

Structure of the Prescription Drug Market & Drug Prices

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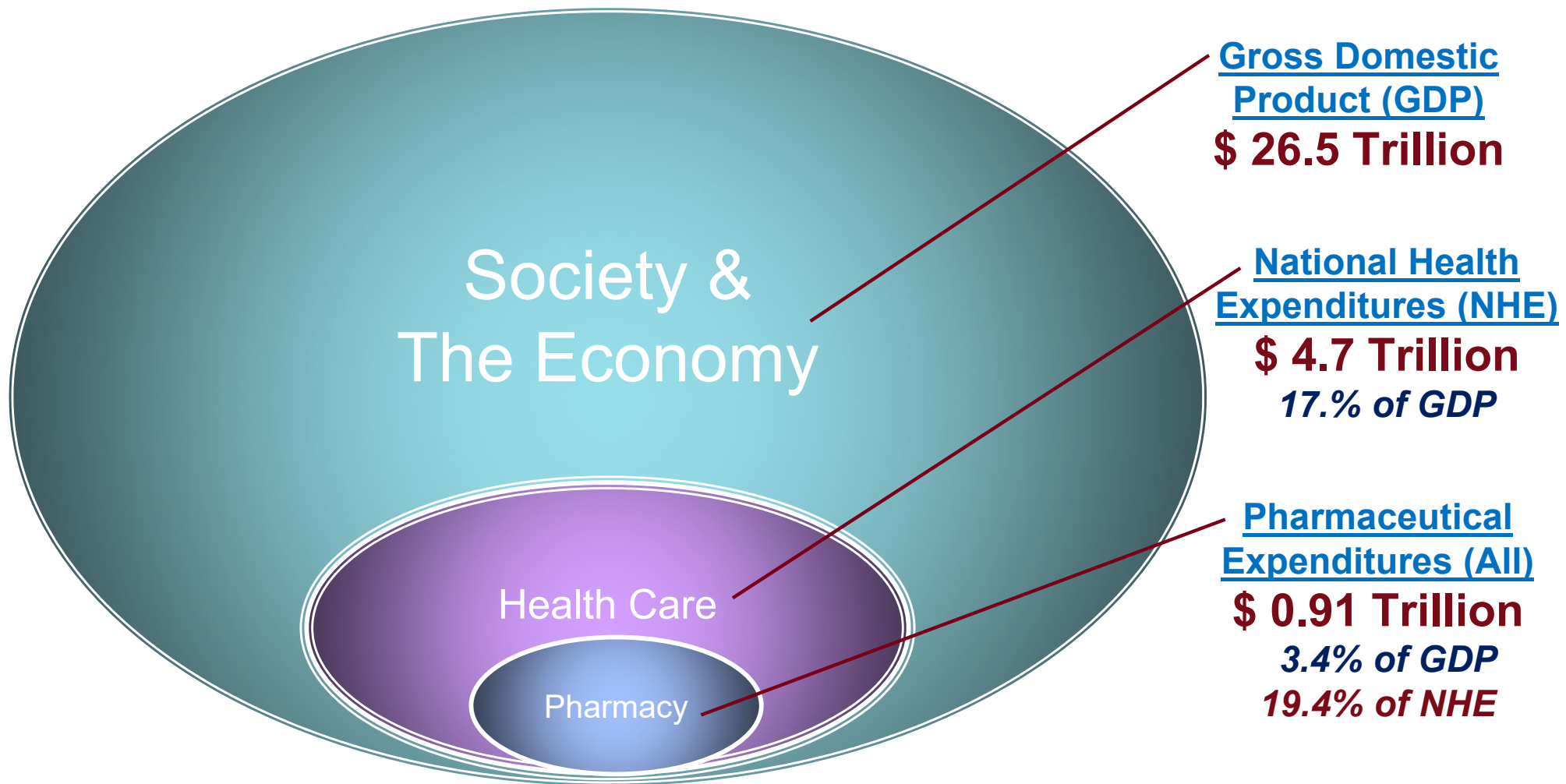
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June 20, 2024

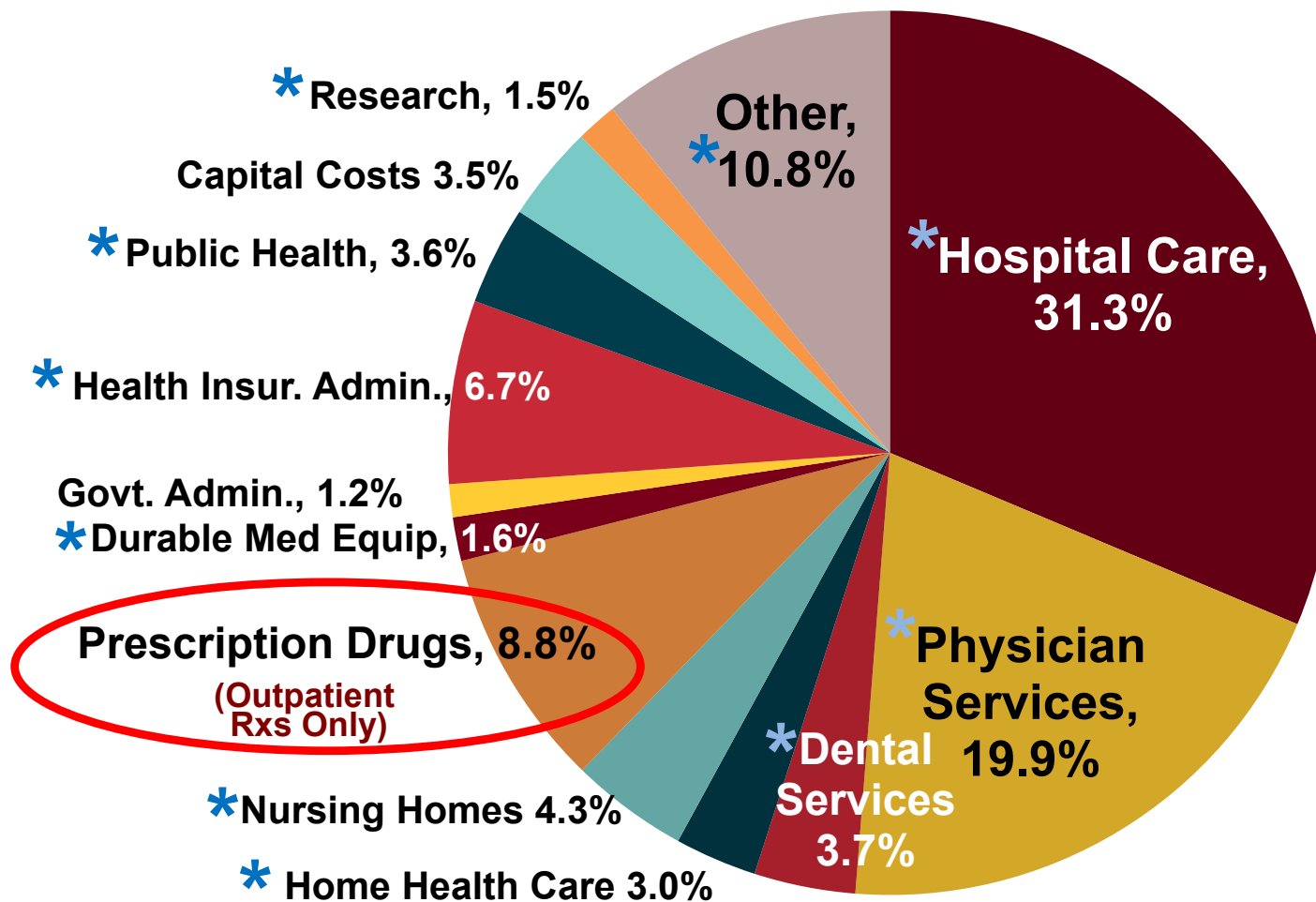
Role of Pharmaceuticals in Health Care & Society & The Economy



The Nation's Health Dollar: 2023

(FY 2023, \$ 4.666 trillion)

Where Did It Go?



What Role Did Drugs Play?

Are Drugs Used in Other Sectors?

YES!

* Other sectors that include Rx drugs.

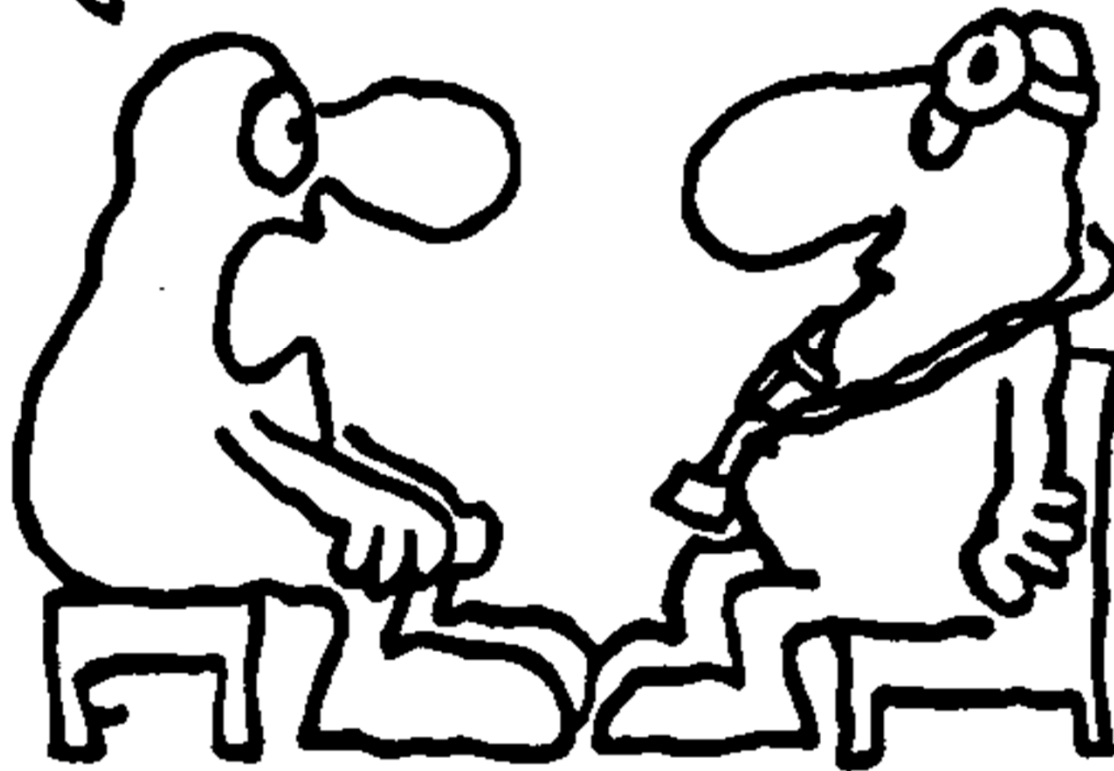
All Settings includes:

- * Hospitals, hospices, other inpatient care
- * Physician dispensing
- * Clinics (specialty meds)
- * Military, VHA, Tricare
- * Federal Qualified Health Clinics, PHS, IHS
- * Patient Assistance Programs, samples
- * Other (prisons, schools, state facilities, etc.)

