State Action on Drug Costs: Trends and Solutions

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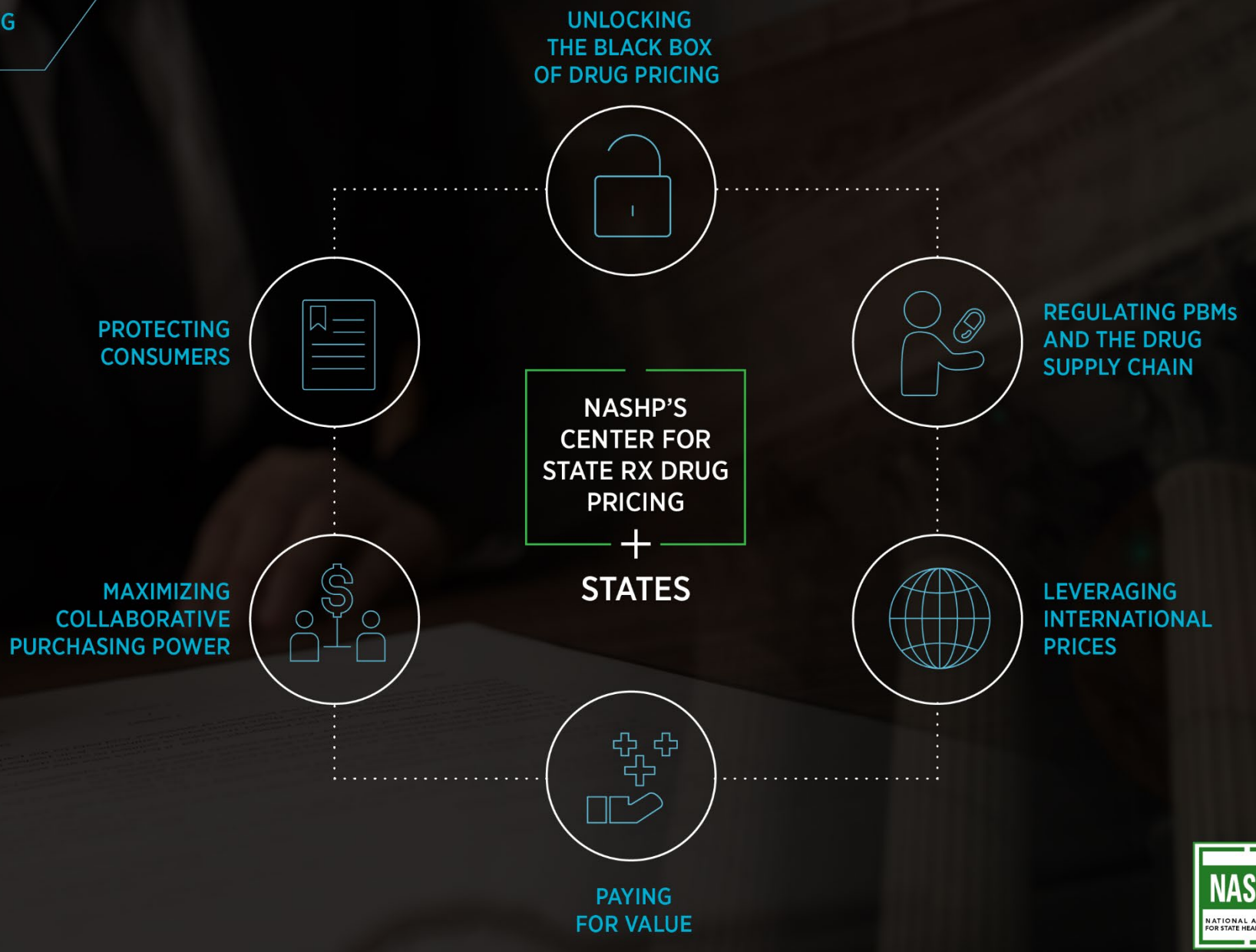
NASHP
NATIONAL ACADEMY FOR STATE HEALTH POLICY

NASHP'S CENTER FOR STATE RX DRUG PRICING

NASHP's Center for State Rx Drug Pricing works with states on model legislation and other strategies to take on high drug costs by:



Pharmacy Supply Chain - Who Participates?

