

August 15, 2019

NAIC PBM Subcommittee Meeting

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Basics of the Pharmaceutical Market & PBMs

Horvath Health Policy, *Innovations in Healthcare Financing Policy*

Topics Today

- Overview of Pharmaceutical Sector
 - Regulatory Framework
 - Who Does What
 - Difference Between Discounts and Rebates
- Concerns with PBM Business Practices
- State Responses to Concerns

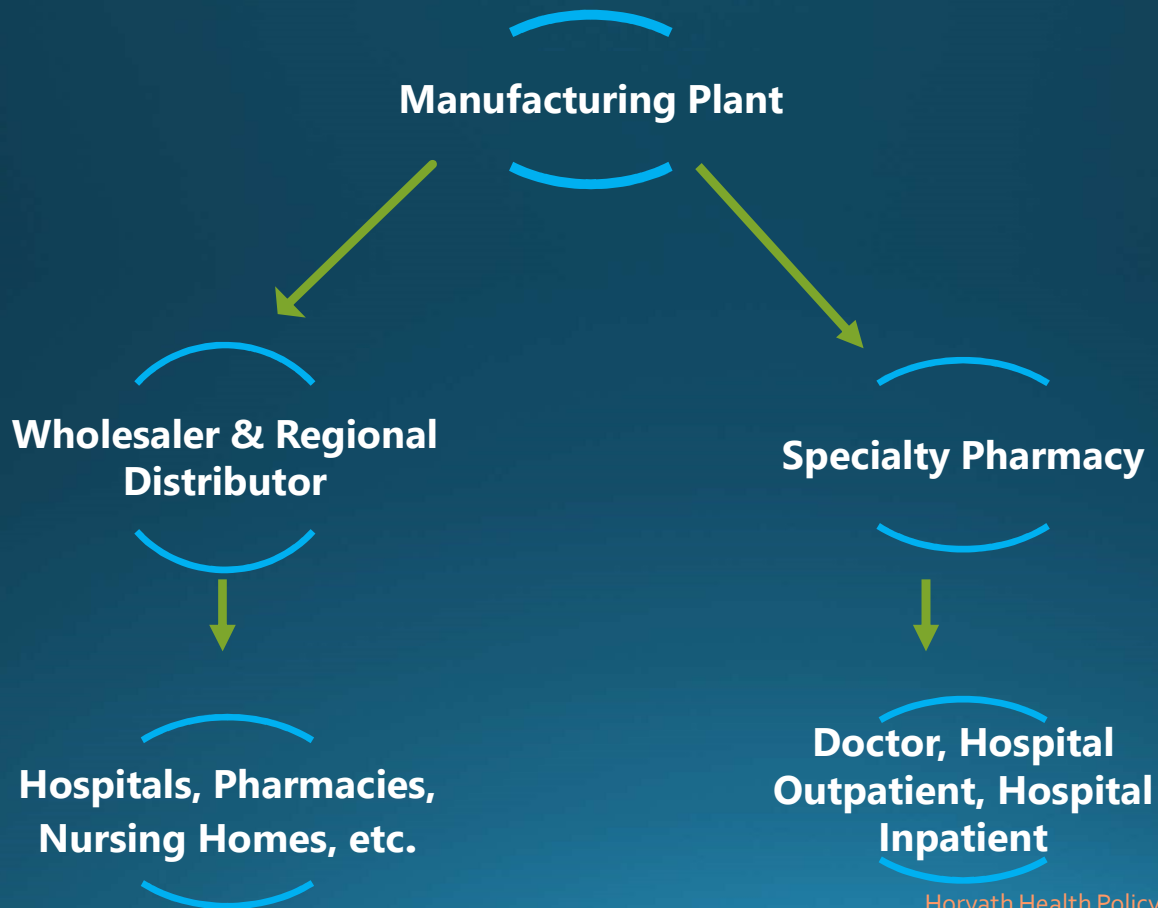
Pharmaceutical Market

Who Does What

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 (AND, 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**
- **Centers for Medicaid and Medicare Services, HHS**
 - Drug Payment Amounts
 - Anti kickback – Medicare and Medicaid (no free goods, new -- *no rebates*)
 - Coverage Policy
 - Medicaid Drug Rebate Program
- **States license supply chain -- wholesaler to end purchasers**
 - Not all states regulate PBMs

Basics of Product Supply Chain



Specialty Pharmacy can be wholesalers, PBMs, hospitals, provider groups, and pharmacies

