Background on NGA Health

Wisconsin Governor's Task Force on Reducing Prescription Drug Prices

National Governors Association
November 20, 2019

National Governors Association

Conference of Governors at the White House, 1908

Over 100 years of serving our nation's governors

Founded in 1908, the National Governors Association (NGA) is the nonpartisan organization of the nation's 55 governors. Through NGA, governors share best practices, address issues of national and state interest and share innovative solutions that improve state government and support the principles of federalism.

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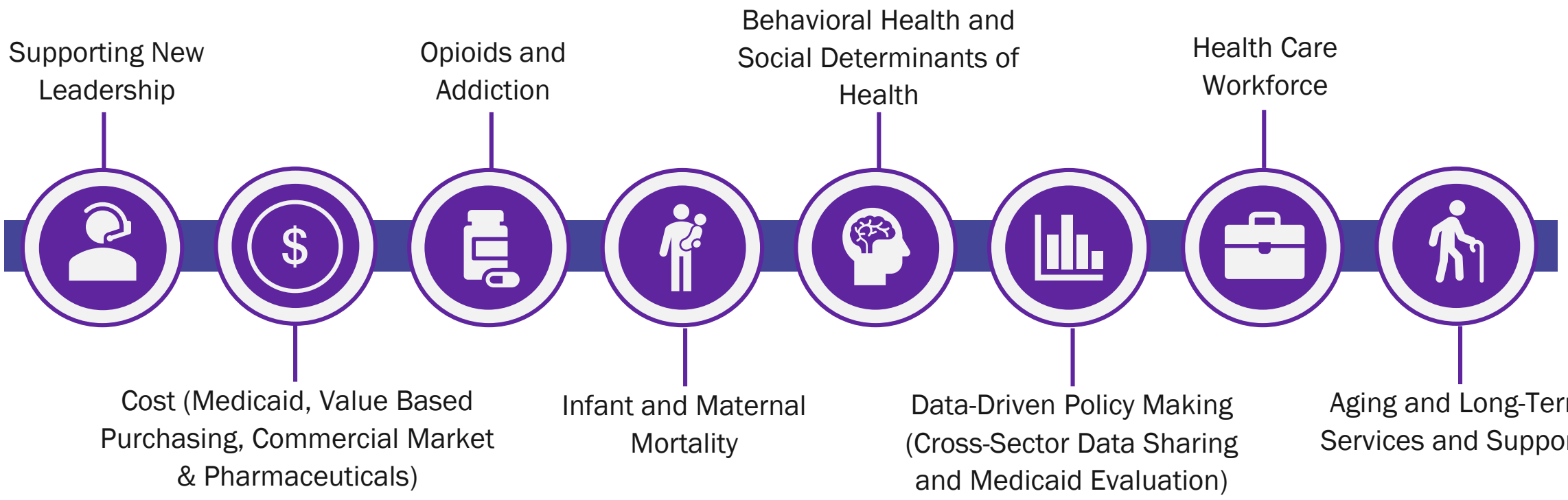
Organizational Structure

The NGA Center for Best Practices is a 501(c)(3) and part of our larger organization.

NGA Health – 2019 Focus Areas



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NGA Health – Recent Work on Pharmaceuticals

NGA Health

- ***Pharmaceuticals and Public Health Crises*** (2017 – 2018)
  - Identify strategies to address public health crises (e.g. opioids, hepatitis C) by increasing access to pharmaceuticals while ensuring fiscal sustainability of public programs
  - Collaborative work with 10 states (Delaware, Louisiana, Massachusetts, New Mexico, New York, Ohio, Oregon, Rhode Island, Virginia and Washington)
  - Publication released August 2018: Public Health Crises and Pharmaceutical Interventions: Improving Access While Ensuring Fiscal Sustainability
- ***Pharmaceuticals Learning Collaborative*** (2019 – 2020)
  - Webinar series and multi-state meetings open to all states
  - Technical assistance with 6 states (Kentucky, Louisiana, Nevada, Ohio, Oregon, Wisconsin)

NGA Advocacy

- 2019 Principles For Federal Action To Address Health Care Costs

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Understanding the Prescription Drug Supply and Financing Chain

