

State Actions to Address Rising Prescription Drug Costs

January 2020



Why are states taking action on Rx prices?

States can't wait for federal action:

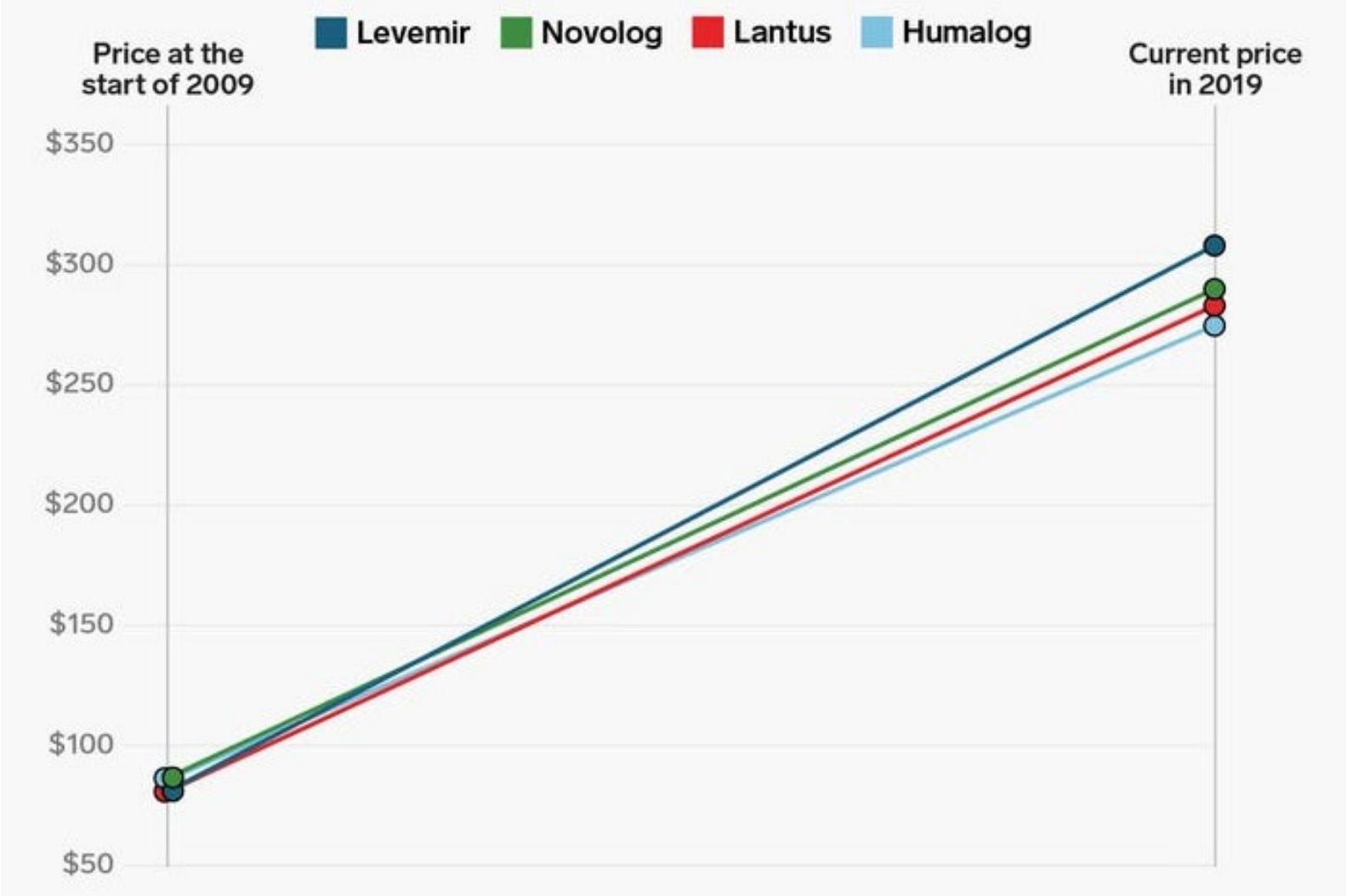
- States are large payers and must fund health benefits for state employees, university, school and municipal employees, corrections staff and Medicaid enrollees.
- States must balance their budgets, and rapid and unpredictable Rx price increases make this difficult.
- Drug pipeline ensures affordability will continue to be a challenge

Why are states taking action on Rx prices?

