Michigan Health Policy Forum

Medicaid and Commercial Pharmacy Topics

Agenda

- Medicaid Program Overview
- Federal and State Funding
- Medicaid Pharmacy Service Delivery
- National Trends in Pharmacy Service Delivery
- Medicaid Drug Rebate Program
- Medicare Part-D Overview
- Pharmacy Benefit Management Tools
- Pharmacy Network Agreements
- Pharmacy Audits
- Spread vs Pass Through Pricing
- Glossary of Terms

Medicaid Program Overview

- According to 2018 state data from the Kaiser Family Foundation,[1] Medicaid is the second largest line item in state budgets behind elementary and secondary education nationwide
- Medicaid provides health coverage to millions of Americans, including eligible:
  - Low-income adults, children, pregnant women, elderly adults, and people with disabilities
- The program is funded jointly by states and the federal government
- Oversight of Medicaid is provided by the Centers for Medicare & Medicaid Services (CMS)
- Medicaid is administered by states, according to federal requirements
- Medicaid is commonly delivered:
  - Fee for service (FFS) – the state pays providers directly for each covered service received by a Medicaid beneficiary
  - Managed care organization (MCO) – used by states to improve patient care (through case management) and to ensure budget predictability under a capitated payment arrangement
  - Combination of FFS and MCO – states utilize a combination of FFS and MCO to deliver Medicaid services

1. Kaiser Family Foundation. Distribution of state expenditures (in millions). 2018. Available at: https://www.kff.org/other/state-indicator/distribution-of-state-spending/?dataView=1&currentTimeframe=0&sortModel= %7B%22colId%22:%22Location %22,%22sort%22:%22asc%22%7D. Accessed January 2021.

Medicaid Is Governed by Federal and State Authorities

- Federal law
- Federal rules and regulations
- Federal policy and sub-regulatory guidance
  - *Federal authorities supersede state authorities*
  - *CMS rules, regulations, and other guidance detail and/or clarify but must stay within the limits of federal law*

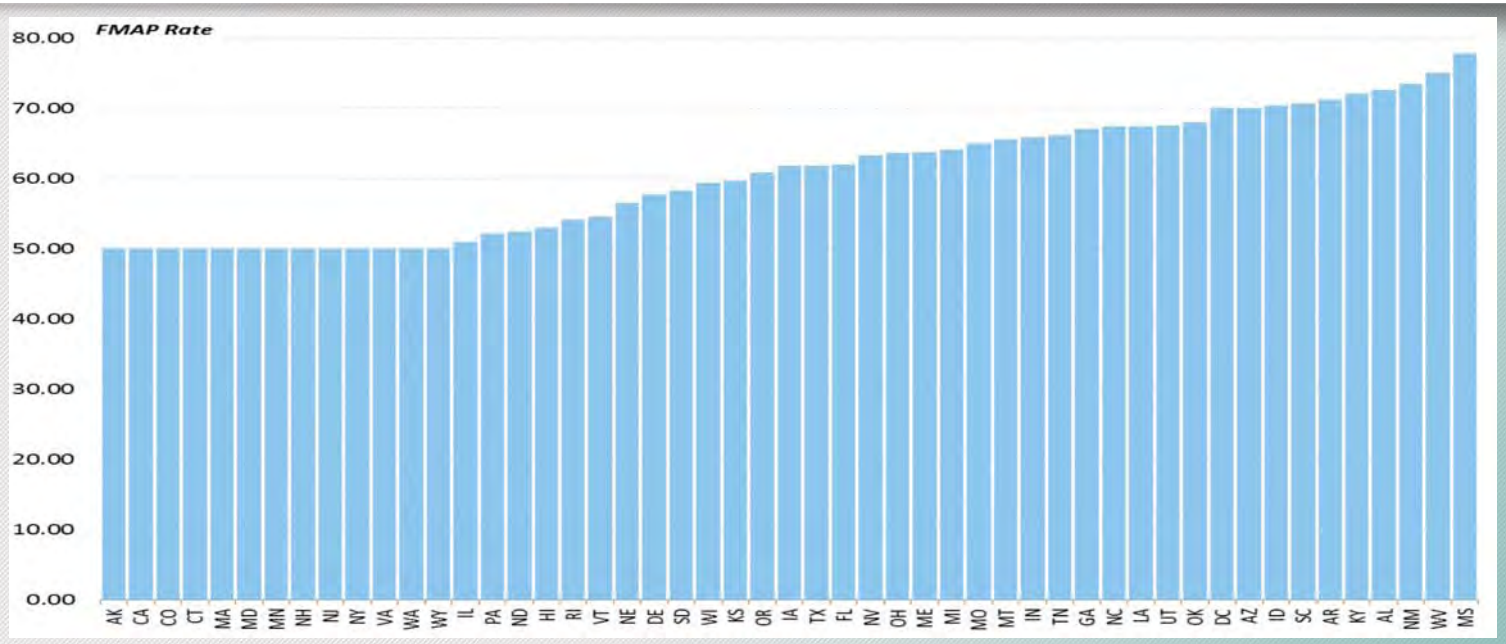
- State law
- State rules and regulations
- State policy and sub-regulatory guidance
  - State law is subordinate to and cannot conflict with federal law, rules, and regulations
  - CMS guidance, on the other hand, does not necessarily limit state choices

