February 12, 2019
Oregon House Committee on Healthcare
Jane Horvath

# Basics of the Pharmaceutical Market

Horvath Health Policy, *Innovations in Healthcare Financing Policy*

# Understanding the Pharmaceutical Market: Supply Chain and Financing Chain -- Agenda

01.

**Pharmaceutical Costs – What Is The Concern?**

Context setting for why this matters.

02.

**Supply Chain**

Overview of the pathway of a drug from market entry to consumers.

03.

**Pricing**

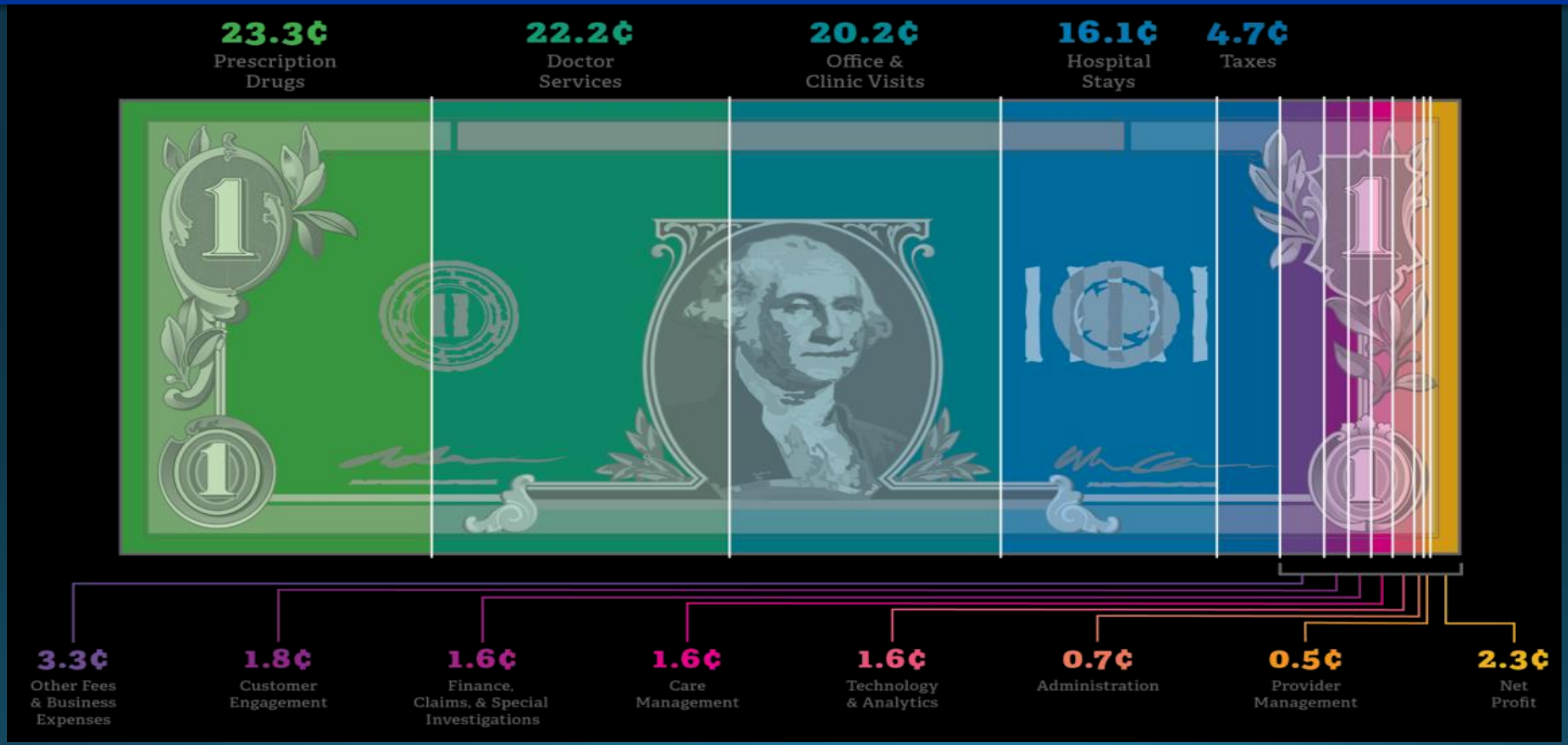
Overview of how drugs are priced and paid for and how competition affects price and cost across drug types.