Rising drug costs financially strain states and consumers.

- Between 2009 and 2017, the wholesale price of a single vial of the insulin Humalog nearly tripled, from **\$92.70 to \$274.70**.
- The average cost of insulin per person increased from \$2,864 in 2012 to \$5,705 in 2016.
- Specialty drugs entering the market have unsustainably high launch prices.
 - Zolgensma launched at \$2.1 million for a one-time treatment.
 - Luxturna costs \$850,000 for a one-time treatment.

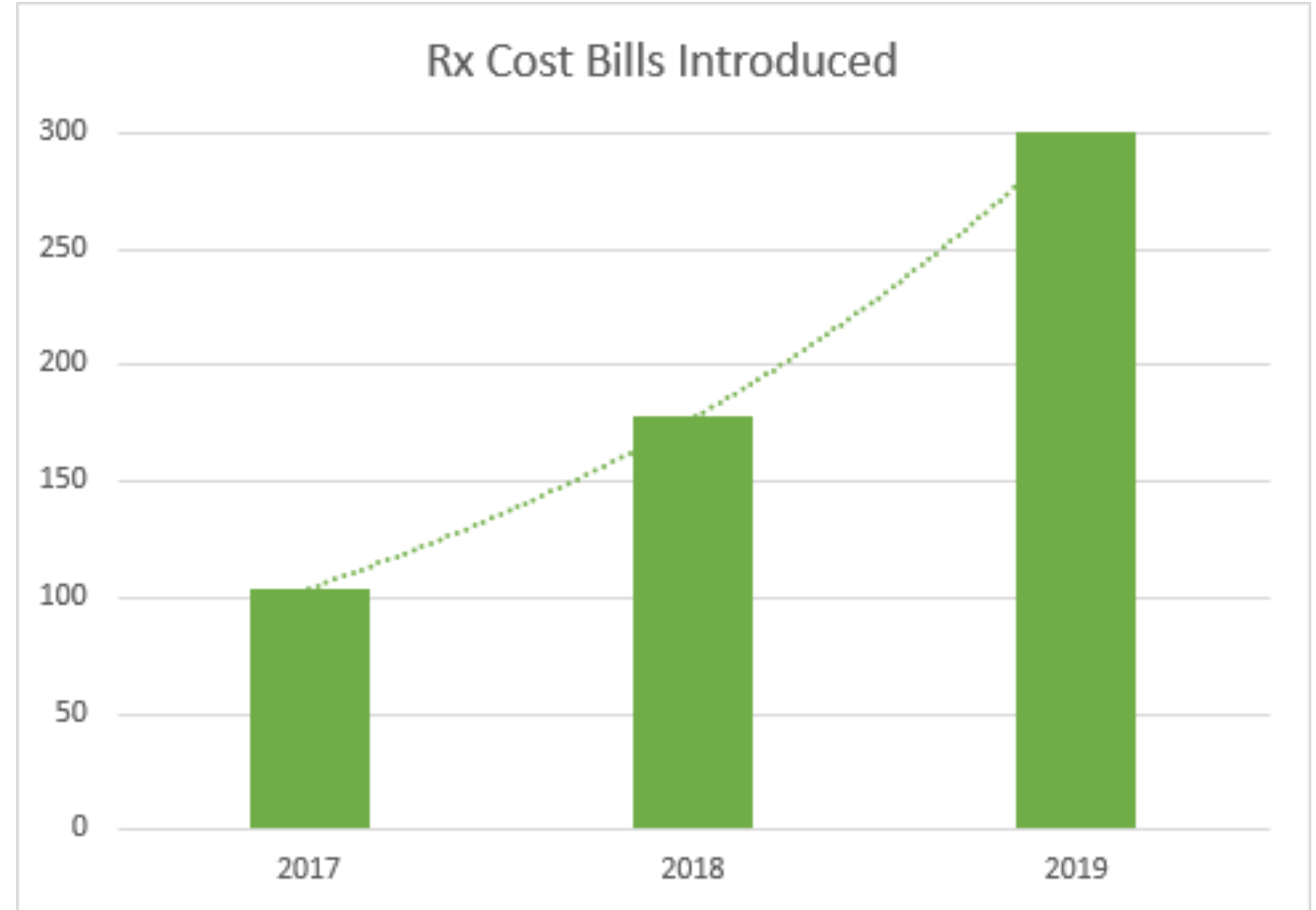
Insulin prices have increased rapidly in the past decade.



