Evolution of PBM Role in Brief (1)

- Retail pharmacy benefit administration was straightforward and low overhead until about 35 years ago.
  - Drugs priced to maximize sales
  - Drugs priced to compete in the market for sales (on-invoice price, not rebates)
  - Whether managed care or fee for service, PBMs paid pharmacy claims without need for strong cost management.
- Wonderful scientific advancement led to more Rx treatments for more illnesses.
  - Lots more people taking lots more drugs, lots more costs
  - Rx management starts to get complicated
- Manufacturers in 1990s started to focus on product *price* rather than *sales* to meet revenue targets.
  - Start of the movement to value based pricing.
  - Even the originator of the industry value-based pricing strategy says it's gone too far. (STAT First Opinion Kember 5/13/2022)
  - PBM role expanded – pharmacy networks, mail order, Rx deductibles, dictate (rather than negotiate) pharmacy reimbursements

Evolution of PBM Role in Brief (2)

- Increasing complexity and cost of Rx benefit led to greater role for PBM
  - Active formulary management (what is covered and how it is covered)
  - Active pharmacy network management (provider network creation)
  - Active pharmacy reimbursement management (not paying just what is billed)
  - Active negotiation with manufacturers for rebates on costly drugs
    - More rebates means a better formulary position for manufacturers drug(s)
- Growth in pharmacy complexity led to growth in size of PBM industry
- Growth of PBM industry led to industry mergers/consolidation
- PBM industry consolidation led to vertical corporate integration (mergers) with mail order pharmacy, then retail pharmacy, then insurers
  - Hypothesis: This is why the industry became so powerful and misaligned with customers and providers

PBM Business Practice Concerns

- Inappropriate Patient Pay and Access Policies
  - Patient copay exceeds what PBM will reimburse the pharmacy
  - Gag on pharmacist patient counseling on costs and alternatives
    - Outlawed in all states with new federal law
  - Financial penalties/higher cost share for patient failure to use mail order or corporate pharmacy chain.
- Independent pharmacies can be collateral damage of PBM competition
  - Discriminatory pharmacy reimbursement policies
  - Discriminatory pharmacy audit and claims payment reviews
  - Arbitrary claw back of money PBM already paid to pharmacy
  - Prohibit community pharmacy from home delivery (boosts PBM mail order operations)
  - *All these provisions may be fine for market battles between corporate titans, but these same provisions drive independent pharmacies out of business.*
  - ***April 2023 ExpressScript announces*** *it will reimburse rural independents more than chains and other support for rural independent pharmacies*

PBM Business Practice Concerns

- Lack of transparency to employer and other health plans
  - Spread Pricing: charging health plan clients more for enrollee drug spend than the PBM actually spent (Centene – 10 state AG settlements)
  - Contracts and operational complexity prevent smaller insurers from innovating
- Contract provisions that can increase Rx spend
  - Prefer covering higher priced drugs with higher rebates over generics or lower cost Rx alternates
    - Increases rebates while increasing total spend
  - Refuse to cover lower cost drugs with lower or no rebates
    - Low-cost versions of insulins and other drugs only available to people without insurance – because PBMs will not cover for insureds
- Vertical integration of insurer, PBM and pharmacy (retail and specialty)
  - Profit Maximizing rather that coordinated policy to improve patient care
  - CVS/CVSCaremark/Aetna over the top behavior

State Government Responses

PBM Business Practice Concerns

Source: Drug Channels 12/2022 https://www.drugchannels.net/

Brief History of PBM Regulation

- Concerns of independent pharmacists morphed into a more general review of PBM business practices. Trends in state regulation
  - 2012-2013 – laws to regulate PBM pharmacy audits, PBM reimbursement/payment to pharmacies
  - 2015-2017– limit patient out of pocket costs relative to cost of the drug, ban gag clauses, reviews of state employee and Medicaid PBM contracts
  - 2017 – 7 states enact laws. Broader PBM business practice concerns, including transparency (NV, OR)
  - 2018 – 14 states enact 25 laws
  - 2019 – 20 states enact 24 laws
  - 2020 – 20 new laws and feds enact transparency law that includes PBM transparency. 1st report due in 2023
  - 2021 – 15 states enact 21 new laws new focus on discrimination of 340B entities
  - 2022 – 11 states enact 18 new laws
- States have returned to their statutes multiple times to address PBM business practice concerns
- Rutledge v PCMA decision December 2020, Supreme Court.
  - States can regulate all health plans in a state with regard to healthcare rate setting. PBM contractors for employer plans not exempt from state regulation.

West Virginia PBM Laws – example of how states have to return again and again to address poor market practices

- **2017 – Pharmacy Audit Integrity Act –** addresses unfair audit practices SB522. Requires PBM registration
- **2019 – Fairness in Cost-Sharing Act –** requires counting of patient Rx cost sharing that is paid for by a third party on behalf of patient HB2770
- **2019 -- Pharmacy Audit Integrity Act –** adds more limits on PBM practices and consumer protections SB489
- **2020-- Pharmacy Audit Integrity Act –** replaces registration requirement with licensure requirement HB4058
- **2021 -- Pharmacy Audit Integrity Act –** add'l consumer protections and PBM rebate reporting HB2263
- **2022-- Pharmacy Audit Integrity Act –** add'l consumer protections and market behavior rules HB4112

PBM Rules in West Virginia (similar to other states)

- Halt inappropriate patient cost and access policies
  - Patient cost share cannot exceed PBM pharmacy reimbursement
  - No gag clause
  - No $ penalties when patient does not use mail order
  - No reimbursement or access discrimination of 340B pharmacies
  - Allow patient choice of pharmacy without penalties
  - Patient cost-share based on PBM's net cost (after rebates)
- Halt policies that disadvantage independent pharmacies
  - No reimbursement policies that disadvantage independents
  - No unfair audit practices
  - Allow independents to provide home delivery
  - Minimum pharmacy dispensing fees of $10.49
  - No performance metrics for dispensed drug (ie generic dispensing rate)
  - Allow performance metrics for pharmacy care
  - Pharmacy reimbursement cannot be less than NADAC (federal drug cost survey file) or wholesale acquisition cost
  - No pharmacy network participation requirements more stringent than State laws

PBM rules in West Virginia

- Improve market transparency
  - Require PBM licensure
  - Ban spread pricing
  - Report to DoI rebates collected, retained by PBM, passed through to the health plan and/or passed through to patient
  - Report to DoI rebates by therapeutic class
  - Report to DoI pharmacy reimbursement formula
  - Report to DoI pharmacy network adequacy
  - Report on annual wholesale acquisition cost (WAC) of 25 highest spend drugs

Feds Get Started Regulating PBMs

- 2019 Congress bans any contract that prohibits pharmacy from advising patients on Rx costs and purchase options
  - Follows laws of many states
- 2021 Require all health plans and their PBMs
  - to report to Dept of Labor and Health and Human Services data:
    - 50 Rx for highest cost, for most prescribed, for biggest spending increase
    - Follows laws of many states
    - Detailed data on patient costs, rebates, fees, etc for each drug
    - Report to public in 2023
- 2022 Federal Trade Commission (FTC)
  - decides to investigate PBM industry
- 2023
  - 7 Senate PBM bills, 3 out of Committee
  - 5 House PBM bills, 2 out of Committee
  - Bills follow several the laws of many states