Draft date: 10/23/24

2024 Fall National Meeting
Denver, Colorado

PHARMACEUTICAL BENEFIT MANAGEMENT REGULATORY ISSUES (B) WORKING GROUP
Monday, November 18, 2024
1:00 – 2:00 p.m.
Gaylord Rockies Hotel—Aurora Ballroom B—Level 2

ROLL CALL

Joylynn Fix, Chair	West Virginia	Chlora Lindley-Myers/ Amy Hoyt/Cynthia Amann	Missouri
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Daniel McIlwain	Kentucky		
Frank Opelka	Louisiana		
Chad Arnold/Joe Stoddard	Michigan	Nathan Houdek	Wisconsin
Norman Barrett Wiik/ T.J. Patton	Minnesota	Jill Reinking	Wyoming

NAIC Staff Support: Jolie H. Matthews

AGENDA

1. Hear a Discussion on Pharmacy Benefit Managers (PBMs) and How They Function—*Joylynn Fix (WV)*
    - *John Jones (Pharmaceutical Care Management Association [PCMA])*
    - *Scott Woods (Pharmaceutical Research and Manufacturers of America [PhRMA])*
    - *Joel Kurzman (National Community Pharmacists Association [NCPA])*

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2. Hear a Discussion on Providing Potential Assistance to the Producer Licensing Uniformity (D) Working Group to Create a New Section on PBM Licensure Best Practices and Uniform Standards in the *State Licensing Handbook—Ashley Scott (OK)*

3. Discuss Any Other Matters Brought Before the Working Group *—Joylynn Fix (WV)*

4. Adjournment

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Agenda Item #1

Hear a Discussion on Pharmacy Benefit Managers (PBMs) and How They Function:

- *John Jones (Pharmaceutical Care Management Association [PCMA])*
- *Scott Woods (Pharmaceutical Research and Manufacturers of America [PhRMA])*
- *Joel Kurzman (National Community Pharmacists Association [NCPA])*

Pharmacy Benefit Companies:

The Intersection of Care and Cost Savings

What to know about pharmacy benefit companies (PBMs)

What is a pharmacy benefit?

A pharmacy benefit is the part of your health insurance that covers prescription drugs.

What are PBMs?

PBMs are companies with expertise in prescription drug benefits and delivery. Public and private employers, unions, retirees, and government programs, hire PBMs to help them provide prescription drug coverage to **more than 275 million people** in the US.

Click here to learn more

What are pharmacy benefit companies' core functions?

PBMs do four main things:

1. Administer insurance claims for prescription drugs in real time when the drug is dispensed.
2. Negotiate savings for brand drugs from drug manufacturers.
3. Negotiate with pharmacies to reduce pharmacy costs, especially for prescription drugs.
4. Provide tools and programs to support patients and clinicians.

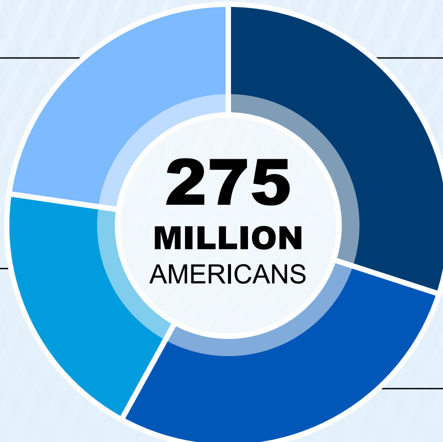
PBMs help the entire health care system by driving down drug costs, **saving payers and patients an average of $1,040 per person per year,** and providing $145 billion in overall value to the health care system.

About PCMA

The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 275 million Americans who have health coverage from a variety of sponsors. PCMA continues to lead the effort in promoting PBMs and the proven tools they utilize, which are recognized by consumers, employers, policymakers, and others as key drivers in lowering prescription drug costs, increasing access, and improving outcomes.

PBMs serve consumers across plan types

Americans With Drug Benefits Managed by PBMs, by Type of Coverage



22.7% Medicaid*

19.3% Medicare Part D

30.0% Self-Insured Employers

28.0% Commercial Health Plans

*Excludes "Medicare/Medicaid Dual Eligibles" where drugs are covered by Medicare Part D, includes Managed Medicaid and fee-for-service Medicaid when a PBM is used.

Source: Visante, estimates prepared for PCMA. (2023).

PCMA Members

What does PBM expertise do for the US health care system?

Pharmacy benefit companies help secure lower health care costs for their customers and patients.

PBMs help save payers and patients 40-50% annually on drug and related medical costs.

Pharmacy benefit companies drive down costs for prescription drugs by pushing drug companies to compete to offer better prices (through rebates) for patients and families.

- History has shown that drug companies repeatedly and arbitrarily increase prices on existing medications, and there is no correlation between the price of a drug and how effective it is in treating a medical condition.
- Without PBMs, there would be no limit on the prices drug companies could charge.
- Evidence shows that there is no correlation between drug prices and rebates. Drug companies take enormous price increases for Part D drugs without rebates and for Part B drugs, for which PBMs do not negotiate rebates.

How do PBMs support patients?

PBMs add clinical value and advance better health outcomes by:

- **Supporting patient safety** by preventing potentially harmful drug interactions and reducing medication errors.
- **Helping patients understand** how and when to take their medication.
- **Improving care coordination** through offerings such as home delivery, saving patients time and money while increasing access and care coordination.

PBMs help patients afford their medications.

Pharmacy benefit companies administer over 3.6 billion scripts annually. Without the savings they negotiate, patients and payers could pay much more for prescription drugs.

- Pharmacy benefit companies offer programs to help patients facing high cost-sharing.

PBMs partner with pharmacists to benefit patients.

- PBMs establish broad networks of affordable, high-quality pharmacies that patients can rely on to get their drugs.
- PBMs help plan sponsors select the right mix of brick-and-mortar, mail order, and specialty pharmacies for their networks.
- PBMs drive competition and quality among retail pharmacies.

PBMs help make drugs accessible to patients.