Source: Business Insider, Truven Health Analytics: Bloomberg

State momentum continues.

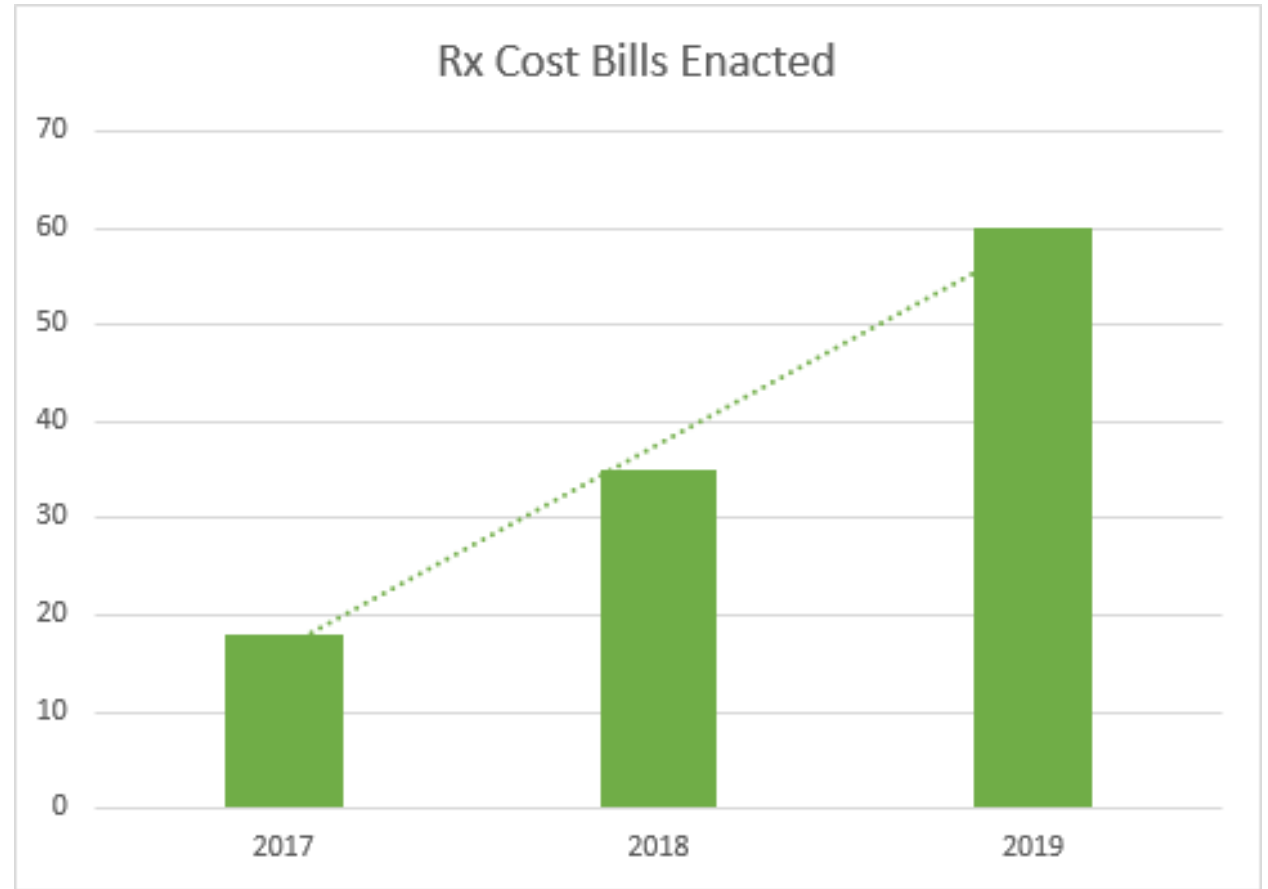
Every state has introduced legislation to address rising prescription drug prices.



