NASHP PRESENTATION TO OKLAHOMA SENATE HEALTH AND HUMAN SERVICES COMMITTEE

STATE ACTIONS TO LOWER RX PRICES

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Jennifer Reck, MA
Project Director
National Academy for State Health Policy
jreck@nashp.org

NASHP Center for State Rx Drug Pricing

2016: NASHP convenes the Pharmacy Cost Work Group
2017: NASHP launches the Center for State Rx Drug Pricing
- Funded by the Laura and John Arnold Foundation

Model legislation: https://nashp.org/model-legislation/
- Transparency (Revised April 2019)
- Regulating PBMs
- Drug Affordability Review Boards
- Wholesale Importation from Canada

NEW MODELS COMING SOON

State legislative tracker:
https://nashp.org/state-legislative-action-on-pharmaceutical-prices/

New state laws library 2017-2019: https://nashp.org/new-laws/

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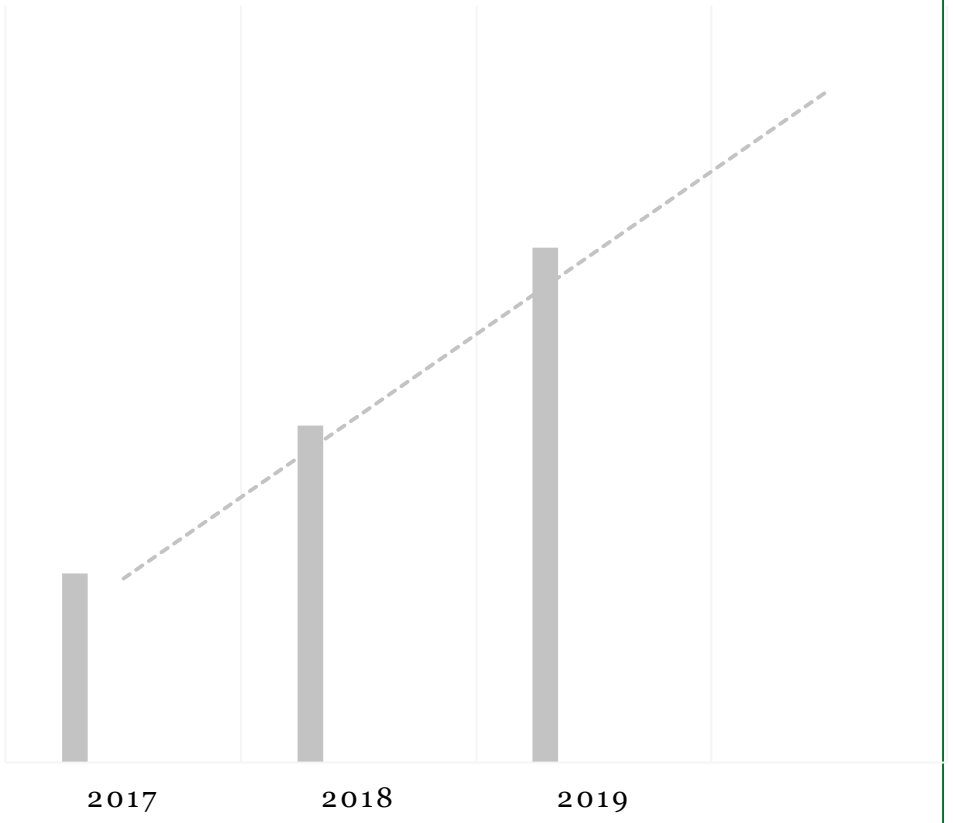
State Action on Rx Prices: Growing Momentum

2017 session: 100 bills

2018 session: 178 bills

2019 session: 272 bills

EVERY STATE HAS INTRODUCED LEGISLATION ADDRESSING DRUG PRICES



State Legislation on Rx Prices

Category	Number of enacted laws: 2017-2019	States
PBMs	90	36 states
Price Transparency	11	CA, CT, ME, NH, NV, OR, TX, VT, WA
Wholesale Canadian Importation	4	VT, FL, CO, ME
Drug Affordability Review	2	MD, ME
Leveraging Purchasing Power	2	DE, NM
Prohibiting Pay for Delay	1	CA