**Rx Drugs
in All Settings*
~ 19.4%**

2023 U.S. Data

DOCTOR, HOW SICK
AM I - IN DOLLARS
AND CENTS?



GDP per Person

\$ 79,508

Median Salary
per Person

\$ 53,490

Personal Health
Exp. per Person

\$ 11,689

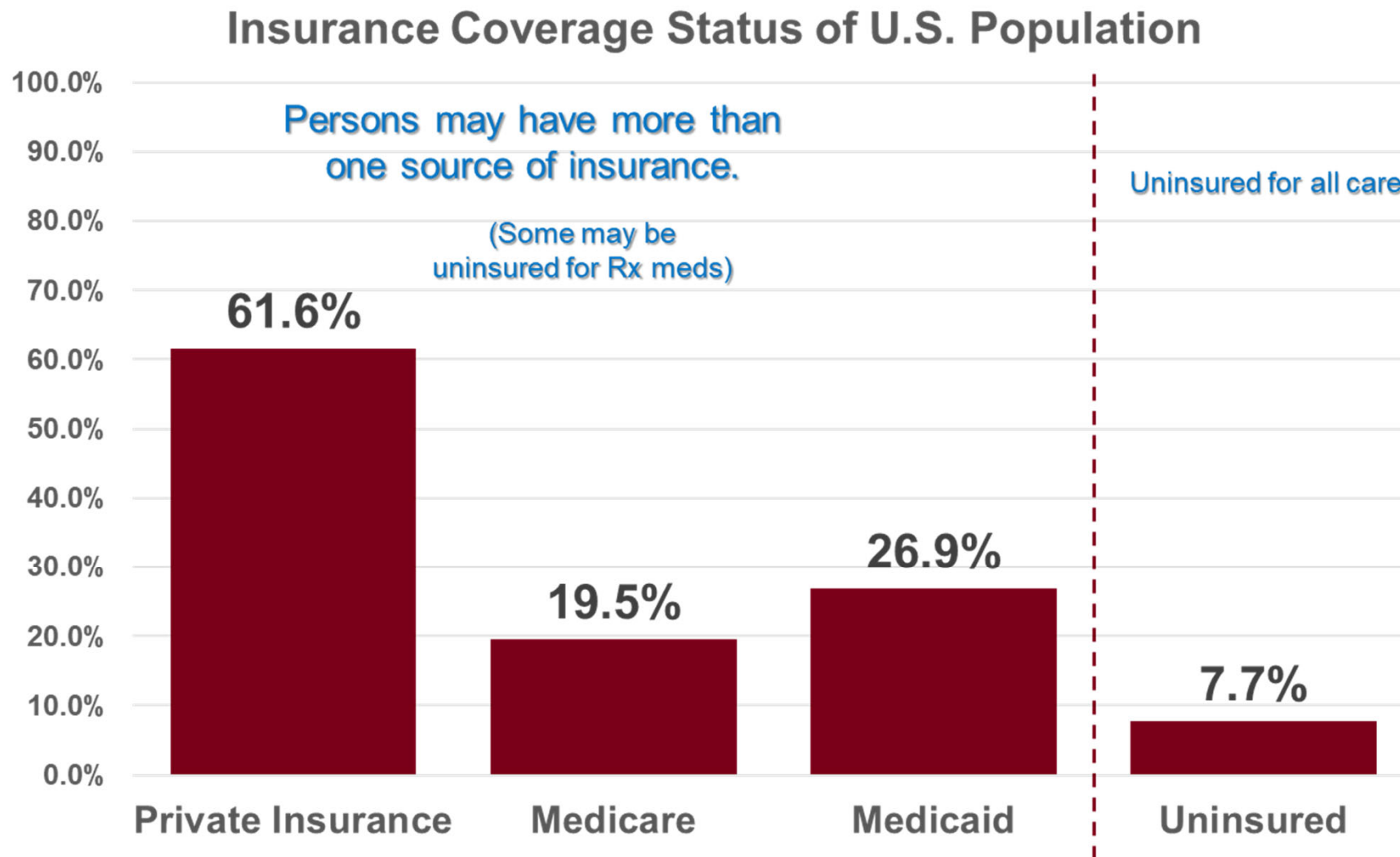
All Rx Drugs
Exp. per Person

\$ 2,714

Outpatient Rx
Exp. per Person

\$ 1,235

Sources of Payment for Health Care



Note: Persons may have insurance from more than one of the above sources so that percentages may total to more than 100.0%.

Source: Keehan SP, Fiore JA, Poisal JA, Cuckler GA, Sisko AM, Smith SD, Madison AJ, Rennie KE, National Health Expenditure Projections, 2022–31: Growth To Stabilize Once The COVID-19 Public Health Emergency Ends, Health Affairs, 42, No. 7 (2023): 886–898, 12 pp., at doi:10.1377/hlthaff.2023.00403

The Pharmaceutical Market

- **Drug Product Market**
 - (manufacturers, therapeutic classes, small molecules vs biologicals)
 - (Rx vs OTC, brand vs generic vs specialty)
- **Pharmacy Services**
 - (dispensing, consultation, pharmaceutical care, shipping, other)
 - (drug administration, vaccine administration, med therapy management)
- **Health Insurance & Benefits Market**
 - (pharmacy benefit vs medical benefit)
 - (fee-for service, capitation or risk, benefit mgmt., salary)

Market Segments by Product Type

What are the major market segments for pharmaceuticals?

- **Brand Name** (NDA or BLA-approved, 1st NDA holder)
 - Single Source (SS)--Patented, Market Exclusivity
 - Innovator Multiple Source (IMS)--Off-Patent Brand
 - **Generics** (ANDA-approved, multiple source)
 - Non-Innovator Multiple Source (NMS)
 - Single Source Generics (SSG)
 - **Specialty Drugs** (Biologics & High Cost Drugs) **Prescription**
-
- **Over-the-Counter (OTC) Drugs** **Non-Prescription**
 - Most New OTCs switched from Rx Status
 - **Vitamins, Minerals, Nutritional & Natural Products**

Methods to Establish Price

What approaches can a pharmaceutical firm use to determine its price?

- ◆ **Cost of Production**
- ◆ **Cost of Production + ROI**
- ◆ **Cost of Production + ROI + R&D**

Cost-Based Methods

Opportunity-Based Cost Methods

- ◆ **Cost of Alternative Therapies** (diet, surgery, exercise, group therapy, etc.)
- ◆ **Cost of Alternative Drug Therapy** (Other drug, dose form, strength, comb.)
- ◆ **Cost of Not Treating the Condition**
- ◆ **Value of Life Extension or Quality-Adjusted Life Years** (QALYs)
- ◆ **Price of Other “Peer” Drug Therapies**

Drug Pricing Trends

- **Price at Introduction**
- **Price In Various Channels** (*discriminatory pricing*)
- **Price Changes Over Time** (*inflation*)
- **Price Relative to Other Products**
(*generics & biosimilars / real price competition begins*)
- **Payment Policy** (*Payer policy & payment limits*)
- **Price Effect on Affordability & Access**
(*coverage & subsidies vs uninsured & lack of health care*)

A Simplified Representation

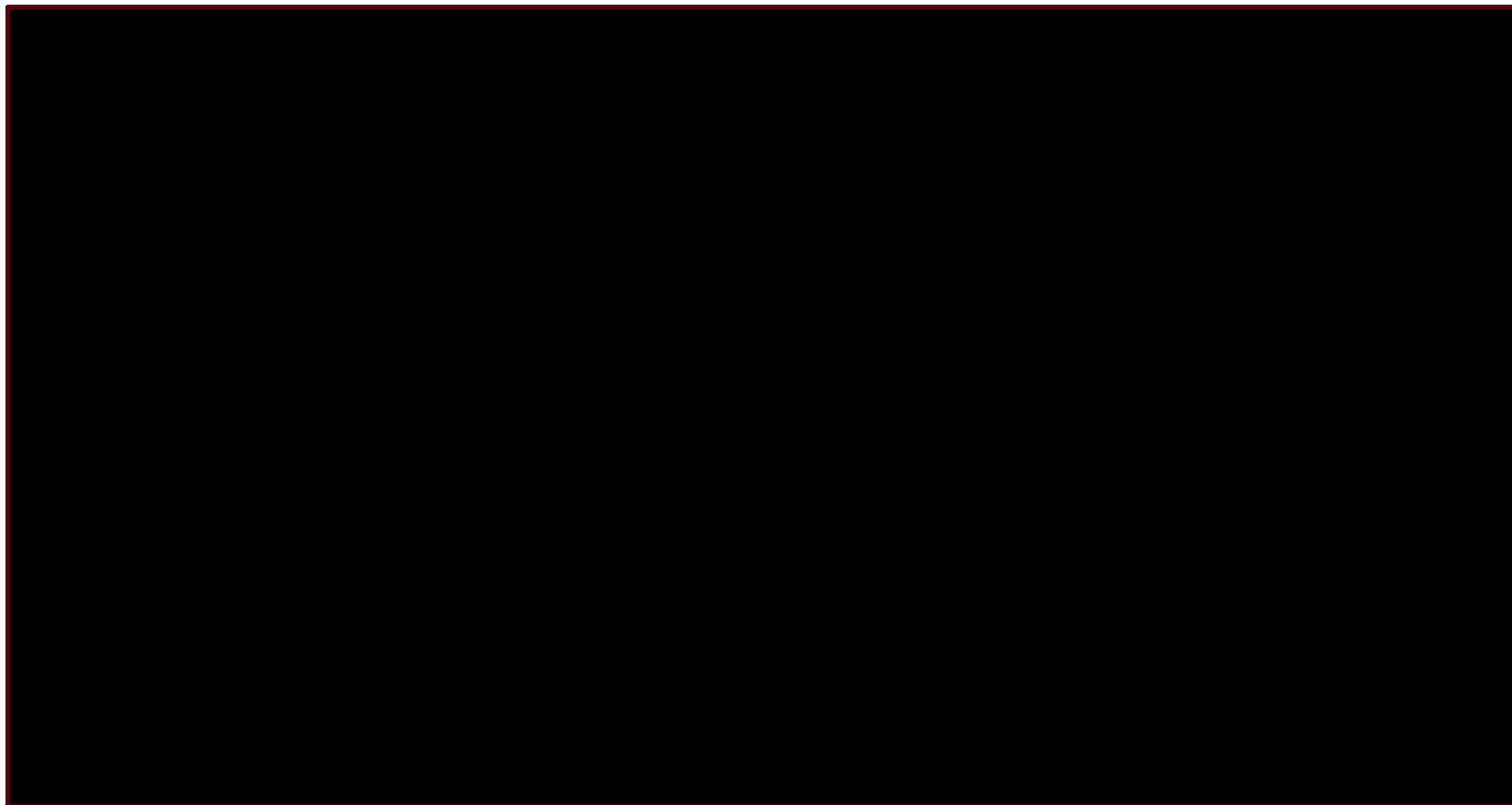


PRIME Institute
University of Minnesota

Distribution & Payment for Prescription Drugs

A Simplified Representation

WAC



Total Paid Amount

* WAC does not represent actual transaction prices and does not include discounts, rebates, or other reductions in price.