Wisconsin Governor's Task Force on Reducing Prescription Drug Prices

Jane Horvath Presentation
November 20, 2019

Pharmaceutical Market

BACKGROUND

Rx Industry Legal and Regulatory Framework

- **Food and Drug Administration, Health and Human Services Department**
  - Licenses prescription drug products
    - New Drug Application (small molecule)
    - Abbreviated New Drug Application (ANDA, generics small molecule)
    - Biologics License Application (large molecule, biologics and biosimilars)
  - Monitors Safety
    - Adverse Events Database
    - Sentinel System
    - Good Manufacturing Practices/physical plant inspections
  - Regulates Advertising
  - Wholesalers must also register
- **Centers for Medicaid and Medicare Services, HHS**
  - Drug Payment Amounts (Medicare Part B)
  - Anti kickback – Medicare and Medicaid (no drug-specific patient discounts or coupons…no inducement to use more services)
  - Coverage Policy (Medicare B and D)
  - Medicaid Drug Rebate Program
- **States license supply chain -- wholesaler to end purchasers**
  - Not all states regulate PBMs or Pharmacy admin service entities

Rx Purchase/Payment Terms

- **List Price – manufacturer catalogue price**
  - Often conflated with wholesale price
- **Wholesale Acquisition Price (WAC)**
  - Average of discounts provided to wholesalers purchasing the drug
- **Average Wholesale Price (AWP)**
  - Average of wholesaler prices to retail pharmacies and other direct purchasers
  - Sometimes used by payers to reimburse for drugs dispensed
    - Often thought to be overstated so payers reimburse @ AWP minus some %
- **Maximum Allowable Cost (MAC)**
  - Payer algorithm used to average prices for multi-source products used to reimburse pharmacies
  - MAC formula and Rx to which it applies varies by payer
- **Average Manufacturer Price (AMP)**
  - Average manufacturer sales price to wholesalers and retail pharmacies
  - Confidential
  - For Medicaid use only

Generic Drug Supply Chain

$20 Drug Example

= supply flow
= money flow
= negotiation

Drug Makers

Set Drug List Prices

Wholesale Acquisition Price (WAC) varies $15-$25, from multiple generic drug makers

PSAO / Wholesaler

PSAO sells/distributes drug to their pharmacy client for discounted price off the Average Wholesale Price; AWP = $18

Pharmacy

Pharmacy buys for $18; charges patient $10 copay

PBM

Depending on contract, PBM pays:
** FFS $8 ($18 minus $10 copay)*
** avg. price/MAC $10 ($20 minus $10 copay)*
PBM charges insurance $11.50 ($20 avg price plus $1.50 dispensing fee, minus $10 copay).

PSAO/PBM contract determines payment methodology to the pharmacy

PBMs/health insurance providers pay pharmacy for drugs dispensed

Health Insurance Provider

Generic drug has $10 copay, insurer pays full amount $11.50, (minus copay of $10).

Patient pays $10 copay for drugs

Pharmacy dispenses drugs to patient for copays

Patient

Copay of $10 to pharmacy.

Branded Supply Chain

$10,000 Drug Example

= supply flow
= money flow
= negotiation

Drug Maker

Set Drug List Price

Sets list price of $10,000

Drug makers pays rebate to PBM per negotiated agreement

PBM

PBM pays pharmacy $10,925; Negotiated $2000 rebate with Drug Maker, keeps $200, sends $1800 to health insurance provider

PSAO negotiates drug reimbursement on behalf of their pharmacy

PSAO / Wholesaler

PSAO buys drug at $10,000 WAC; sells/distributes drug to their pharmacy client for $10,500 AWP

PBM/ health insurance provider pays pharmacy for drug dispensed

Health Insurance Provider

Pays PBM $10,925; receives $1800 rebate from PBM; records total drug spend of $9,125.

Pharmacy

Pharmacy charges $11,000; charges patient $75 copay

Patient pays $75 copay

Pharmacy dispenses drug to patient for copay

Patient

Who Does What? Manufacturers

- **Bring Drugs to Market**
  - Buy promising molecules from research centers (Universities) that do the 'bench science'
  - Outright purchase price and/or contract for royalties if molecule is commercialized
  - Apply for patent (20 years),
    - or purchase patent from original developer, or lease rights from patent holder
  - Generally conduct R&D on molecules through Phase 1-3 clinical trials
  - Submit to FDA for approval
  - Manufacturer R&D can take 10 or 13 years, so 7-10 years left on patent at FDA approval
- **Set the price**
  - Often years before a drug reaches the market
- **Lease the drug license** to another company to market
- **Sales and marketing, life cycle management**
  - Price changes, price concessions, patient assistance
- **Regulated @ federal level**
  - States may license manufacturers whose drugs are sold in-state