Medicaid Funding

- Medicaid is funded by a combination of federal and state dollars
- Federal Financial Participation (FFP) in a state's Medicaid program is based on each state's per capita incomes relative to the national average and is revised on an annual basis.
- The level of FFP is expressed as a percentage of the total cost of each states Medicaid program and is known as the Federal Medical Assistance Percentage (FMAP)
- Federal law sets the minimum regular FMAP at 50% and the maximum percentage is capped at 83%.
  - In fiscal year (FY) 2021, the regular FMAP ranges from 50% for New York and 12 other higher-income states to 77% for the lowest income state (Mississippi).

For more details on FMAP, see https://www.kff.org/wp-content/uploads/2013/01/8352.pdf

Regular FMAP Rates



State Distribution of Regular FMAP Rates
(FY2021)

Sources: Department of Health and Human Services, "Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2020 Through September 30, 2021," 84 Federal Register 66204, December 3, 2019. Note: State-by-state FY2021 regular FMAP rates are listed in Table A-1.
https://fas.org/sgp/crs/misc/R43847.pdf
https://www.federalregister.gov/documents/2020/11/30/2020-26387/federal-financial-participation-in-state-assistance-expenditures-federal-matching-shares-for

Medicaid Pharmacy Service Delivery

- Medicaid MCO
  - MCOs accept a capitated reimbursement per beneficiary and are at risk for both the medical and pharmacy drug spend
  - MCOs, under a single Preferred Drug List (PDL) model, use similar utilization management (Prior Authorization) practices as the State FFS program.
  - Reimbursement to pharmacies is based a percent of WAC or AWP methodology coupled with a dispensing fee between $0.50 to $3.00[2]
  - Many use a narrower provider network as a cost containment measure.
  - MCOs use PBMs to administer the Rx benefit
- Fee for Service (FFS)
  - State Medicaid Programs manage to a legislative appropriation
  - FFS uses utilization management (Prior Authorization) practices to ensure compliance with the Preferred Drug List and the clinical appropriateness of prescription drugs
  - States reimburse pharmacies using National Average Drug Acquisition Cost (NADAC) which more accurately reflects the actual prices paid by pharmacies for drugs. To offset lower reimbursment, NADAC is coupled with a professional dispensing fee of $10 to $12 per claim
  - State use any willing provider network
  - States contract with PBAs to administer the Rx Benefit

2. Commonwealth of Kentucky Cabinet for Health and Family Services. Preliminary feasibility study of a pharmacy carve-out model. 2019. Available at: https://d3dkdvqff0zqx.cloudfront.net/groups/kpa/attachments/ky%20carveout %20report_final_11_19_19.pdf. Accessed January 2021.

Medicaid Pharmacy Benefit Management

Understanding the difference between a PBM and a PBA

- Pharmacy Benefit Manager (PBM)
  - Funding is provided by the state to the MCO/PBM under a capitated rate, set through an actuarially sound process
  - The PBM is at risk for total drug spend.
  - The administrative fees under a capitated risk model are significant because of the financial risk that MCOs take.
  - This model provides budget predictability for states
- Pharmacy Benefit Administrator (PBA)
  - States contract with a PBA to manage the pharmacy benefit under a fixed fee contract
  - The State is at risk for total drug spend.
  - In this model, the state Medicaid program staff retain decision making authority and have responsibility for managing the cost of the program within the states' budget appropriation.