- Manufacturers
  - Develop & Market
  - Set list price
  - Sell to wholesalers
- Wholesalers: Move drugs from manufacturers to end dispensers
- Dispensers: Pharmacies and Institutional Health Care Providers (Hospitals, Clinics, Nursing Homes) that dispense drugs to patients/consumers
- PBMs – Negotiate discounts, create formularies, manage payments (on behalf of health plans)
- Patients/Consumers – Rely on drugs/impacted by affordability

Government Participants

- Medicare, Medicaid and CHIP (CMS/HHS)
  - Medicare spent $129 billion for prescription drugs in 2019, covering 60 million people
  - Medicaid and CHIP (CMS/HHS) – Spent $29.1 billion (net of rebates) for prescription drugs in 2019, covering over 83 million people
- Health Resources Services Administration (HHS) – oversees the 340B discount program
- Food and Drug Administration (HHS)
  - Approves new drugs
  - Approves implementation plans for states seeking to import drugs
- States
  - Purchaser (Medicaid, SEHP, Dept. of Corrections, etc.)
  - Regulate Insurance/PBMs

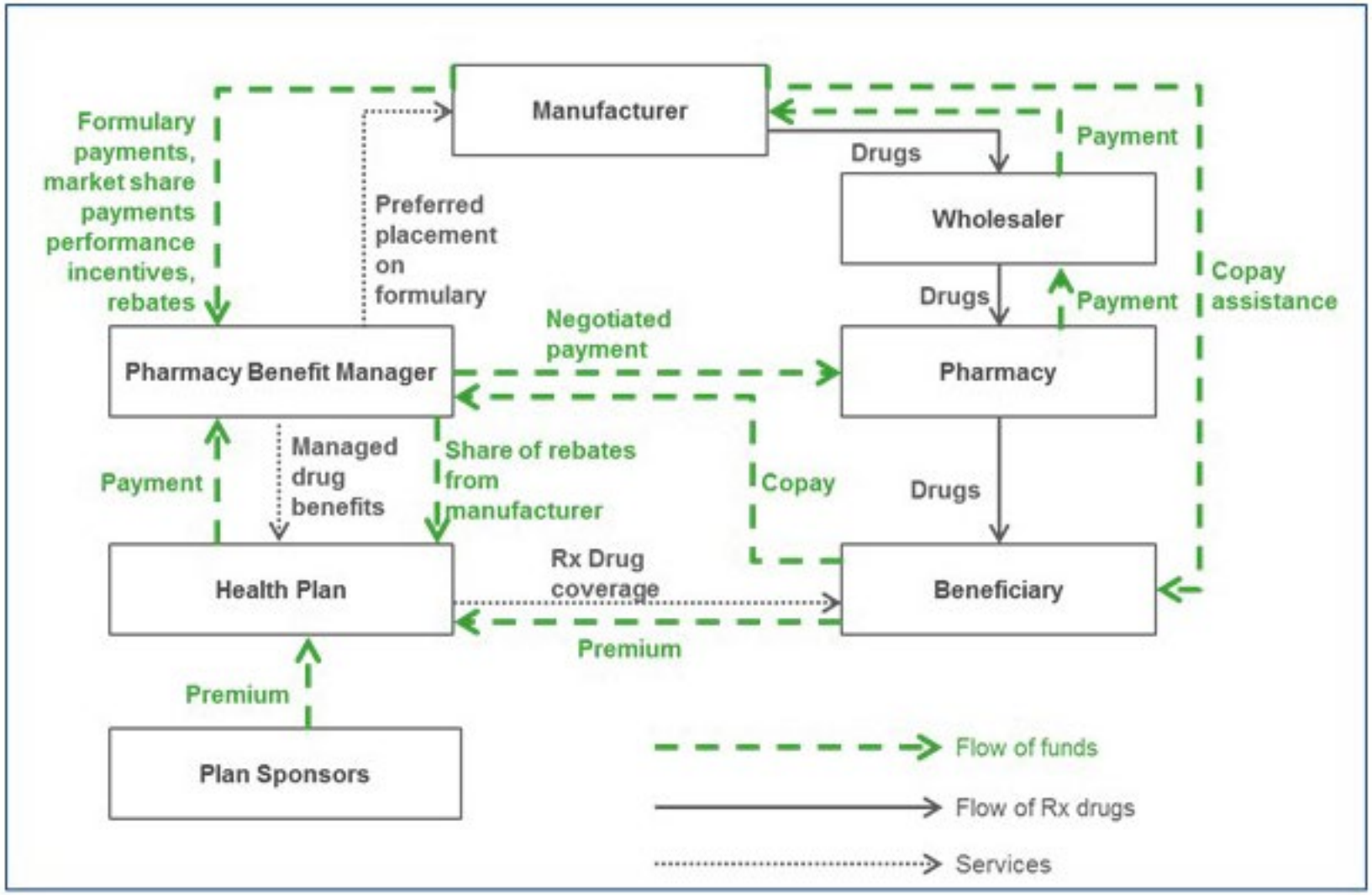
The Role of PBMs

- PBMs have become the central hub of the payment chain
  - Although they never handle the products most of the money flows through them
- The PBM Market is highly concentrated: Three companies make up 77% of the market (CVS Health, Express Scripts, OptumRx)