Wholesale Acquisition Cost (WAC)

WAC – is a list price set by the manufacturer that does not include discounts or rebates.

The term “wholesale acquisition cost” means, with respect to a drug or biological, the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

Source: 42 USC § 1395w-3a(c) (6) ([/uscode/text/42/1395w-3a#c_6](#))

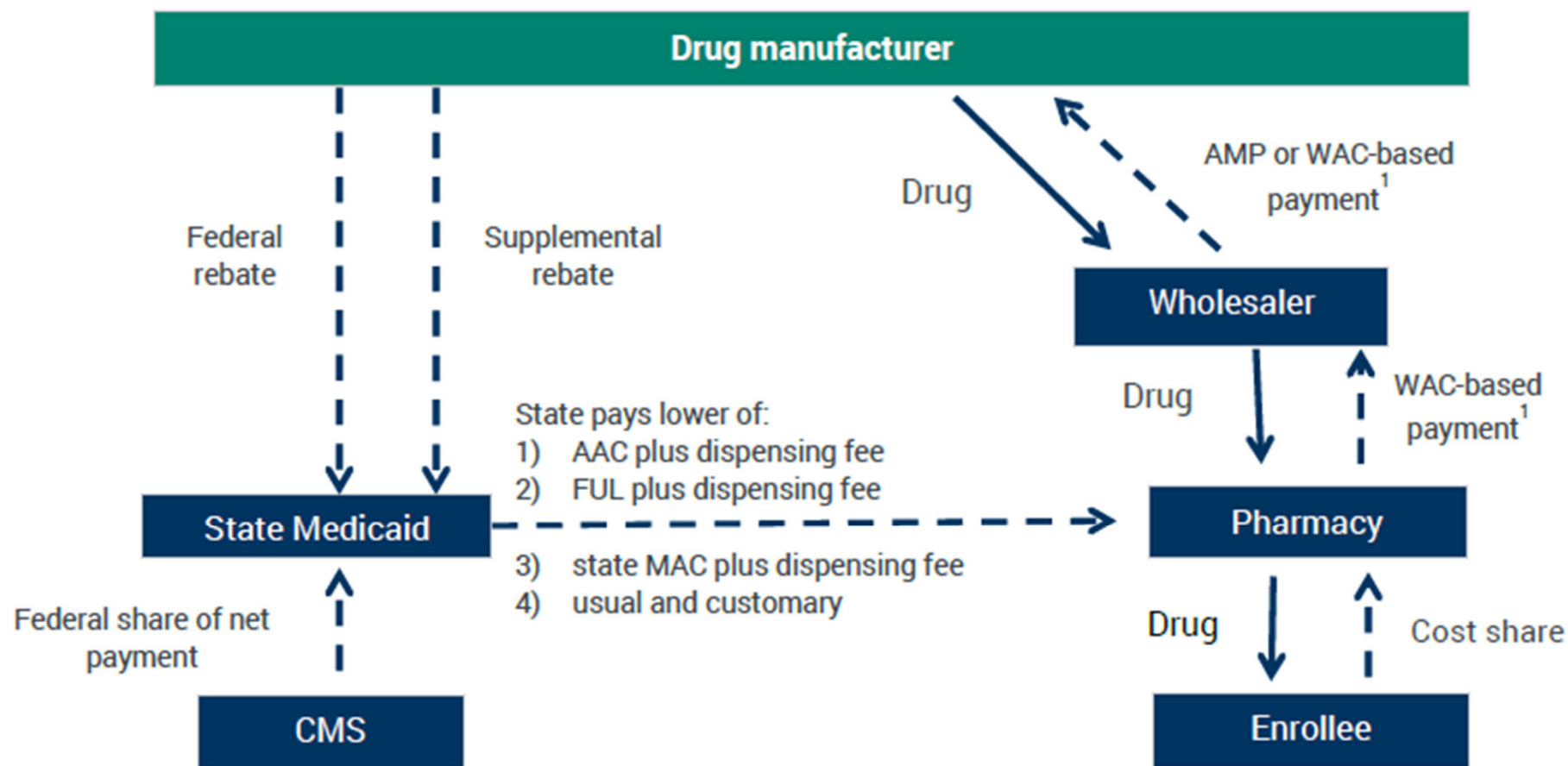
Table 1. Common Terms and Acronyms Used in Drug Pricing

Term	Definition
Federal upper limit (FUL)	A price ceiling used by the Centers for Medicare and Medicaid Services (CMS) to control prices for certain medications paid to pharmacies
Maximum allowable cost (MAC)	A price ceiling, similar to the FUL, established at the state level
Usual and customary price (U&C)	The average cash price paid at a retail pharmacy
Average wholesale price (AWP)	An estimate of the price retail pharmacies pay for drugs from their wholesale distributor. This price is calculated and published by companies such as Medi-Span and First Databank
Wholesale acquisition cost (WAC)	An estimate of the manufacturer's list price for a drug to wholesalers or other direct purchasers, not including discounts or rebates. This price is defined by federal law
Average manufacturer price (AMP)	The price a manufacturer charges wholesalers or pharmacies that purchase directly from the manufacturer after discounts. This price is defined by federal law
Average sales price (ASP)	A calculation of the weighted average of manufacturer's sales price for a drug for all purchasers, net of price adjustments. This price is defined by federal law
Estimated acquisition cost (EAC)	An estimate of the price generally paid by providers for a drug. Formula specific for each state as defined by the state Medicaid agency
Average Actual cost (AAC)	An estimate of retail pharmacy acquisition costs for drugs through a review of actual pharmacy invoices
Dispensing fee	The amount reimbursed to the pharmacy to cover the charge for professional services and overhead costs
National Drug Code (NDC)	An 11-digit code used by Medicaid to identify a drug based on its manufacturer, strength, and package size

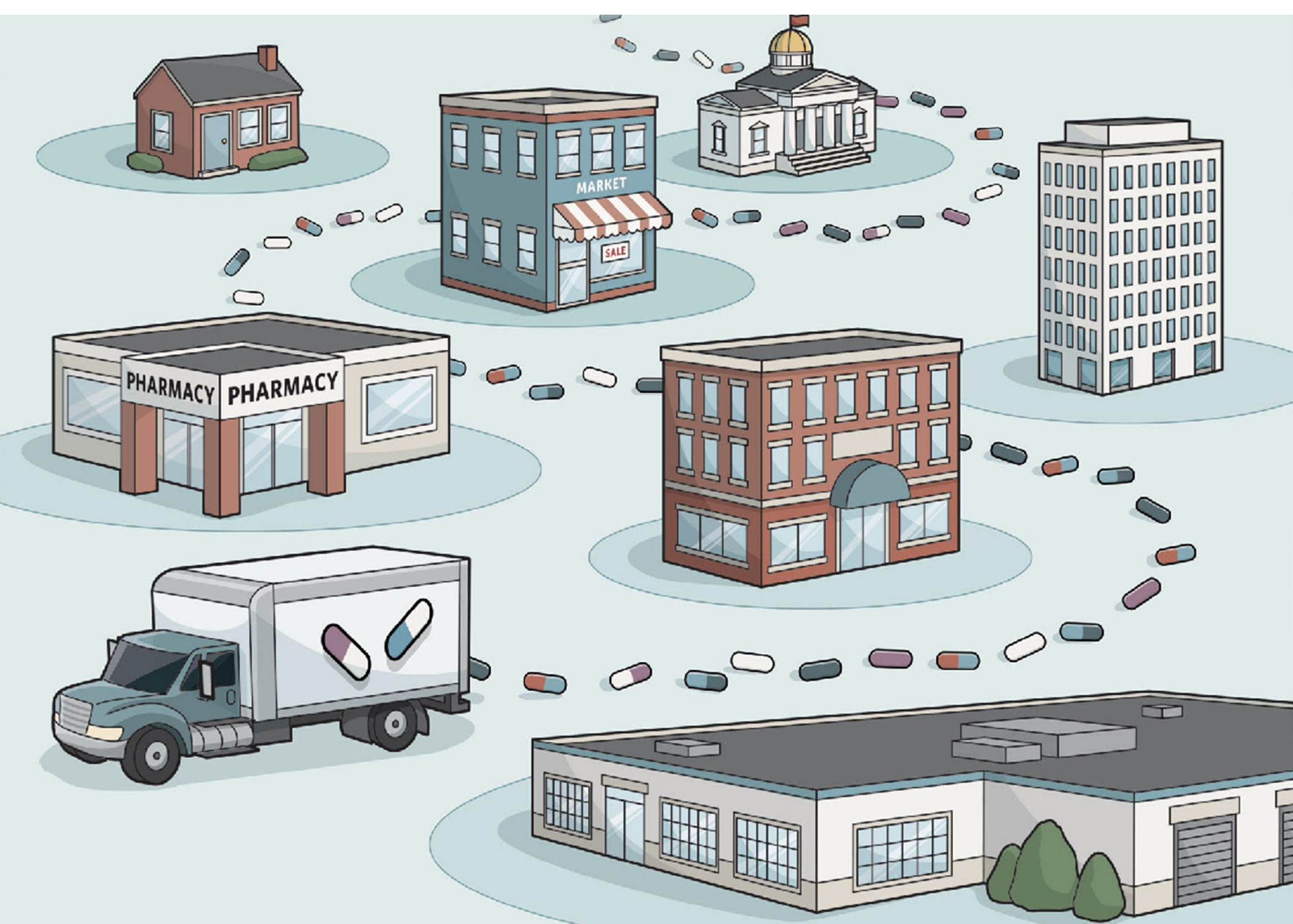
Source: References 3-5, 7, 14.

Source: Joey Mattingly, Understanding Drug Pricing, US Pharm. 2012;37 (6) (Generic Drug Review suppl):pp. 40-45.