Who Does What? Wholesalers

- **Buy in large quantity** from manufacturers
  - Manufacturers can create 'tie-ins' buy all products direct from manufacturer
- **Store Rx**
- **Sell and Ship**
  - to very large purchasers
  - to regional distributors
  - to large pharmacies (local distributors)
- **A wholesaler can have several roles**
  - Specialty Pharmacy – on behalf of manufacturers or health plans for distribution of specialty drugs
  - Pharmacy Services Administration Organization (PSAO)
- **Regulated by States and Federal Food and Drug Administration (FDA)**

Who Does What? PBMs (or Insurers without PBM)

- **Create pharmacy networks**
  - Negotiate pharmacy professional (or dispensing) fees
  - Set drug reimbursement amounts
  - Operate mail order pharmacy
- **Operate formulary**
  - Small plans take PBM national formularies, large plans may design their own
  - Negotiate manufacturer rebates based on formulary placement
  - Decide on pharmacy utilization management strategies
- **Claims payment**
  - Reimburse pharmacies and providers for drugs dispensed or administered
  - Bill insurer/client for Rx claims reimbursement
- **Collect manufacturer price concessions** based on paid Rx claims
- **Not all states license PBMs**

Who Does What? Insurers

- **Contract with PBMs**
  - Scope of PBM role depends on insurer, usually size of insurer
  - Reimburse PBM for pharmacy 'claims paid'
- **Why contract with PBMs?**
  - Running pharmacy benefit has become complex
    - Response to rising prices (utilization management)
    - Negotiate and managing manufacturer rebates
    - Need to negotiate with pharmacies and create networks
- **Set overall premiums** based on expected medical and pharmacy costs
  - Rx costs are increasing share of premium (27% or so)
- **Run grievance and appeals** for pharmacy benefit
- **Are state licensed** (other than ERISA plans which are federally regulated)

Who Does What? Pharmacies

- **Retail pharmacies** – open to public
  - Purchase drugs from wholesalers and distributors
  - May hire administrative services companies to handle claims wrangling and group purchase negotiations (PSAOs, see next slide)
  - Counsel patients
  - Can't drive brand name market share but can drive generic market share
- **Specialty pharmacies** – not open to public
  - May contract with manufacturers to handle specific 'specialty' drugs
  - May work with administering providers to get product to offices as needed
  - May provide case management for patients
  - May provide administrative assistance to administering providers (handling, billing etc.)
- **Licensed by States and somewhat by Federal programs** in which they participate

Who Does What? PSAOs

- **Pharmacy Services Administration Organization**
  - Target client is independent pharmacies
  - Independent pharmacies make ~90% of their revenue from dispensing
  - PSAO market increasingly dominated by large wholesalers – McKesson, Amerisource Bergen, Cardinal (See next slide)
- **PSAO Services**
  - Network contracting with PBMs and health plans
  - Discount negotiations with Manufacturers and Suppliers for Rx purchase/acquisitions
  - Claims processing/dispute resolution and other administrative services
  - Performance monitoring in compliance with health plan/PBM contracts
  - Regulatory updates on pharmacy or durable medical equipment (DME) provider rules
- **Regulatory Framework**
  - State and federal regulation of pharmacies
  - State and federal regulation of wholesalers

PSAO Ownership

Largest Pharmacy Services Administrative Organizations, by Members and Ownership, 2017

Pharmacy Services Administrative Organization (PSAO)	Participating Pharmacies	Ownership	Wholesaler Ownership?
AccessHealth	5,900	McKesson	Y
LeaderNET / MSInterNet / Managed Care Connection	5,600	Cardinal Health	Y
Elevate Provider Network[1]	4,500	AmerisourceBergen	Y
Arete Pharmacy Network	2,500	H.D. Smith[2]/AAP[3]	Y
Third Party Station	2,100	Wholesale Alliance LLC[4]	Y
EPIC Pharmacy Network, Inc.	1,700	Member-owned	N
Unify Rx	1,200	PBA Health/PPOK[5]	N
American Pharmacy Network Solutions	700	American Pharmacy Cooperative	N

Sources: Drug Channels Institute research and estimates
1. ABC's PSAO was previously called the GNP Provider Network
2. In November 2017, AmerisourceBergen announced its acquisition of H.D. Smith's drug wholesaling business. Arete was not included in the transaction.
3. Arete was formed in 2016 by the merger of H.D. Smith's Third Party network and United Drugs' American Associated Pharmacies. The participating pharmacies figure includes the members of RxPride, which Arete acquired in December 2016.
4. Wholesale Alliance LLC is jointly owned by the following wholesalers: Burlington Drug, Dakota Drug, NC Mutual Drug, Rochester Drug, Smith Drug, and Value Drug.
5. Unify Rx figures include the estimated PSAO members from TriNet Third Party Network (PBA Health) and RxSelect Pharmacy Network (PPOK).