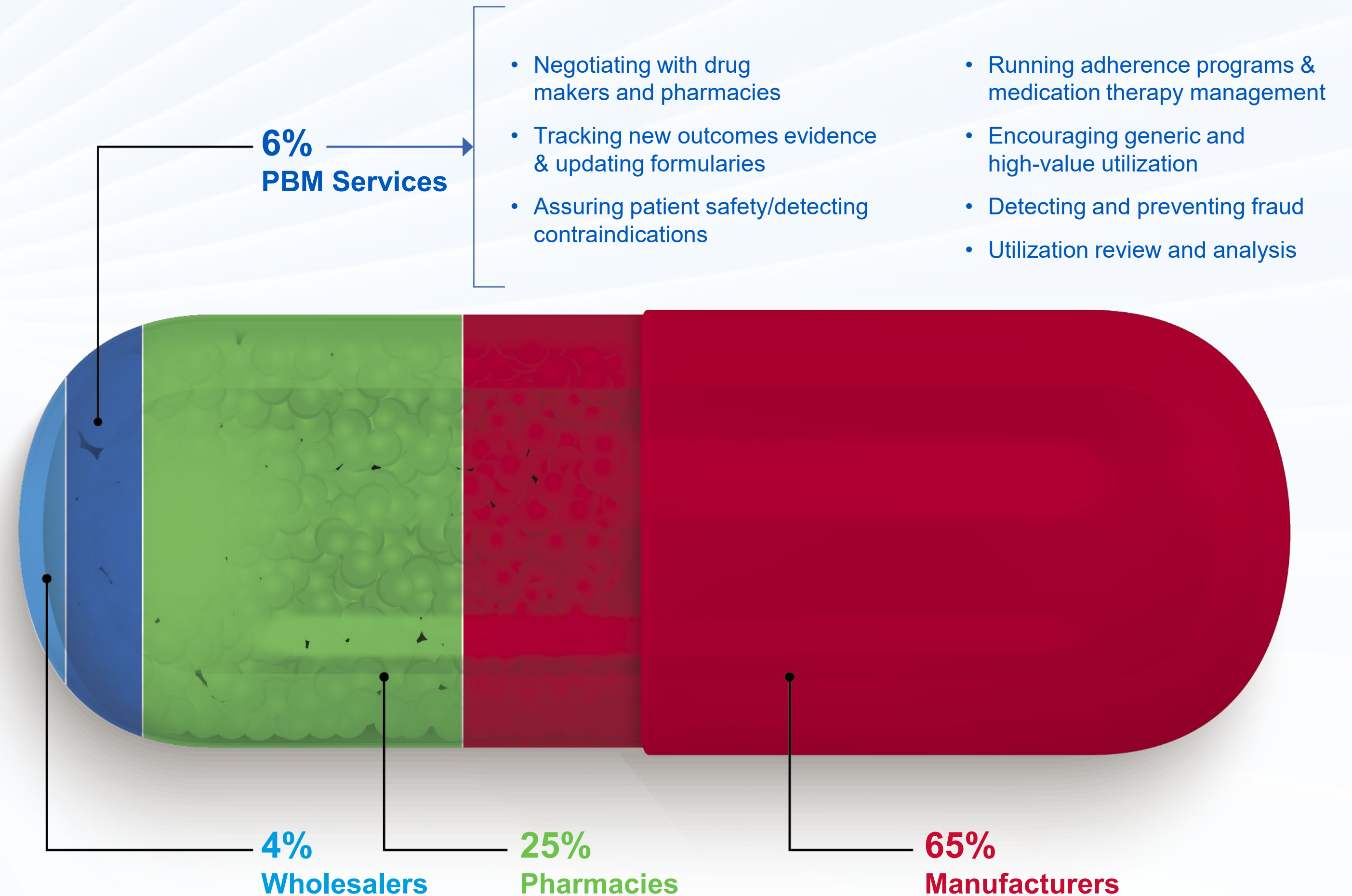
- Pharmacy benefit companies and health plan sponsors recognize the challenges posed by social determinants of health and proactive explore solutions.
- PBM programs like home delivery help to improve access for patients with transportation challenges and those living in areas where pharmacies are less accessible.

Employers and other health plan sponsors decide how they pay for pharmacy benefit company services.

- **Most rebates are passed through the PBM to the employer or health plan sponsor** (99.6% in Medicare and 91% in commercial health plans).
- **Sometimes, employers and health plan sponsors choose to pay PBMs by asking them to retain a portion of drug company rebates**, aligning incentives toward cost savings. This is a less common payment model among large employers.

Share of drug dollar retained by drug supply chain participants

90% of the Rx dollar is retained by drug manufacturers and pharmacies



Source: Visante estimates, based on data published by IQVIA, Pembroke, Altarum, USC Schaefer, and Health Affairs. Figure displays estimated total net expenditures (after rebates), both brands and generics. Includes only traditional PBM services, and excludes prescriptions filled by PBM-owned mail/specialty pharmacies, which cost less than retail but provide added margins to PBMs who own mail/specialty pharmacies.

How do PBMs support plan sponsors?

Plan sponsors are entities—employers, government programs like Medicare and Medicaid, labor unions, health insurers, state employee, and retiree plans, etc.—**that provide health care coverage.**

- **Health plan sponsors choose the design of their drug benefits and participant cost sharing.** PBMs offer a wide range of services and choices.

PBMs help employers and other plan sponsors by:

- **Negotiating with drug companies and pharmacies to lower drug costs.** PBMs also encourage the use of generic drugs, push pharmacies for high-quality performance, and negotiate value-based purchasing programs.
- **Providing business and operations expertise.** PBMs provide plan sponsors with a variety of coverage choices and flexibility in benefit design and payment structure.
- **Providing coverage recommendations.** PBMs help plan sponsors navigate coverage options, beginning with recommendations based on analyses performed by independent pharmacy and therapeutics (P&T) committees made up of clinical experts who review and evaluate clinical evidence.

How do plan sponsors choose a PBM?

Plan sponsors solicit PBM bids. PBMs must compete for business and tailor their offerings to meet plan sponsors' needs.

Adhering to contractual requirements. PBM contracts are comprehensive and include everything the PBM is required to do to fulfill its obligations to the plan sponsor.

Pharmacy benefit companies provide value and achieve savings in part by:

Designing formularies. These lists of drugs covered by a health plan play a large role in driving rebates.

Sharing savings with patients. Differential patient cost sharing encourages patients to use lower-cost alternatives.

Promoting generic drugs. PBM formularies incentivize use of generics, and PBM contracts with pharmacies encourage generic substitution.

Promoting biosimilars. PBMs recognize the value of Biosimilars and strongly support policies to enhance biosimilar competition in the market.

Pharmacy benefit companies improve drug adherence by:

- Improving patient affordability, reviewing claims for indicators of non-adherence, providing clinical and other patient support programs, and providing targeted services focused on adherence for the elderly, disabled, home bound, non-English speaking, and other groups in need of additional support.

Pharmacy benefit companies provide additional value by:

- Preventing fraud, waste, and abuse through pharmacy audits.
- Increasing efficiency with shorter claims processing times and reducing the need for paper claims.
- Providing real-time reimbursement and coverage information for patients and their prescribers (RTBT).
- Streamlining the prior authorization process using technology (ePA).

PBM clinical expertise at work: How pharmacy benefit companies enable better health outcomes

CDC data shows that adherence to prescribed medication is associated with improved clinical outcomes for chronic disease management and reduced mortality from chronic conditions, and nonadherence is associated with higher rates of hospital admissions, poor health outcomes, increased morbidity and mortality, and increased health care costs. To help address this, PBMs use their expertise to provide medication adherence programs. These involve both clinical and operational components.

Clinical components.

- Reviewing drugs to identify over or under-utilization or non-adherence.
- Flagging safety issues, including harmful drugs and drug combinations.
- Partnering with a wide range of expert clinicians, including specialty and community pharmacists, on identifying barriers to adherence and implementing the best strategies to meet a patient's needs.

Operational components.

- Providing counseling and coaching services that help patients stay on course with their treatment and anticipate side effects.
- Providing 24/7 patient access to customer service representatives and pharmacists as well as other clinicians.
- Sending reminders through text messages or phone alerts.
- Making dosages understandable and manageable by packaging drugs with dates and times.
- Making prescription access easy through home delivery, 90-day fills, and automatic refills.
- Providing targeted services focused on adherence for the elderly, disabled, home bound, non-English speaking, and other groups in need of additional support.

Impact of PBM role in medication adherence

PBMs help patients stick to their drug regimens, preventing more than ...

440,000 heart failures	**60,000** cases of kidney disease
300,000 strokes	**150,000** amputations

PBM clinical programs support patients

Click here to learn more about how PBMs make a difference in medication adherence for diabetics taking insulin

PBMs SUPPORT PATIENTS WITH DIABETES

PBMs HELP PATIENTS WITH ASTHMA BREATHE EASIER

Click here to learn more about how PBMs make a difference in medication adherence for asthmatic patients

Beyond adherence: Other clinical and quality initiatives where pharmacy benefit companies use their expertise to empower patients

Pharmacy benefit companies are an integral part of a patient's coordinated care management.