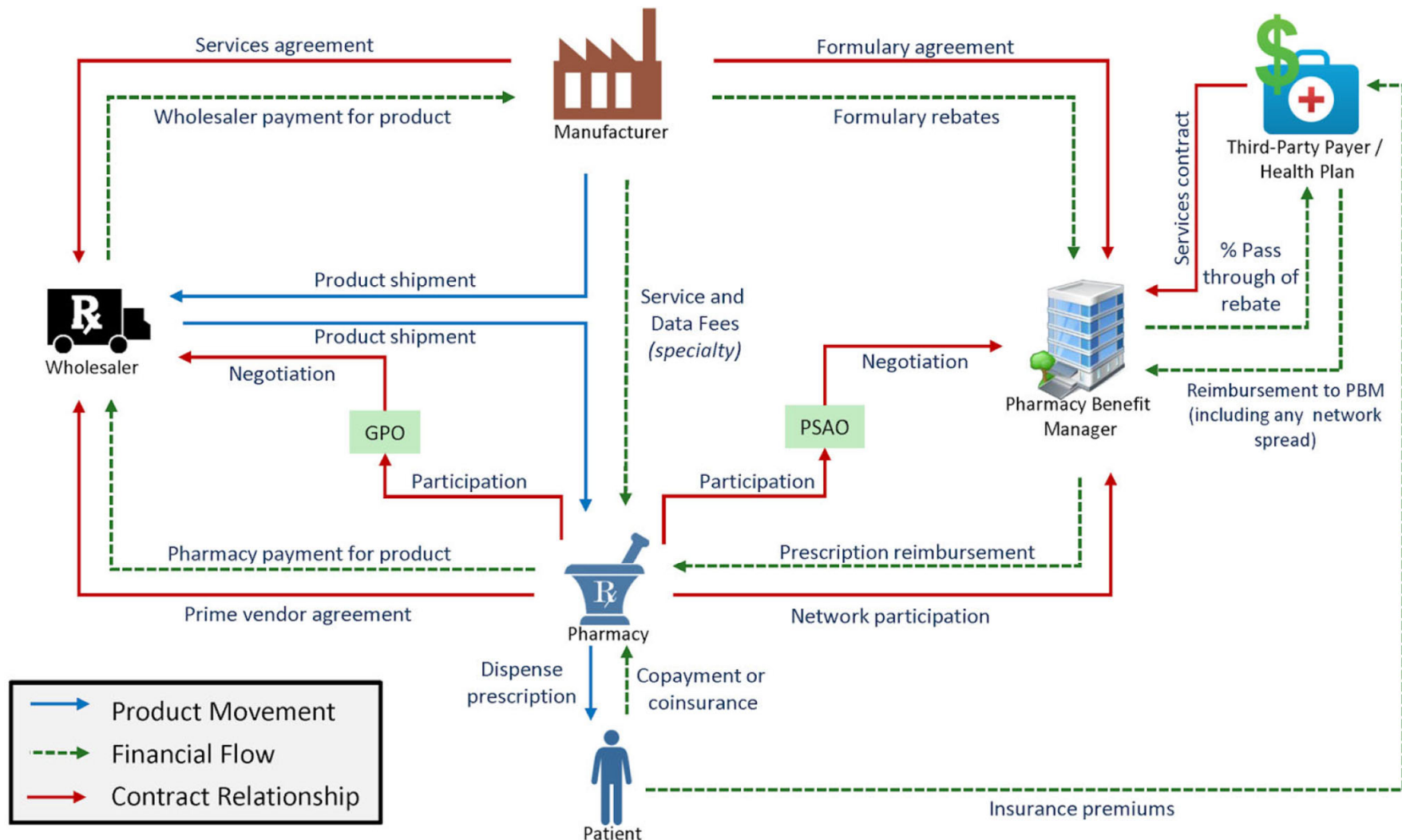
Medicaid Fee-For-Service Drug Payment & Rebate Flow



Source: MACPAC (Medicaid and CHIP Payment and Access Commission), Medicaid Payment for Outpatient Prescription Drugs, Issue Brief, May 2018.

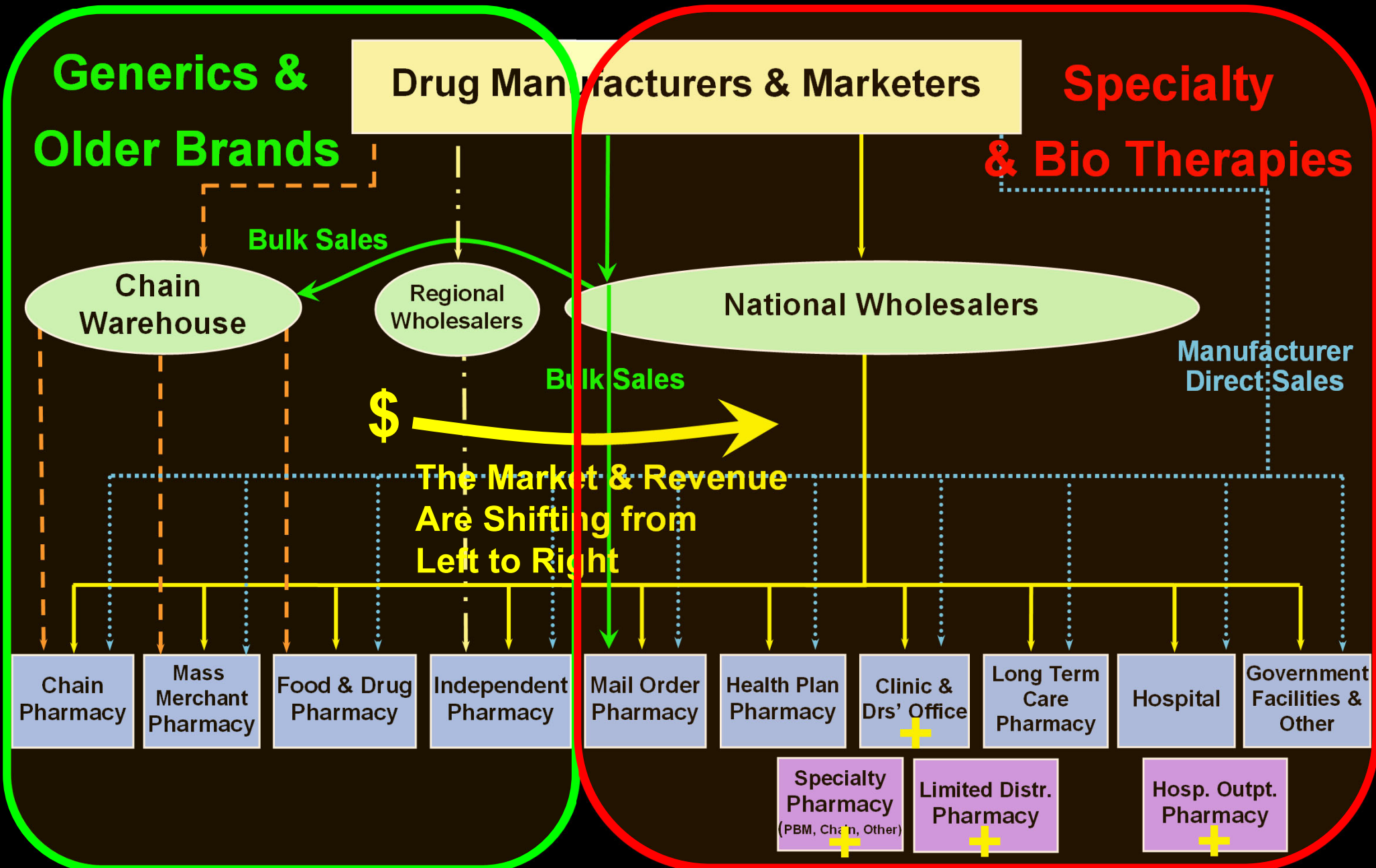


Drug Product & Drug Payment Flow for Outpatient Prescriptions

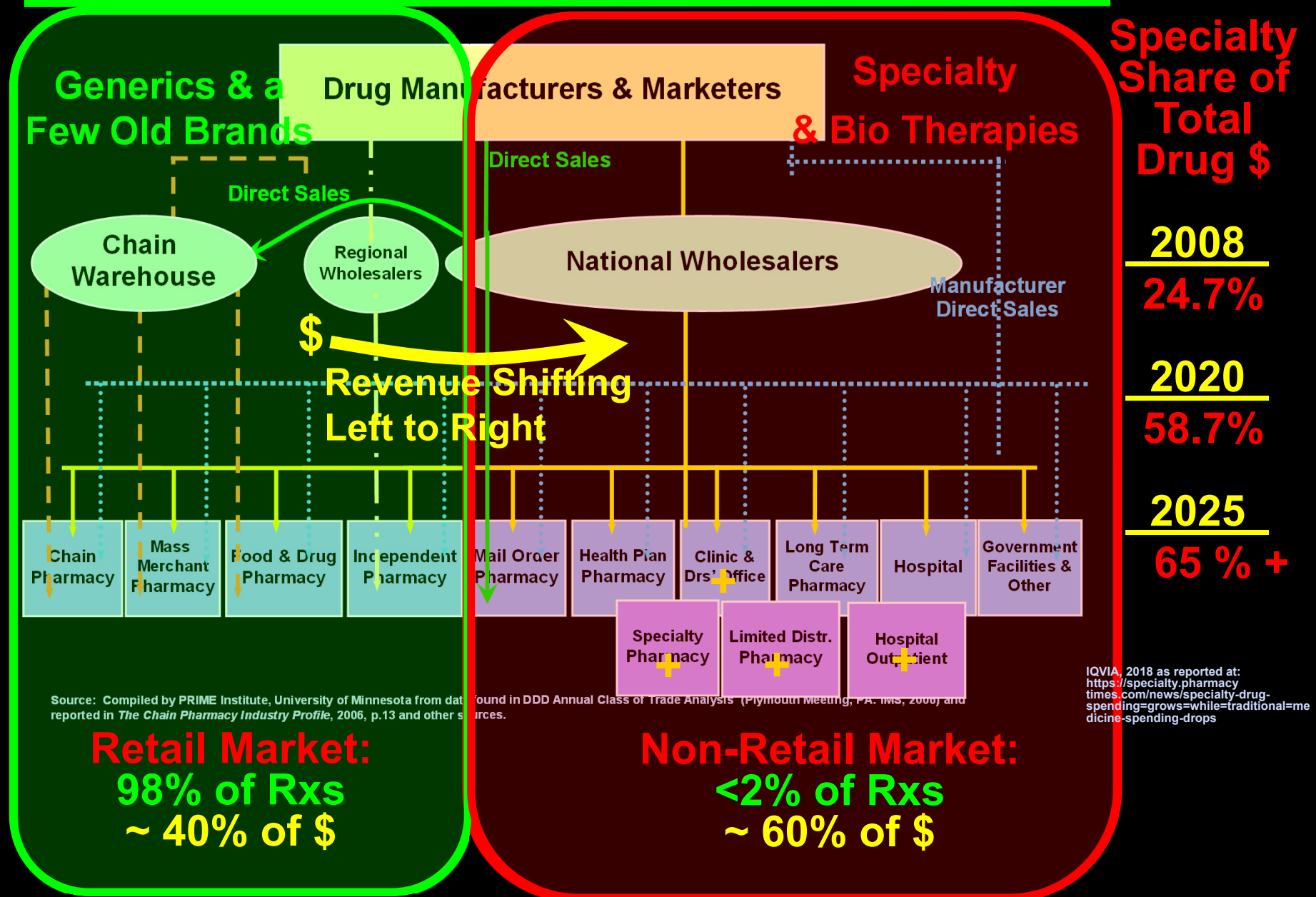


Source: Data from: Fein, Adam J., The 2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute, 2020.