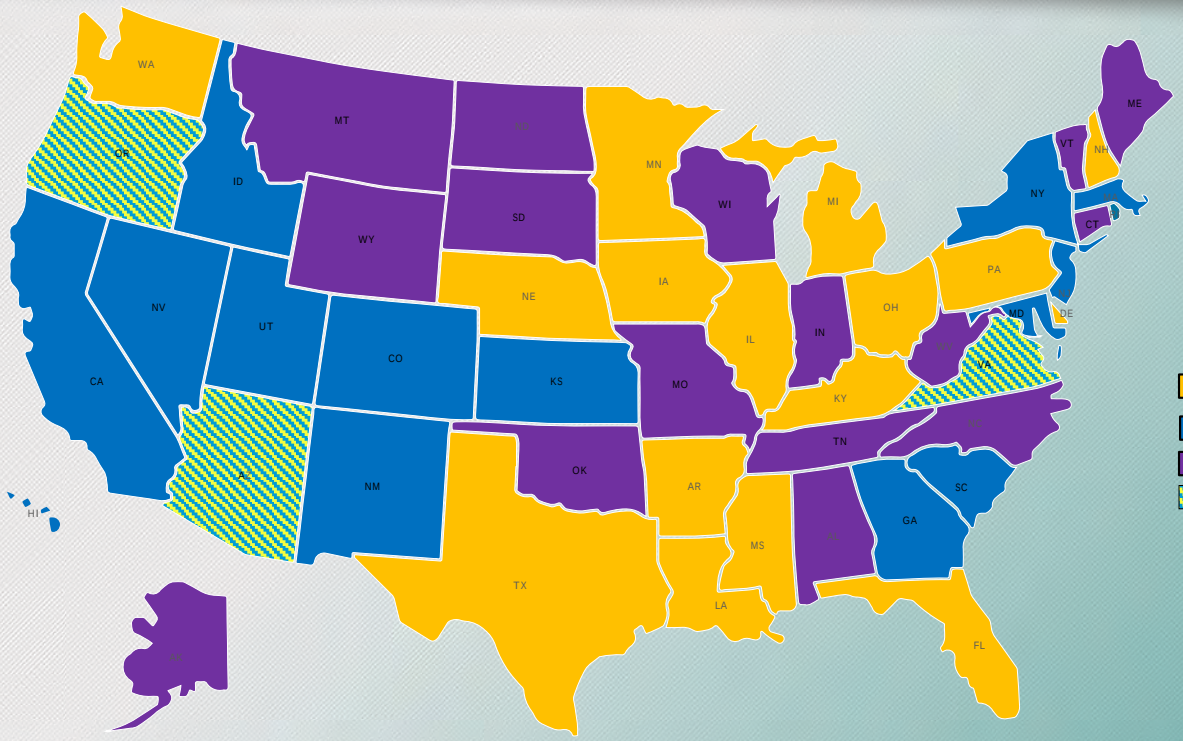
Service Delivery National Trends

Pharmacy issues facing policy makers across the country

- Lack of financial transparency and provider dissatisfaction with MCOs (and their PBMs) is forcing state legislators to take a hard look at who should manage the Medicaid pharmacy benefit
  - Pharmacists prefer the Medicaid reimbursement algorithm (NADAC) to commercial plans
  - Physicians prefer a single Prior Authorization process and a single PDL for all Medicaid Beneficiaries
  - Spread pricing is perceived to benefit PBMs at the expense of pharmacies and taxpayers
- *State legislatures around the country are addressing these issues by eliminating spread pricing, moving to a single PDL or carving the pharmacy benefit out of the MCO altogether.*

Separate MCO & FFS Pharmacy Management, Unified or Single PDL and FFS Only PDL as of April 2021

California is expected to carve-out the pharmacy benefit from the MCOs by July 2021



Medicaid Drug Rebate Program (MDRP)

- The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) established the MDRP. At that time, Medicaid was paying more for drugs than commercial plans. Three key elements to the program to ensure cost savings:
  1) *Established a minimum discount for brand and generic drugs*
  2) *Included a Consumer Price Index - Urban (CPI-U) penalty to protect states against inflation*
  3) *Established Best Price (BP) as a component of the rebate calculation to ensure the state received, at a minimum, the same discount as the most efficient purchasers (Commerical PBMs)*
- Pharmaceutical pricing is transparent to states but protected from public disclosure under the Social Security Act at 42 U.S.C. 1396-r8 (b)(3)(d).
- Participation in the MDRP by manufacturers is voluntary but must include their entire product portfolio

Overview of the MDRP

- Federal Rebate Statistics 2019
- Federal rebates return 54.6% of rebate-eligible drug spend to the states
- Supplemental rebates returned 4.8% of total drug spend to the states
- 100% of rebate dollars, both federal and supplemental, are paid to the state
- Federal rebates are capped at 100% of AMP
- Congress will remove the drug rebate cap in 2024. Removing the cap is expected to yield billions of dollars in new rebate revenue for states and the Federal Government

2019

MAGELLAN RX MEDICAID PHARMACY TREND REPORT / 2020

*Rebate percentage based on pharmacy reimbursement amount, not a percentage of AMP