04.

**Trends**

Overview of business and policy changes impacting the market and important considerations for state leaders.

# Why Is There Concern About Costs?




*Source: America's Health Insurance Plans, 2018*

# States Carry Majority of Rx Costs

State taxpayers fund some portion of pharmacy benefits for ~25%-30% of a state's population, depending on the state.

| | | |
|---|---|---|
| Medicaid | State Tax Expenditures For Income Tax Exemption of Employee & Employer Premiums | State Corrections |
| State And Local Public Health | State And Local Employee And Their Dependents | State Higher Education |

Horvath Health Policy, *Innovations in Healthcare Financing Policy*

# Common Rx Terms

## Brand/Generic "Small Molecule Drugs"

- **Brands**
  - Require original research and development for approval / approved under a New Drug Application (NDA)
  - Can be 'first in class" or a "me too drug"
- **Generics**
  - Clinically equivalent to a branded product
  - Do not require original research for approval / licensed under an Abbreviated New Drug Application (ANDA)

## Biologic/Biosimilar "Large Molecule Drugs"

- **Biologics**
  - Made from living cells; typically not taken orally
  - Licensed under a Biologic License Application (BLA)
- **Biosimilars**
  - Highly similar to a previously approved biologic (not absolutely equivalent)

## Price

- The (public) dollar amount charged by the seller

## Cost

- The amount paid by the purchaser (may or may not be public)
- Cost may be include an front-end discount or back-end rebate