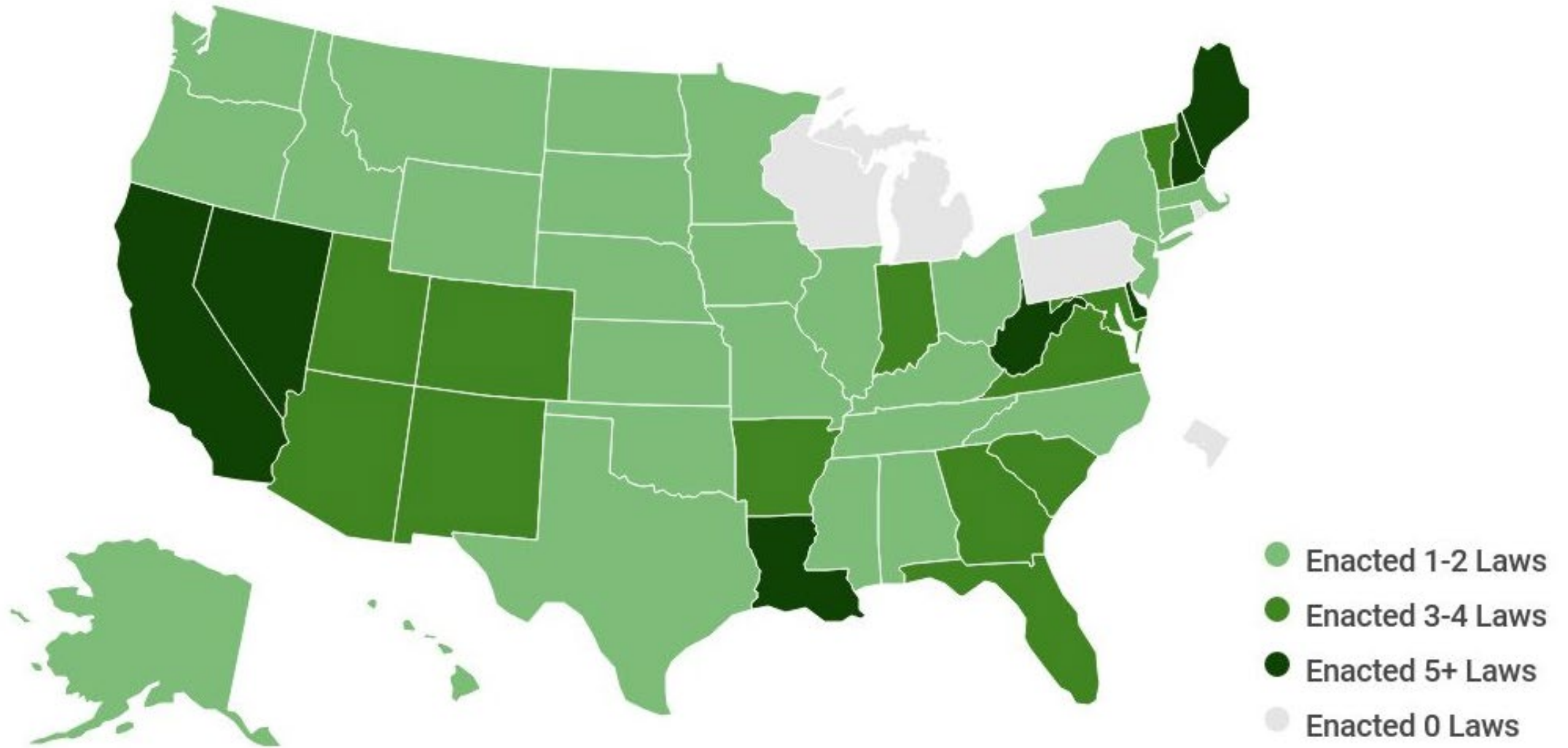
States enact more drug cost laws each year.