Overview of the MDRP *(continued)*

- *Mandatory* federal rebate:

Brand drugs	The greater of (23.1% x AMP or AMP - BP) + CPI-U
Clotting factors / drugs approved exclusively for pediatric use	The greater of (17.1% x AMP or AMP - BP) + CPI-U
Generic drugs	13% x AMP + CPI-U

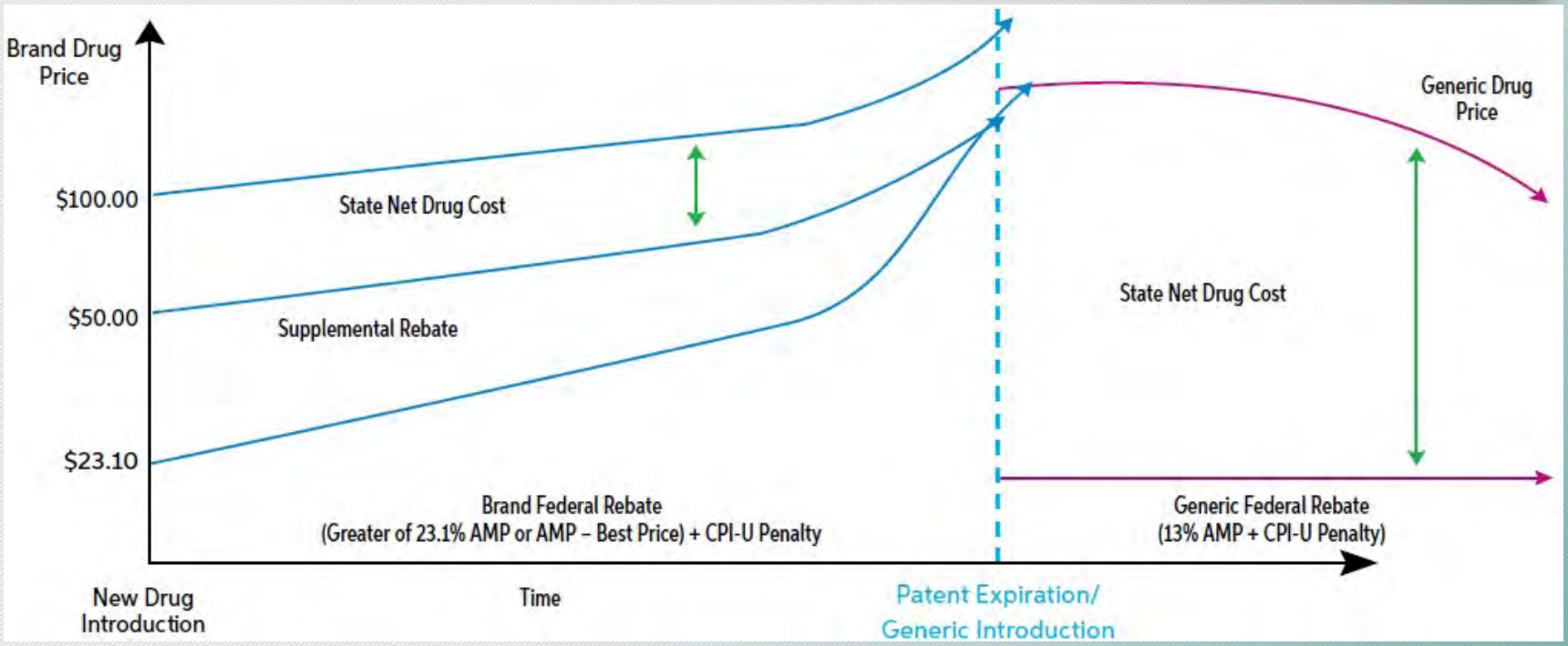
- The federal rebate was extended to Medicaid managed care plans under the ACA such that states could collect the mandatory federal rebate on MCO utilization.
- States ***must*** invoice and collect the federal rebate
- States share those rebates with the Federal Government according to their Federal Medical Assistance Percentage

Example Federal Rebate Calculation

Illustrative Example	Average Manufacturer Price	Best Price	CPI-U
	$100	$60	$20
Brand drugs	The greater of (23.1% x AMP or AMP - BP) + CPI-U		
	The greater of ($23.10 or $40) + $20		
	Federal rebate = $60		

Overview of the MDRP *(continued)*

Medicaid Pharmacy Economics



Magellan RX Management. Medicaid pharmacy trend report. 2020. Available at: https://issuu.com/magellanrx/docs/mtr20_final_v2?fr=sNTNiODE4MzMzMDk. Accessed January 2021

Brand vs Generic Drugs

- Generic utilization rates are similar between Medicaid MCO and Medicaid FFS management (high 80% vs mid 80%) but one of the primary drivers of this difference pertains to the accounting for new-to-market generic drugs.
- Observers often criticize Medicaid FFS programs as ineffective for having lower generic dispensing rates and a higher gross drug spend than MCOs. However, brand name drugs, net of federal rebates, are often less expensive than new-to-market generic drugs.
- There are many states, including NY, who publish a list of preferred brand drugs that providers should dispensed instead of their generic equivalent solely based on net of federal pricing.
- In 2019, brand-over-generic programs saved State Medicaid programs $320 million for the states included in the Magellan Medicaid Trend Report or an average of $70 per claim.

