

Understanding the Prescription Drug Supply and Financing Chain

Ohio Prescription Drug Transparency and
Affordability Advisory Council

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Horvath Health Policy

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BACKGROUND

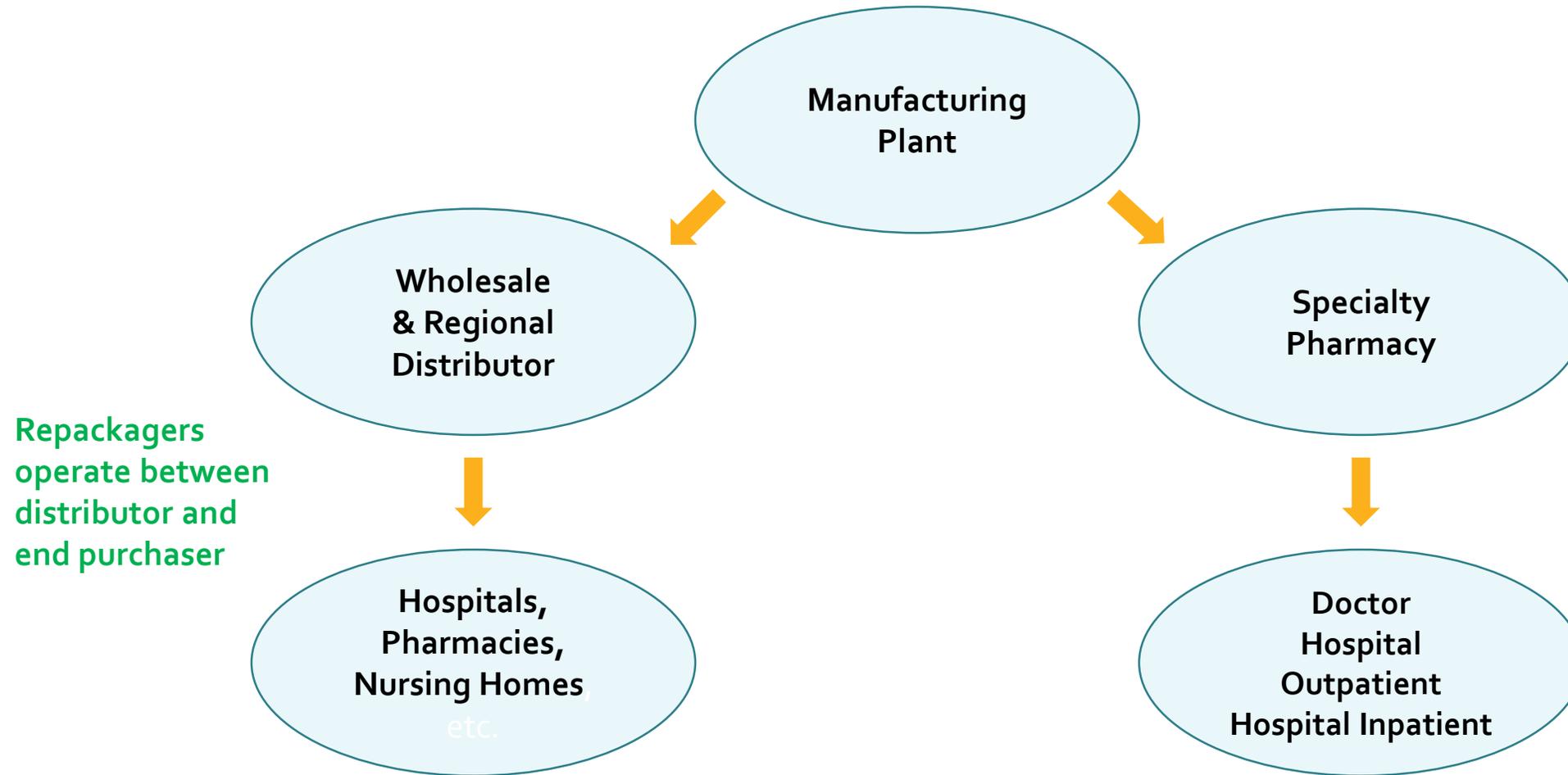
Rx Industry Legal and Regulatory Framework

- **Food and Drug Administration, U.S. Department of Health and Human Services (HHS)**
 - 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 Medicare and Medicaid Services, HHS**
 - Drug Payment Amounts (Medicare Part B)
 - Anti-Kickback Statute - 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 pharmacy benefit managers or pharmacy administrative 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

Basics of Product Supply Chain





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), purchase 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 (PSAO)**

- 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.

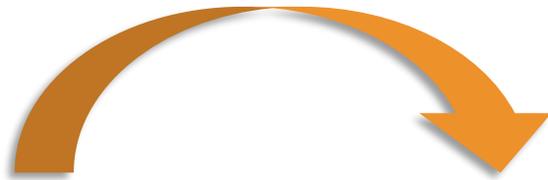
5. Unify Rx figures include the estimated PSAO members from TriNet Third Party Network (PBA Health) and RxSelect Pharmacy Network (PPOK).

