

Pharmacy Benefit Managers in the U.S. Prescription Drug Market

Statement of Rena M. Conti, Ph.D.

Associate Professor

Department of Markets, Public Policy, and Law

Questrom School of Business

Co-Director, Technology Policy, and Research Institute

Boston University

Boston, MA

rconti@bu.edu

617-645-6375

The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part II: Not What the Doctor Ordered

U.S. House of Representatives

Committee on Oversight and Accountability

2154 Rayburn

Tuesday September 19, 2023, 10am

SUMMARY OF REMARKS

Representative Comer, Representative Raskin, and members of the House of Representatives Committee on Oversight and Accountability, thank you for the opportunity to discuss with you the U.S. prescription drug market and the role of pharmacy benefit managers (PBMs) within it.

I am Rena M. Conti, Ph.D., Associate Professor of Markets, Public Policy and Law in the Questrom School of Business, and co-director of the Technology Policy and Research Institute, a joint program of Boston University's Business and Law Schools. Between 2006 and 2018, I was faculty at the University of Chicago. I hold a Ph.D. in Health Policy, concentration economics, from Harvard University. I currently teach strategy and leadership in the biopharmaceutical industry at Questrom School of Business. I have taught business statistics, health economics and health policy over the past two decades at Harvard University, University of Chicago, and Boston University. I am an expert on the pricing of prescription drugs and have extensively published peer reviewed studies on how drug companies price their products, how patients access prescribed drugs, and whether and how payers pay for these products. I have studied the pricing, supply and demand of many prescription drugs, including those used to treat mental illness, substance abuse, cancer, HIV and hepatitis C, and those to treat rare and 'orphan' disease. I have researched and written on the function of PBMs in the sale of retail prescription drugs in the U.S.²

The objective of the current policy proposals considered by U.S. Congress on PBMs (and the prescription drug market more generally), is to promote patient access to retail prescription drugs that will improve individual and population level health and be affordable. ^{3,4,5,6} Additional objectives of current policy proposals include reductions in overpayments to U.S. pharmaceutical chain members and the elimination of potential distortions in patient access to prescription drugs, without imposing additional costs on payers or harming innovation incentives for innovative drug makers. These are laudable goals.

Here I review (1) the high costs of prescription drugs and associated spending levels and trends, and the likely transformative impact of IRA implementation on these levels and trends for Medicare Part D, (2) the function of PBMs, and (3) PBM contract features and evidence supporting PBMs intended and unintended impacts on patients, payers, and pharmaceutical industry. I conclude that while PBMs do provide efficiencies in the U.S. retail prescription drug market, there are emergent challenges. Greater transparency into the PBM market may improve consumers and employers' ability to select plans and PBMs that meet their needs at the

¹ My research work is in part supported by grants, including in the past three years from the National Science Foundation, National Cancer Institute, National Institute on Drug Abuse, the Veterans Administration, the Sloan Foundation, the Commonwealth Fund, the Leukemia and Lymphoma Society and Arnold Ventures.

² See for example, Royce TJ, Kircher S, Conti RM. "Pharmacy Benefit Manager Reform: Lessons from Ohio." JAMA. 2019 Jul 23;322(4):299-300; Conti RM, Frandsen B, Powell ML, Rebitzer JB. "Common Agent or Double Agent? Pharmacy Benefit Managers in the Prescription Drug Market." National Bureau of Economic Research Working Paper Series No. 28866, May 2021. Available at http://www.nber.org/papers/w2886; Dusetzina SB, Conti RM, Yu NL, Bach PB. "Association of prescription drug price rebates in Medicare Part D with patient out-of-pocket and federal spending." JAMA Intern Med. 177(8): 1185–8 (2017). 10.1001/jamainternmed.2017.1885; National Academies of Sciences, Engineering, and Medicine. 2018. Making Medicines Affordable: A National Imperative. Washington, DC: The National Academies Press. https://doi.org/10.17226/24946.

³ https://www.wsj.com/health/healthcare/generic-drugs-should-be-cheap-but-insurers-are-charging-thousands-of-dollars-for-them-ef13d055

⁴ https://oversight.house.gov/report/comer-releases-report-on-pbms-tactics-leading-to-soaring-prescription-drug-prices/

 $^{^5\,}https://www.wsj.com/health/healthcare/generic-drugs-should-be-cheap-but-insurers-are-charging-thousands-of-dollars-for-them-ef13d055$

⁶ https://www.finance.senate.gov/imo/media/doc/A%20Tangled%20Web.pdf

pharmacy counter. However, I caution policymakers to beware of simple solutions to these challenges as policymaking may act perversely in such a complicated market.

My conclusions are based on my own research, teaching, and first-hand experience with the healthcare ecosystem. They do not necessarily represent the views of Boston University nor my collaborators.⁷

⁷ I thank Brigham Frandsen, Jim Rebitzer, Mike Powell, Richard Frank, Abby Alpert and Lawton Burns for helpful discussions. My comments and opinions are my own.