Who Does What? Manufacturers

- **Bringing 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)
 - 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
 - Manufacturers are often state-licensed to have product sold in the state
- **Set the price**
 - Years before a drug reaches the market
- **Can lease the drug license** to another company to sell
- **Sales and marketing, life cycle management**
 - Price changes, price concessions, patient assistance

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 other roles
 - Specialty Pharmacy: McKesson administers the Vaccine for Children supply to pediatrician offices
 - Pharmacy Services Admin Org (PSAO): bill and negotiate with PBMs on behalf of pharmacies
- Are state licensed and FDA-registered

Who Does What? PBMs (or Insurers without PBM)

- **Create pharmacy networks**
 - Negotiate pharmacy professional (aka dispensing) fees
 - Set drug reimbursement amounts
 - Pay pharmacy claims
 - Operate mail order pharmacy (PBM only)
- **Operate formulary**
 - Small plans use PBM national formularies, large plans may design their own
 - Negotiate manufacturer rebates based on formulary placement
 - Decides on pharmacy utilization management application*
- **Reimburse pharmacies and providers** for drugs dispensed or administered to enrollees
- **Operate/Corporate Link to Mail Order Pharmacy and Specialty Pharmacy**
- **Collect manufacturer price concessions** based on paid Rx claims
- **States recently started to license PBMs**

Who Does What? Insurers

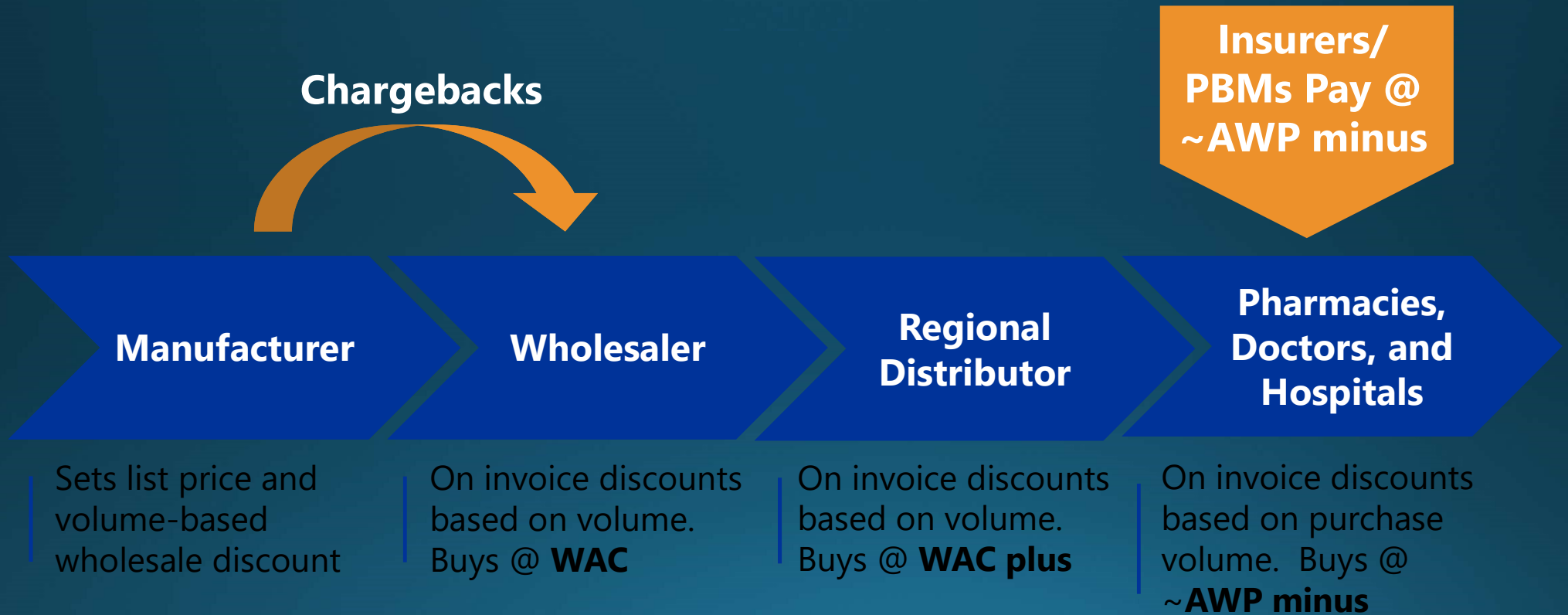
- **Contract with PBMs**
 - Scope of PBM role depends on insurer, usually size of insurer
 - Reimburse PBM for pharmacy 'claims paid'
- **Why contract with PBMs?**
 - Running pharmacy benefit has become complex
 - Response to rising prices (utilization management)
 - Managing rebates
 - Need to negotiate with pharmacies for fees and Rx reimbursement to 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)