Brand vs Generic Drugs *(continued)*

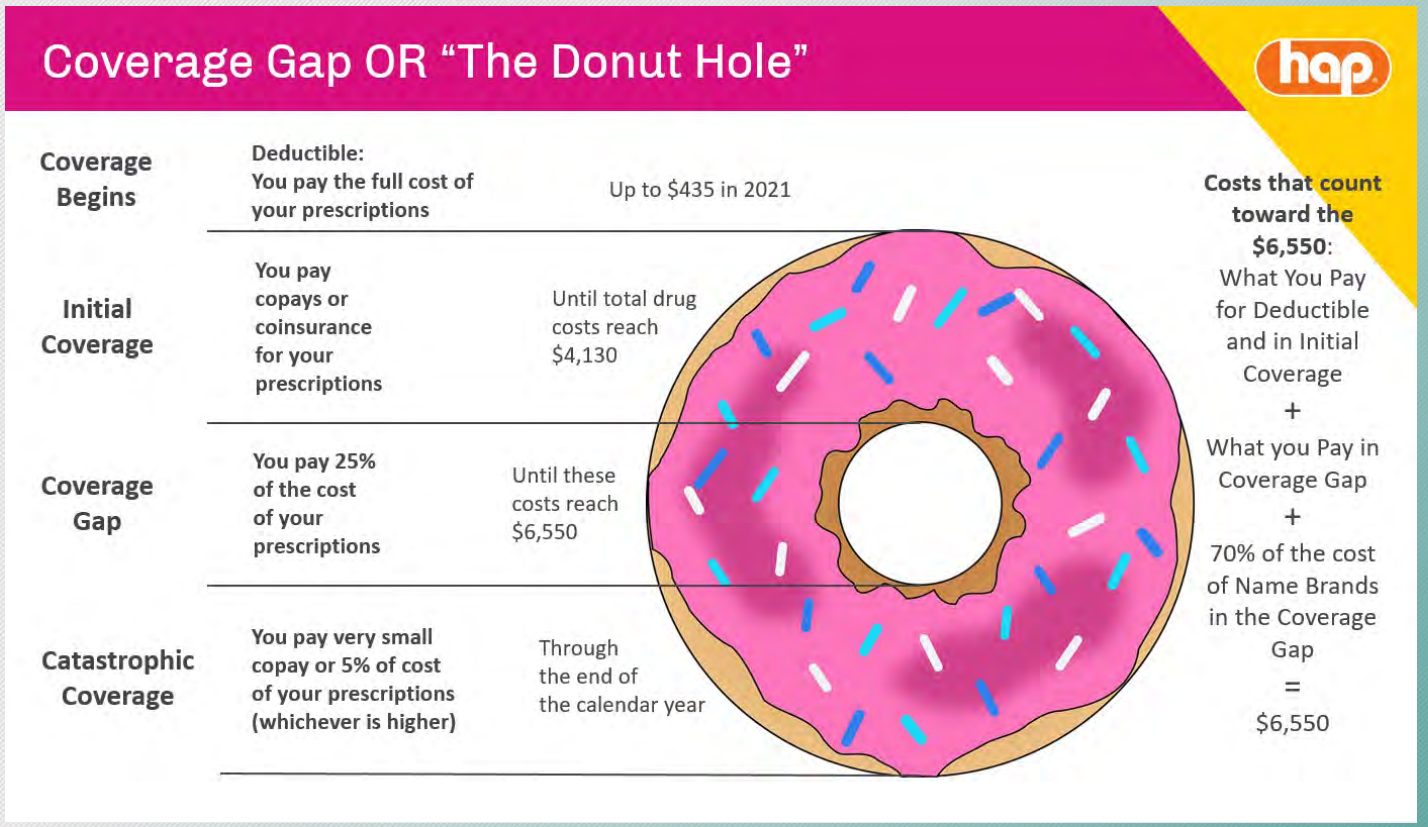
- Prior to transition from a Common Formulary to a PDL, MCOs required use of generic medications before preferred brands
- MCO Concerns-
  - Reimbursement costs for PDL brand drugs are higher than generic alternatives, increasing ingredient cost paid to pharmacies and MCO drug costs
  - MCO capitation rates have not been adjusted to offset the additional costs
- Pharmacy Provider Concerns-
  - PDL brand drugs are more expensive than previously preferred generics, increasing inventory costs and reducing margins on brand vs generics