- PBM relationships with other stakeholders (including plan sponsors, pharmacists, and prescribers) give them the ability to engage with the patient (directly or indirectly) and influence better patient outcomes.
- PBMs directly engage with patients through programs like medication therapy management and assessment.
- PBMs coordinate drug regimens with other health care services the patient is receiving, including from specialists.
- **Case study.** PBMs' efforts with pre-diabetic patients and the related efforts to manage co-morbidities for both diabetics and pre-diabetics (e.g., hypertension and obesity) demonstrate how this coordination works.

Click here to listen to the PBMs and Diabetes Care podcast

Click here to learn more about PBM involvement in care coordination

How PBMs Work

Scott Woods, Vice President, Policy & Research

November 18, 2024

Emerging Trends in the PBM Marketplace

Since the NAIC began its work on PBMs, the market has drastically changed

Where the PBM Working Group should focus its future work

Vertical integration is amplifying PBMs’ influence within the health care system

Perverse incentives can allow PBMs to profit at the expense of patients, employers, and the health care system

PBMs’ business practices challenge patient access to medicines

Today's PBM Marketplace

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The Influence PBMs Have Over Patient Access and Affordability Continues to Grow

Negotiating power is increasingly concentrated among a small number of PBMs.

Insurers & PBMs determine:

IF MEDICINE IS COVERED
on the formulary

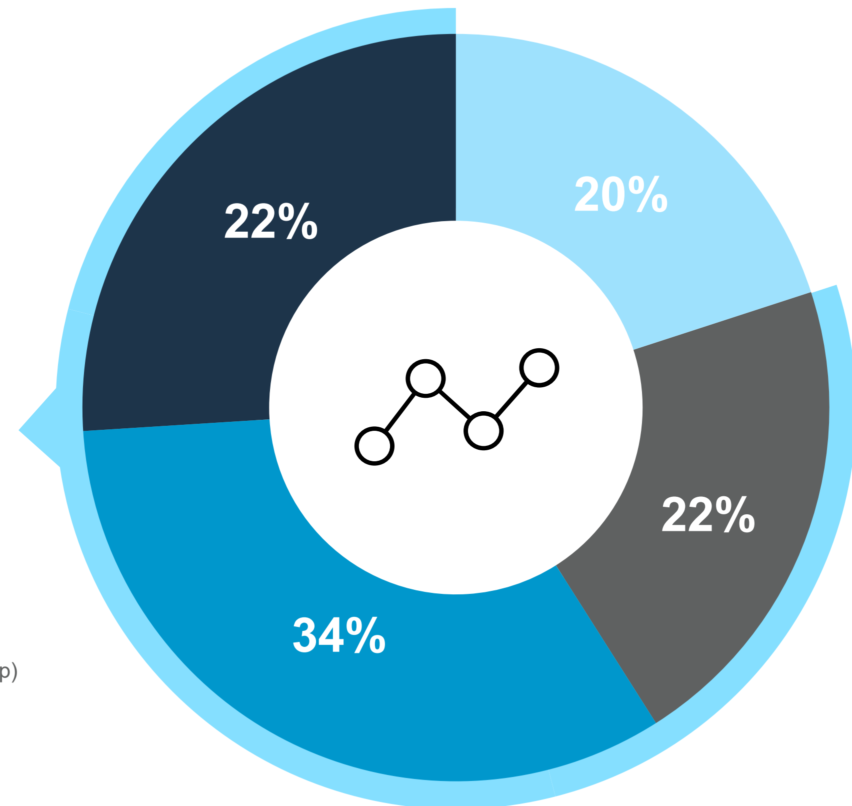
PATIENT OUT-OF-POCKET COST
based on tier placement

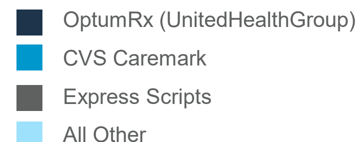
ACCESS BARRIERS
like prior authorization or fail first

PROVIDER INCENTIVES
through preferred treatment guidelines and pathways

Top 3 PBMs' Market Share:

80%





Source: Drug Channels Institute, April 2024.

A Snapshot of PBM Market Consolidation

1. Centene began outsourcing its PBM operations to Express Scripts in 2024. In 2023, Centene rebranded its Envolve Pharmacy Solutions pharmacy benefit subsidiary as Centene Pharmacy Services. In 2022, Prime Therapeutics completed its acquisition of Magellan Rx from Centene.
2. Synergie is a buying group focused on medical benefit drugs. Its ownership includes Blue Cross Blue Shield (BCBS) Association, Prime Therapeutics, Elevance Health, and other independent BCBS health plans.
3. Since 2021, Prime's Blue Cross and Blue Shield plans have had the option to use Express Scripts or AllianceRx Walgreens Pharmacy for mail/specialty pharmacy services. In 2021, Walgreens purchased Prime Therapeutics' 45% ownership interest, so this business had no PBM ownership as of 2022. In 2022, the company was rebranded as AllianceRx Walgreens Pharmacy. In August 2024, AllianceRx Walgreens Pharmacy will become Walgreens Specialty Pharmacy.
4. In 2021, Centene sold a majority stake in its U.S. Medical Management to a group of private equity firms.
5. Since 2020, Prime has sourced formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.
6. In 2023, Cigna's Evernorth business made a significant minority investment CarepathRx Health System Solutions.
7. Previously known as Evernorth Care Group and Cigna Medical Group.
8. In 2021, Cigna's Evernorth business acquired MDLive.
9. Walgreens owns a majority of VillageMD. In 2022, Cigna invested $2.7 billion for an estimated 14% ownership stake in VillageMD. In 2024, Cigna recorded a $1.8 billion loss on its investment.
10. In 2023, CVS Health completed its acquisitions of Signify Health and Oak Street Health.
11. Previously known as IngenioRx.
12. In 2023, Elevance Health completed its acquisition of BioPlus Specialty Pharmacy from CarepathRx. In 2024, Elevance Health acquired Paragon Healthcare, which operates specialty pharmacies and infusion centers, and Kroger Specialty Pharmacy.
13. Includes CareMore Health and Aspire Health. In 2024, CarelonRx announced a primary care partnership with investment firm Clayton, Dubilier & Rice.
14. In 2021, Partners in Primary Care and Family Physicians Group businesses were rebranded as Centerwell Senior Primary Care.
15. In 2022, Kindred at Home was rebranded as CenterWell Home Health. In 2022, Humana announced an agreement to divest its majority interest in Kindred at Home's Hospice and Personal Care Divisions to Clayton, Dubilier & Rice. Humana also announced plans to close a majority of its SeniorBridge home care locations.

Source: *The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Exhibit 254. Companies are listed alphabetically by corporate name.

DRUG CHANNELS INSTITUTE
An HMP Global Company

May 2024

Costs in Context: The Emerging PBM Business Model

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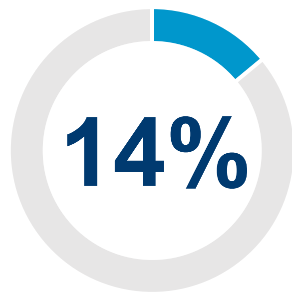
Spending on Medicines Is a Small and Stable Share of Total Health Care Spending