Who Does What? Pharmacies

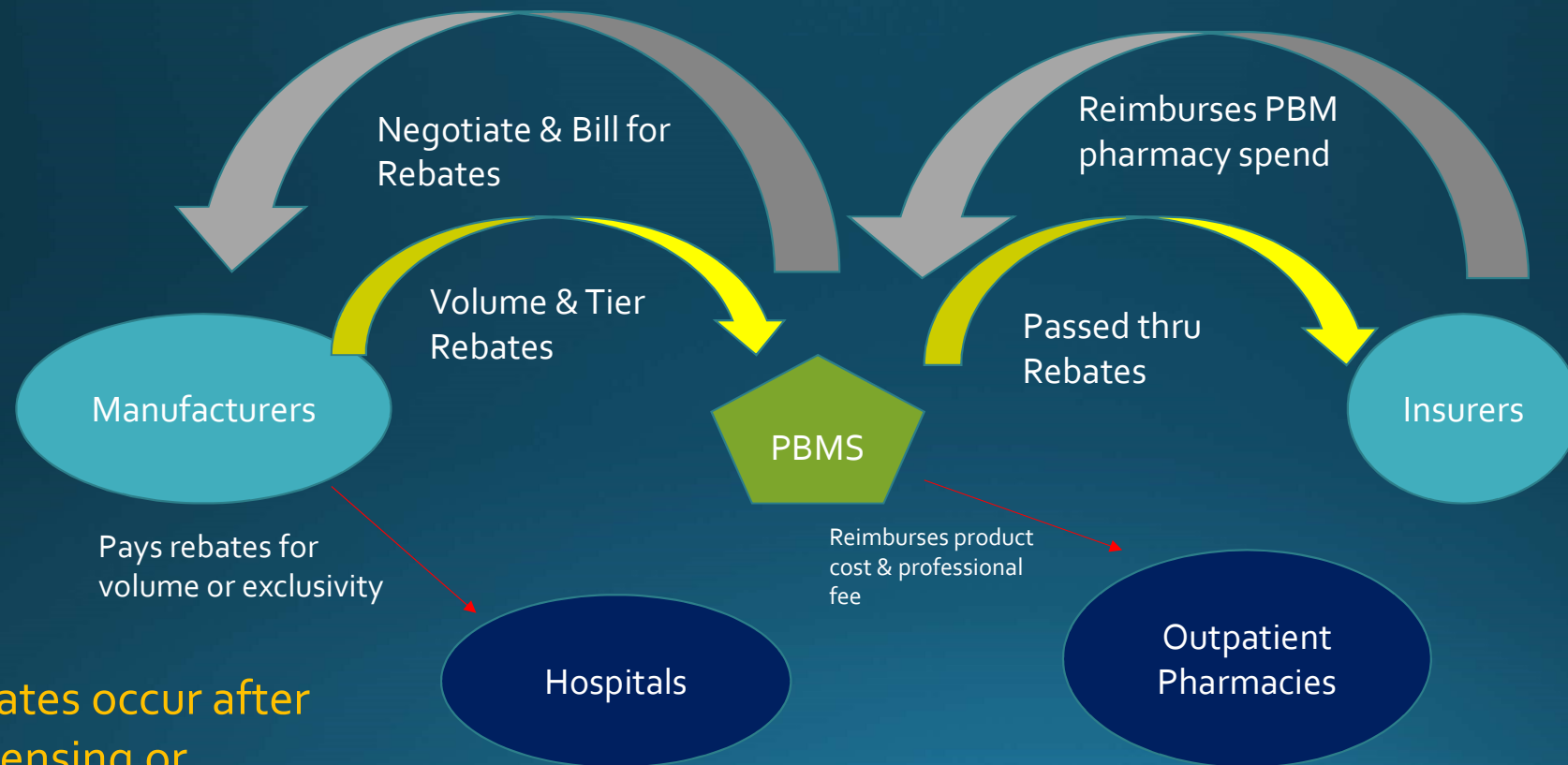
- **Retail pharmacies** – open to public
 - Purchase drugs from wholesalers and distributors
 - Hire administrative services companies to handle claims wrangling and often to group purchase negotiations
 - Counsel patients
 - Can't drive brand name market share but can drive generic market share
- **Specialty pharmacies** – not open to public
 - Contract with manufacturers to handle specific, 'specialty' drugs
 - Work with administering providers to get product to offices as needed
 - Case management for patients on the drug
 - Administrative assistance to administering providers (handling, billing etc.)
 - Can also be almost any part of the supply chain
- **Pharmacies can be**
 - Independent, regional, or national chain
 - Linked to a PBM (applies to national chains CVS/CVS Caremark, Walgreens/BootsAlliance)
 - Wholesalers