- Technically an agent of Health Plans but at the center of the pricing and payment system
  - Negotiates with manufacturers for discounts and rebates in exchange for formulary placement
  - Receives payment from manufacurers
  - Receives copay from consumers
  - Pays rate to dispenser
  - Paid by insurer
  - ***Seek to create create profit through spread pricing***

Regulating PBMs

- Since 2017 states have enacted >100 laws related to the conduct of PBMs
- Increasing Oversight and Protecting Consumers
  - Banning gag clauses
  - Licensure/Registration (>30 states)
  - Limiting Patient Cost Sharing
  - Transparency
- Ensuring Adequate Pharmacy Reimbursement
- Improving State Contracts - Medicaid Carveouts and Reverse Auctions
- The Impact of ***Rutledge***

Flow of Products, Funds and Services



Drug Pricing Laws 2017-2022

Year	2017	2018	2019	2020	2021	2022*	Total	In # of states
Number of States Enacting Laws	13	28	37	17	22	15	50	
Total Laws Enacted	17	45	63	41	49	26	241	50
Pharmacy Benefit Manager	7	32	32	19	22	15	127	47
Transparency	3	4	7	5	7	2	28	21
Wholesale Importation from Canada	0	1	4	2	1	1	9	6
Affordability Review	1	0	3	0	2	2	8	8
Volume Purchasing	0	0	2	0	1		3	3
Coupons/Cost Sharing	1	0	4	12	10	4	31	20
Study	0	1	6	1	2	2	12	9
Other	5	7	5	2	4		23	18