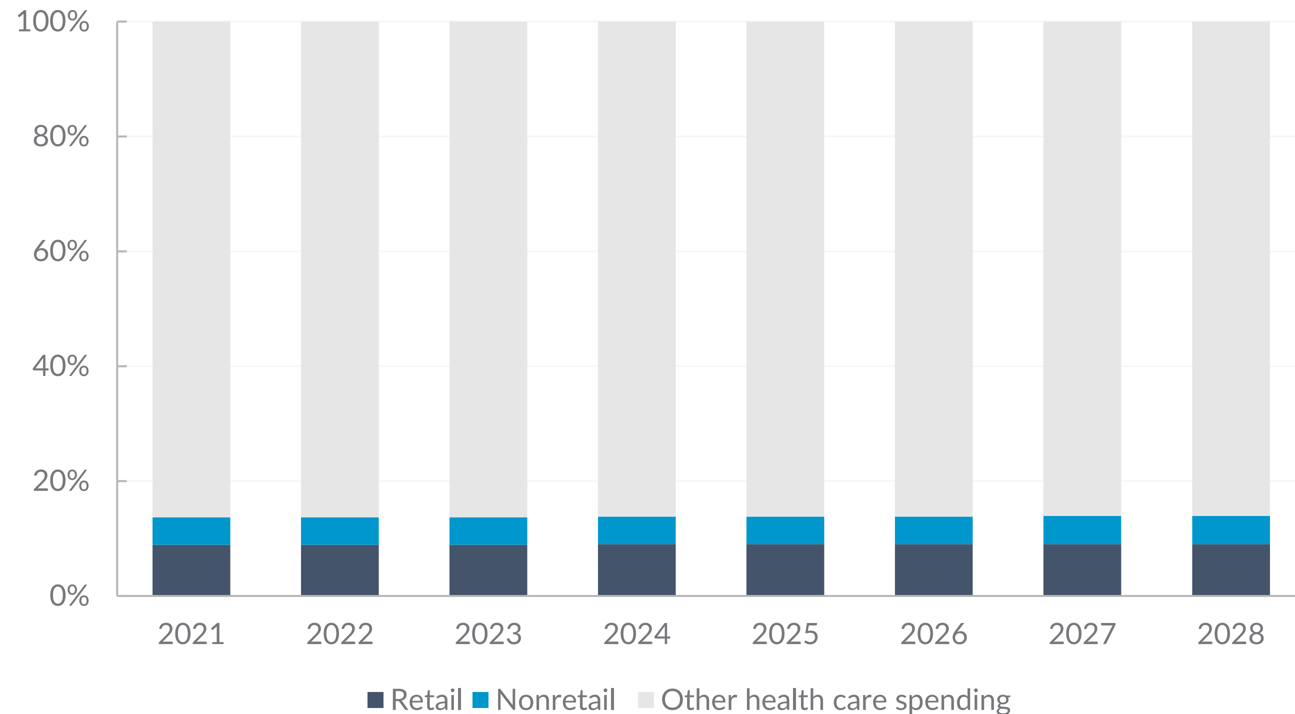
Prescription medicines account for just



of total health care spending

In 2023, net spending on medicines increased just

2.5%



Source: Altarum, 2022. IQVIA, 2023.

Note: Nonretail prescription medicines are those purchased through physicians' offices, clinics and hospitals and are typically administered to the patient by the provider. Retail prescription medicines are those filled at retail pharmacies or through mail service.

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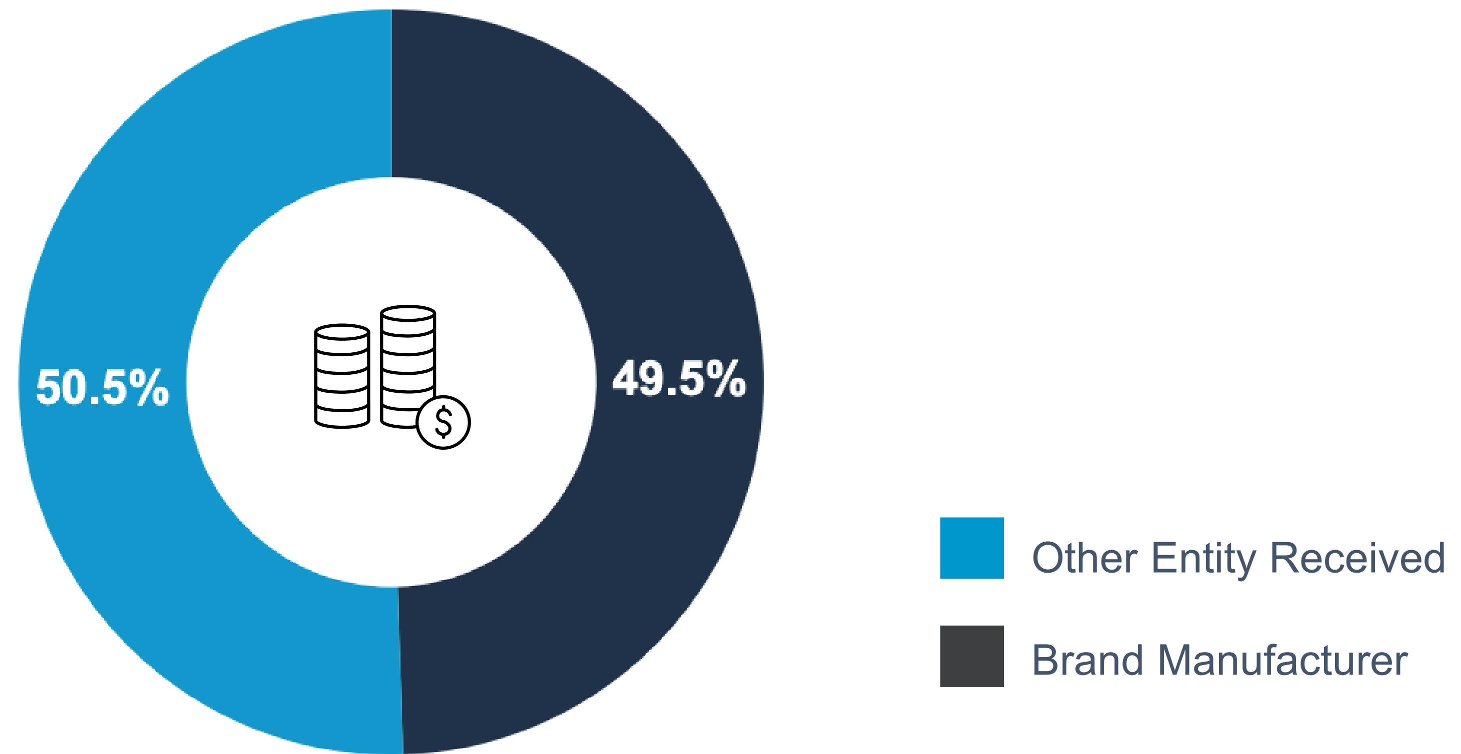
More than Half of Every Dollar Spent on Brand Medicines Goes to Entities Who Did Not Develop Them



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Source: Berkley Research Group, 2022.

Shift in PBM Profits from Rebates to Fees & Specialty Pharmacy

PBM profits from fees have increased >4x

Sources of PBM Profit

	2012	2016	2020	2023E
Fees	5%	10%	21%	22%
Specialty Pharmacy	16%	26%	35%	39%
Mail Order Pharmacy	24%	22%	18%	16%
Spread & Price Protection	9%	17%	12%	11%
Rebates	46%	25%	14%	13%

Y-axis: 0.0% – 100.0%

Legend: Rebates, Spread & Price Protection, Mail Order Pharmacy, Specialty Pharmacy, Fees

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Source: Nephron Research LLC. Available at: https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities/.

250% Increase in Manufacturer Fees Obtained By PBMs

$3.5B increase in administrative fees, $1.2B increase in data fees, and ~$1B increase in in PBM contracting entity (GPO) fees.

Manufacturer Fees Obtained By PBMs and PBM Contracting Entities (PBM GPOs)

Year	Total ($, Billions)
2018	$3.8
2019	$4.8
2020	$6.1
2021	$7.9
2022	$9.5

Y-axis: $, Billions ($0–$10)

Legend: Administrative Fees; PBM GPO Vendor Fees; Data/Portal Fees; Uncategorized Fees

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Source: Nephron Research LLC. Available at: https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities/.