Medicare Part D Overview
and
Commercial Pricing Considerations

2021 Medicare Part D Prescription Program

- Voluntary outpatient prescription drug benefit for people with Medicare
- Provided by private health plans:
  - PDP (Prescription Drug Program only)
  - MA-PD (Integrated Prescription Drug and Medical Program)
- Four phases:

-Deductible	$0-$445
-Initial	Up to $4130
-Coverage Gap (aka Donut Hole)	Up to $6550
-Catastrophic or	Greater of copay 5% of Rx cost



The U.S. Pharmacy Distribution and Reimbursement System for Patient-Administered, Outpatient Prescription Drugs

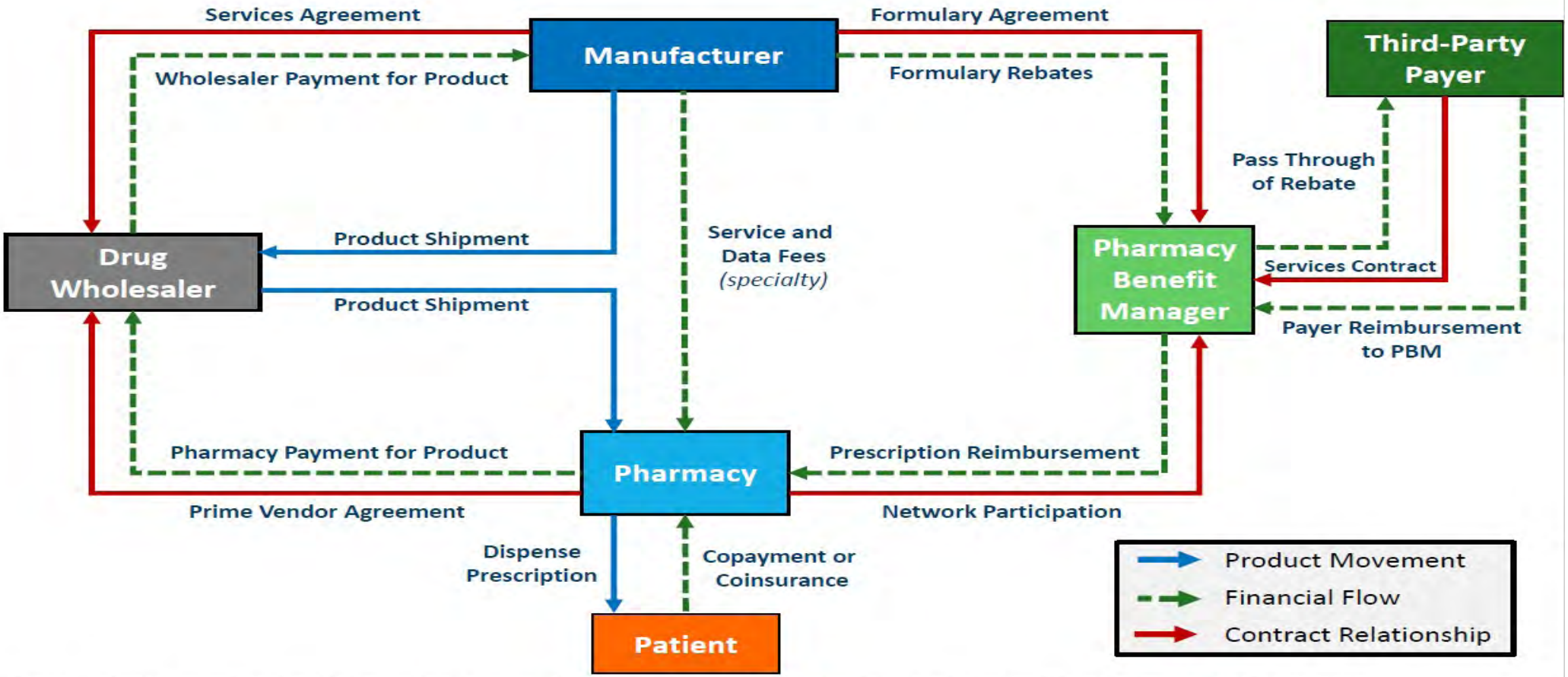


Chart illustrates flows for patient-administered, outpatient drugs. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.
Source: Fein, Adam. J., *The 2016 Economic Report on Retail, Mail and Specialty Pharmacies*, Drug Channels Institute, January 2016.
(Available at http://drugchannelsinstitute.com/products/industry_report/pharmacy/)