*As of July 19, 2022

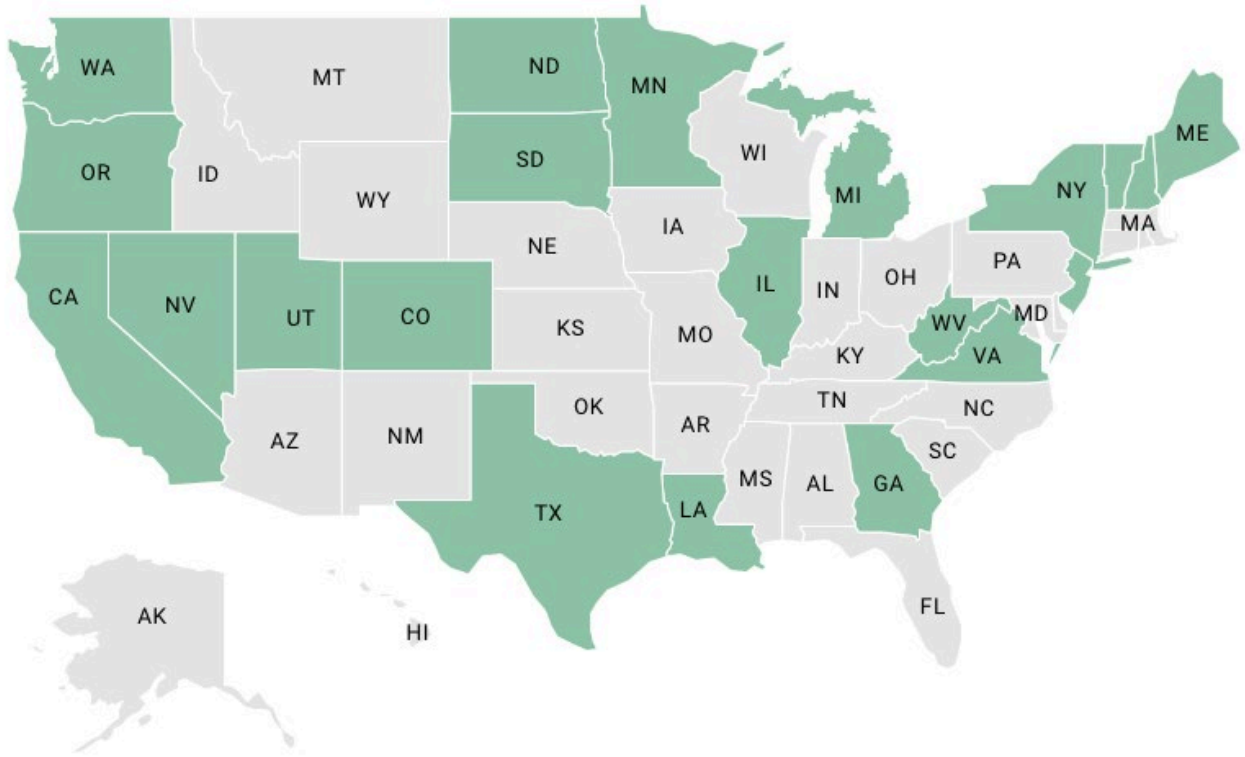
50 State Legislative Landscape

Since 2017, legislation to address prescription drug costs has been ***enacted*** in all 50 states.

More than 240 laws

State Drug Price Transparency Legislation

- Variation in reporting thresholds & requirements across states
- Entities required to report include:
  - Drug manufacturers
  - Pharmacy Benefit Managers (PBMs)
  - Insurers
  - Wholesalers
  - Pharmacy Service Administrative Organizations (PSAOs)