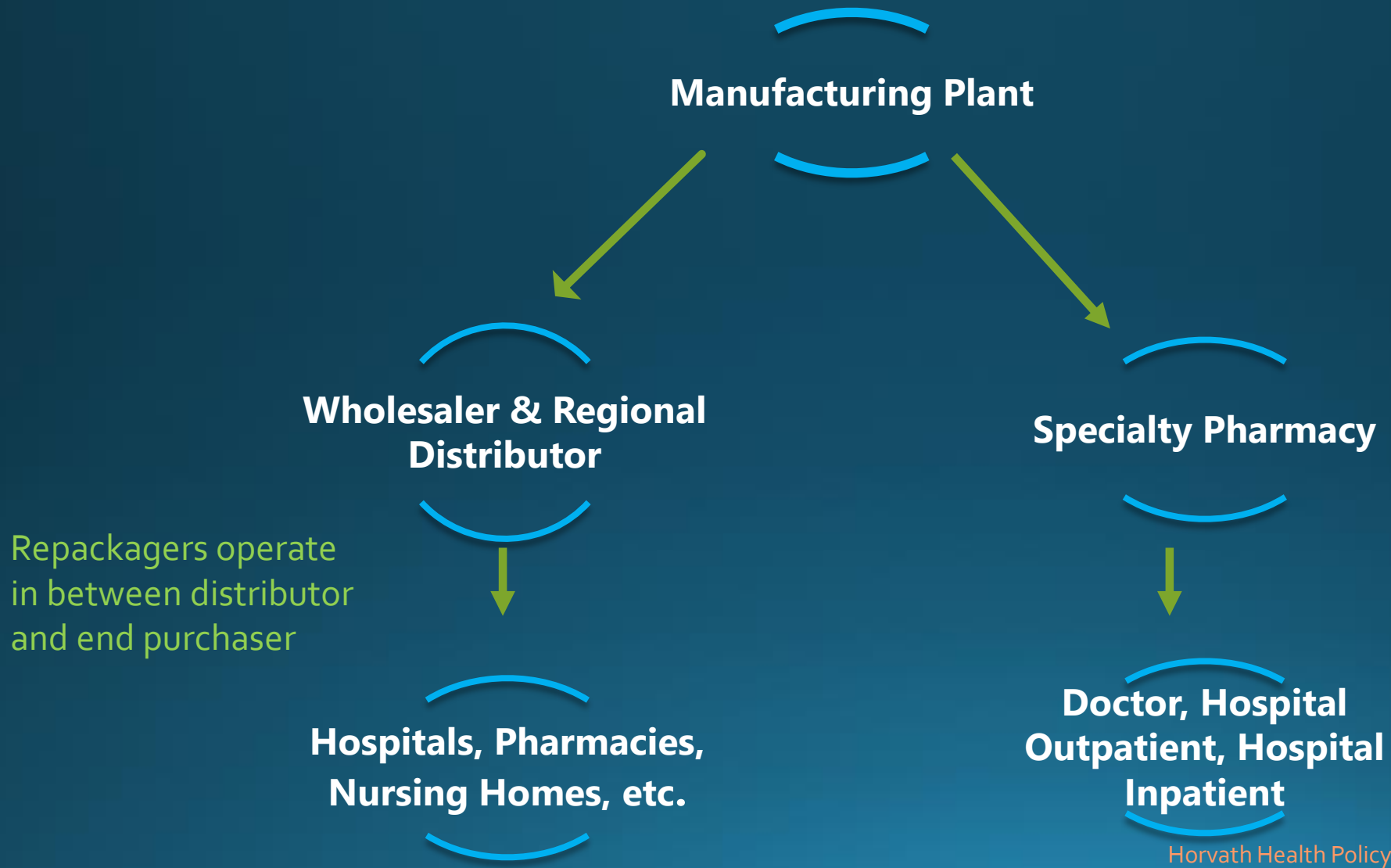
## Price Concession

- Any manufacturer activity that lowers the net cost of a drug for a purchaser or payer
- Rebates (back end) vs. discounts (front end)

# 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




Horvath Health Policy, *Innovations in Healthcare Financing Policy*

# 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
  - often 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 be a specialty pharmacy
  - McKesson administers the Vaccine for Children supply to pediatrician offices

# 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 take 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 to or administered to enrollees
- Collect manufacturer price concessions based on paid Rx claims
- Health plans are state-licensed; not all states license PBMs

# Who Does What? Insurers

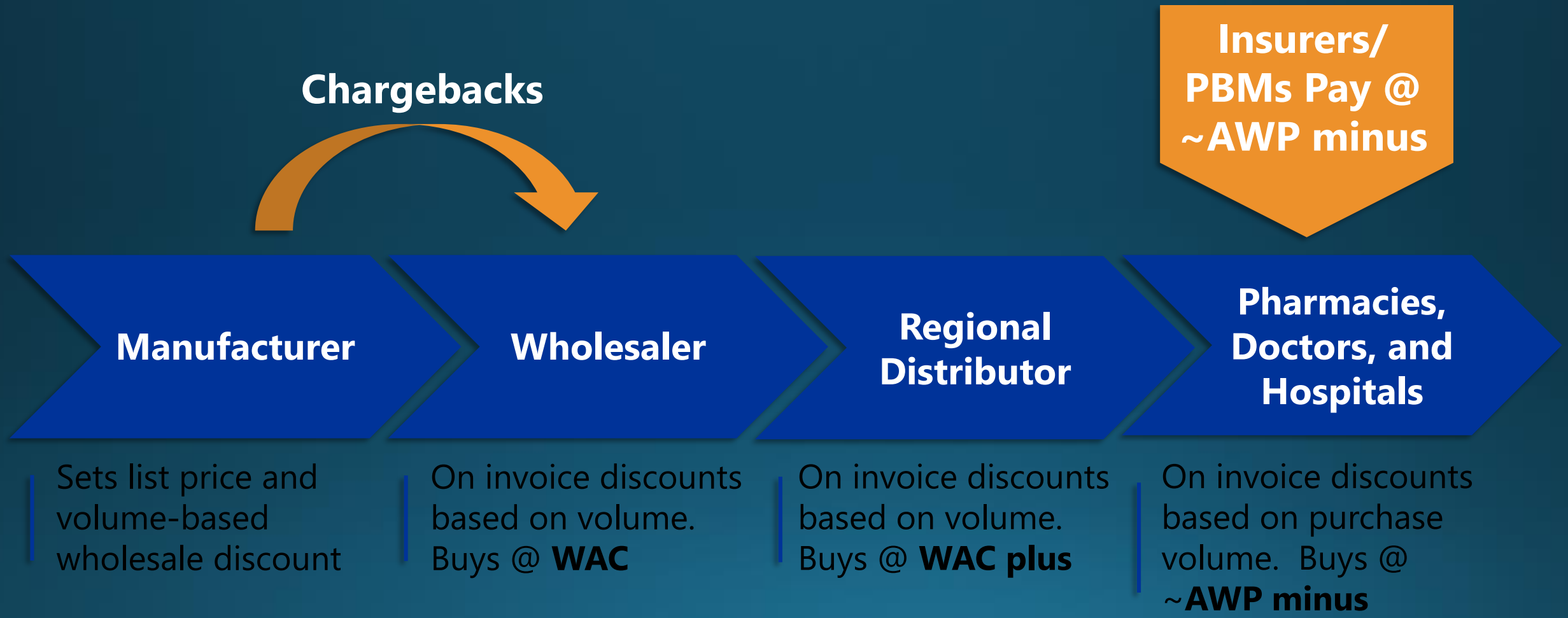
- Contract with PBMs
  - Scope of PBM role depends on insurer, usually size of insurer
  - Reimburse PBM for pharmacy 'claims paid'
- Why contract with PBMs?
  - Running pharmacy benefit has become complex
    - Response to rising prices (utilization management)
    - Managing rebates
    - Need to negotiate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