Enacted State Rx Pricing Bills: 2017-2019 (As of Jan. 1, 2020)			
Year	2017	2018	2019
States enacting laws	13	28	37
Total laws enacted per year	18	45	60
Pharmacy Benefit Manager	8	32	33
Transparency	3	4	6
Wholesale from Canada Importation	0	1	3
Affordability Review*	1	0	3
Volume Purchasing	0	0	2
Coupons	1	0	3
Study	0	1	5
Other	5	7	5

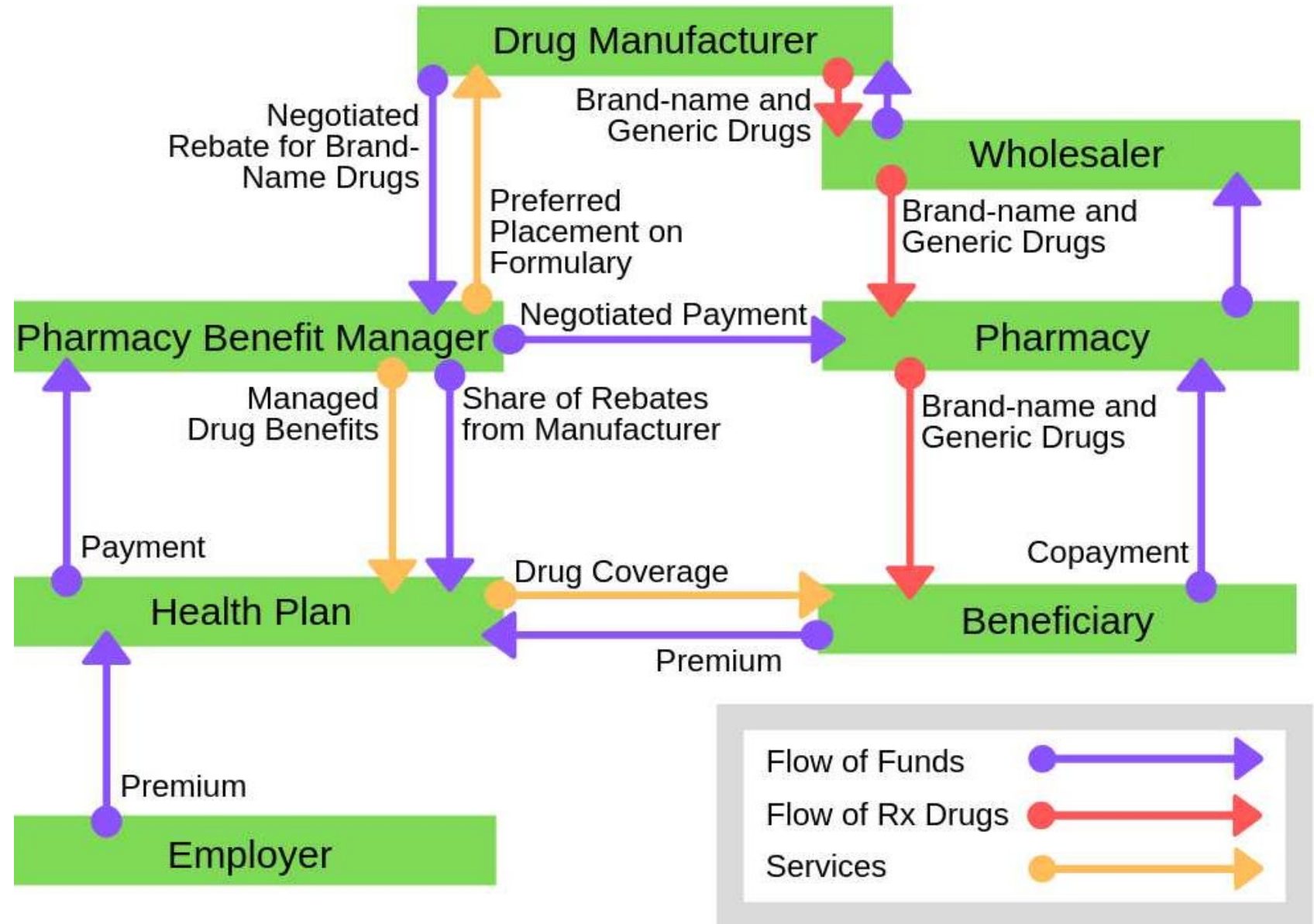
**Includes New York's Medicaid drug cap and Massachusetts' enhanced negotiating authority.*