Channels of Distribution for Prescription Drugs



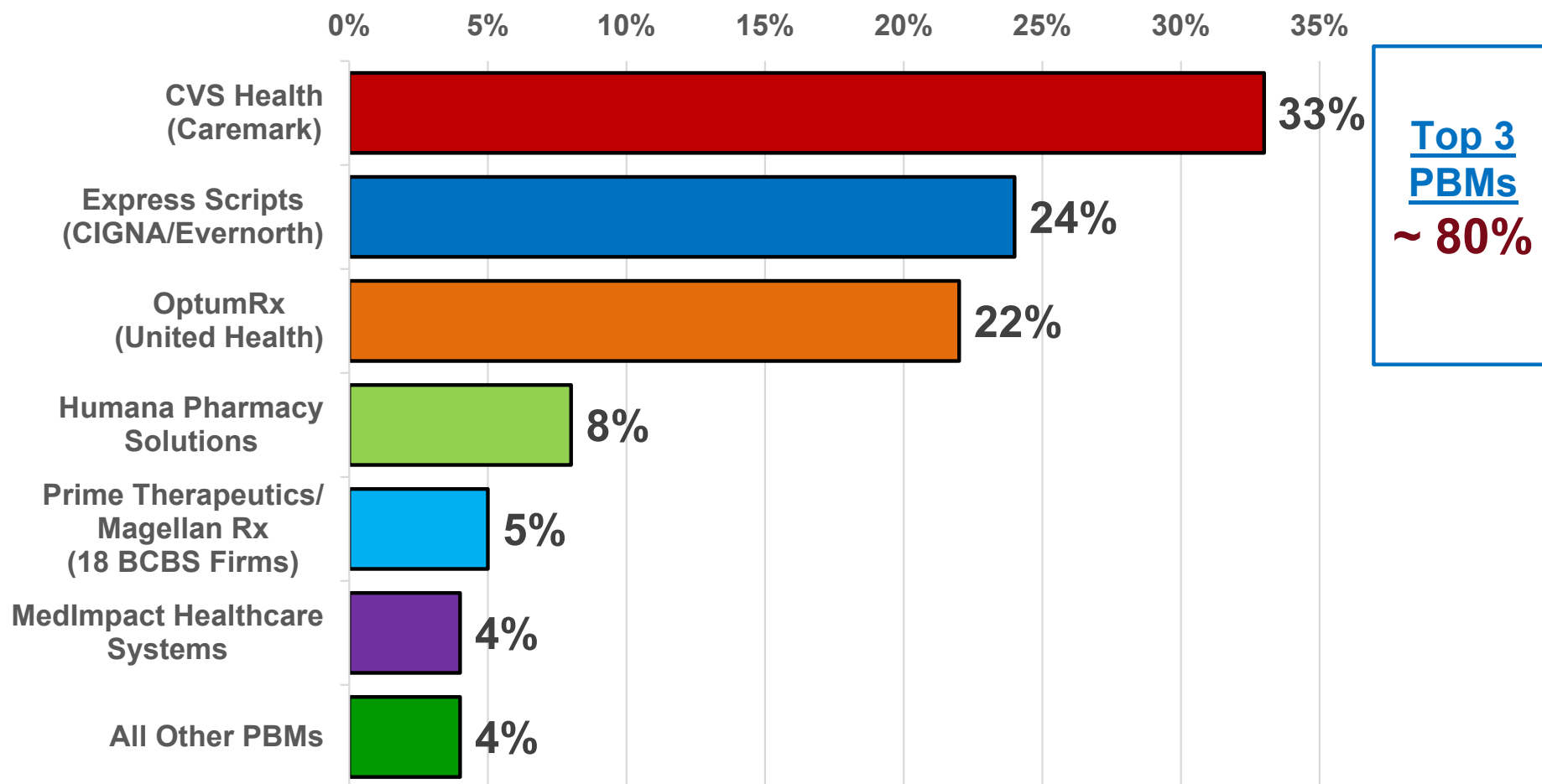
Shift in Channels of Distribution & Drug Type





Top PBMs in the Market

PBM Market Share of Prescription Claims: 2022



Source: Data from The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute, May 23, 2023, Exhibit 98.

PBM Functions

A Partial List of Functions

Benefit Management

- Process Rx Claims
- Benefit Design & Coverage

Clinical Programs

- Develop & Maintain Drug Formulary
- Encourage Generic & Therapeutic Substitution
- Perform Utilization Management & Review
(e.g., Prior authorization, Step Therapy, Quantity Limits)
- Encourage Patient Compliance

Distribution Programs

- Operate a Network of Retail Pharmacies
- Operate (and Own) a Mail Order Pharmacy
- Operate (and Own) a Specialty Pharmacy

Financial Programs

- Negotiate Rebates
- MAC Prices for Generics
- Manage Copay Accumulators & Cost-Share Maximizers
- Administer Coupons & Discount Card Programs

Source: Understanding the Evolving Business Models and Revenue of Pharmacy Benefit Managers, PBM Accountability Project, 2021, www.pbmaccountability.org

Vertical Integration in Health Care

Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2023



- Vertical systems provide opportunity for efficiency and integration.
- Vertical systems can channel patients from Insurer to PBM to Pharmacy, or other providers.
- Vertical systems have potential conflicts of interest & may pay their own providers more than they pay others.

Source: Adam J Fein, Mapping the Vertical Integration of Insurers, PBMs, Specialty Pharmacies, and Providers: A May 2023, Update, Drug Channels, Drug Channels Institute; see also, Jose R Guardado, Competition in Commercial PBM Markets and Vertical Integration of Health Insurers with PBMs: 2023 Update, Policy Research Perspectives, American Medical Association, September 2023.

Why Are There Rebates?

Rebates:

A means to alter the pattern of drug prescribing and use based on payments from the manufacturer to achieve objectives that otherwise would not have happened.

Manufacturer objectives for rebates:

- Increased volume of sales
- Increased market share of a defined set of products
- Improved outcomes by a defined measure
- Or, other factors defined by contract

PBM objectives for rebates:

- Place Brand in a favorable position
- Create a revenue stream from rebates
- Create a revenue stream from rebate administration

Private Market Rebates: 2023

Which product would you put on the formulary based on economics?

- Drug Product A or Drug Product B

- 50% Rebate Off of WAC 0% Rebate Off of WAC

- AWP = \$11.01 / Cap AWP = \$ 8.52 / Cap
- WAC = \$ 9.18 / Cap WAC = \$ 0.51 / Cap
(Nexium, 40 mg, DR cap, AstraZeneca) (esomeprazole mag., 40 mg, DR cap, Teva)

- \$4.59/Cap Rebate \$ 0.00/Cap Rebate
If the PBM Keeps the Rebate, Which Product Would the PBM Prefer?

- Net Cost = \$ 9.18 – 50% Net Cost = \$0.51 – 0%
= \$ 4.59 **= \$ 0.51**

If Plan Sponsor Wants to Pay Lowest Net Cost, Which Product Would the Plan Prefer?

More Rebate Does Not Always Mean Lowest Net Price

Rebates By Any Other Name...

What are the various forms of rebates?

- Rebate Administration Fees are Rebates
- Price Protection Payments are Rebates
- Data Management Fees are Rebates
- Research Access Fees are Rebates
- Formulary Placement Fees are Rebates
- Other Types of Payments may be Rebates

A Larger Rebate Does Not Necessarily Mean You Get a Lower Net Cost

Rebates by Any Other Name are Still *KICKBACKS*

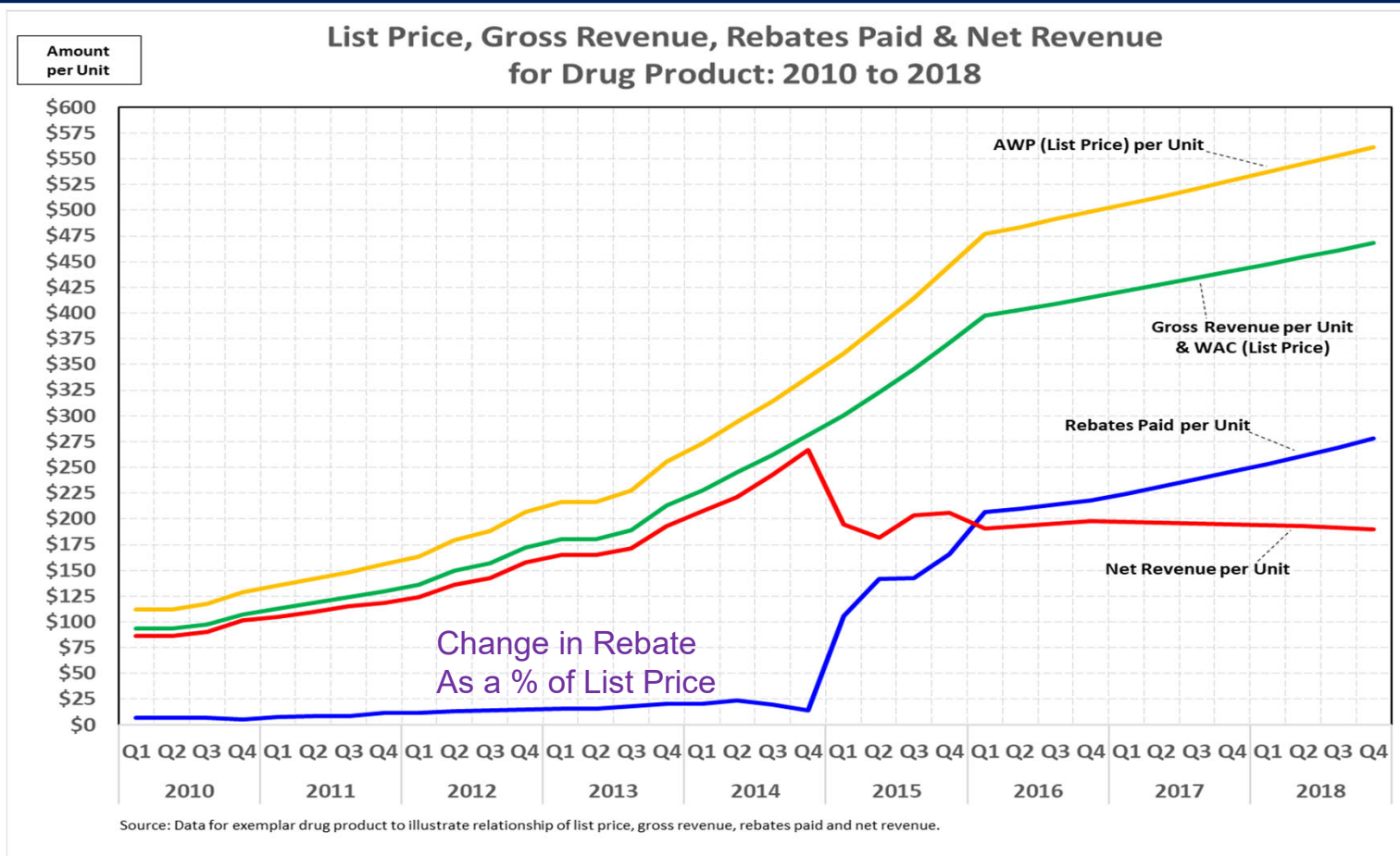
Private Market Rebates: 2023

What are rebate levels in the private market?