Prices and Spending on Retail Prescription Drugs and the Likely Transformative Impact of the IRA

U.S. Retail Prescription Drug Prices 101

The U.S. is the largest market for prescription drugs in the world.⁸ Approximately 40% of all prescription drug sales is in the U.S. market. There were 6.3 billion prescriptions dispensed in the U.S. market in 2020.⁹ Corporate profits off the sale of prescription drugs are expected to reach over \$1.3 trillion in 2021 and the top drug makers are more profitable than those in non-pharmaceutical industries, including the technology giants Apple and Amazon.¹⁰

Drug makers strongly prefer to launch new prescription drugs in the U.S. where they can set the highest prices. Unlike other OECD countries, U.S. payers place no limits on the prices pharmaceutical companies can charge for drugs while they are protected from competition by patents and market exclusivities. These features lead drug makers to set high prices well above standard measures of clinical and economic benefit.¹¹

Drug makers also pursue price increases that greatly exceed the general rate of inflation.^{12,13} In fact, evidence suggests drug makers target U.S. payers for drug price increases, while at the same time decreasing prices in other countries. House Oversight reports suggest Celgene's Revlimid¹⁴ and Teva's Copaxone¹⁵ took significant price increases to increase revenue in the U.S. at the same time as cutting prices in other countries.

According to an analysis by the Kaiser Family Foundation, half of all Part D covered drugs (50% of 3,343 drugs) had price increases greater than inflation between July 2019 and July 2020. Moreover, 23 of the top 25 Part D drugs had price increases above inflation between 2019 and 2020. To See Figure 1 for details.

Figure 1. Price Trends Paid by Medicare Beneficiaries Outpace Inflation

⁸ International Federation of Pharmaceutical Manufacturers & Associations. *The Pharmaceutical Industry and Global Health. Facts and Figures 2021.* April 2021.

⁹ Hales CM, Servais J, Martin CB, Kohen D. "Prescription drug use among adults aged 40–79 in the United States and Canada." NCHS (National Center for Health Statistics) Data Brief. 347. August 2019.

¹⁰ Ledley FD, McCoy SS, Vaughan G, Cleary EG. "Profitability of Large Pharmaceutical Companies Companies Companies With Other Large Public Companies." JAMA. 323(9): 834-843. March 2020.

¹¹ Lu J, Comanor WS. "Strategic pricing of new pharmaceuticals." Rev Econ Stat. 80(1):108–18 (1998).

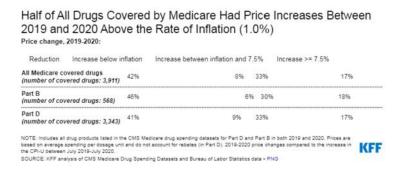
¹² See for example, U.S. House of Representatives. *Drug Pricing Investigation AbbVie—Humira and Imbruvica*. Staff Report Committee on Oversight and Reform. May 2021. The report states "New documents show that these settlements allowed AbbVie to delay competition far beyond what its own internal assessments of the strength of its patent portfolio predicted. In 2014, AbbVie's executives estimated that three to five biosimilar competitors would enter the market by the first quarter of 2017. AbbVie ultimately entered into settlement agreements with four of these competitors, delaying their entry into the market until 2023."

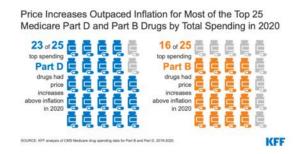
¹³ Annual price increases are also inconsistent with the notion that prices are optimized for profit maximization at launch and appear unrelated to approval of supplemental indications, additional information about the benefits associated with treatment, and potential increases in manufacturing costs. See Bennette CS, Richards C, Sullivan SD, Ramsey SD. "Steady Increase in Prices for Oral Anticancer Drugs after Market Launch Suggests a Lack of Competitive Pressure." Health Affairs (Millwood). 35(5):805-12. May 2016.

¹⁴ U.S. House of Representatives. *Drug Pricing Investigation Celgene and Bristol Myers Squibb—Revlimid*. Staff Report Committee on Oversight and Reform. September 2020.

¹⁵ U.S. House of Representatives. Drug Pricing Investigation Teva—Copaxone. Staff Report Committee on Oversight and Reform. September 2020.

¹⁶ Cubanski J, Neumann T. "*Prices Increased Faster Than Inflation for Half of all Drugs Covered by Medicare in 2020.*" KFF Issue Brief. February 2022. ¹⁷ Ibid.





In many cases, price inflation is the direct result of drug makers ensuring their profitability by delaying competition in specific drug markets. 18

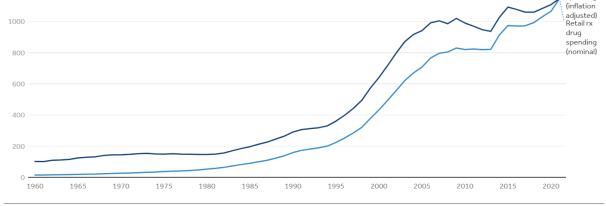
U.S. Spending on Retail Prescription Drugs

U.S. prescription drug spending currently represents approximately 14% of overall healthcare spending, ¹⁹ including 4% of spending in non-retail outpatient clinics and hospital settings. Spending on drugs has risen by 20% over the past 10 years; an average of 2% per year. 20 Inflation adjusted spending on prescription drugs has increased over the past two decades (see Figure 2).21

Figure 2. Spending per capita on retail prescription drugs, 1960-2021

Nominal and inflation-adjusted per capita spending on retail prescription drugs, 1960-2021





Source: KFF analysis of National Health Expenditures Accounts (NHEA) • Get the data • PNG

Health System Tracker

Retail rx drug

spending

¹⁸ For an explanation and summary of activities, see Statement by Michael A. Carrier to House Judiciary Committee (Subcommittee on Antitrust, Commercial and Administrative Law). House Subcommittee of House Judiciary Committee hearing. April 27, 2021.