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

Basics of Rx Brand Discounting

*Discounts are “up front” on the invoice

Chargebacks



**Insurers/
PBMs Pay @
~AWP minus**

Manufacturer

Sets list price and volume-based (WAC) with wholesale discount

Wholesaler

On invoice discounts based on volume. Buys @ **WAC or WAC minus**

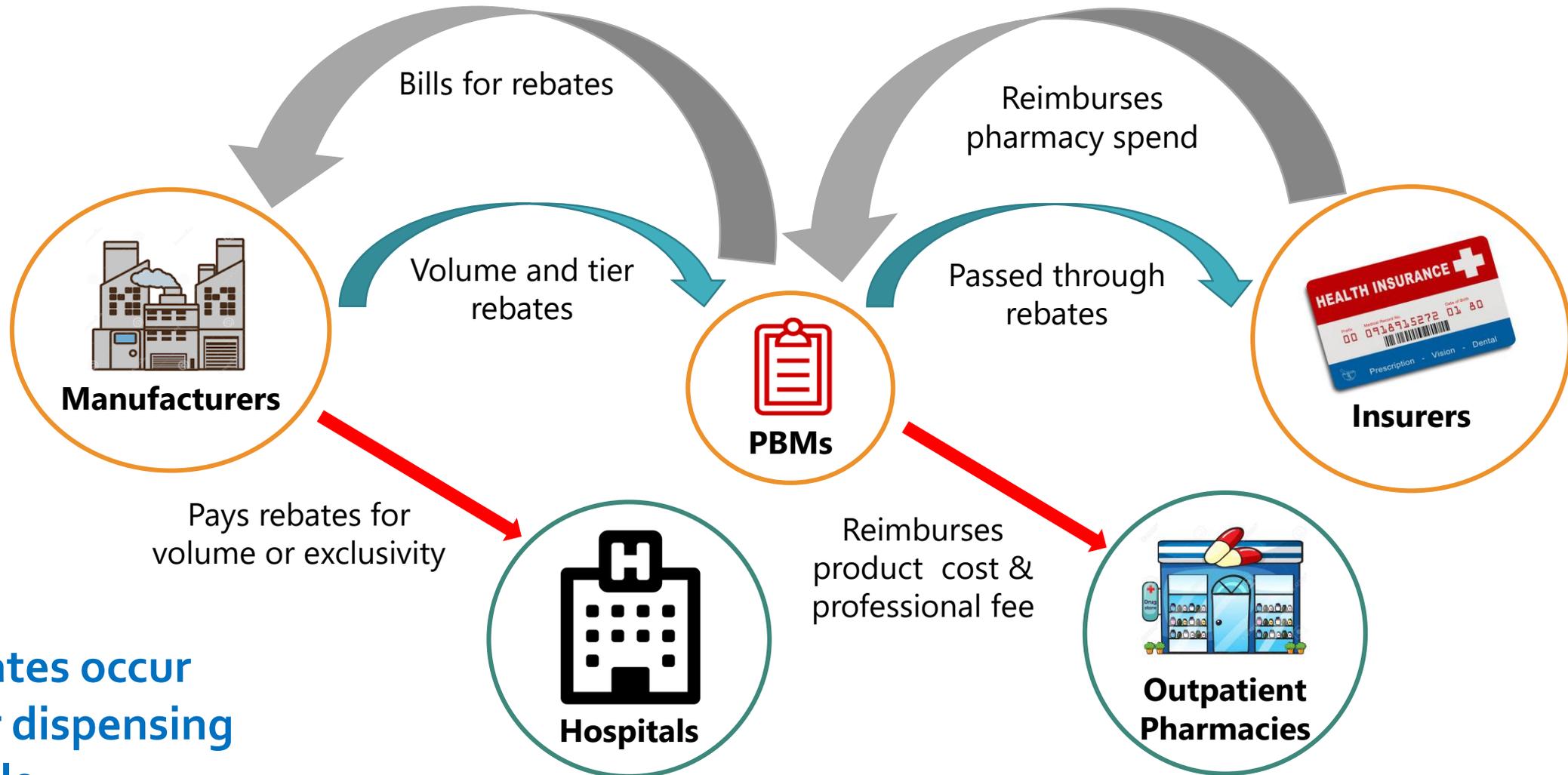
Regional Distributor

On invoice discounts based on volume. Buys @ **WAC or WAC plus**

**Pharmacies,
Doctors, and
Hospitals**

On invoice discounts based on purchase volume.

Basics of Manufacturer Rebates



Rebates occur
after dispensing
or sale

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).

Status of FDA Expedited Review

- **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, VA, 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

\$1000 Rx Example

Statutory rebate = 23.1%

Best price = 25% rebate



\$1000 Rx
@ 25% rebate
\$250 total rebate

\$170
17% rebate on
\$1000
(Shared @ 50/50 FMAP)

\$80
8% rebate on
\$1000
(all to feds)

\$85 total state
rebate
(8.5%)

\$85 fed rebate
(8.5%)

\$165 total fed
rebate
(16.5%)

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 CPI penalty in this example)

Thank You!

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