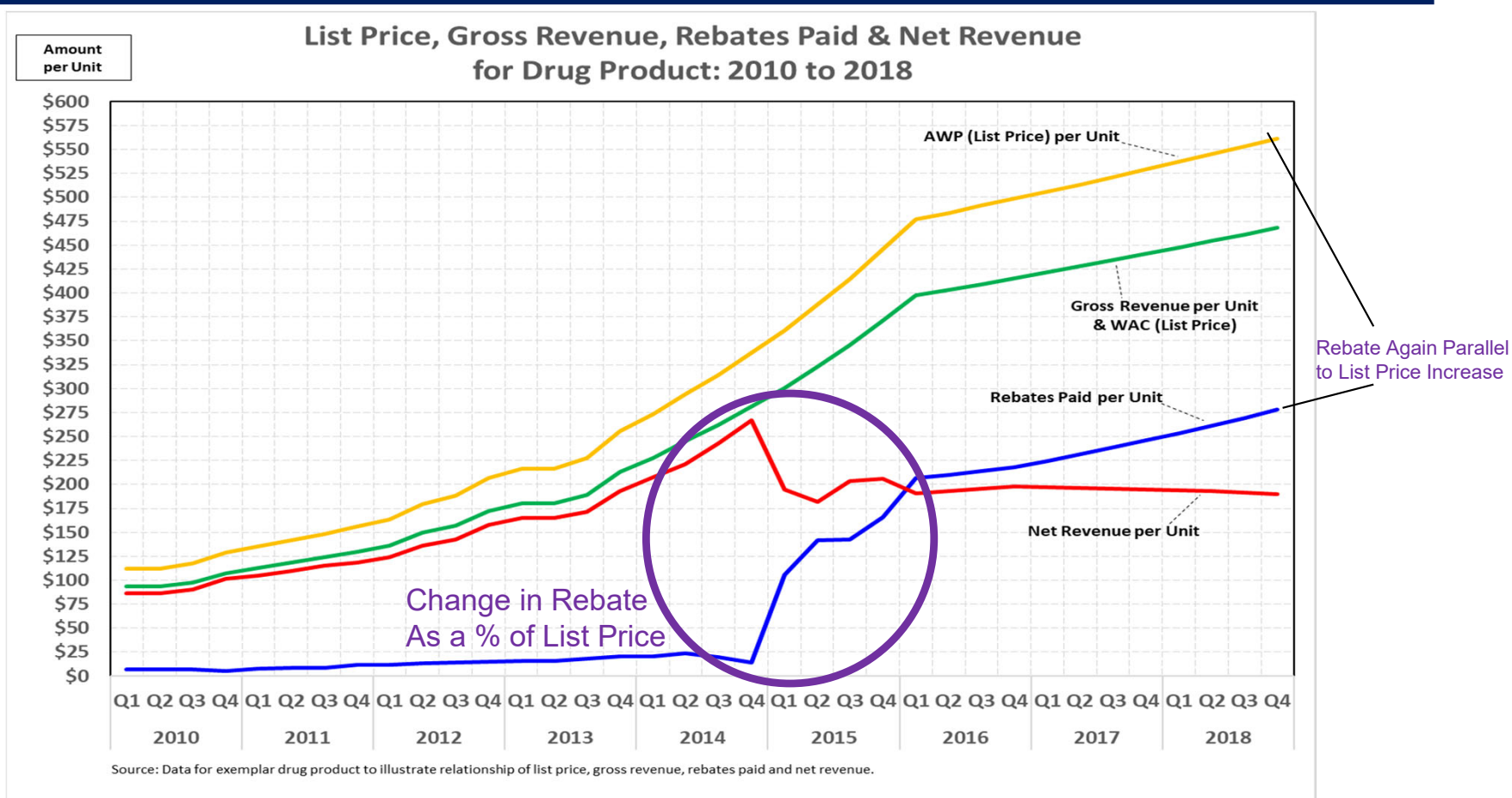
- 8,824 NDCs Covered & Used in 2023
 - 401 NDCs (4.5%) Have Rebate in 2023
-
- Rebates are 30.5% of Total Paid for All NDCS
 - Rebates are 43.5% of Total Paid for NDCs w/Rebate
 - NDCs with Rebates are 70.2% of Total Paid
-
- Rebates for Single Source Brands: 42.5%
 - Rebates for Co-Licensed Brands: 58.5%
 - Rebates for Originator Off-Patent Brands: 74.7%
-
- Rebates for Generics: 0.0%
 - Rebates by Formulary Tier 1: 53.4%
 - Rebates by Formulary Tier 2: 43.6%
 - Rebates by Formulary Tier 3: 27.7%