¹⁹ Conti RM, Turner A, Hughes-Cromwick P. "Projections of US Prescription Drug Spending and Key Policy Implications." JAMA Health Forum. 2(1): e201613. January 2021.

²⁰ IQVIA Institute. The Use of Medicines in the United States. May 2021. To put these figures in broader context, industry reports expect global medicine spending through 2025 to amount to about \$1.6 trillion. Projected global spending on pharmaceuticals by IQVIA, the industry gold standard, is \$88 billion higher than their pre-COVID outlook.

²¹ https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drugspending/#Annual%20change%20in%20per%20capita%20retail%20prescription%20drug%20spending,%201970%20-%202021;%20projected%202022%20-%202031%C2%A0

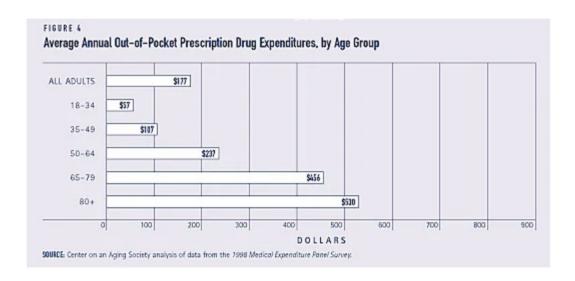
Two types of on patent 'branded' prescription drugs contribute substantively to spending growth: new drugs and the expanded use of existing drugs. Also notable is that specialty drugs, including those in the protected Medicare Part D categories of oncology and immunology,²² have been increasing as a share of spending.²³ In 2020, specialty drugs comprised 47% of spending, up from 24% 10 years earlier. Specialty drug spending is expected to increase to 60% of total pharmaceutical spending in the U.S. by 2025.

Although relatively speaking prescription drug prices account for a small share of overall healthcare spending, Americans pay more out-of-pocket for prescription drugs than for less commonly used hospital care or health insurance.²⁴ These spending levels and trends have imposed costs of payers.

Retail Prescription Drugs are the Most Commonly Consumed Medical Care in the U.S.

In addition to high prices, widespread use contributed to these levels and trends. Prescription drug use is the most consumed medical care in the U.S.²⁵ More than 131 million people — 66 percent of all adults in the United States — use prescription drugs.²⁶ Utilization is particularly high for older people and those with chronic conditions. Adults pay almost half — 48 percent — of their expenses for prescription drugs out-of-pocket, and persons aged 65 to 79 pay 56 percent and those age 80 and older pay 67 percent of their total drug expenditures out-of-pocket (see *Figure 3*).





Recent results from national polling (July 2023) found that more than 1 in 4 adults taking prescription drugs report difficulty affording their medication.²⁷ The costs of retail prescription drugs particularly bind on seniors

²² Centers for Medicare and Medicaid Services. Medicare prescription drug benefit manual: chapter 6 –Part D drugs and formulary requirements. Available from: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.

²³ US Department of Health and Human Services Office of Inspector General. "Increases in reimbursement for brand-name drugs in Part D." Available from: https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf.

²⁴ Yusra M. "As Drug Prices Soar, Policymakers Eye Dose of Government Intervention". MORNING CONSULT (Dec. 20, 2018), https://morningconsult.com/2018/12/20/drug-prices-soar-policymakers-eye-dose-governmentintervention/.

²⁵ Retail prescription drug spending was estimated to account for nearly 12% of total personal health care services spending in the U.S. in 2019 (up from about 7% in the 1990s). See https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

 $^{^{26}\} https://hpi.georgetown.edu/rxdrugs/\#: ``:text=More \% 20 than \% 20131\% 20 million \% 20 people, Prescription \% 20 drugs\% 20 are \% 20 costly.$

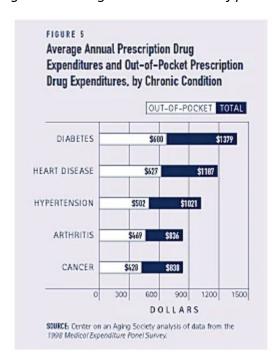
²⁷ https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/

(see *Figure 2 and Figure 3*), low-income households (see *Figure 3*) and those managing chronic illness (see *Figure 4*), such as diabetes, heart disease and cancer.

Figure 3. Retail prescription drug use by US population socioeconomic and health characteristics.

P	ROPORTION OF ADULTS USING PRESCRIPTION DRUGS (%)	AVERAGE NUMBER OF PRESCRIPTIONS RLIED ANNUALLY
AGE		
18-34	53	3
35-49	62	6
50-64	75	13
65-79	87	20
80+	91	22
GENDER		
Male	56	7
Female	75	11
RACE		
White	68	10
Black	58	8
ETHNICITY		
Not Hispanic	67	10
Hispanic	53	5
ANNUAL FAMIL	Y INCOME	
< \$20,000	72	13
\$55,000+	63	7
HEALTH STATUS	5	
Excellent/Very god	od 59	5
Fair/Poor	87	24

Figure 4. Average annual and out of pocket retail prescription drug expenditures, by chronic condition.