This table appears as Exhibit 87 in *The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute*. Available at http://drugch.nl/pharmacy

DRUG CHANNELS INSTITUTE

Potential Areas of Focus

Key Issues in Pharmaceutical Market

Specialty Drugs

- **Definition**
  - Costly and/or
  - Requires special handling and/or
  - Requires provider training and/or
  - Requires patient case management or education
- **Startling Pricing**
  - Triage therapies become first line therapies
  - Rare disease treatment becomes chronic care treatment but pricing based on rare disease or salvage therapy (example: cystic fibrosis, HIV).

More Treatments Get Expedited Review/Less Data

- **FDA fast track/reduced data approval paths 2018 ~56 NME Rx**
  - 13 – Breakthrough – substantial treatment improvement
  - 42 – Priority Review – FDA decision within 6 months
  - 24– Fast track – Rx treats serious conditions with unmet medical need
  - 4 – Accelerated Approval – serious medical condition with unmet medical need using surrogate clinical trial endpoints
  - 31 – Orphan Drug – treats patient populations of <200,000 people
- **Expedited drug products may then be used for additional illnesses, but pricing remains the same**

Key Policy Issues in Rx Supply and Financing

Insurer

- Insurer mergers
- Insurer/PBM mergers
- Rise of costly breakthrough/fast track drugs on patient costs and access
- All the price-protected programs (Medicaid, CA, 340B, Medicare Part D) limit commercial insurer price negotiation ability

PBM

- PBM/chain drugstore mergers
- Treatment of independent pharmacies
- How rebates are used
- Lack of transparency/transparency laws