Pharmacy Benefit Management Tools

- Negotiate Pharmacy Network Agreements
  - Retail, Mail Order and Specialty Pharmacy
- Establish a clinically sound, cost-effective formulary
- Control generic pricing through MAC program (Maximum Allowable Cost)
- Negotiate manufacturer discounts on preferred brand medication
- Implement step-therapy and prior authorization program
  - Promotes generics first and appropriate use of preferred brands
  - Reduces cost and enhances safe and appropriate use of medications
- Establish drug utilization review (DUR) programs
  - Reduces waste, over-use, duplication and adverse events
  - Identifies opportunities for quality and safety programs
- Implement quality programs to improve medication adherence and manage appropriate medication use
  - *Right drug, Right place, Right time*

Pharmacy Network Agreements

- A PBM or Payer/Health Plan contracts with pharmacies to provide prescription drugs covered by a pharmacy benefit
- Pharmacy Network Agreements include:
  - Ingredient cost payment
  - MAC pricing (Generics)
  - Dispensing fees
  - Qualifying claim payment criteria
  - Payment terms and timelines
  - Claim submission timelines and reversals
  - Service expectations
  - Audit guidelines
- Open Networks vs Preferred or Narrow Networks

Importance of Pharmacy Provider Audits

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- Allow PBMs and Payers/Health Plans to ensure contract and regulatory compliance
- Reduce Pharmacy Fraud, Waste and Abuse (FWA)
- Contain healthcare cost for purchasers and consumers

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Desk-top

- Prescription copies and patient signature logs requested

On-site

- Pharmacy notified of audit with a list of claims and signature logs for review
- On-site may include request for manufacturer invoices to support claims billed

Prepay or claims check

- Claims submitted by the pharmacy reviewed for appropriateness prior to payment

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Triggers

- Unusual claim patterns or trends compared to other pharmacies
- Unusually high number of prescription types
- Regulatory sanctions or restrictions
- Patient or provider complaints

Findings

- Following the audit, pharmacy receives a report of findings
- Opportunity to appeal findings/produce documentation
- Audit financial recovery may differ based on PBM or Payer contract

Spread vs. Pass Through Pricing

- Spread Pricing-Difference between amount PBM pays the pharmacy and amount charged to payer/plan
- Pass Through Pricing-Pass through of same discounts and dispensing fees charged by pharmacy to the payer/plan

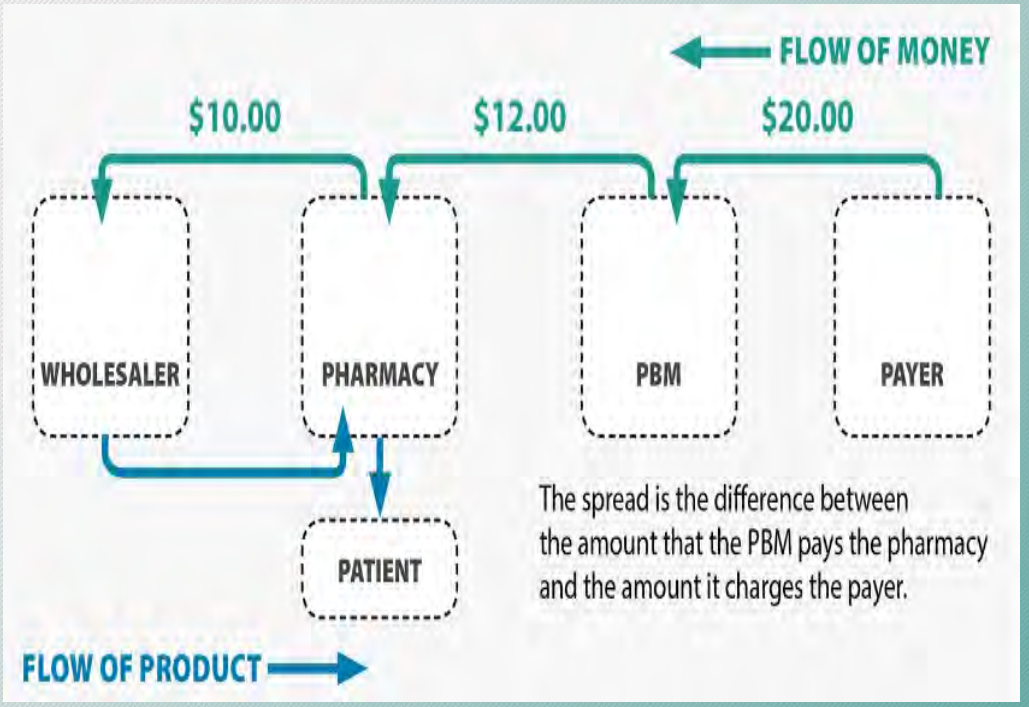
How spread pricing works

Step 1: The pharmacy buys the prescription from a wholesaler or distributor for a certain amount—say, $10.