Value of State Drug Price Transparency

Manufacturer accountability for price increases & launch prices

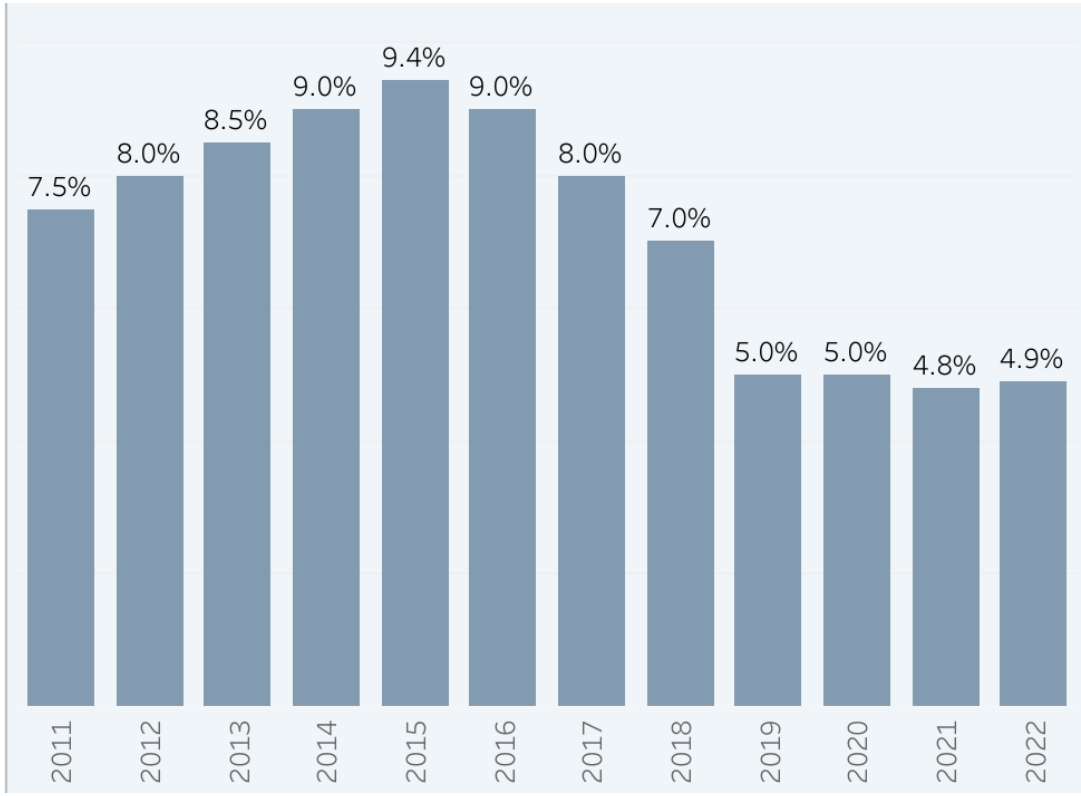
Pressure to limit drug price increases

Building staff capacity and infrastructure for future Rx action

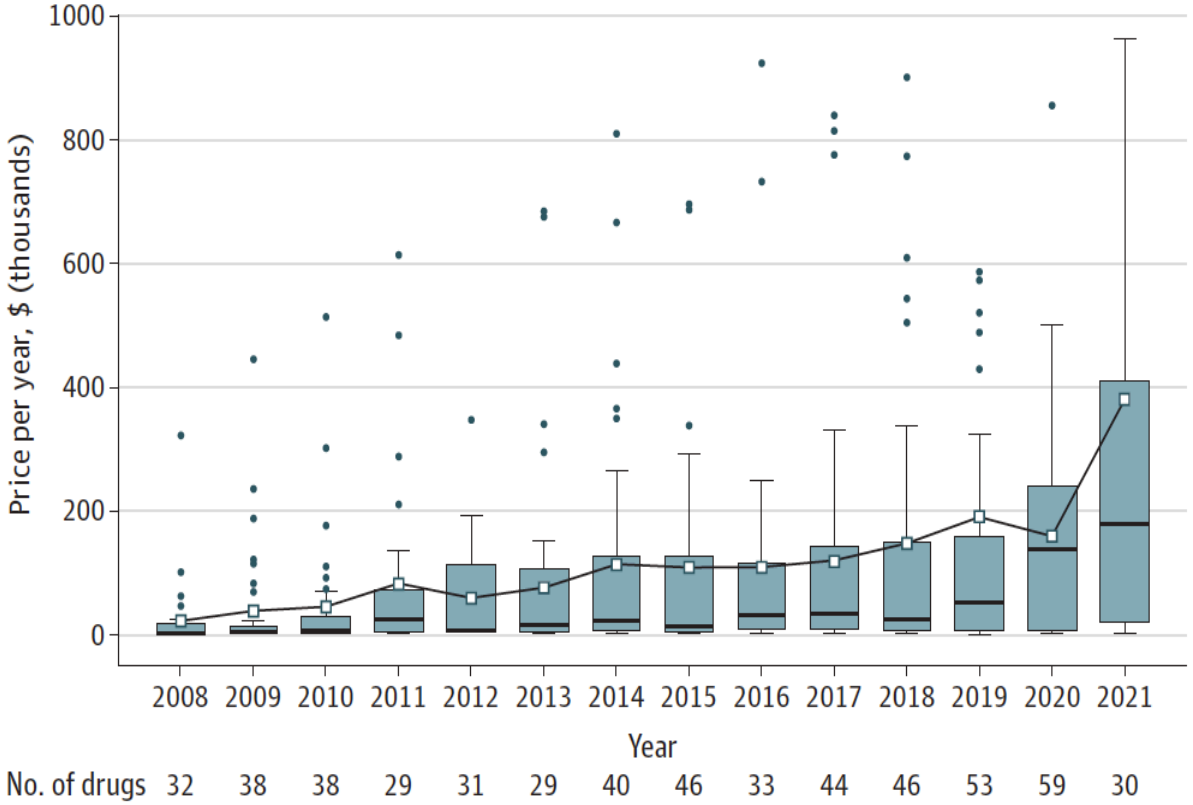
Identifying price trends & issues for policy action