Patient Financial Toxicity Associated with Retail Prescription Drug Use

The U.S. has expanded retail prescription drug insurance coverage over the past three decades and expanded pharmaceutical insurance coverage has benefited many. ²⁸ Yet, too many patients are locked out of the promise of pharmaceuticals currently available. The prices of some retail prescription drugs Americans need to stay alive – such as Tysabri and Rebif for MS and Revlimid and Imbruvica for cancer - are now so high that they exceed the costs of a private university education. A recent survey suggests 18 million Americans can't pay for the drugs they need. ²⁹ The substantial costs of cancer care on patients are now so common they are termed 'financial' toxicity, a play on the commonly encountered medical toxicities patients experience with chemotherapy. ³⁰

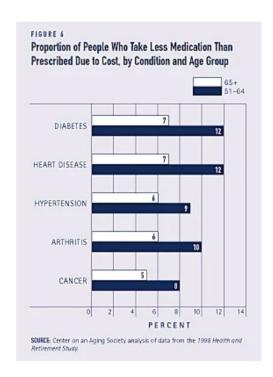
Some people take less medication than prescribed because of the cost. This is a particular problem for more vulnerable populations (see *Figure 5*).

Figure 5. Proportion of people who take less medication than prescribed due to cost, by age group and condition.

²⁸ Conti R, Dusetzina SB, Sachs R. "How The ACA Reframed the Prescription Drug Market and Set the Stage for Current Reform Efforts." Health Aff (Millwood). 2020 Mar;39(3):445-452.

²⁹ Witters D. "In U.S., an Estimated 18 million Can't Pay for Needed Drugs." Gallup. September 21, 2021.

³⁰ National Institutes of Health, National Cancer Institute. Financial Toxicity Associated with Cancer Care – Background and Prevalence.



Reports of financial burden are associated with worrisome deficits in care - medication non-adherence including skipping medication, taking less medication, or not filling recommended prescriptions at all. The practice of taking less medication than prescribed may increase overall health care costs if the result is more emergency room visits, hospital admissions, or physician visits. In addition, reports of financial burden commonly include an inability to pay for necessities such as food and utility bills, the presence of medical debt and high out of pocket burdens relative to income.

High spending on retail prescription drugs also imposes costs on taxpayers and harms workers in the form of higher health insurance premiums and lower wages.

The Likely Transformative Impact of the IRA on Medicare Part D Retail Prescription Drug Levels and Trends

The <u>Inflation Reduction Act of 2022</u> (IRA), passed by U.S. Congress in August 2023, ³¹ is a significant evolution in the regulation of the U.S. pharmaceutical industry.

The IRA includes several provisions to lower retail prescription drug costs for people with Medicare Part D and reduce drug spending by the federal government. The IRA took shape amidst strong bipartisan, public support for the government to address high and rising drug prices. 32 CBO 33 estimates that the drug pricing provisions in the law will reduce the federal deficit by \$237 billion over 10 years (2022-2031). 34 Spending per capita associated with retail prescription drugs covered under Medicare Part D is expected to moderate with

³¹ https://www.congress.gov/bill/117th-congress/house-bill/5376

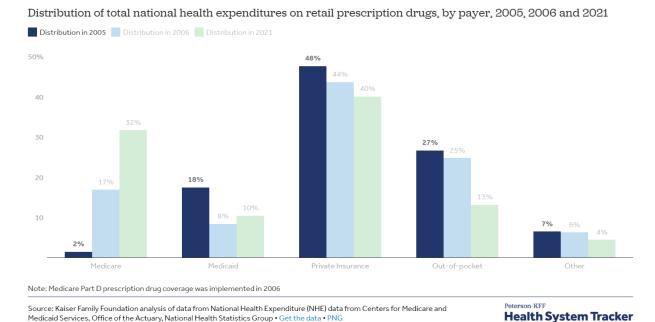
³² https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-march-2022/

³³ https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf

³⁴ IRA includes numerous provisions aimed at reducing retail prescription drug spending levels and trends for those insured by Medicare Part D. These provisions include capping Medicare Part D out of pocket spending to \$2000 annual effective starting in 2025, requiring drug makers to pay rebates to Medicare if their prices rise faster than inflation starting in 2023, and requiring drug makers to negotiate with Medicare for certain high spending drugs covered by Medicare (negotiation starts in 2024, and negotiated prices take effect in 2026).

the implementation of the IRA, which has taken on an increasing role in in paying for this medical care over time (see *Figure 6*).³⁵

Figure 6: Distribution of total national health expenditures on retail prescription drugs, by payer.



Passage of the IRA has led to a shift in projected out of pocket spending on retail prescription drugs among those covered by Medicare Part D (see *Figure 7*). ³⁶ IRA provisions are also not expected to harm future drug innovation. ³⁷

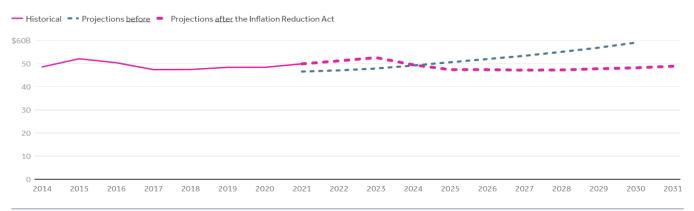
Figure 7. Total out of pocket spending on prescription drugs, projections before and after the passage of the IRA.