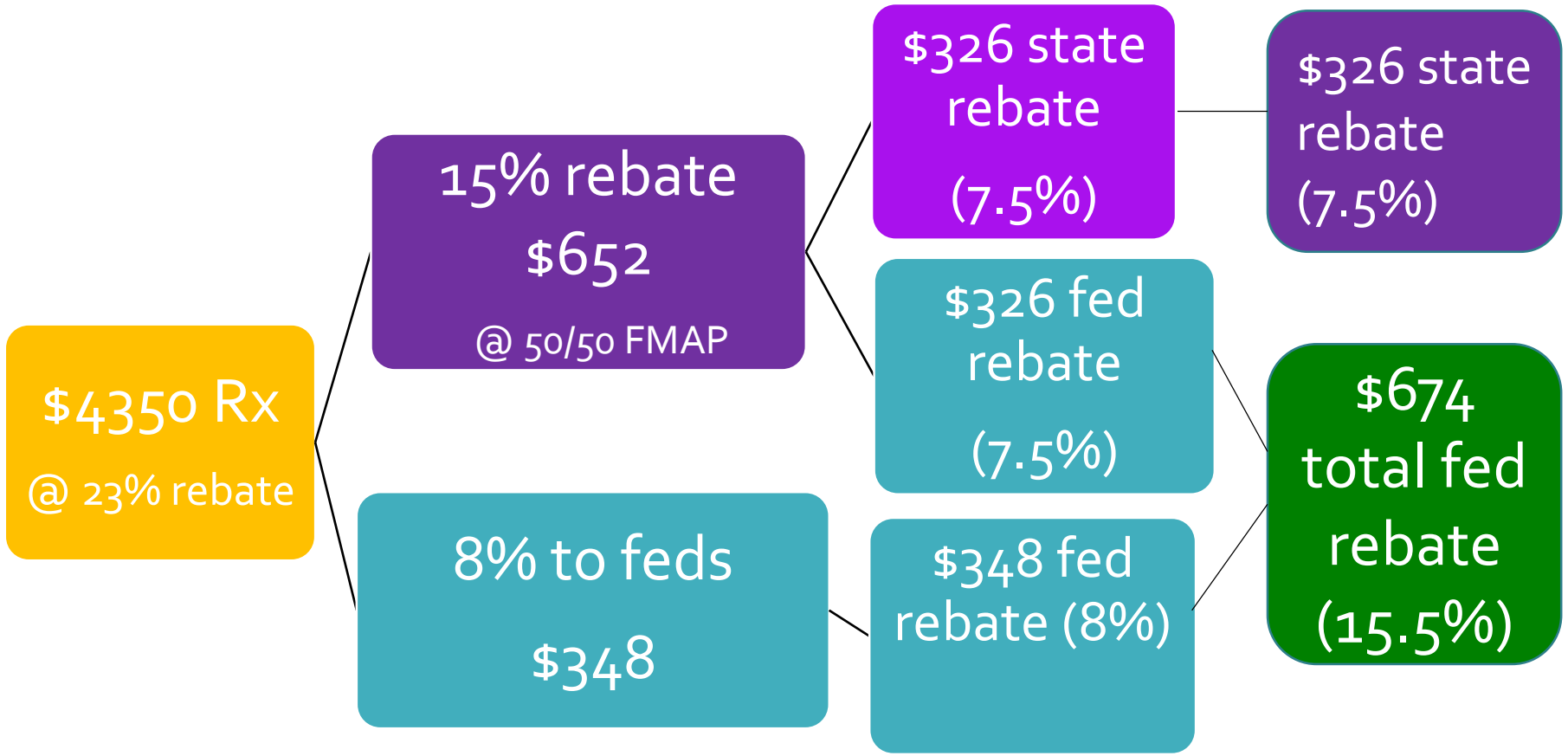
Manufacturer

- Corporate mergers
- Focus on oncology and rare diseases (high-priced biologics)
- Profits from price and price increases rather than sales
- Gross to net bubble
- Patent extensions

Provider

- 340B program creates market inequities between eligible providers and ineligible providers
- 340B program driving some provider consolidation

Medicaid Rebates Complicate Policy



States tend to think that there is too much $$ at stake for Medicaid to work with other state agencies in joint Rx purchase

State MDRP experimentation has high federal score thus barrier to law changes. CBO assumes joint purchase/waiver of BP experiments undermine 'best price' & federal revenues. Federal share of rebates also affects 1115 waiver federal budget neutrality math.

(FMAP of 50%, no best price, no CPI penalty in this example)

Thank You!

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State and Federal Action Addressing Prescription Drug Access and Affordability

Wisconsin Governor's Task Force on Reducing Prescription Drug Prices

National Governors Association
November 20, 2019

Agenda

01 Overview of State Action

02 Legal Challenges to State Action

03 Overview of Federal Action

04 Overview of Industry Action

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Overview of State Action

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Strategies Across Markets

States are pursuing a variety of strategies that have broad impact on pharmaceuticals access and costs across public, commercial, and self-insured markets:

- Regulation of Pharmacy Benefit Managers (PBMs)
- Regulation of Insurers
- Price Transparency
- Affordability Boards
- Importation
- Public-Private Group Purchasing
- Pay for Delay
- Price Gouging

Regulation of Pharmacy Benefit Managers (PBMs)

Regulation of PBMs has been the most prominent areas of action across states in recent years (40 bills addressing PBMs have been enacted in 2019 across 27 states):

- Prohibiting gag clauses in pharmacy contracts
- Imposing stronger disclosure and reporting requirements for PBMs
- Requiring PBMs to obtain licensure from the state
- Requiring PBMs to act as a fiduciary
- Regulating or prohibiting spread pricing
- Requiring that rebates and discounts received from manufacturers be fully passed on to the insurer
- Ensuring fair auditing of pharmacies by PBMs
- Prohibiting pharmacy copay clawbacks
- Regulating PBMs Maximum Allowable Cost (or MAC) lists
- Prohibiting PBMs from exclusively requiring mail-order pharmacies

Regulation of Insurers

States are pursuing a variety of approaches to regulate insurer benefit design and limit consumer cost sharing (32 bills addressing insurance design have been enacted in 2019 across 24 states):

- Restrict charging more than retail price at the point of sale
- Cap copayments for select drugs or drug classes
- Limit coinsurance percentage for specialty tier drugs
- Require prorated daily cost sharing rates for drugs dispensed by network pharmacies
- Limit the number of tiers on a formulary
- Establish step therapy protocol and override processes
- Restrict mid-year formulary changes, with certain exceptions