Perverse Incentives and Conflicts of Interest Drive Damaging PBM Behavior

How do PBMs distort the market and flip competition on its head?

Favoring medicines with higher list prices and large rebates over lower-priced brands, generics, and biosimilars

Preferring biosimilars in which they have a direct financial stake over lower cost alternatives

Steering patients to PBM-owned pharmacies that grossly overcharge for medicines

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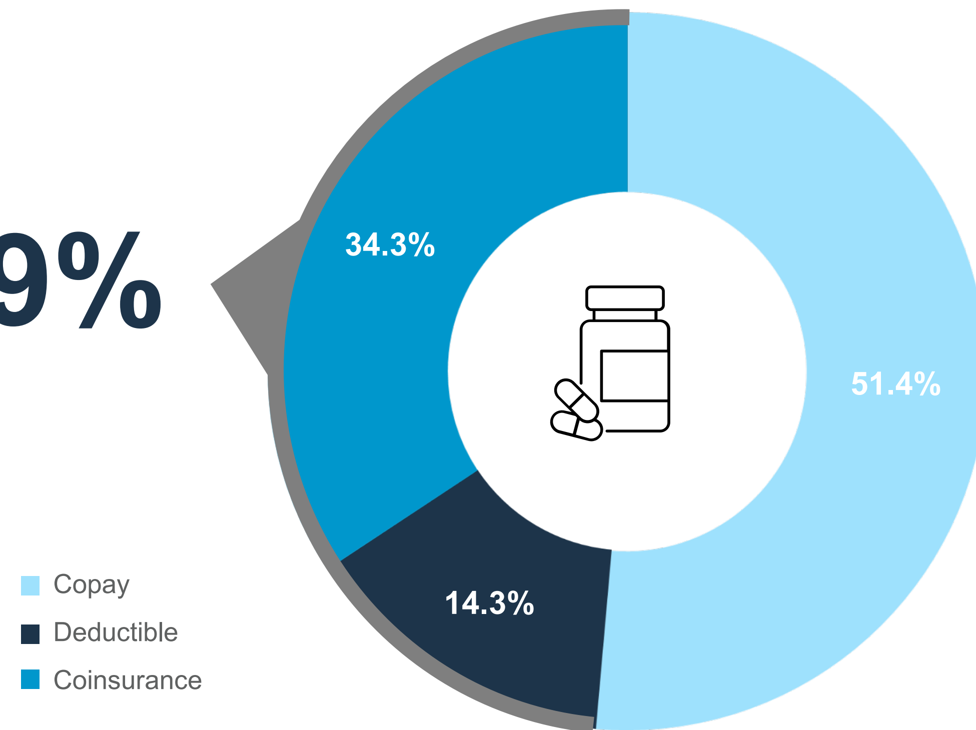
Middlemen are Shifting Costs to Patients Through Coinsurance and Deductibles

In 2023, rebates, discounts and other payments made by brand manufacturers reached $334B, but insurers and PBMs do not always share these savings directly with patients.

Half of commercially insured patients' out-of-pocket spending for brand medicines is based on the full list price



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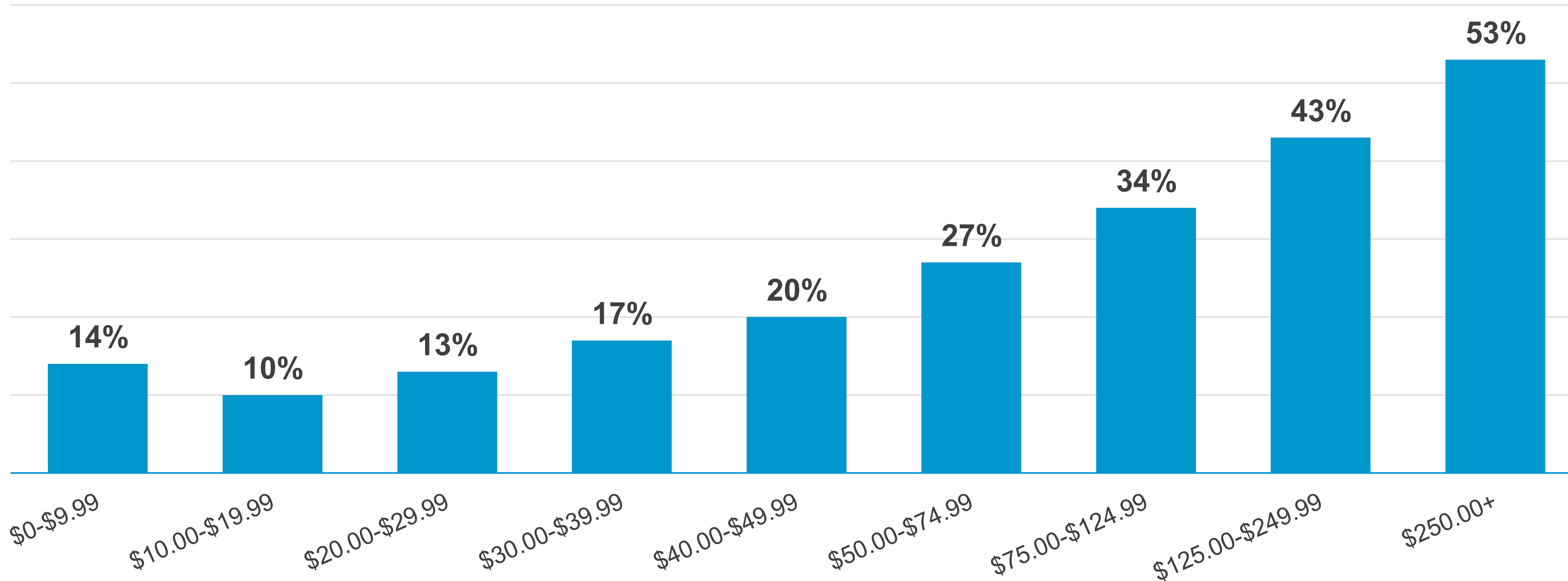
IQVIA, August 2020. Fein A, March 2024.

Patients With High Cost Sharing Are More Likely to Abandon New Prescriptions



Note: Includes new-to-product medicines filled by all patients across all payers. Newly prescribed medicines are those for which patients have not had a prescription for the specific brand or generic drug within the prior year. Pharmacies in the sample provide information on prescriptions that were prepared for dispensing and whether they were dispensed, with abandonment defined as the prescription in question not being dispensed to the patient within 14 days of the initial fill.

Source: IQVIA. The use of medicines in the US. 2023. Usage and spending trends and outlooks to 2027. April 2023. Accessed May 2023. https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2023#:~:text=The%20U.S.%20market%20for%20medicines,25%25%20early%20in%20the%20pandemic