Enacted State Drug Pricing Laws 2017-2019



Supply Chain Complexity



Graphic credit: Heather Sanborn, Senate Chair, Joint Committee on Health Coverage, Insurance, and Financial Services, Maine State Senate.

Prescription Drug Pricing Transparency

Goal: Actionable transparent price data from across the supply chain

NASHP's [model](#) offers a comprehensive approach to transparency reporting

- Requires reporting from across the supply chain
 - Manufacturers, pharmacy benefit managers, wholesalers, and health plans
- Includes a common data set to align reporting across states and to minimize reporting burden
 - Adopted by Maine and Connecticut
- Includes stronger penalties for failure to report, including giving subpoena power to state agencies to collect information from entities in the supply chain

Transparency laws highlight drugs that create affordability challenges.

- Eight states have passed transparency laws: CA, CT, ME, NV, OR, TX, VT, WA.
- Transparency data from states already reporting has identified high-cost drugs whose costs are rising fastest and/or are most frequently prescribed.
- CA, ME, NV, OR, and VT have already started collecting data and have developed public lists of drugs that account for high total cost or high-cost growth.
 - Seventeen drugs were reported in common across at least three states.
 - The most commonly reported high-cost drugs across states were diabetes medications.

Highest Total Cost or Highest Cost-Growth Drugs Reported by at Least Three States	
Diabetes	Humalog Januvia Lantus Solar Novolog Metformin HCL Metformin HCL ER Victoza
Psoriasis, Psoriatic Arthritis, Rheumatoid Arthritis	Stelara Cosentyx Enbrel Humira Syringe Humira Pen
Asthma	Symbicort
Hepatitis C	Harvoni Epclusa
Multiple Sclerosis	Copaxone Tecfidera
Cardiovascular Issues	Xarelto
HIV	Descovy

At least three of five states (CA, ME, NV, OR, VT) had 17 drugs in common on lists of highest cost and highest cost-growth drugs reported by states.

Pharmacy Benefit Managers (PBMs)

- PBMs contract with health plans to administer pharmacy benefits.
- NASHP developed two model PBM bills that allow states to define standards for PBM business practices.
 - [Model Legislation A](#) enables states to directly regulate PBMs.
 - [Model Legislation B](#) requires health carriers to monitor activities performed by a contracted PBM.
- Both models require PBMs to:
 - Obtain a state license;
 - Have a fiduciary to their health plan clients; and
 - Limit patient cost sharing at the point of sale.

Requirements on PBMs vary by state.