Price Transparency

Transparency has been a big focus in recent years regarding both drug prices (launch and increases) and PBM behavior (gag clauses and spread pricing):

- 2017 – 2019, 121 bills introduced across 33 states; 17 bills enacted across 11 states
- Transparency has also been implemented in conjunction with other strategies in some states (e.g., MA, NY)

Price transparency laws have typically included the following elements:

- Require manufacturers to report on and provide justification for drug launch prices and price increases over a certain threshold
- Require health plans to report on which drugs are driving plan spending
- Impose penalties for failure to report
- Publicize information (California, Nevada, Vermont have all released initial reports)

Affordability Boards

To address prices directly, several states have introduced and a few (Maine Maryland and Ohio) have enacted laws to establish authorities to review drug pricing and affordability:

- Boards or commissions tasked with reviewing and making recommendations regarding pricing, purchasing, and affordability challenges and opportunities in a state
- The charge and authority of affordability boards vary slightly across states
- In some states, these boards would have authority to set “allowable rates” for certain drugs

State Example: Massachusetts

Massachusetts recently introduced comprehensive health care legislation, which includes provisions related to pharmaceuticals:

- Creates a multi-pronged approach for increasing accountability for drug manufacturers
  - Subjects manufacturers of new, high-cost drugs to accountability reviews similar to existing processes for insurers and providers
  - Imposes a penalty on manufacturers that exponentially increase the cost of drugs which are sold or distributed in the Commonwealth

- Aims to increase state oversight of pharmacy benefit managers
  - Establishes a PBM certification requirement within the Division of Insurance
  - Requires PBMs to report financial data to increase transparency

Strategies for Public Programs

In addition to broader market strategies, states have been very active in advancing strategies to improve purchasing and manage access and costs for public programs:

Pharmacy Benefit Management	PBM Contracting	Reverse Auction Procurement	340B Oversight
340B for Corrections	Alternative Payment Approaches	Affordability Approaches	Multi-Agency Purchasing

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Legal Challenges to State Action

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Manufacturer Challenges

- Primarily related to state efforts to address price transparency and price gouging
- Alleged violations of trade secret laws, dormant commerce clause, due process, free speech laws, and federal patent laws
  - Alleged violations of trade secret laws are most compelling

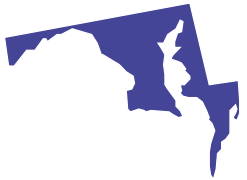
State Examples

California

Lawsuit against California (PhRMA v Brown) is ongoing (lawsuit was dismissed in 2018 then amended and allowed to proceed in 2019)

Nevada

Lawsuit against Nevada (PhRMA and BIO v Sandoval) was dropped after state agreed to trade secret protection regulations



Maryland

Federal appeals court struck down Maryland's law ruling that it violates the dormant commerce (AAM v Frosh)

PBM Challenges

- Primarily related to state efforts to address transparency and disclosures, fiduciary duty, and MAC pricing
- Largely focused on alleged violations of ERISA preemption
  - Challenges have also included alleged violations to the dormant commerce clause, contract clause (Art 1, Sec. 10), Medicare Part D preemption, takings (5th amendment) and void for vagueness

State Examples

- The Pharmaceutical Care Management Association (PCMA) has challenged 5 state laws regulating PBMs and won three of those challenges (District of Columbia, Iowa, Arkansas)
- Thirty-three states filed an amicus brief with the Supreme Court, detailing that the Eighth Circuit rulings are not consistent with Supreme Court rulings on state authority to regulate payment rates and protect residents.

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How Legal Challenges Affect State Policy

PBMs

- Inconsistent rulings raise questions but have not limited activity
- States can mitigate risk by avoiding explicit reference to "ERISA" in legislation and clarifying that nothing is intended to conflict with existing law

Price Gouging

- Price gouging legislation limited to generics and off-patent brands in response to DC Circuit ruling on supremacy clause/patent law
- But then the 4th circuit found that limiting price gouging to generics was not fair

Affordability Boards

- New legislation has been more limited to state/local government purchasers and payers
- Such limitations protect a state from a dormant commerce clause lawsuit, but undermine the intent and effectiveness of the boards

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Overview of Federal Action

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Federal Action – 116th Congress

- Over 20 hearings
  - Senate: Finance, Health Education Labor and Pensions (HELP), Judiciary, Aging
  - House: Energy and Commerce, Ways and Means, Oversight and Reform