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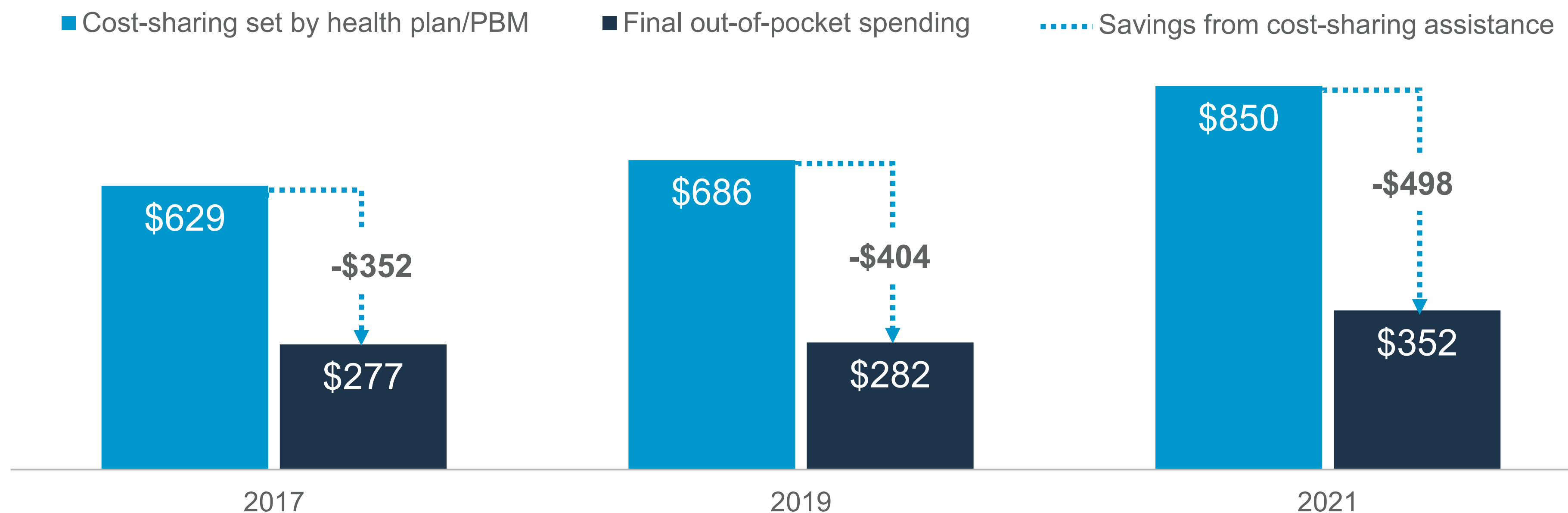
Without Cost-Sharing Assistance, Patients Taking Brand Medicines Would Be Required to Pay an Increasing Amount Out of Pocket

By helping commercially insured patients pay their out-of-pocket costs, manufacturer cost-sharing assistance can reduce prescription abandonment.

Annual Average Cost-Sharing Set by Health Plan and PBMs and Final Out-of-Pocket Spending Among Patients Using Cost-Sharing Assistance



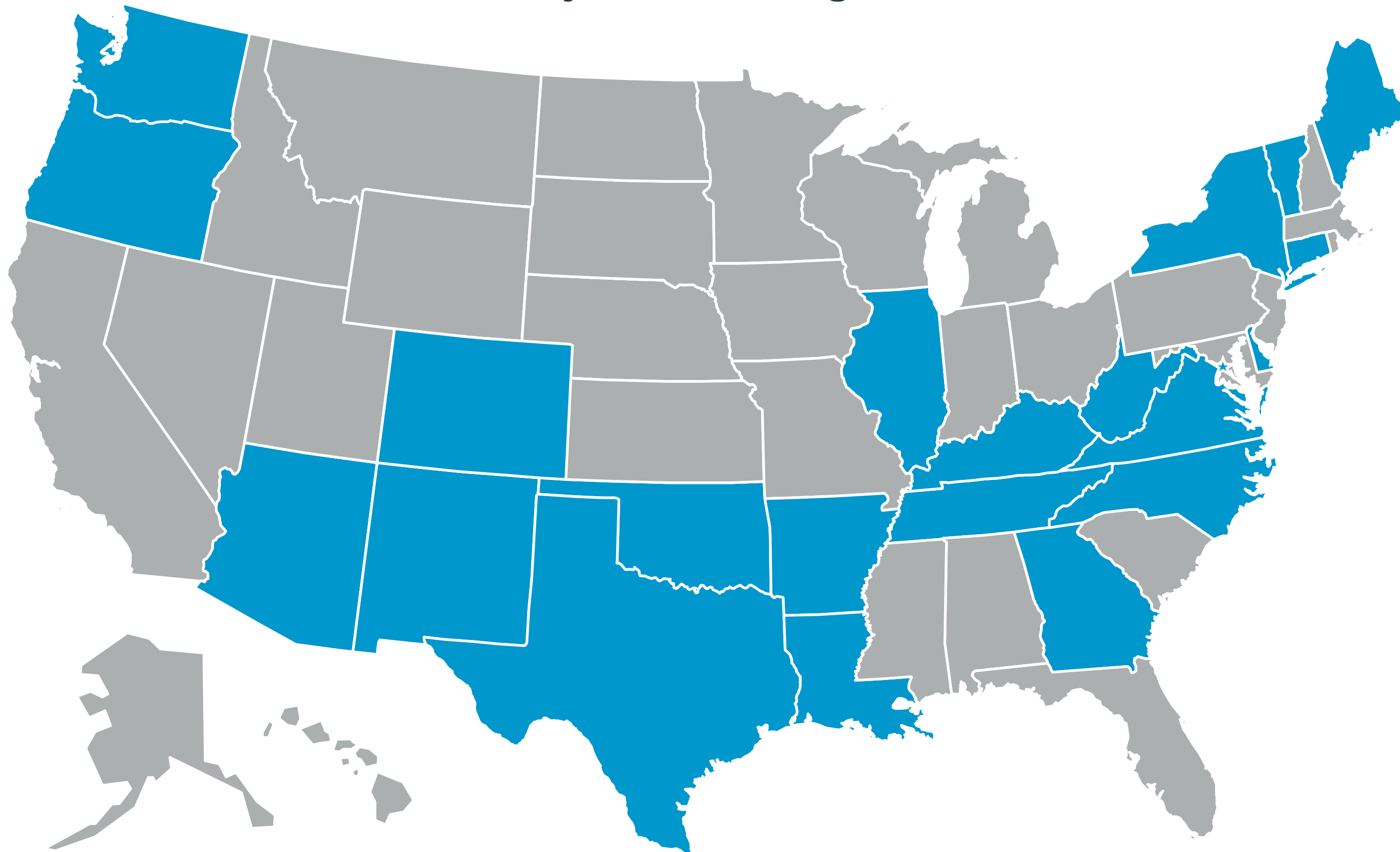
Notes: Includes out-of-pocket spending by commercially insured patients taking brand medicines. The difference between the health-plan- and PBM-set cost-sharing and final out-of-pocket spending represents the savings from use of cost-sharing assistance. Manufacturer cost-sharing assistance administered as debit cards are not captured in the data. As a result, the data may overestimate final out-of-pocket costs.

1. PhRMA. Deductibles and coinsurance drive high out-of-pocket costs for commercially insured patients taking brand medicines. November 14, 2022. https://phrma.org/en/resource-center/Topics/Access-to-Medicines/Deductibles-and-Coinsurance-Drive-High-Out-Of-Pocket-Costs-for-Commercially-Insured-Patients-Taking-Brand-Medicines

States Continue to Ban Accumulators in Commercial Plans

About half of all commercially insured patients are enrolled plans that fail to count all patient cost sharing towards annual maximum out-of-pocket amounts

State Accumulator Adjustment Program Bans, October 2024



- 21 states have AAP bans as of October 2024
- Some state insurance commissioners are providing enforcement guidelines for state-regulated plans to ensure all cost sharing count towards patient out-of-pocket costs