³⁵ Medicare covered 32% of national drug spending in 2021. See https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

³⁶ CMS expects retail prescription drug spending by Medicare to increase initially due to Medicare Part D redesign. CMS actuaries expect a 20 percent reduction in aggregate drug costs from negotiation and inflation rebates (See <u>National Health Expenditure Projections, 2022–31: Growth To Stabilize Once The COVID-19 Public Health Emergency Ends | Health Affairs</u>). CBO estimates the drug pricing provisions in the IRA will reduce the federal deficit by \$237 billion between 2022 and 2031 (See Explaining the Prescription Drug Provisions in the Inflation Reduction Act | KFF).

³⁷ https://www.cbo.gov/system/files/2022-09/PL117-169 9-7-22.pdf

$Total\ out-of-pocket\ retail\ prescription\ drug\ spending,\ projections\ before\ \&\ after\ passage\ of\ the\ Inflation\ Reduction\ Act$



Source: KFF analysis of National Health Expenditures Accounts (NHEA) • Get the data • PNG

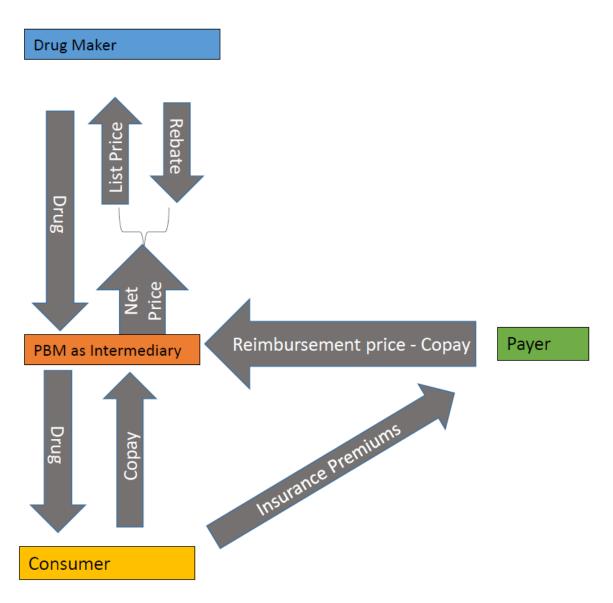
Peterson-KFF **Health System Tracker**

The Role of PBMs in the US Retail Prescription Drug Market

PBMs are third-party administrators of pharmacy benefits, and they arose in the 1980s to manage patient access to retail prescription drugs on behalf of payors. The influence of PBMs on patients' access to prescription drugs dispensed in the retail setting (at pharmacies and through mail order) and the affordability of medications has increased substantially since then.

PBMs act as intermediaries that bargain on behalf of payers (health plans and patients) for lower prescription drug prices, while receiving payments from drug makers (see *Figure 8*).

Figure 8. Schematic of PBM as Intermediary between drug maker, health plan (payer) and U.S. consumer.



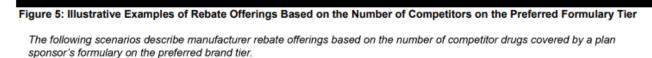
PBMs create an arena for retail prescription drug maker competition. The arena is predicated on PBMs use of tiered formularies on behalf of health plans to steer patients to use certain retail prescription drugs over others. Consumer steering is largely (but not solely) predicated on differential out of pocket costs (see *Figure 9*).

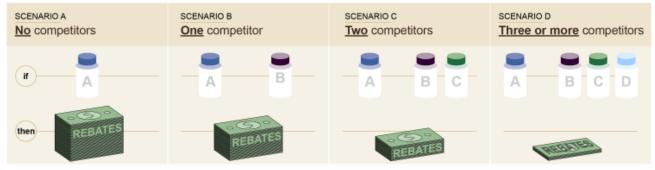
Figure 9. Schematic of tiered formulary and consumer costs employed by PBMs to steer retail prescription drug sales.

Tier	Drug Type	Cost to consumer
1	Generics	\$
2	Preferred branded	\$\$
3	Non-preferred branded	\$\$\$

Drug makers offer PBMs rebates to compete in the arena. Rebates offered grow by the extent of competition in drug's therapeutic class (see *Figure 10*). ³⁸ PBMs deploy other tools to create competition between drug makers and to promote patient access and payer affordability to needed drugs. ³⁹

Figure 10. Schematic of rebate offerings by drug makers based on preferred formulary tier and competition withing therapeutic class.





Source: GAO analysis of selected rebate contracts between manufacturers and Medicare Part D plan sponsors; GAO (illustrations). | GAO-23-105270

Note: GAO reviewed 2020 rebate agreements negotiated between six drug manufacturers and six Medicare Part D plan sponsors for 24 brand-name drugs.

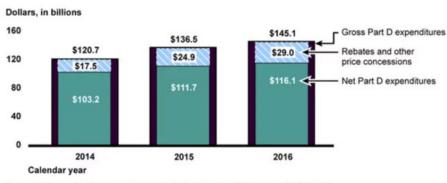
A recent report by GAO suggests the amount of drug maker rebates paid to Medicare Part D plans has been growing over time (see *Figure 11*). Rebates paid to PBMs acting on behalf of Part D plans may have the effect of moderating net retail prescription drug expenditures.

Figure 11. Medicare Part D Expenditures 2014-2016.

³⁸ Sarpatwari A, DiBello J, Zakarian M, Najafzadeh M, Kesselheim AS. "Competition and price among brand-name drugs in the same class: A systematic review of the evidence." PLoS Med. 2019 Jul 30;16(7): e1002872.

https://oversight democrats. house. gov/sites/democrats. oversight. house. gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3. pdf

Medicare Part D Expenditures, 2014-2016



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-19-498

Indeed, PBMs can enhance the efficiency of retail prescription drug markets relative to the alternative of selling branded prescription drugs at profit-maximizing prices. This can benefit consumers and payers through promoting access to needed drugs at more affordable prices.