- Over 130 bills have been introduced this Congress
  - At least 60 bills have bipartisan support and approximately 20 of those have support in both chambers
  - Bipartisan bills include those focused on:
    - Generic and biosimilar development (CREATES Act, FAST Act)
    - Pay-for-delay/anti-competitive behavior (Preserve Access to Affordable Generics and Biosimilars Act)
    - Patents and transparency (FAIR Drug Pricing Act, Biologic Patent Transparency Act, Prescription Drug Price Transparency Act, BLOCKING Act)
    - Importation (Safe and Affordable Drugs from Canada Act 2019)

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Federal Action – Bills to Watch

- **S.2543 - Prescription Drug Pricing Reduction Act of 2019**, sponsored by Sen. Chuck Grassley (R-IA)
  - Major ***Medicare*** provisions
    - Impose an inflationary rebate on Part B and Part D drugs
    - Establish a maximum add-on payment for Part B drugs
    - Establish a beneficiary out of pocket maximum for Part D drugs
    - Shift risk during the catastrophic phase to plans and manufacturers
    - Establish new reporting and transparency requirements
  - Major ***Medicaid*** provisions
    - Raise cap on rebates from 100 to 125 percent of the Average Manufacturer Price (AMP)
    - Exclude authorized generics from the calculation of AMP
    - Enable collection of rebates on certain drugs provided as part of outpatient hospital services
    - Prohibit spread pricing by pharmacy benefit managers
    - Permit value based purchasing arrangements for gene therapies
    - Create new standards related to reporting and conflicts of interest

Federal Action – Bills to Watch

- **S.1895 - Lower Health Care Costs Act**, sponsored by Sen. Lamar Alexander (R-TN) and Sen. Patty Murray (D-WA)
  - Broad package addressing health care costs that includes provisions on pharmaceuticals, such as:
    - Allowing certain generic or biosimilar drugs to enter the market earlier
    - Imposing new rules for insurers' contracts with pharmacy benefit managers and health care providers
    - Imposing new transparency requirements
- **S.1391 - Fair Accountability and Innovative Research Drug Pricing Act of 2019**, sponsored by Sen. Baldwin (D-WI)
  - Reporting and justification for certain drug price increases
- **H.R. 3 - Lower Drug Costs Now Act of 2019**, sponsored by Rep. Frank Pallone (D-NJ)
  - Would establish price negotiation for certain drugs in Medicare
  - Negotiated prices must also be offered under private health insurance unless insurers opt out
  - The negotiated maximum price may not exceed an international benchmark
  - Drug manufacturers that fail to comply would be subject to civil and tax penalties

Federal Action – Administration

? **International Pricing Index:** Advance notice of proposed rulemaking issued in October 2018 to set target sales prices for certain Medicare Part B drugs using an international benchmark based on prices in select foreign countries.

? **Importation**: Safe importation action plan was announced in July

- Pathway 1: HHS will outline a process for states, wholesalers, or pharmacists to submit plans for approval of demonstration projects to import drugs from Canada
- Pathway 2: Would allow manufacturers to import versions of their drugs sold in other countries if they can ensure it is the same version sold in the U.S. and meet other requirements.

X **Pricing in Television Advertisements**: A rule requiring drug price disclosure in television advertisements was blocked in federal court in July, the U.S. Department of Health and Human Services (HHS) filed a notice of appeal in August.

X **Safe Harbor Proposed Rule**: A proposed rule that would have eliminated safe harbor protection for drug rebates for Medicare Part D plans and Medicaid managed care organizations was withdrawn in July

Overview of Industry Action

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Consolidation

Recent Mergers and Acquisitions

Insurers, PBMs, and Pharmacies

- Aetna/CVS
- Cigna/Express Scripts
- Anthem/IngenioRx

Manufacturers

- Takeda/Shire
- BMS/Celgene
- Eli Lilly/ Loxo Oncology

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New and Existing High-Cost Drugs

- Price Increases
  - The costs of oral and injectable brand-name drugs increased annually by 9.2 percent and 15.1 percent, respectively, largely driven by existing drugs
- Pipeline/New Specialty
  - Late stage pipeline growth is mostly driven by specialty and niche therapies across a range of diseases
    - Oncology leads new launches
  - The prices of new drugs entering the market continue to rise, especially for oncology and orphan drugs
- Notable Products Highlight Challenges
  - Naloxone – opioid overdose reversal
  - Insulin - diabetes
  - Zolgensma – spinal muscular atrophy