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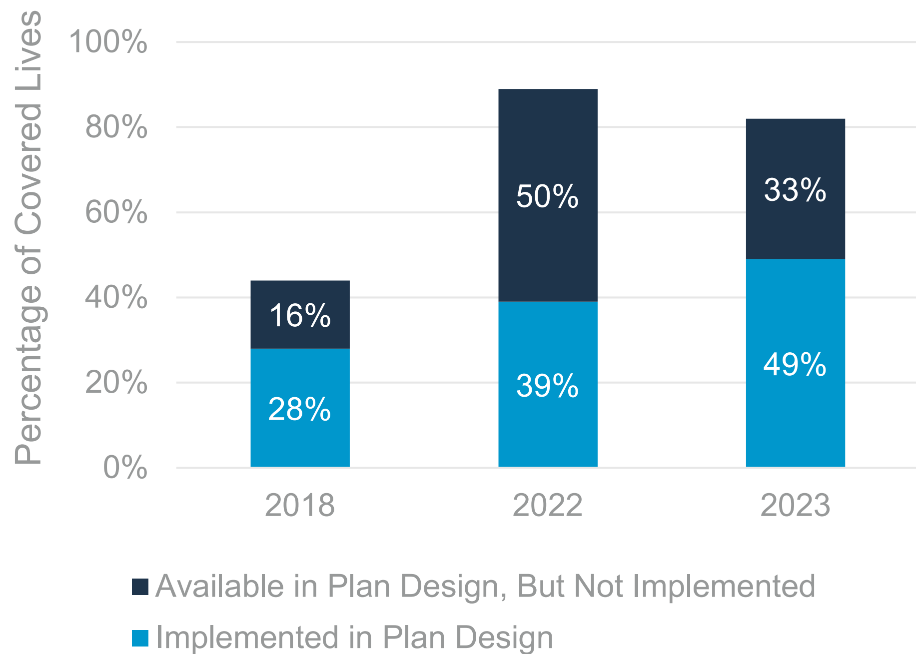
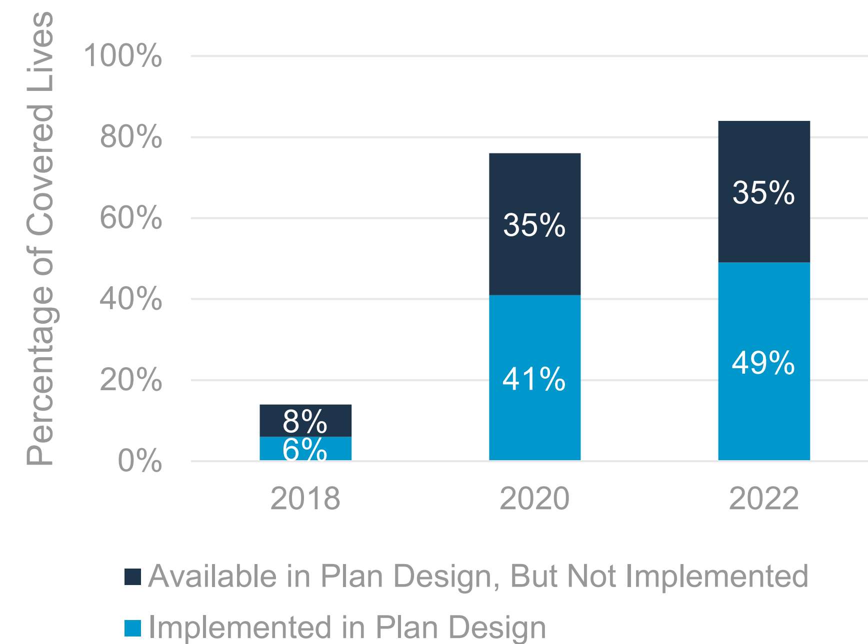
Shifts in Insurance Coverage Have Contributed to the Rise of Accumulator Adjustment Programs and Copay Maximizers





1. Drug Channels. Copay Accumulator and Maximizer Update: Adoption Expands as Legal Barriers Grow. February 2024. https://www.drugchannels.net/2024/02/copay-accumulator-and-maximizer-update.html
2. Drug Channels. Employers Expand Use of Alternative Funding Programs—But Sustainability in Doubt as Loopholes Close. May 2024. https://www.drugchannels.net/2023/05/employers-expand-use-of-alternative.html

Patients Face Increasing Medicine Access Challenges

PBM Working Group should explore market problems and consider policy solutions

Restrictive approaches that limit patient access…	…can lead patients to never initiate treatment or experience substantial delays
Formulary exclusions and utilization management • Four in 10 patients have encountered at least one health insurance challenge, with prior authorization and formulary exclusion being most common reasons[1] **Tier placement / cost sharing** • In 2025, on average 50 – 76% of drugs are on a coinsurance tier in Part D[2]	• 93% of physicians report delays associated with prior authorization[3] • One in three cancer patients who faced a rejection at the pharmacy experienced a treatment delay of 2+ weeks[4]

1. PhRMA 2024 Patient Experience Survey. Available at: https://www.ipsos.com/sites/default/files/ct/news/documents/2024-10/PES%20Wave%205%20-%20External%20Report%2010-25-24%20-%20FINAL.pdf.
2. Avalere Health. Available at: https://avalere.com/insights/2025-part-d-formularies-shift-to-more-coinsurance-and-um#:~:text=The%20average%20percentage%20of%20all%20drugs%20on%20coinsurance%20tiers%20is,percentage%20points%20for%20MA%2DPDs.
3. 2023 AMA Prior Authorization Survey. Available at: www-ama-assn-org.proxy.library.upenn.edu/system/files/prior-authorization-survey.pdf.
4. Chino, F. et al. JAMA Netw Open. 2023 Oct 18;6(10):e2338182. doi: 10.1001/jamanetworkopen.2023.38182.

Policy Solutions

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Our Proposed Policy Solutions

- Delink PBM compensation from the list price of medicines. Limit PBM compensation to flat service fees.
- Pass on savings negotiated between manufacturers and PBMs directly to patients. Calculate patient cost sharing based on the net price, rather than list price, of medicines.
- Ensure patients benefit from manufacturer assistance programs and foundation support. Prohibit use of accumulator adjustment programs, copay maximizers, and alternative funding programs.
- Hold PBMs and health plans accountable for providing quality patient care. Increase oversight of utilization management and enhance the data available to identify PBM and health plan abuse.

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NAIC PBM Regulatory Issues (B) Workgroup

Community Pharmacy Perspective

November 18, 2024

Joel Kurzman
Director, State Government Affairs

NCPA®
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Who are we?

Founded in 1898, the National Community Pharmacists Association is the voice for the community pharmacist, representing over 18,900 pharmacies that employ more than 205,000 individuals nationwide. Community pharmacies are rooted in the communities where they are located and are among America's most accessible health care providers.

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Profile of community pharmacies

- **18,900 pharmacies nationwide**
- **Local employers**
  - Contribute to the tax base
  - Provide civic leadership
- **65% located in areas with populations <50,000**
  - Essential health care providers in underserved areas
  - Local health care problem solvers

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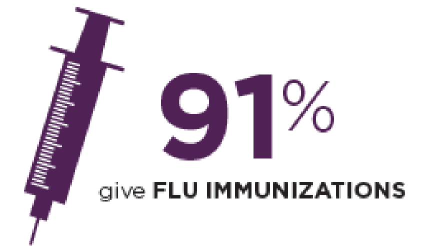
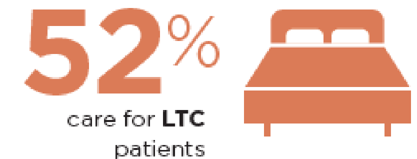
What community pharmacies provide





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Community pharmacies' role

10% OWNERS AND/OR EMPLOYEES

are lifelong friends with a councilman

49% OWNERS AND/OR EMPLOYEES

are members of the chamber of commerce

61% OWNERS AND/OR EMPLOYEES

provide more than $3,000 in monetary support to community organizations

57% OWNERS AND/OR EMPLOYEES

are members of a local business or civic organization

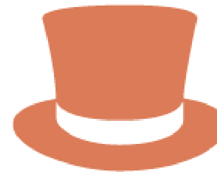
32%

of owners provide monetary support to 10 or more community organizations

AN ADDITIONAL **28%**

of owners provide monetary support to between five and nine community organizations

7%



OWNERS AND/OR EMPLOYEES are lifelong friends with a mayor

2%

OWNERS AND/OR EMPLOYEES hold an elected local or state office

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Reality for community pharmacies

- Take-it-or-leave-it contracts
- A lack of transparency in reimbursement pricing
- Underwater reimbursements often without recourse
- Retaliatory audits
- Network exclusion
- Prior authorization headaches
- No process for appeals or remedy for unfair practices
- Retroactive fees are unpredictable and often untraceable

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Reality (cont.)