# Who Does What? Pharmacies

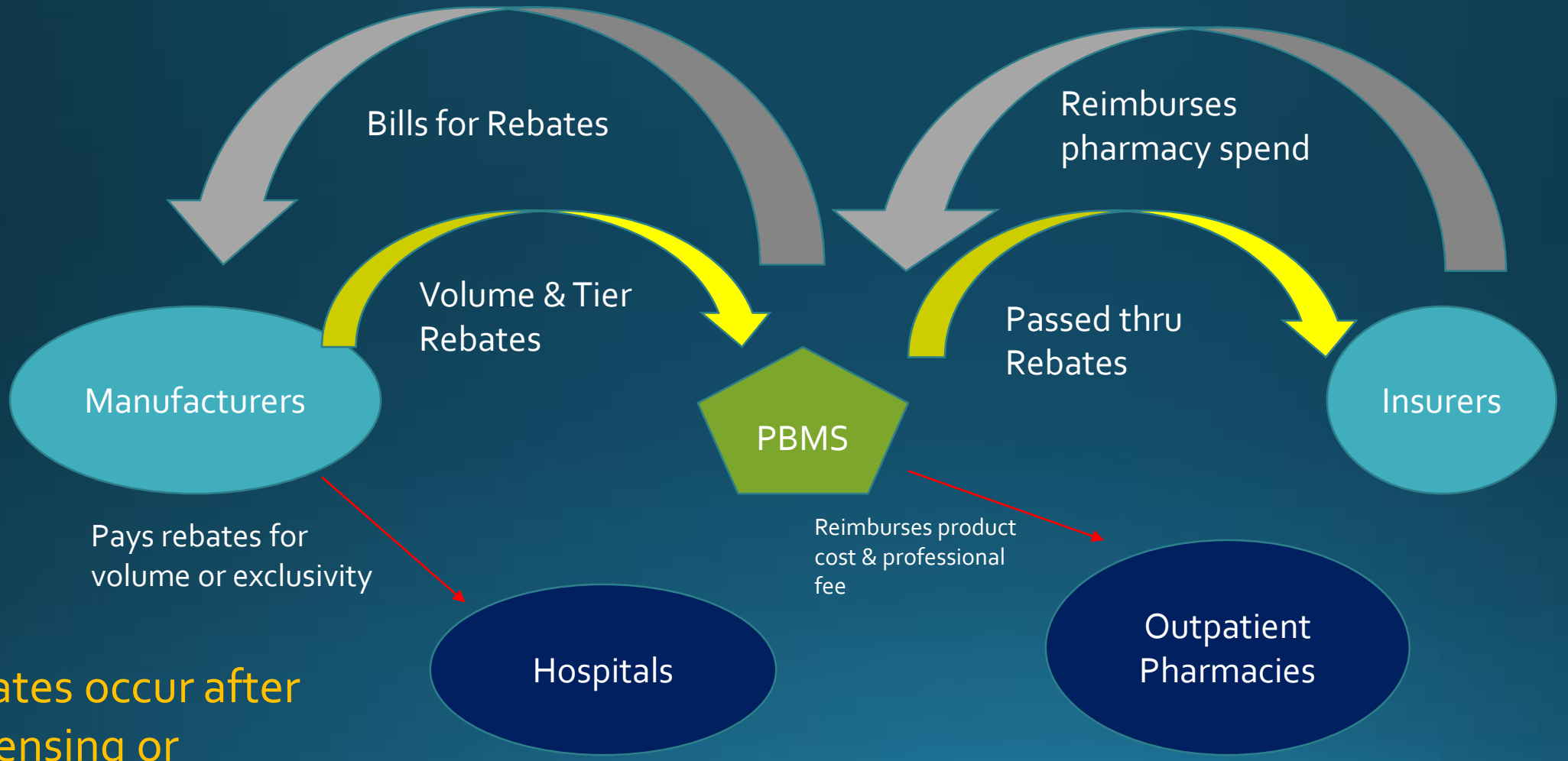
- Retail pharmacies – open to public
  - Purchase drugs from wholesalers and distributors
  - Hire administrative services companies to handle claims wrangling and often to group purchase negotiations
  - Counsel patients
  - Can't drive brand name market share but can drive generic market share
- Specialty 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.)