Price Increases Moderate, Launch Prices Rise

Median Percentage WAC Increase on Brand-name Drugs



Average Launch Prices Increased by 20% per year



How Rx Transparency Data Shapes Policy

- Identifying high-priced, highly-utilized drugs to target action to lower drug prices (e.g. establishing a PDAB or reference pricing)
- Informing state cost-growth benchmark and prescription drug affordability board work with state-specific data
- Building staff capacity and state infrastructure for tracking drug prices and identifying effective policies to lower prices
- Understanding how drug prices and rebates impact premiums

How Rx Transparency Data Shapes Policy: Equity Considerations

- Chronic conditions and high drug prices disproportionately impact low-income and communities of color
- Lowering drug prices improves health equity - if the right drugs are targeted
- State transparency programs can help identify and study drugs to mitigate health inequities

- Nearly 15% of Black people have received a diabetes diagnosis and are more than twice as likely to die from the disease.
- The cost of the four most popular types of insulin have tripled in the past 10 years.
- As many as 1 in 4 of the 7.5 million Americans dependent on insulin are skipping or skimping on doses.

Volume Purchasing / Consumer Savings

- There are successful models for volume purchasing among state/county/municipal entities going back to the implementation of MMCAP Infuse in 1985

- **Northwest Prescription Drug Consortium (2006); Now ArrayRx**
  - Combination of the Oregon and Washington Prescription Drug Programs (~1 million lives)
  - Administered by Moda Health: transparent pricing / no spread pricing / pass-through of manu. rebates / fixed admin. fees / audits
  - Open to state agencies, local government, private sector businesses, labor organizations
  - Offers a discount card program for underinsured/uninsured individuals: savings of 42% off retail; up to 60% for generics
  - Nevada residents can now enroll for an ArrayRx discount card as of Sept. 2022

Licensing Sales Representatives

- **Why:** PhRMA invests heavily in marketing directly to providers
  - $6 billion for DTC vs $20.3 billion for marketing to providers in 2016
  - Sales reps are compensated on volume – not cost-effective, evidence-based use
    - e.g. Sales reps' role in encouraging over-prescribing of opioids
- **What:** The Model Act requires:
  - State licensure of sales reps
  - Professional Education: Ethics, whistleblower protections, regulations
  - Reporting: Drugs marketed and extent of marketing to providers
  - Disclosure to providers: Cost of drug being marketed – and availability of generics
- **Impact:** Will not lower drug prices directly - but can cut costs by increasing utilization of generics

Referenced Based Prices: International Reference Rates Model

Why:

- Foreign countries pay a fraction of what Americans pay for prescription drugs
- Rate setting is a common approach in the health care sector – one that can be extended to setting rates for prescription drugs
- International prices offer a fair, easy-to-implement approach to rate setting

Implementation Structure:

- State Employee Health Plan identifies 250 costliest drugs
- Insurance Commissioner crosswalks to Canadian prices Payers cannot pay more than that limit for drug
- Canadian price becomes upper payment limit for all payers (except Medicaid)
- ERISA: Self funded plans may participate voluntarily
- Protects local pharmacies

Examples of Canadian Rates

Drug Name & Dosage	US Price (NADAC)	Canadian Reference Rate*	Price Difference	Savings off US Prices
Humira syringe (40 mg/0.8 ml) (arthritis, psoriasis, Crohn's)	$2,706.38	$541.29	$2,165.09	80%
1 ml of Enbrel (50 mg/ml syringe) (arthritis, psoriasis, Crohn's)	$1,353.94	$272.28	$1,081.66	80%
1 ml of Stelara (90 mg/1 ml syringe) (arthritis, psoriasis, Crohn's)	$21,331.28	$3,267.64	$18,063.64	85%
1 ml of Victoza (2-pak of 18 mg/3 ml pen)* (diabetes)	$103.44	$17.30	$86.14	83%
Truvada tablet (200 mg/300 mg) (PrEP for HIV)	$59.71	$19.78	$39.93	67%
Xeljanz tablet (5 mg) (rheumatoid arthritis)	$76.07	$17.50	$58.57	77%
Eplcusa tablet (400 mg/100 mg) (hepatitis C)	$869.05	$541.32	$327.73	38%
Zytiga tablet (250 mg) (cancer)	$87.63	21.47	$66.16	75%
	Average discount based on 8 top selling drugs in 2018			**73%**

Referenced Based Prices: Leveraging the IRA

- **The recently enacted Inflation Reduction Act (IRA) presents another source of reference based pricing for states**
- **How Many Drugs and When:** HHS will negotiate for top 10 Part D drugs, with prices effective 2026, eventually reaching top 20 drugs across Parts B and D in 2029
- **Which Drugs:** Single-source drugs that (1) are at least 7 years (small molecule) or 11 years (biologic) beyond approval; **and** (2) account for at least $200 million spend across Parts B and D
- **Exceptions:** Drugs marketed as generic/biosimilar (or biologics with reference biosimilar pending entrance within 2 years), orphan drugs targeting single approved disease, and plasma products
- **Maximum Fair Price (MFP):** Range from 75% to 40% of non-federal AMP; the longer a drug has been on the market, the lower the MFP

Medicare Drug Price Negotiations

Process:

- HHS compiles list of drugs that meet the criteria
- From those drugs HHS selects the first 10 drugs off the list in order of highest to lowest spending (not discretionary)
- HHS requests information from manufacturers of drug on list
- HHS reviewing information and offers a Maximum Fair Price
- Manufacturers can accept or propose a counteroffer
- HHS publishes final and binding Maximum Fair Price which is binding
- Strong penalties for lack of compliance/No judicial review
-

Drug Price Negotiation Program: Possible High-Spend Drugs for Negotiation

Brand Name	Generic Name	Manufacturer	Therapeutic Treatment	Total Spend (2020)
Eliquis	Apixaban	Bristol-Myers Squibb	Blood clots	~$9.9 billion
Xarelto	Rivaroxaban	Janssen Pharmaceuticals	Blood clots	~$4.7 billion
Humira	Adalimumab	AbbVie	Rheumatoid arthritis	~$4.2 billion
Januvia	Sitagliptin Phosphate	Merck	Type 2 diabetes	~$3.8 billion
Trulicity	Dulaglutide	Eli Lilly & Co.	Type 2 diabetes	~$3.3 billion

Medicare Drug Price Negotiations: Opportunities for States to Reference MFPs

NASHP's International Reference Rate Model can be adapted to:

Reference Medicare Maximum Fair Prices instead of Canadian Prices

or

Reference Medicare Maximum Fair Prices and Canadian Prices

Thank you!

NASHP's Drug Pricing Center Resources:

- Written research and analysis & state legislative tracking
- Model legislation, regulation & contracts to address prescription drug prices
- Legal resources
- https://nashp.org/policy/health-costs-and-value/prescription-drug-pricing/

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