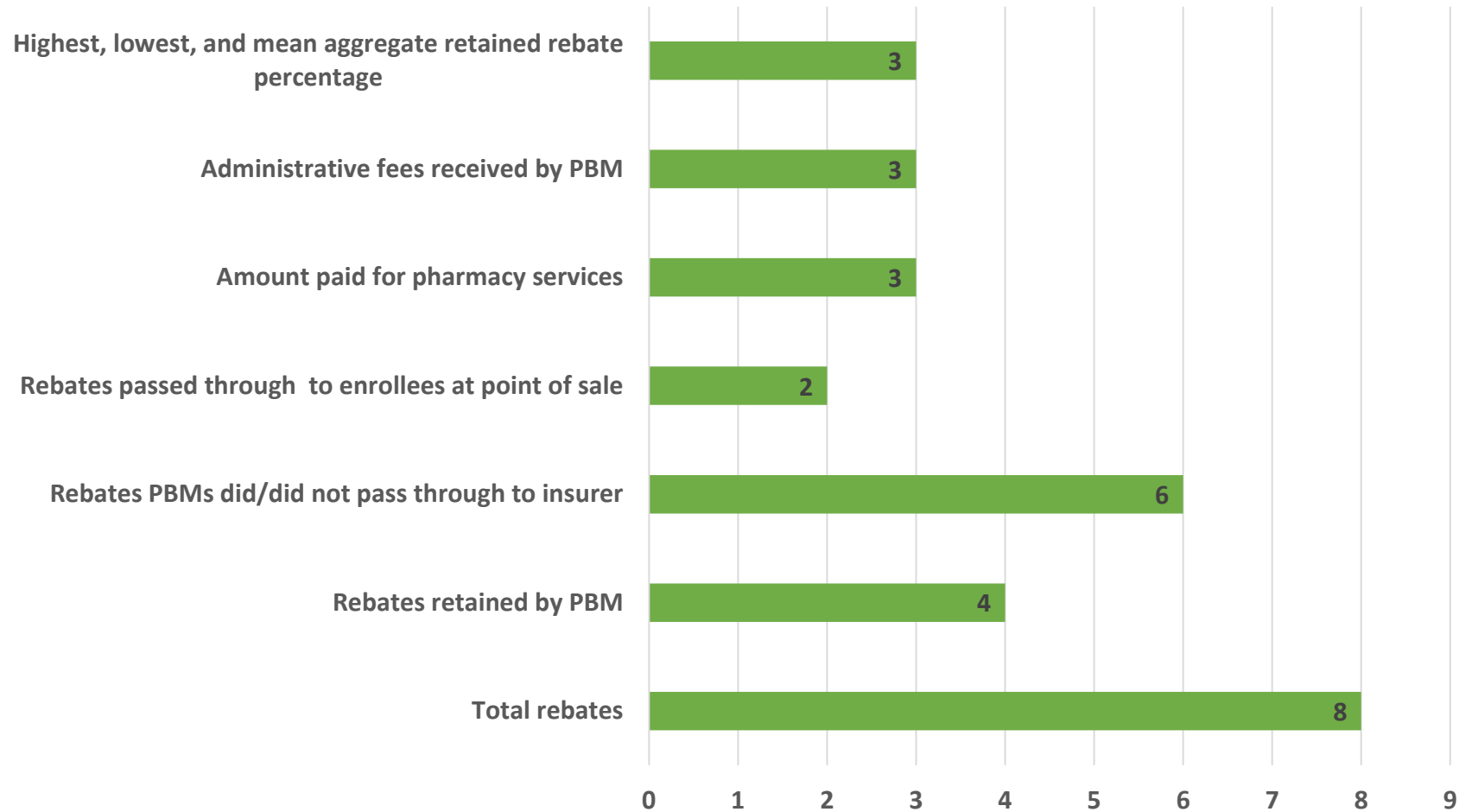
- Twenty-eight states require PBMs to obtain licenses that:
 - Show how many and what entities operate as PBMs in a state; and
 - Give states the power to suspend/revoke licenses if PBMs engage in fraudulent activity.
- Nine states require PBMs to report financial information as part of targeted PBM transparency or as part of broader drug cost transparency efforts (CT, NV, WA, TX, ME, LA, AR, IA, MN).

States require varied information from PBMs.

- Eight of the nine states with PBM transparency laws require PBMs to report total rebates.
- Six of those states require PBMs to disclose whether rebates were passed through to the insurer.
- States also require reporting about:
 - The amount of money retained by PBMs;
 - Administrative fees paid to PBMs;
 - Amount paid for pharmacy services; and
 - Whether rebates were passed through to insurers and consumers.

States require varied information from PBMs.

Number of States with PBM Requirements



Background: Wholesale Canadian Drug Importation

Federal certification:

- Federal Food, Drug, and Cosmetic Act (FDCA), Section 804, allows the Department of Health and Human Services Secretary to approve a *program* of wholesale importation of prescription drugs that will:
 - Poses no additional risk to the public's health and safety; and
 - Results in a significant cost reduction in the covered products to the American consumer.

Federal 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 is permitted.
- All safety provisions in the FDCA must be followed (e.g., track and trace) as well as additional laboratory testing requirements.