In addition, PBMs, through their use of formularies, create incentives that steer patients to use generic drugs when available.^{40,41} The use of generic drugs when available contributes to significant cost savings for payers (see *Figure 12*),⁴² and patients, especially among those using drugs to manage chronic illnesses and acute conditions (see *Figure 13*), and using selected drugs (see *Figure 14*).

Figure 12. Savings from generics and biosimilars totaled \$408 billion in 2022.

Generic and Biosimilar Savings Increased by \$35 Billion from 2021 to 2022

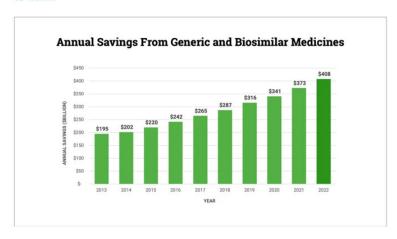


Figure 13. Savings from generics and biosimilars for patients managing chronic illness.

 $https://static1.squarespace.com/static/5b3660f9b98a78542ce0faa9/t/6453f1c1f5d2ee0e3d779950/1683222977933/PBM_paper_web_version.pdf.$

⁴¹ Ho K, Lee RS. "Insurer Competition in Health Care Markets". Econometrica, 2017, 85,379–417.

⁴² Together, generics and biosimilars represent 90 percent of all U.S. prescriptions but less than 18 percent of spending. Generic and biosimilar competition saved more than \$408 billion. AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf (accessiblemeds.org)

Generics And Biosimilars Save Billions for Patients

Generic and biosimilar medicines provide significant relief for patients with chronic and acute conditions alike

Savings by Condition				
CONDITION	TOTAL SAVINGS (PRIMARY CONDITION + COMORBIDITIES)			
Heart Disease	\$104.5 Billion			
Anxiety and Depression	\$60.5 Billion			
Diabetes	\$59.5 Billion			
Epilepsy	\$42.2 Billion			
Allergies and Asthma	\$11.3 Billion			
Breast Cancer	\$8.9 Billion			
Parkinson's Disease	\$6.4 Billion			
Alzheimer's Disease	\$6.2 Billion			
Chronic Obstructive Pulmonary Disease (COPD)	\$6.1 Billion			

Figure 14. Top generic prescription drugs with the greatest savings in 2022.

Top 10 Generic Products with Greatest Savings in 2022					
PRODUCTS	GENERIC ENTRY YEAR	BRAND PRE-EXPIRY PRICE (PER UNIT)	PRICE OF GENERIC EQUIVALENT 2020 (PER UNIT)	2021 SAVINGS (\$BILLION)	PERCENT SAVINGS
Glucophage	2021	\$0.66	\$0.04	\$5.63	94%
Neurotin	2023	\$1.02	\$0.06	\$7.60	95%
Lipitor	2010	\$3.29	\$0.08	\$22.38	97%
Toprol XI	1993	\$0.41	\$0.06	\$2.09	85%
Norvasc	2006	\$1.54	\$0.02	\$7.92	99%
Zestril	1998	\$0.67	\$0.03	\$3.18	96%
Cozaar	2009	\$1.51	\$0.08	\$5.85	95%
Prilosec	2001	\$3.31	\$0.04	\$12.87	99%
Amoxil	1993	\$0.04	\$0.03	\$0.02	14%
Cephulac	1993	\$0.02	\$0.01	\$0.03	41%

PBMs in their role as a contractor for health plans also create opportunities for consumers to access pharmacy services that are lower priced compared to the alternative and may be more convenient. For example, PBMs commonly construct 'preferred' pharmacy networks on behalf of health plans. Researchers have found that Medicare Part D plans with preferred pharmacy networks pay lower out of pocket prices for retail prescription drugs.⁴³ PBMs also may produce benefits to patients and health plans

⁴³ Starc A, Swanson A. "Preferred Pharmacy Networks and Drug Costs." American Economic Journal: Economic Policy, 2021, 13 (3): 406-46.

through the operation of their own mail order pharmacies. 44,45 The availability of mail order creates value to consumers by promoting easy accessibility to drugs that treat or maintain chronic disease. This may in turn create health benefits and generate potential savings from forestalling additional medical care costs. PBM owned pharmacies also create competition with pharmacies, including those owned by massive corporate chains, such as Walgreens (see *Figure 15*). Competition between pharmacies may act to reduce prices and enhance quality. 46

Figure 15. Largest 15 U.S. Pharmacies, by Total Prescription Revenues in 2022.