More Rebate Does Not Always Mean Lowest Net Price

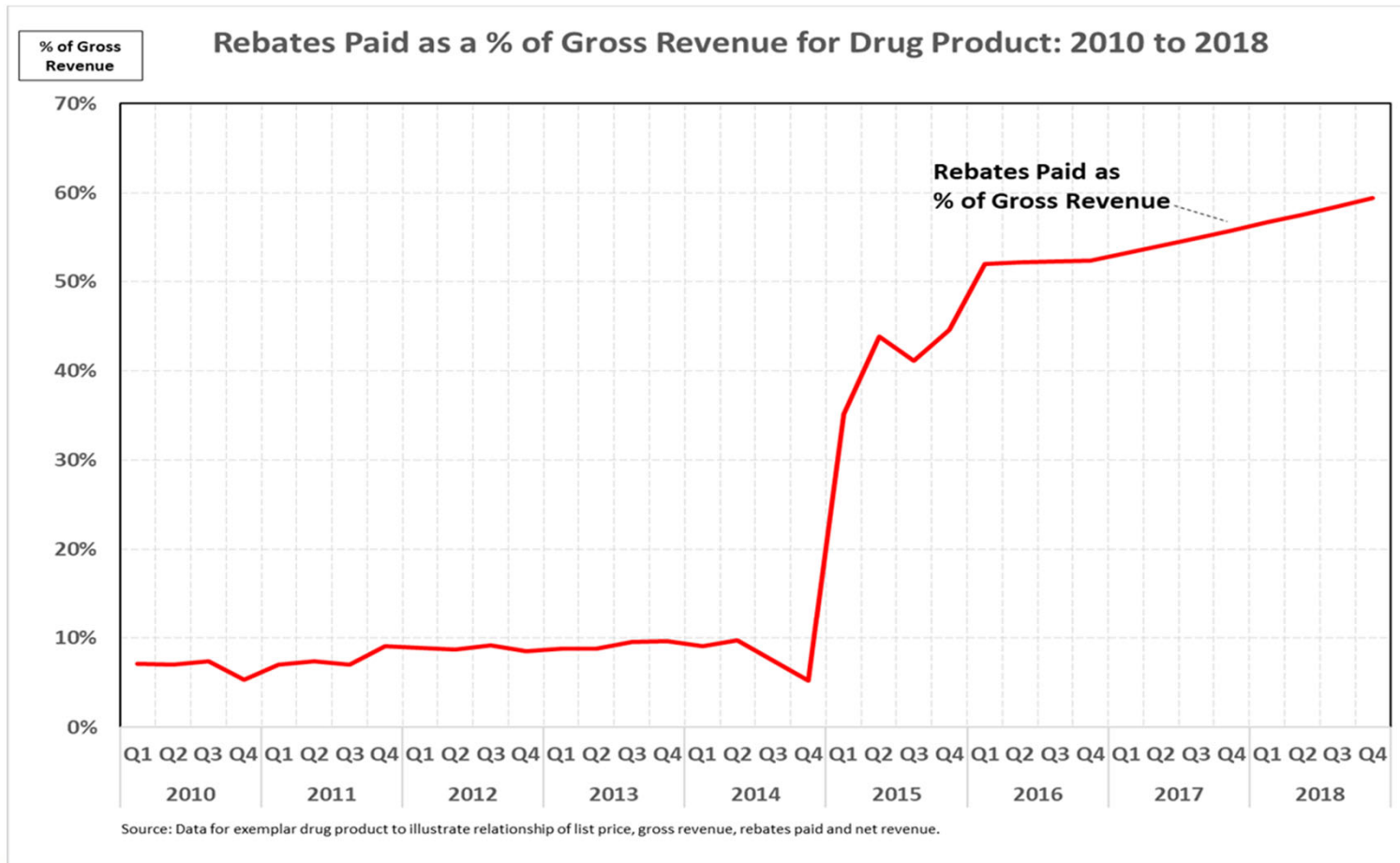
Impact of Rebates on Drug Prices



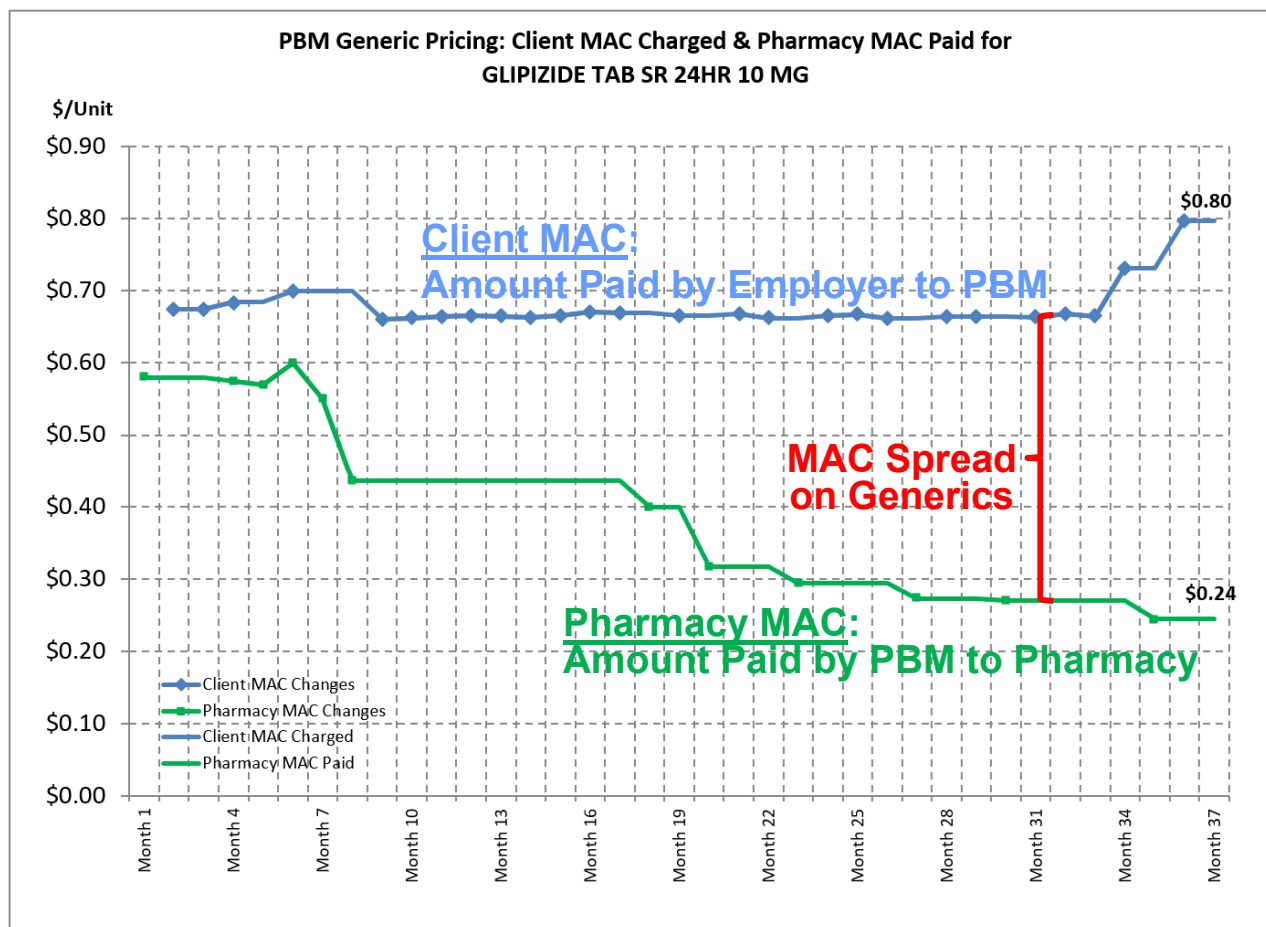
Impact of Rebates on Drug Prices



Impact of Rebates on Drug Prices



Generic MAC Amount Paid/Unit to PBM to Pharmacy & by Client to PBM



Market Observations

Sometimes a PBM has a different MAC list to pay pharmacies & to bill its clients.

PBMs charge a SPREAD on some prescriptions: the client pays more to the PBM than the PBM paid the pharmacy.

PBMs also may use different MAC lists for different clients.

Who benefits from the MAC spread on generic prescriptions?
---the PBM

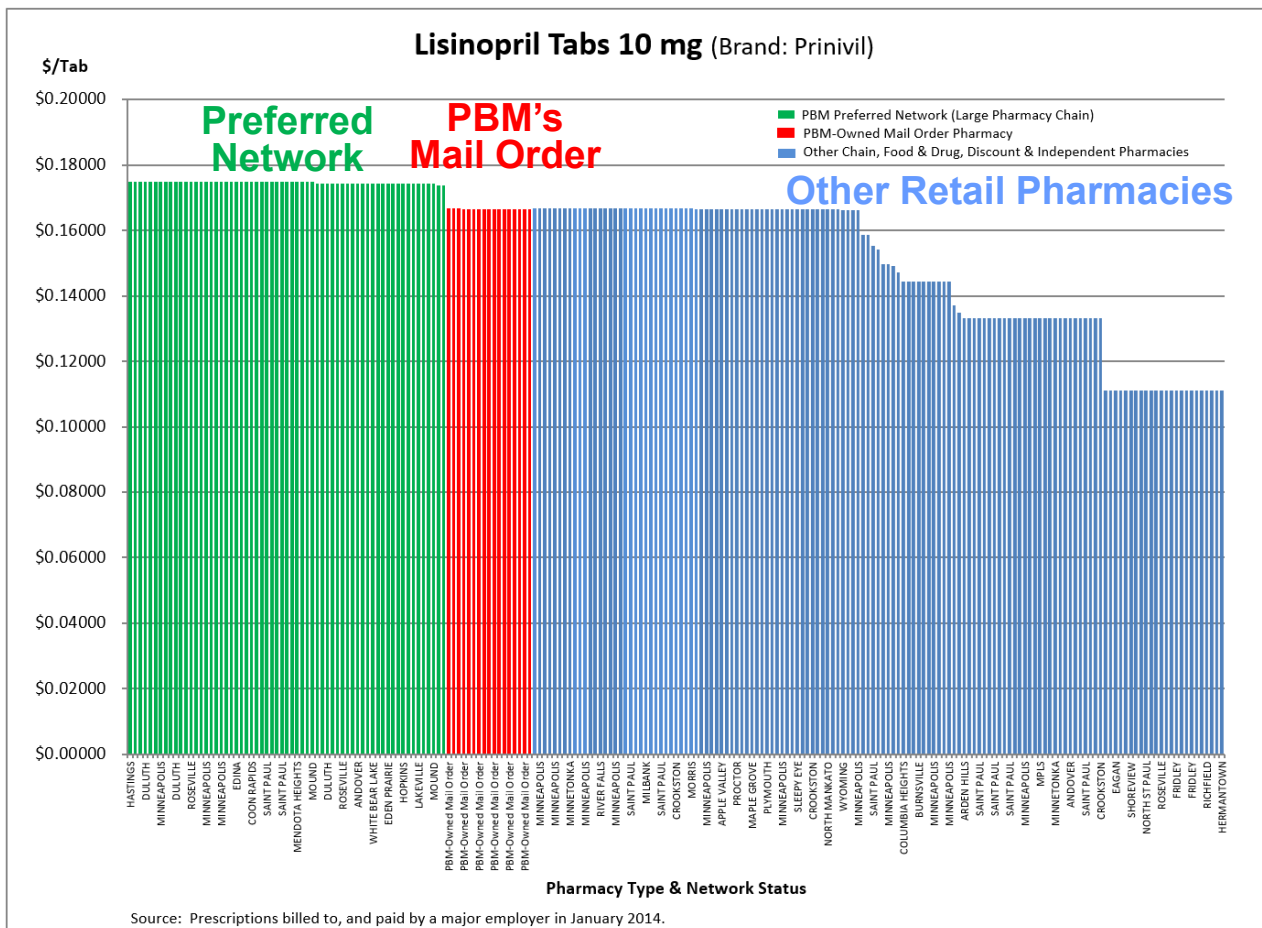
Who benefits when the pharmacy MAC is reduced?
---the PBM

Is Mail order paid the same MAC as other retail pharmacies?
---Not always, sometimes it is higher

Who owns the mail order?
---the PBM

This Market is Broken.

Amount Paid/Unit for Generic Prescription Drug by Pharmacy Type & Network Status



Market Observations

Is the Preferred Network
---Less Expensive? or
---More Expensive?

Why Are Prices Higher for
Preferred Network Pharmacies?

Who owns the Preferred
Network Pharmacies?
---the PBM owns most of them

This Market is Broken.

Factors Influencing Drug Expenditures

Total Drug Expenditures =

[Population x Intensity x Efficiency] + Admin. Costs - Rebates
 (& Other Fees)

of People
 Age, Gender
 Region
 Ethnicity

Units/Person/Yr
 (Rx/Person/Yr)
 Dose Intensity
 Indication
 Diagnosis
 Severity

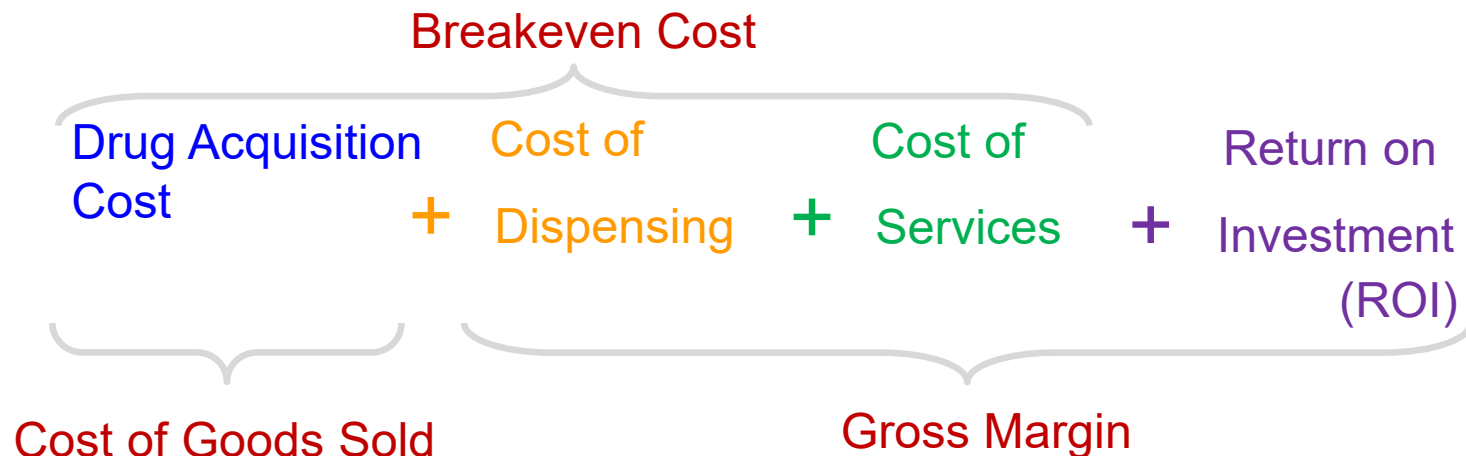
Cost/Unit
 (Cost/Rx)
 Drug of Choice
 Brand vs. Generic

Benefit Mgmt.
 DUR
 Formulary Mgmt.
 Prior Auth
 Step Therapy

Rebate Negot.
 Rebate Admin.
 Rebate \$ (& %)
 DIR Fees
 Net Drug Cost

Components of Prescription Price

Retail Prescription Price =



Payer

Who Is the Payer?

- **Insurer** (Not Really Payer → Processes Transactions)
- **PBM** (Not Really Payer → Processes Transactions)

So Who Really Is the Payer?

