

ACCC **2023**

Oncology
Reimbursement
MEETINGS

Pharmacy Benefit Managers: The What and How?

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Objective



- Understand the role pharmacy benefit managers (PBMs) play in oncology drug spending and how advocates are working at the state and federal level to regulate PBMs, including requiring greater transparency, banning “spread pricing,” and reining in high prescription costs for which patients are often responsible.

Who Are PBMs?^{1,2}



- Plan sponsors (insurance companies, self-insured employers, and government programs) contract corporations to negotiate with pharmaceutical companies to provide drug coverage to their insured population.
- The United States drug supply chain comprises visible entities and virtual ones.
- Visible entities: Manufacturers create a drug, distributors buy the drug and sell it to pharmacies, pharmacists then dispense the drug to a patient.
- Virtual entities: Health insurance pays some of the cost of the drug and decides which pharmacies are allowed to dispense the drug. PBMs become the middleman to contract reimbursement with pharmacies, drug manufacturer rebates, and insurance plans to set formularies.

Who Are PBMs?



- Five PBMs control more than 80% of prescription coverage for Americans³
- In 2018, the PBM market was as follows:⁴
 - CVS Caremark 31%
 - Express Scripts 23%
 - OptumRx 23%
 - Humana 7%
 - MedImpact 6%
 - Prime Therapeutics 6%
 - Other 4%

Who Are PBMs?⁵



- According to the Pharmaceutical Care Management Association (PCMA), the lobbyist for PBMs in D.C. work to lower patient costs by negotiating rebates and discounts, create pharmacy networks to dispense medications at a lower rate, and strive to maximize generic drug usage and medication adherence.
- Due to the lack of transparency, PBMs have created practices that delay patient's access to medications and raise drug costs considerably. Delay in access equals prior authorization, step therapy.
- Lack of transparency equals vertical mergers.
- PBMs merge with the insurance company, own the pharmacy benefit and specialty pharmacy that dispenses the medication(s).
 - CVS Caremark merged with Aetna and CVS/Pharmacy.
 - Express Scripts merged with Cigna and Express Scripts mail-order pharmacy and Accredo Specialty.
 - Optum Rx merged with UnitedHealthcare and runs its own mail-order pharmacy.

Who Are PBMs?



- These mergers create businesses that control pricing and have no competition.
- Pricing is controlled through DIR fees (direct or indirect remuneration), rebates, and spread pricing.
- No competition is controlled through “steering.” Also, setting low reimbursement to competitors causes local pharmacists to not be able to fill the prescription.
- Pharmacist “gag” orders: PBMs block pharmacists from discussing a cheaper option for a prescription (i.e., a, drug was on a \$4 list vs. paying a \$10 co-pay).
 - There are now federal and state laws that prohibit this practice from happening.

Who Are PBMs? DIR Fees



- DIR fees were created by Medicare Part D to lower drug costs to patients.
- However, there is **no** transparency on calculations of the “fee.”
- The “fee” can be taken back (clawback) a year or more after the claim has been paid.
- Often, the “fee” is based on performance, usually not specialty specific.
- As PBMs continue to profit off these “fees,” the rest of the drug supply chain must increase prices to make a profit, ultimately, hurting the patients the “fee” was supposed to help.

Who Are PBMs? Rebates



- Rebates were intended to reduce manufacturers' drug list price and ultimately save patients money.
- If a manufacturer refuses to give a rebate to the PBM, the PBM can exclude their drug from coverage or their preferred list.
- As PBMs seek larger rebates, pharmaceutical manufacturers lose profits and increase costs elsewhere to make up for these losses.
- Again, patients pay higher prices for drugs in the long run.

Who Are PBMs? Spread Pricing

- Spread pricing is used by PBMs to reimburse pharmacies for less than the pharmacy paid for the drug.
- Ultimately, the PBM pockets the difference between what they charge an insurance provider for a drug vs. what they pay the pharmacy.
- States are now auditing the “spread pricing” of PBMs in the Medicaid system.
- Maryland found that a \$72 million profit was paid to PBMs over a year in its state Medicaid program.⁶
- Kentucky discovered \$123.5 million in profit by PBMs in 1 year.⁷
- Congress has now introduced legislation to stop such profiting off federal taxpayers.

Who Are PBMs? Patient Steering

- As a part of the mergers, PBMs own specialty pharmacies and mail-order pharmacies.
- The National Community Pharmacy Association disclosed that 79% of pharmacists say their patients' medications were transferred to a PBM-owned pharmacy without the consent of the patient.⁸
- Most commercial insurance patients are “steered” to the PBM-owned pharmacies. These patients are not allowed to fill their prescriptions locally.
- Specifically, in the oncology space, more pharmaceutical companies are developing oral treatments.
 - This moves treatment from the medical benefit to the pharmacy benefit.

What Can We Do? At the State Level



- On December 10, 2020, the U.S. Supreme Court ruled 8-0 in *Rutledge v Pharmaceutical Care Management Association*.⁹ This action controls reimbursements to pharmacies by the PBMs. They no longer can pay a pharmacy less than that pharmacy pays for the drug.
- This case has opened the door for similar legislation on the state level.
- In 2022, Tennessee enacted a law about steerage and reimbursement. Tennessee has hired a PBM enforcer in the Tennessee Department of Commerce and Insurance.¹⁰
- Many other states are pursuing legislation imposing transparency in reporting; blocking PBMs from managing Medicaid pharmacy plans; stopping spread pricing by making it illegal; restricting rebates to PBMs, or ensuring the rebates return to the state, or offsetting the premiums for commercial plans; prohibiting clawbacks; stopping steerage, placing limits on PBM management tools that delay therapy (prior authorization, step therapy, non-medical drug switching).

What Can We Do? At the National Level

- Congress has considered 2 key bills: the Pharmacy DIR Reform to Reduce Senior Drug Costs Act and Drug Price Transparency in Medicaid Act of 2021.^{11,12}
- In February 2019, the Centers for Medicare & Medicaid Services (CMS) sent a notice of rulemaking to reduce spending for pharmacy patients. Rebates would be delivered to the patient at pick up and DIR fees would be assessed when the claim was adjudicated.
- This rule has a legislative delay until 2026.

What Can We Do? At the Local Level



- Advocate for our patients! Let your voice be heard among your state and national representatives.
- Educate yourself on how bills are introduced and how laws are passed.
- Become an active member in your local associations (i.e., Tennessee Pharmacists Association, Association of Community Cancer Centers, Tennessee Oncology Practice Society)

Summary



- PBMs are attracted to the oncology arena because of the costliness of the drugs.
- With more oral anti-cancer drugs in development, PBMs can benefit from high rebates, high DIR fees, and even higher spreads. All ultimately affect the cost of the medication.
- Regulators at both the state and federal levels have laws that need to be enforced.
- We need to rise up and be advocates for our patients and our jobs!

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