Company	Stock Ticker	Estimated 2022 Prescription Revenues (billions)	Share of 2022 Prescription Revenues	Change in Revenues vs. 2021	Primary Dispensing Format(s)
CVS Health Corporation	CVS	(billions)	Nevendes	VIN LOLL	Timery Superioring Formacity
Retail/LTC pharmacy		\$81.1	14.8%	+9.7%	Chain drugstore/Long-term care pharmacy
Pharmacy Services ¹		\$59.0	10.8%	+21.3%	Mail & specialty pharmacy
Valgreens Boots Alliance ²	WBA	\$85.2	15.5%	-5.7%	Chain drugstore / Mail & specialty pharmacy
igna (Evernorth/Express Scripts)	CI	\$61.3	11.2%	+12.7%	Mail & specialty pharmacy
InitedHealth Group (OptumRx)	UNH	\$37.8	6.9%	+10.4%	Mail & specialty pharmacy / Community pharmacies
Valmart Stores, Inc. ³	WMT	\$24.1	4.4%	+6.1%	Mass merchant with pharmacy / Mail & specialty pharmacy
he Kroger Company ⁴	KR	\$16.8	3.1%	+10.1%	Supermarket with pharmacy / Specialty pharmacy
Rite Aid Corporation ⁵	RAD	\$12.9	2.3%	+5.0%	Chain drugstore / Mail & specialty pharmacy
lumana (CenterWell)	HUM	\$9.7	1.8%	+7.0%	Mail & specialty pharmacy
libertsons Companies ⁶	ACI	\$6.4	1.2%	+17.8%	Supermarket with pharmacy
ublix	Private	\$6.1	1.1%	+26.0%	Supermarket with pharmacy
ostco Wholesale Corporation	COST	\$3.0	0.6%	+8.2%	Mass merchant with pharmacy
rightSpring Health Services ⁷	Private	\$2.8	0.5%	-2.0%	Long-term care pharmacy
Centene (Envolve Health)8	CNC	\$2.7	0.5%	-38.7%	Specialty pharmacy
Ahold Delhaize ⁹	ADRNY	\$2.7	0.5%	+4.2%	Supermarket with pharmacy
CarepathRx ¹⁰	Private	\$2.4	0.4%	+20.0%	Specialty pharmacy
subtotal Top 15		\$413.9	75.6%		
otal Pharmacy Industry Prescription Revenues		\$547.9	100.0%		
benefit. Revenues reflect pro forma calendar year 2022, which I. Indudes pro forma annualident venues from 15 Bitiservices. 2. Indudes Retail Pharmacy USA segment (which indudes Aflan 3. Indudes Walmart and Sam's Club totres. 4. Indudes retail pharmacies and forger Specialty Pharmacy. 5. Indudes Drag Channels institute estimated revenues from th 6. Grounds tarte based on revised revenue figure for 2021. 7. In 2029, Pharmacies.	nay not corres Excludes Drug coRx Walgreer e mail and spec s. Prescription arial lealth, For	pond to fiscal year of Channels Institute is Pharmacyl. cialty pharmacies of revenues include p undation Care, Hom	or public reporting, estimates of presc f Elixir Rx. roforma estimated sescripts, and Speci	Excludes revenues revenues revenues from I alty Therapeutic	spensing formats. Excludes estimated infusion services covered by medical res from administration of COVID-19 vaccines. If CP long term care, from 90-day Maintenance Choice claims filled in CVS retail pharmacies. The Pharmacy Alternatives. Care. Excludes PANTHURS fare Pharmacy, which Centene divested in 2022. It services organization of Chartwell Pennsylvania, in 2022, Carepathilix
 Growth rate based on revised revenue figure for 2021. Includes Drug Channels institute estimated revenues from 8 	ioPlus Specialt	A comment of the control			
9. Growth rate based on revised revenue figure for 2021.	iomus speciart	A t statement's married			

⁴⁴ Central-fill, mail pharmacies operated by large PBMs, and health insurers have displaced retail chains as the largest prescription drug dispensers by revenues. Five of the largest U.S. pharmacies were central fill mail and specialty pharmacies owned by vertically integrated organizations that also own a PBM: Caremark (CVS Health), Express Scripts (Cigna), Envolve Health (Centene), CenterWell (Humana), and OptumRx (UnitedHealth Group). Revenue growth at the PBMs' pharmacies is being driven by the dispensing of more-expensive specialty medications, which accounted for nearly 40% of the pharmacy industry's prescription revenues in 2022. https://www.drugchannels.net/2023/03/the-top-15-us-pharmacies-of-2022-market.html

⁴⁵ According to the House oversight report, another key function of PBMs is to establish a network of pharmacies from which plan beneficiaries can get their prescriptions filled. However, the three largest PBMs—CVS Caremark, Express Scripts, and Optum Rx— own their own pharmacies. They also control 80 percent of the market. But they are not the only ones – smaller PBMs own their own pharmacies too. PBMs "steer" patients to the pharmacies they control, making it difficult for independent pharmacies to survive. PBMs also reimburse unaffiliated pharmacies at low rates and charge several fees to independent pharmacies. These retroactive fees can be for just participating in the network, or they can be tied to performance metrics, such as pharmacy refill rates, error rates, or audit rates, which the PBM establishes. These retroactive fees add up – sometimes it costs a pharmacy more to fill a prescription than it is reimbursed. For specialty pharmacies, they accrue fees based on irrelevant metrics.

⁴⁶ Tirole J. The theory of industrial organization. Boston: MIT Press; 1988.

PBMs provide these benefits to the US health system without significantly altering incentives for innovation by drug makers. ⁴⁷ In addition, PBMs only interact with the market for drugs covered under the pharmacy benefits of health plans and therefore have no impact on the net prices paid nor revenue gained from specialty drugs covered under the medical benefit, many orphan drugs and branded drugs without competition. ⁴⁸ Among Medicare Part D plans evidence generated recently by the GAO suggests drug makers that sell the majority of branded drugs in the protected classes do not offer rebates to PBMs in exchange for formulary coverage. ⁴⁹ Indeed, rebates offered to Medicare Part D plans concentrated in a small number of products (see *Figure 16*).