Basics of Brand Rx Discounting

*Discounts are “up front” on the invoice



Basics of Manufacturer Rebates



Rebates occur after dispensing or sale

Concerns:

PBM Business Practices

PBM Business Practice Concerns (1)

- **Disadvantage independent and regional pharmacy chains**
 - Discriminatory pharmacy reimbursement policies
 - Discriminatory audit and claims payment review policies
 - Independents don't have market leverage like national pharmacy chains
 - Prohibiting home delivery (block competition with PBM mail order business)
- **Inappropriate patient pay and access policies**
 - Patient copay can exceed retail price or exceed what pharmacy will be reimbursed by PBM
 - Pharmacist contract 'gags' patient information on lower cost ways to buy Rx
 - (outlawed in most states and now outlawed at federal level for ERISA, Medicare and Medicaid, and Exchange Plans)
 - Financial penalties for not using PBM mail order or corporate pharmacy chain

PBM Business Practice Concerns (2)

- Lack of Transparency to Health Plan Clients

- Charging Clients more for paid claims reimbursement than PBM actually paid out to pharmacy (spread pricing)
- Lack of transparency
 - level of rebates obtained from manufacturers
 - percentage share of rebates retained by PBM
- Prohibit (smaller) health plans from innovating for cost containment – joint purchasing, group purchasing

PBM Business Practice Concerns

State Responses

State Government Responses (1)

- **Trend:** independent pharmacy concerns created morphed into general review of PBM business practices toward pharmacies, health plan clients (including public programs), and enrollees. States with less comprehensive bills have amended laws in later years to become comprehensive
- **2012-2013** PBM pharmacy audits, PBM pharmacy payment formulas
- **2015-2017** Limits of patient out of pocket costs relative to cost of drugs, gag clauses, Medicaid and state employee PBM contracts
- **2017** – 4 states 4 enacted laws transition to broader concerns about business practices
- **2018** – 14 states enacted 25 laws, state AG activity, congress bans gag clauses
- **2019** – 20 states enacted 24 bills

State Statutory Constructions

- **Insurance Statute:**
 - Obligations and requirements for PBM run through existing insurance law – obligation/requirements for insurer pharmacy benefit whether contracted to PBM or not
- **New PBM Statute:**
 - New statute for PBMs specifically focused on contract law with pharmacies and health plans
- **Licensure and/or permits**
 - Through Insurance Department and/or Board of Pharmacy with rules for contracts and business relationships

State Law Policy Approaches: Fair Dealing

- **Business relationships with health plans**
 - Fee-only contracts
 - PBM fiduciary responsibility
 - Ban spread pricing (billing insurer more than what was paid out to pharmacy)
 - Specific reporting on costs and rebates to health plan clients
- **Business relationships with pharmacies**
 - Contract provisions no longer permitted (eg gag clause)
 - Audit rules
 - Pharmacy payment algorithm rules and transparency to pharmacies
 - No discriminatory payment or participation standards based on financial link to PBM

State Law Policy Approaches: Transparency

- **PBMs report financial information**
 - Rebates received and retained
 - Fees received and retained
 - Payments to pharmacies and charges to health plan
- **PBMs report to state government**
 - Aggregated data to protect trade secrets
 - Reports made public
- **PBM reports to health plans**
 - More financial detail include

State Law Policy Approaches: Medicaid and State Employees

- **Medicaid/Medicaid MCO**
 - Consolidate pharmacy operations at state level
 - New contract rules for transparency and spread pricing
- **State employees**
 - New contract rules for transparency and spread pricing
 - Reverse Auctions

Thank You!

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