- PBMs control the pharmacy benefits of more than 270 million Americans[1]
- 3 PBMs control nearly 80% of the market, 6 PBMs control 94%[2]
- Small business "negotiating" with Fortune 10 companies.

1: https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf

2. Ibid.

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Reality (cont.): vertical integration

https://www.drugchannels.net/2024/05/mapping-vertical-integration-of.html

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Reality (cont.)

- Nearly 90% of prescriptions are covered by insurance
  - Pharmacy sets the price only with cash pay
- Community pharmacies compete with PBM-owned or affiliated retail, mail-order, and/or specialty pharmacies
- PBMs reimburse their owned/affiliated pharmacies more than community pharmacies[1]

1 Just a few examples include:

https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/5e384f26fc490b221da7ced1/1580748598035/FL+Master+Final+Download.pdf and https://wahealthalliance.org/groundbreaking-pbm-study-wspa-and-wha-release-results/ and https://www.mbp.ms.gov/news/mississippi-board-pharmacy-completes-audit-optum-2022-claims

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PBM impact on patient access

- Steering to PBM-owned retail, mail-order, or specialty pharmacies leaves patients with little control over healthcare decisions
- Network access hurdles – particularly in preferred networks – limit patient access to pharmacies
- Between 2013 and 2022, 10% of rural independent pharmacies closed.[1]
- In 2023, independent pharmacies closed at rate of nearly one per day. On track for the same in 2024.[2]
- 1 in 4 neighborhoods is considered a pharmacy shortage area[3]

1 https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf

2 IQVIA and 2023 NCPA Digest

3 USC/NCPA Pharmacy Access Initiative

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Growing consensus on need for reform

- Bipartisan issue
- 400 + bills in recent years, 225 + bills in 2024
- Coverage in major media
- Reports
- OIC enforcement actions
- Legal activity

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States' rights to regulate PBMs

- *Rutledge* is law
- *Mulready v. PCMA* only a 10th Circuit issue
- Amicus brief filed June 2024
- 32 State AGs, Solicitor General urging SCOTUS to take case

No. 23-1213

In the Supreme Court of the United States

GLEN MULREADY, IN HIS OFFICIAL CAPACITY AS INSURANCE COMMISSIONER OF OKLAHOMA, ET AL., PETITIONERS

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

BRIEF FOR AMERICAN PHARMACIES, INC., THE AMERICAN PHARMACISTS ASSOCIATION, THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC., THE NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, AND THE OKLAHOMA PHARMACISTS ASSOCIATION AS AMICI CURIAE SUPPORTING PETITIONERS

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Solutions: oversight

PBM licensure

- Licensure with the insurance commissioner
  - PBMs administer a health insurance benefit
  - Defining PBM, including their role as both a drug benefits manager and a pharmacy.
- 50 states currently register or license PBMs in some capacity
  - Not all as PBMs (e.g., third-party administrators)
  - Not all licensed by insurance commissioner (e.g., Board of Pharmacy, Attorney General)
- Broad OIC authority, including rulemaking and enforcement
- Access to data is critical

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Solutions: enforcement

- NCPA 50-state resource to help members file complaints with their state insurance regulators
- NCPA developing tools to facilitate patient complaints in the pharmacy
- NCPA advocates Best Practices for Enforcement of PBM Regulations

BEST PRACTICES
for Enforcement of PBM Regulation

This document shares the best practices we have seen in states for enforcing regulations of pharmacy benefit management companies (PBMs). This is needed perspective because even the most comprehensive laws and regulations addressing the egregious business practices of PBMs fall short if they are not enforced. The National Community Pharmacists Association advocates for strong oversight authority granted to departments of insurance with specific expertise, resources, and tools to implement an enforcement program. For more information, please visit our PBM reform webpage.

STRUCTURE
- Oversight and enforcement authority for the Office of Insurance Commissioner (OIC)
  - Authority included in state's PBM licensing language, but authority is not limited to licensing process (Arkansas)
  - OIC authority expressly stated throughout statutes (Colorado)
- OIC authority should include requirement for rulemaking (North Dakota, West Virginia)
  - Example of what rulemaking can include (Arkansas)
- Applicable to all PBMs, including those serving ERISA plans (Tennessee)

LICENSING FEES
- Funds should be placed in an account dedicated to PBM oversight (Florida, Kansas)
- Application fees and renewal application fees should be sufficient to fund the OIC's duties (West Virginia)
- Appropriations for implementation (Florida)
- Application fee minimum of $5,000

COMPLAINTS AND REPORTING
- Designate a primary contact or contacts in the OIC for consumer and pharmacy PBM concerns (Florida, Indiana)
- Should include state tracking of Insurance Department capacity for PBM oversight (headcount, budget, funding sources, etc.) in the NAIC Insurance Department Resources Report
- Standardized PBM complaint form on OIC websites should allow a consumer, pharmacy, or pharmacist to file administrative complaints (Alabama, South Carolina, Tennessee)
- Electronic system for submitting such complaints and tracking the Insurance Department's investigation and resolution of any such complaint
- Director can delegate adjudicative function to subordinate employees of the Insurance Department and hold fact-finding hearings to adjudicate complaints
- Establish a process for timely resolution of such complaints
- Annual and quarterly reporting (West Virginia)
- Network adequacy not less strict than Medicare standards (Arkansas)

AUDITING OF PBMs
- OIC authority and prerogative (Colorado, Georgia, Tennessee proposed, West Virginia)
- Require at least biennial audits (Florida)
- Access to all information needed to conduct audit (Georgia, Tennessee proposed)
- Costs associated charged to PBM (Florida, Georgia, Tennessee proposed)
- Example of what PBM audits can examine: Indiana

FINES
- Up to $10,000 per violation, no maximum (West Virginia)
- Fines to above-mentioned account should be dedicated to PBM oversight

REPEAT VIOLATIONS
- Should be expressly stated in statute/rule with increasing penalties (Arkansas, Georgia, Minnesota)
- Cease and desist
- Suspension from servicing state employee health plans
- Suspension of license
- Revocation of license
- Defining "knowing and willful" violations (Florida)
- OIC may refer to state attorney general for additional investigation or enforcement action (South Carolina)

APPEALS PROCESS
- Appeals process with timelines (Tennessee, West Virginia)
  - External appeals process with OIC or delegated third-party reviewer (Tennessee, South Carolina proposed)
- Authority for restitution (Tennessee proposed, West Virginia)
- Successful appeals applicable to similar claims by other providers (Florida, Tennessee)

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Solutions: what NAIC can do

- Craft a uniform electronic state-level and PBM-specific complaint form for use across all states and maintain database of complaints
- Track insurance department resources dedicated to PBM oversight in its Insurance Department Resources Report (IDRR)

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Agenda Item #2

Hear a Discussion on Providing Potential Assistance to the Producer Licensing Uniformity (D) Working Group to Create a New Section on PBM Licensure Best Practices and Uniform Standards in the State Licensing Handbook—Ashley Scott (OK)

Agenda Item #3

Discuss Any Other Matters Brought Before the Working Group—*Joylynn Fix (WV)*