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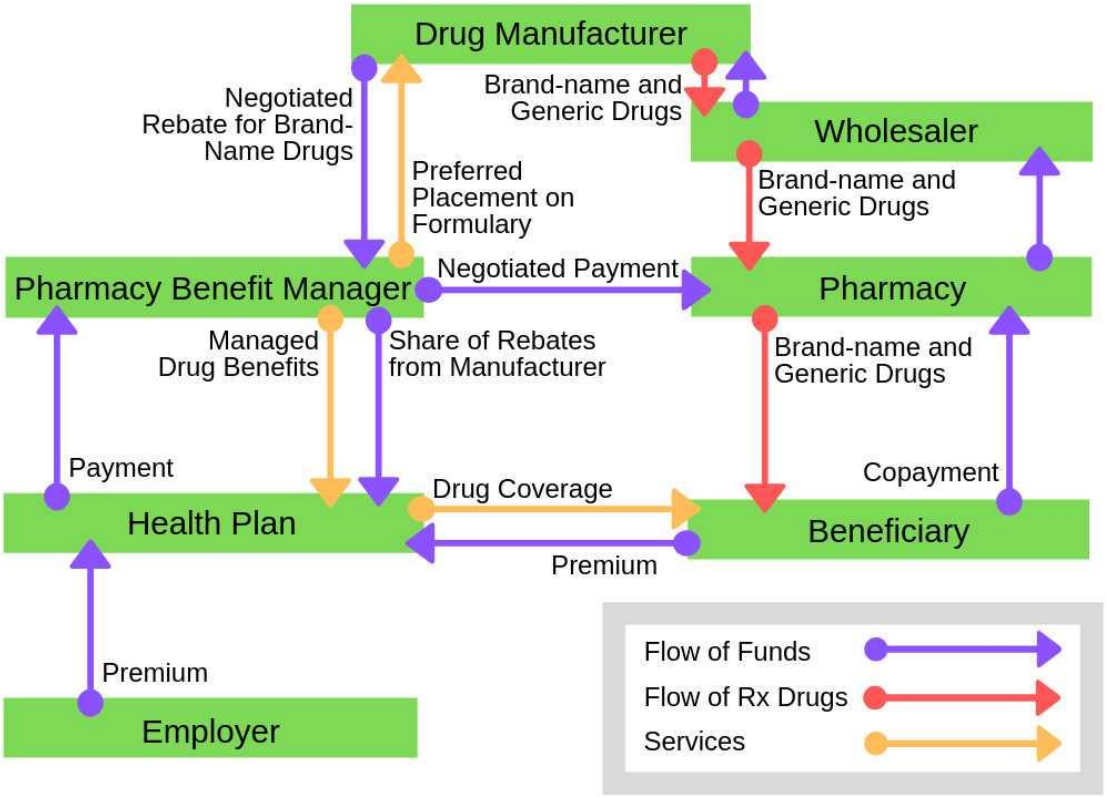
Rx Supply Chain Complexity



* Thanks to Heather Sanborn, Senate Chair, Joint Committee on Health Coverage, Insurance, and Financial Services, Maine State Senate.

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Transparency

Laws implemented in: CA, NV, OR, VT

Laws enacted in: CT, ME, NH, WA, TX

NASHP Model:

- Requires reporting across the supply chain:
  - manufacturers, pharmacy benefit managers, wholesalers, and health plans
- Includes a common data set to align reporting across states and minimize reporting burden
  - adopted by ME and CT
- Includes stronger penalties for failure to report
- Reporting threshold set to generate reporting on approximately 30 brand name and 30 generic drugs

Importation: Federal Law Background

CERTIFICATION:

- Federal Food, Drug, and Cosmetic Act (FDCA) section 804 allows the HHS Secretary to approve a *program* of wholesale importation of prescription drugs that will:
  - Pose no additional risk to the public's health and safety; and
  - Result in a significant reduction in the cost of the covered products to the American consumer

REQUIREMENTS:

- Prescription drugs may only be imported from Canada
- NO importation of a controlled substance, biological product, infused drug, intravenously injected drug, or a drug inhaled during surgery
- All safety provisions in the FDCA must be followed (e.g. track and trace) as well as additional laboratory testing requirements

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Importation: Federal Law Updates

- July 2019: FDA/HHS published the "Safe Importation Action Plan."

The plan outlines two potential pathways for importation:

1) Wholesale state importation

- FDA/HHS will publish a Notice of Proposed Rulemaking ("NPRM"), relying on the authority in FDCA section 804 to authorize demonstration projects to allow importation of drugs from Canada

2) New National Drug Codes (NDCs) for manufacturers to enable manufacturers to sell drugs originally intended for foreign markets, that are the same as the US versions, at reduced prices in the US

- Federal Guidance currently under review at OMB

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Importation: State Law Updates

State	Status of Application
ME	May 1, 2020 deadline for application
FL – Canadian importation (public payers)	Aug. 20, 2019: Submitted concept paper; July 1, 2020 deadline for application
VT	Jul. 1, 2019: Original deadline for application; now July 1, 2020
FL – International import program (private payers)	July 1, 2020 deadline for application
CO	September 1, 2020 deadline for application

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