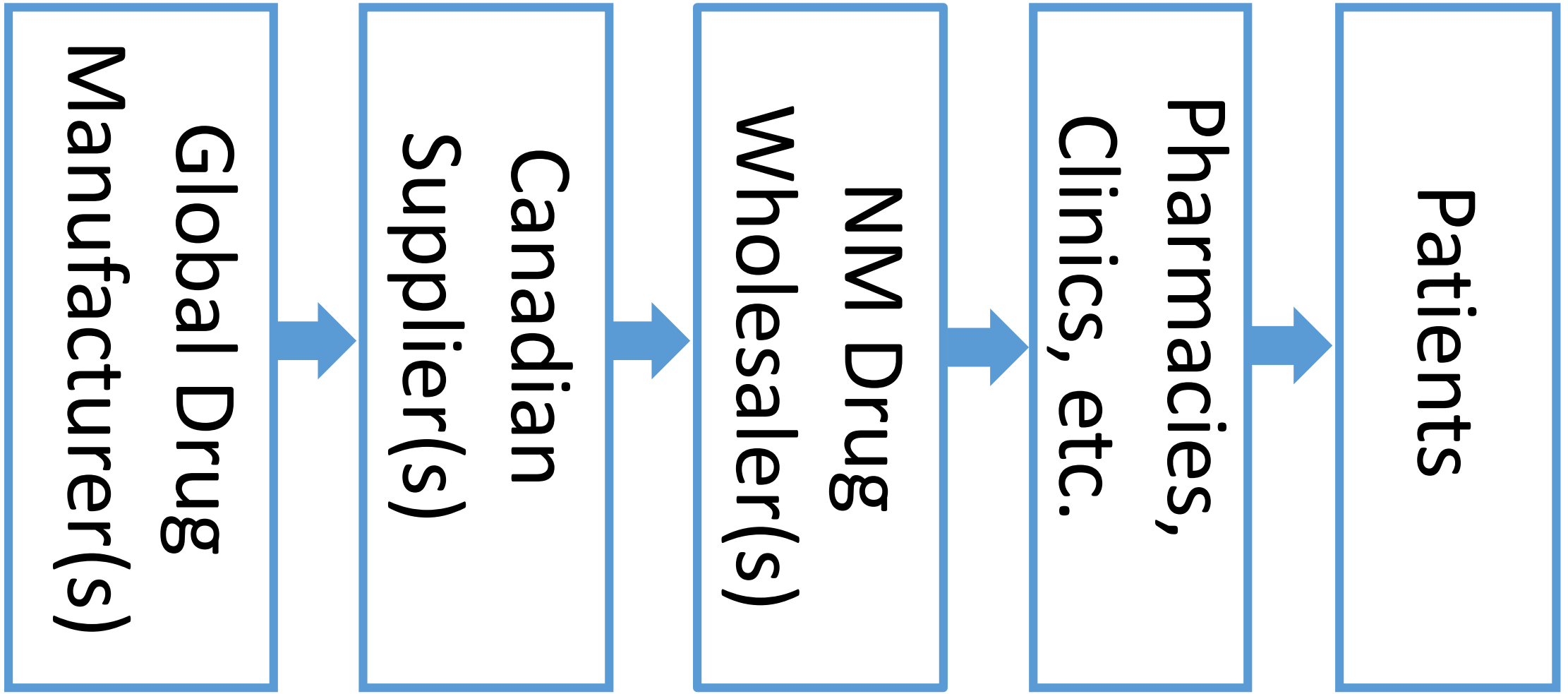
# Populations who may benefit

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

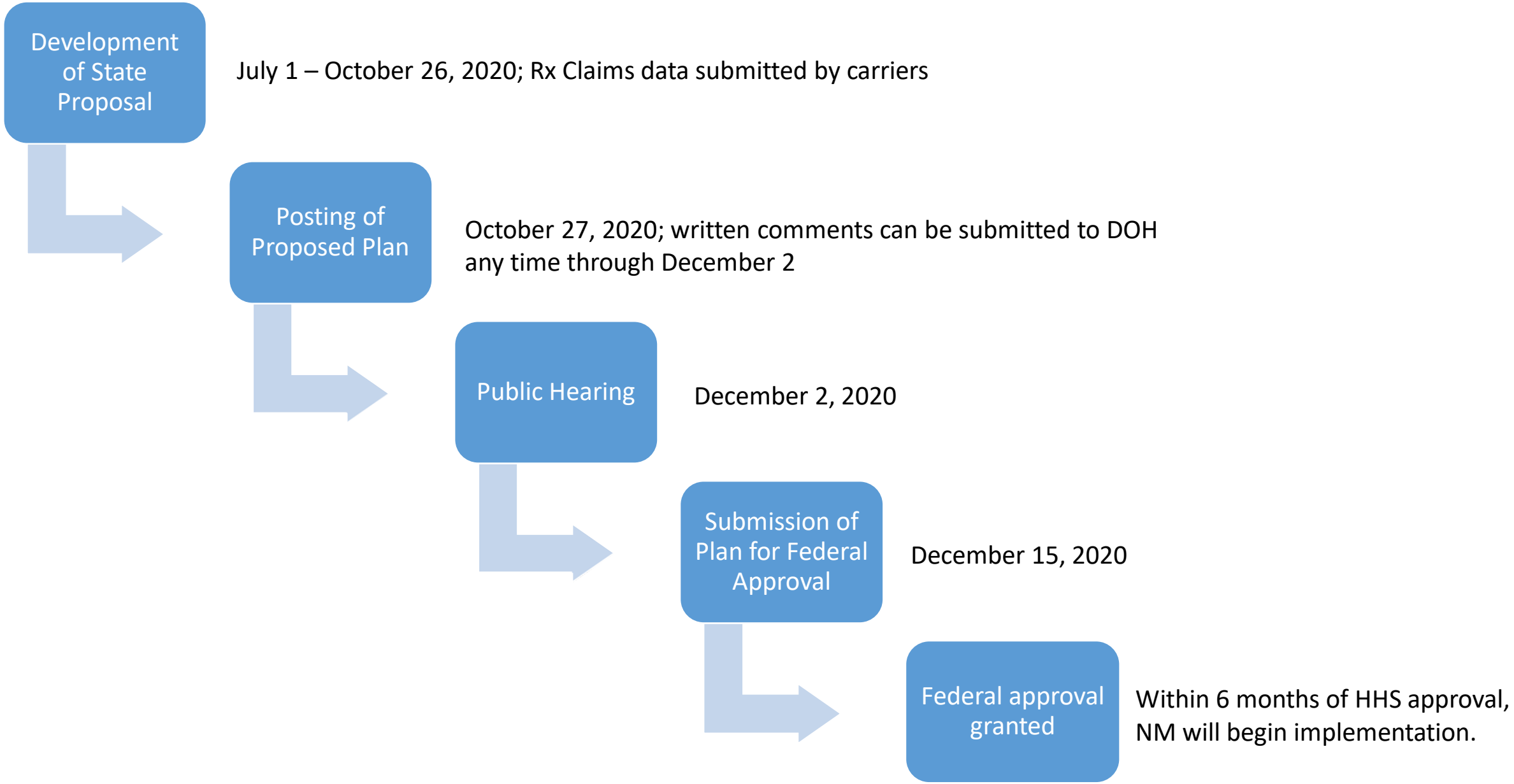
# State agencies involved

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

# SB 1 Supply Chain To Mimic Existing Flow



# Timetable


Development of State Proposal
July 1 – October 26, 2020; Rx Claims data submitted by carriers
Posting of Proposed Plan
October 27, 2020; written comments can be submitted to DOH any time through December 2
Public Hearing
December 2, 2020
Submission of Plan for Federal Approval
December 15, 2020
Federal approval granted
Within 6 months of HHS approval, NM will begin implementation.

# 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 ≤ 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 – can partner with private sector
      - 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 (2)

- 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

# The Basics (3)

- NM may want to start slow –import ~20-30 products to start
- Imports can replace US product version if everyone ‘opts in’ to program participation
  - Full opt-in means pharmacies do not have to double stock a product
- 340B products may be less costly than Canadian product
  - 340B entities will want to stock the US version
  - 340B entities should be limited to billing only up to the import price
    - 340B Rx margins reduced somewhat on the 20-30 products that are also imported

# Discussion

1) What seems like the right number of products to import?
2) Will carriers assist in determining which products should be imported?
3) What will it take for carriers to support an importation program?
4) How should we determine consumer savings needed for the federal application?
    a) Will carriers reduce patient cost sharing for imports?
    b) How will pharmacies be impacted?
5) How can plans and the state work together to communicate about the import program?