Step 2: When a person uses insurance coverage to buy a prescription, the PBM pays the pharmacy a certain amount—say, $12. The pharmacy makes $2 on the transaction. In terms of how the money flows, this is the same as the reimbursement insurers make to doctors or hospitals after they provide a service.

Step 3: The PBM also turns around and bills the payer (the employer or a state Medicaid program if it is a Medicaid PBM) for that prescription. Say it bills for $20. The PBM pockets that $8 difference.

The result: The $8 difference between what the PBM paid the pharmacy ($12) and the amount it billed the payer ($20) is the spread.



Silverman, E, 2019, "Spread Pricing: From Largely Unknown to Much Scrutinized and Criticized", *Managed Care*,2019/09, pp 31-32, viewed 4/17/21, https://www.managedcaremag.com/archives/2019/9/spread-pricing-largely-unknown-much-scrutinized-and-criticized/

Questions?

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Glossary of Terms

- ACA – Affordable Care Act – passed by Congress in 2010, the ACT expand health care coverage to low income Americans.
- AMP – Average Manufacturer Price – means, for a covered outpatient drug, the average price paid to the manufacturer for that drug in the United States by wholesalers and retailers for drugs distributed to retail class of trade.
- AWP – Average Wholesale Price –Average price paid by a retailer to buy a drug from a wholesaler.
- BP or Best Price – The lowest price available for covered outpatient drugs, includes all prices, including applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly to best price eligible entities.
- CMS – Centers for Medicare & Medicaid Services – Federal agency within the Department of Health and Human Services that administers the Medicaid, Medicare, and CHIP programs.
- CPI-U – Consumer Price Index-Urban – A measure of the average change over time of the prices paid by urban customers for a market basket of consumer goods and services.
- DUR – Drug Utilization Review - structured, ongoing review of healthcare provider prescribing, pharmacist dispensing, and patient use of medication.
- FMAP – Federal Medical Assistance Percentage – The percentage of the total state Medicaid cost that the federal government pays in each state to operationalize its Medicaid program.
- FFP - Federal Financial Participation - The portion paid by the Federal Government to states for their share of expenditures for providing Medicaid services and for administering the Medicaid program and certain other human service programs.
- FFS – Medicaid Fee for Service – The state reimburses providers directly for each covered service received by a Medicaid beneficiary.

Glossary of Terms

- MAC - Maximum Allowable Cost - is the upper limit that a PBM or health plan will reimburse a pharmacy for generic drugs.
- MCOs – Managed Care Organizations – are used by states to improve patient care (through case management) and to ensure budget predictability under a capitated payment arrangement.
- MDRP – Medicaid Drug Rebate Program – is a program that includes CMS, state Medicaid agencies, and participating drug manufacturers that helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients.
- NADAC – National Average Drug Acquisition Cost – is the rate determined by CMS to be the average acquisition cost for drugs by retail community pharmacies.
- PA – Prior Authorization – a process required by a payer (Medicaid or Commercial) that a physician obtain approval before a drug or procedure is administered to ensure reimbursement.
- PBA – Pharmacy Benefit Administrator – Generally speaking, a PBA is not at risk for the pharmacy drug spend and is under contract with a state Medicaid program or commercial entity to provide administrative services for a predetermined fixed cost.
- PBM - Pharmacy Benefit Managers - Generally speaking, a PBM takes financial risk for the pharmacy drug spend and is under contract by health plans and other payers on a capitated rate basis.
- PDL – Preferred Drug List – A list of covered outpatient drugs deemed by payers as medically appropriate, cost effective, and not generally requiring prior authorization.

Glossary of Terms

- Single or unified PDL – Occurs when MCOs are required to use the same PDL as the state Medicaid FFS program.
- UM – Utilization Management – Techniques used by payers, such as prior authorization, to manage the cost of healthcare benefits by assessing their appropriateness before they are provided using evidence-based criteria or clinical guidelines.
- WAC – Wholesale Acquisition Cost – means, the manufacturer's list price for a drug to wholesalers or direct purchasers but does not include discounts or rebates.