# Basics of Brand Rx Discounting

*Discounts are "up front" on the invoice



# Basics of Manufacturer Rebates




Rebates occur after dispensing or sale

Horvath Health Policy, *Innovations in Healthcare Financing Policy*

# Business Trends

**Insurer**

- Insurer mergers
- Insurer/PBM mergers
- Rise of breakthrough/fast track drugs

**PBM**

- PBM/Chain Drugstore Mergers and treatment of independent pharmacies
- Reliance on/impact of rebates
- Transparency laws

**Mfr**

- Corporate Mergers
- Focus on oncology and rare diseases (high priced biologics)
- Focus on Wall Street rather than increased product sales
- Gross to Net Bubble
- Profits from price and price increases

**Provider**

- 340B Program driving provider consolidation and implications for competition
- Rise of Specialty Pharmacy

Horvath Health Policy, *Innovations in Healthcare Financing Policy*

# Policy Innovations

**Insurer**

- Transparency on Rx costs and impact on premiums
- Loss of rebates = Lower Prices?

**PBM**

- PBM pharmacy network business model under pressure from regulators (pharmacy contracting rules)
  - Transparency laws
  - State licensure
- Proposed federal rule to ban rebates in Medicare Part D and Medicaid Managed Care

**Mfr**

- State and Federal activity to constrain prices and costs in malfunctioning market:
  - Drug product and drug price importation
  - rate setting
  - price increase reporting
  - Medicare cost negotiations
  - pressure on patent law

**Provider**

- Federal efforts capture more 340B Rx cost savings from hospitals to payors (Medicare)
- State and federal action on drug costs will squeeze profit margins

# Why State Policy Choices Seem Limited

- Federal Patent law – no direct price controls on manufacturers
  - Federal case law
  - Supremacy Clause
  - 340B should be a precedent on congressional intent
- Dormant Commerce Clause
  - States cannot regulate commerce outside their borders but have right to protect health and welfare of residents
  - Case law creates challenge to state regulation in world of national and global commerce. Even state regulation of public utilities could come under challenge if 4th Circuit stands (Maryland Price Gouging law decision)
- Medicaid Best Price
  - State programs (state employees, corrections, are not exempt while federal programs are exempt).

# Thank You!

Jane Horvath

Horvath Health Policy, *Innovations in Healthcare Financing Policy*

*Linkedin.com/in/horvathhealthpolicy*

*HorvathHealthPolicy@gmail.com*

*202/465-5836*