Wholesale Importation Supply Chain Safety

- The drug supply chain is already a global one.
 - 63% of drugs sold in the US are manufactured in other countries.
 - 88% of raw materials in US drugs come from abroad.
- Safety standards are comparable.
 - Federal regulations already ensure the safety of foreign-produced drugs entering the US market.
 - More than 30 Canadian drug manufacturers are FDA-registered to produce drugs for the US market.



Identify administrative agency responsible for the program.

Establish a list of eligible, high-spend drugs across payers to be imported to establish savings.

Establish revenue source/s for program (e.g., licensing fees, dispensing fees, etc.) and supply chain margins.

Submit an application to the US Department of Health and Human Services that meets federal requirements to ensure safety and consumer savings.

Establish an agreement with a licensed Canadian prescription drug supplier, licensed drug wholesaler.

Establish limits on mark-up by distributor, drug quantity, and mark-up by pharmacies.

The state remains responsible for ensuring drug safety.

State Wholesale Importation Activity

Vermont, Colorado, Florida, and Maine are engaged in the multi-step process of designing and implementing importation programs.

Example of importation program cost savings

- Lower Canadian drug prices have the potential to save states and consumers money.
- Importing Zytiga, a prostate cancer drug, is 64% cheaper, even after mark-up along the supply chain.

Zytiga

US price: \$87.63
Canadian price: \$21.56
Difference: \$65.97

Zytiga in the supply chain:

Repack/relabel: ~15% [\$3.23]
+
Testing: ~5% [\$1.08]
+
Records/recall management: ~5% [\$1.08]
+
Profit to supply chain: ~20% [\$4.31]
=
Overall supply chain markup: \$9.70

Resulting cost to state: \$31.26
Savings after supply chain costs: ~64%

Drug Affordability Review Board

NASHP's [model](#) creates a drug affordability review board that can establish upper payment limits for high-cost drugs that cross certain thresholds.

- A state determines triggers to review drugs.
- Drug companies have the opportunity to justify prices.
- The board reviews information and establishes an upper payment limit that applies throughout the health care system.

Maine and Maryland are implementing modified drug affordability boards:

- Maine allows its board to determine drug spending targets for public entities.
- Maryland's board may begin to set upper payment limits for drugs purchased by public entities in 2022, pending approval by the General Assembly. In 2023, the board will recommend whether the assembly should pass legislation to expand upper payment limits to all purchasers.

States seek more control over Medicaid pharmacy benefits.

- West Virginia carved pharmacy benefits out of its Medicaid managed care program in 2017.
 - The state saved over \$54 million from its shift to fee for service.
 - Michigan is considering implementing a similar policy.
- Ohio now requires all managed care plans to contract with a single PBM that will be selected by its Medicaid department.
 - It previously required managed care plans to use a transparent, pass-through payment model that prohibited spread pricing.
- Washington State's Medicaid program implemented a single formulary for all managed care and fee-for-service pharmacy benefits.

States explore alternative Medicaid payment models.

- Louisiana and Washington are implementing a “Netflix” subscription-based payment model to treat hepatitis C.
 - States solicit bids for a contract with a drug manufacturer, and
 - Pay a “subscription” fee to a winning drug company for unlimited access to a drug for a fixed, predetermined cost.
- CO, MA, MI and OK have received approval for State Plan Amendments that allow for outcomes-based contracts with drug manufacturers.
 - Enables states to negotiate contracts based on agreed-upon outcome measures tailored for specific drugs.

Spending caps and enhanced negotiating authority

- New York Medicaid has authority to negotiate with drug companies for supplemental rebates if drug spending is projected to exceed the annual spending limit.
 - If unable to reach an agreement, drugs are referred to its Drug Utilization Review Board for a “value assessment.”
- Massachusetts’ Health and Human Services has authority to negotiate supplemental rebate agreements with manufacturers.
 - If unable to reach an agreement and the drug meets price thresholds, the drug is referred to the Health Policy Commission for further review.

NASHP's [Prescription Drug Pricing Center](#) is supported by Arnold Ventures.

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[Administrative Actions](#)

[Legal Resources](#)

[Model Legislation](#)

[Newly-Enacted Laws](#)

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