Person Who Pays Cash → **Individual**
Employer → **Employee** → **Individual**
Government → **Taxpayer** → **Individual**
(Medicare, Medicaid, DOD, VA, IHS, Other)

Health Care is Not a Free Benefit*

We all pay for health care, directly or indirectly.

- ◆ **Out-of-Pocket Cost** (copays, co-insurance, deductible)
- ◆ **Insurance Premiums** (employer, self-insured)
- ◆ **Employer Paid Insurance v. Lower Wages**
- ◆ **Tax Supported Govt. Programs**
(Medicare, Medicaid, VA, IHS, NIH, other)

-
- *Insurance does not reduce the cost of health care, it merely redistributes it.*
 - *Insurance premiums are also an out-of-pocket cost.*

Cost-Sharing Methods

- **Premium**

- *\$700 per month*

- **Deductible**

- *\$200 per occurrence / \$500 per year (or more)*

- **Coinsurance**

- *10% to 50% of expenditures incurred*

- **Copayment**

- *\$10 to \$150 per event or use*

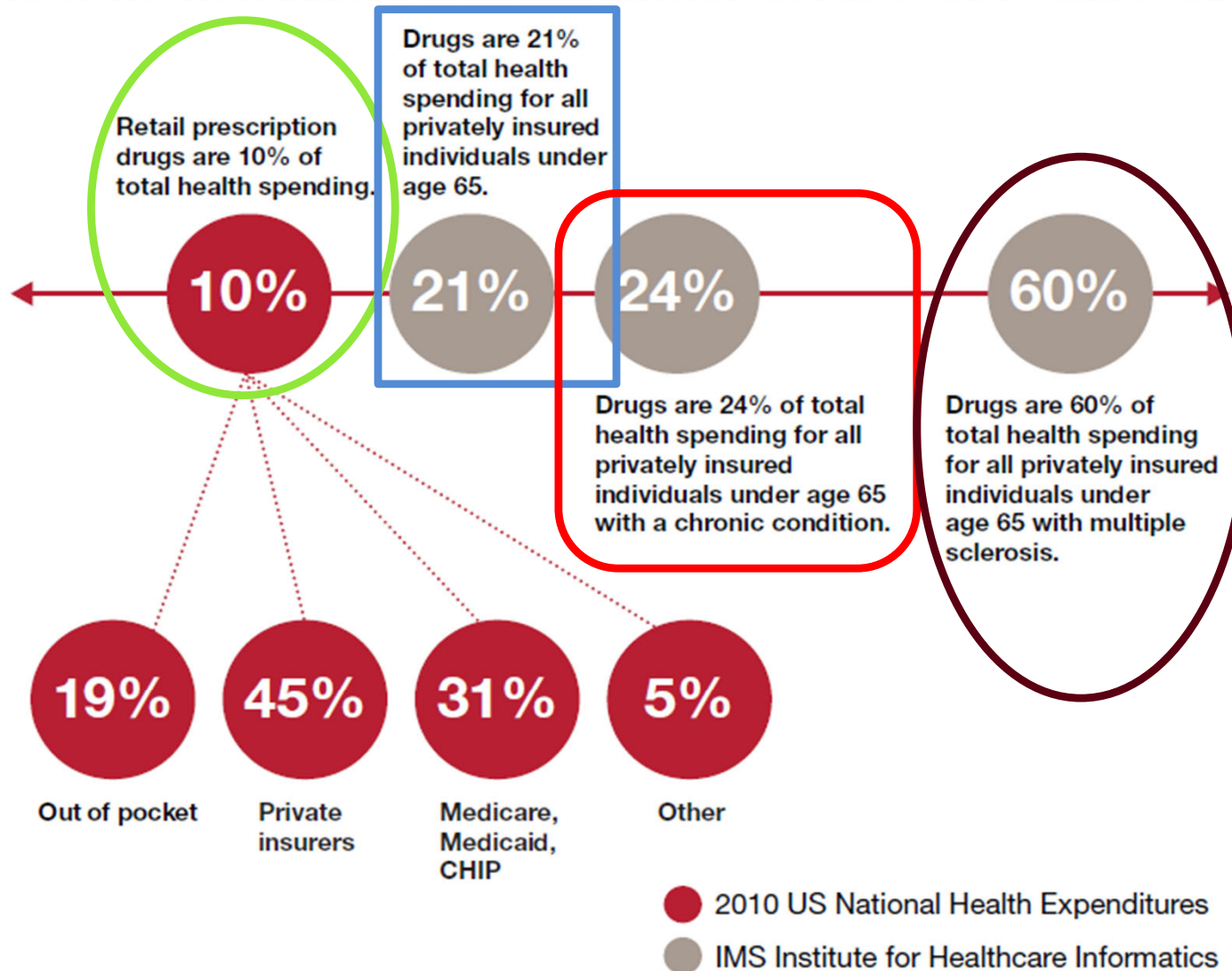
- **Annual Cap**

- *\$1,000 per year*

- **Lifetime Cap**

- *\$1,000,000 health expenditures*

Figure 4: What's in a number? Data about total US prescription drug spending

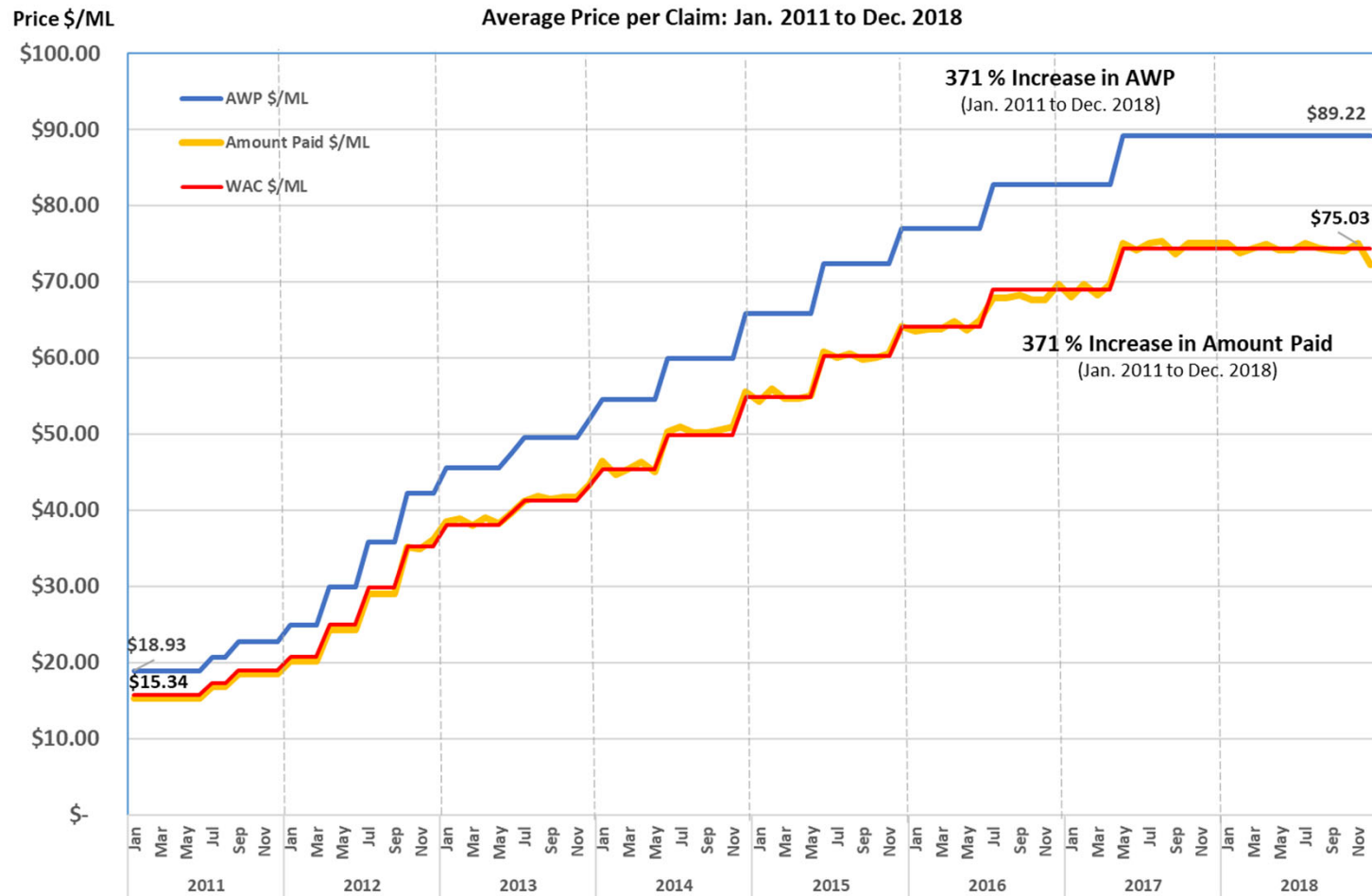


HRI analysis of sources: 2010 US National Health Expenditures and IMS Institute for Healthcare Informatics

Source: *Unleashing value: The changing payment landscape for the US pharmaceutical industry*, Health Research Institute, May 2012, pwc

Humulin R (Concentrated): Insulin Regular (Human) Inj 500 Unit/ML (Lilly, 00002-8501-01)

Average Price per Claim: Jan. 2011 to Dec. 2018



Source: Compiled by PRIME Institute (University of Minnesota) based on amount paid for claims by self-insured employer in Minnesota from Jan. 2011 to Dec. 2018.

Is Affordability An Issue?

What evidence do we have of affordability issues?

Poll of Americans found that:

- *25% say difficult to afford cost of medications*

Affordability of medications is a problem for:

- *33% of those who take 4 or more prescription drugs*
- *31% of those who are age 18-49*
- *58% with >\$100 monthly drug cost*
- *49% of persons with fair or poor health*
- *40% of Hispanics, 30% of Blacks, & 24% of Whites*
- *33% with < \$40,000 annual income have not filled Rx or skipped a dose*

Actions taken due to cost of prescription drugs:

- *23% did not fill prescription, cut pills in half, or skipped doses due to cost*
- *10% purchased or attempted to get drugs from outside the U.S.*
- *8% traded, accepted meds from another person, or used leftover meds*

Source: Alex Montero, Audrey Kearney, Liz Hamel. Mollyann Brodie, Americans' Challenges with Health Care Costs, Kaiser Family Foundation, Published: Jul 14, 2022, <https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs/#>

How Much is Your Life Worth?

**How Much Do You Have
in the Bank?**

**That Is How
Economic Markets Work !**

**Is That How Access to
Health Care Should Work ?**

**Our Expectations & Choices
May Not Be Ethical or Sustainable!**

The Pharmaceutical Market is Very Dynamic and Constantly Changing

**It is important to be explicit about the assumptions
we make and to monitor for exceptions and
changes in expected relationships.**