Figure 16. Percent of rebates, gross expenditures, and utilization for 100 highest-rebated Part D drugs compared to all other drugs 2021.

Table 3: Percent of Rebates, Gross Expenditures, and Utilization for 100 Highest- Rebated Part D drugs Compared to All Other Part Drugs, 2021				
	100 highest rebated drugs	All other Part D drugs		
Percent of Part D drugs	1.3%	98.7%		
Percent of rebates	84.2%	15.8%		
Percent of gross expenditures	42.5%	57.5%		
Descent of utilization	6.20/	02.79/		

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. I GAO-23-105270

Notes: We analyzed 2021 CMS Medicare Part D expenditure and rebate information for Part D drugs based on their rebates—discounts manufacturers provide to Part D plan sponsors after a drug is purchased. We identified the 100 drugs that received the highest rebates in 2021 and compared them to all other Part D drugs. Gross expenditures reflect what was paid to a pharmacy by Part D plan sponsors and beneficiaries. Utilization reflects the number of unique 30-day supplies for a drug.

⁴⁷ Conti RM, Frandsen B, Powell ML, Rebitzer JB. "Common Agent or Double Agent? Pharmacy Benefit Managers in the Prescription Drug Market." National Bureau of Economic Research Working Paper Series No. 28866, May 2021. Available at http://www.nber.org/papers/w2886.

⁴⁸ Non-oral drugs, orphan drugs and other specialty drugs are where drug companies make money and where the industry has largely been innovating.

⁴⁹ GAO-23-105270, MEDICARE PART D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending

Emerging concerns regarding the PBM market

I am worried that PBMs activities may also contribute to behaviors that have the potential to harm patients and payers.

PBMs and misallocated formulary incentives

Concerns have been raised that PBMs design formularies based on what maximizes revenues and profit rather than what lowers costs for patients.⁵⁰ If rebates are based off a drug's list price, PBMs have an incentive to select a higher-priced drug over a lower-priced product to collect the higher rebate amount. Accordingly, PBMs may include more expensive products on formularies rather than therapeutically equivalent cheaper alternatives to garner the largest rebate. A recent report by the GAO,⁵¹ do not support the widespread use of these actions in Medicare Part D plans (see *Figure 17*). However, such behaviors, if they do exist in the public and commercial insurance markets, will act to erode the substantial benefits gained from generic and biosimilar competition for U.S. patients and payers.

Figure 17. Percentage of formulary placements among 40 highly rebated brand-name drugs with generic counterparts in Medicare Part D Formularies

Generic listed, brand not listed

Neither brand nor generic listed

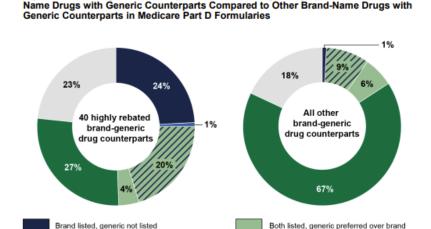


Figure 6. Percentage of Formulary Placements among 40 Highly Rebated Brand-

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-23-105270

Both listed, brand preferred over generic

Both brand and generic listed on same tier

Note: The 40 highly rebated brand-name drugs were those that accounted for the top 98 percent of the \$6.4 billion in rebates among Medicare Part D brand-name drugs for which we identified generic counterparts in 2021. For all other brand-name drugs and generic counterparts, the formulary placement type "both listed, brand preferred over generic" is not shown as it accounted for 0.1 percent of formulary placements. For purposes of this analysis, we included drugs marketed under a brand name and biologics as brand-name drugs, and we included the following as generic counterparts: (1) non-branded drugs that shared the same ingredient, strength, and dose form as brand-name drugs, which included both authorized generics and generic drugs produced by competing manufacturers and (2) biosimilars for reference biologics. Percentages do not total 100 percent due to rounding.

⁵⁰ See for example Socal M, Bai G, Anderson G. "Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics Are Available." JAMA Internal Medicine 179(6) (2019): 832-833; Dusetzina S, Cubanski J, Nshuti L, et al. "Medicare Part D Plans Rarely Cover Brand-Name Drugs When Generics Are Available." Health Affairs 39(8) (2020): 1326-1333; and Buttorff C, Xu Y, Joyce G. "Variation in Generic Dispensing Rates in Medicare Part D." American Journal of Managed Care 26(11) (2020): e355-361.

⁵¹ GAO-23-105270, MEDICARE PART D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending

PBMs also have been accused of switching patients to therapeutically similar drugs for which they have negotiated more favorable rebate terms. ⁵² In a practice called "therapeutic substitution," patients are switched from one brand name drug to a generic form of a different drug in the same class or to a lower-cost brand name drug in the same class. While therapeutic substitution offers the potential for significant cost savings, at least one PBM agreed to pay \$29.3 million to settle claims that it switched patients to drugs that were more expensive for payers and patients, but for which the PBM had negotiated more favorable rebate terms.

In response, PBMs highlight that their formularies are developed by a Pharmacy & Therapeutics Committee, which reviews clinical evidence in determining what products to place on the formulary. However, in general, there is little detail provided about how such committees reach their decisions.⁵³

Formulary designs have powerful financial consequences for consumers at the pharmacy counter, particularly because beneficiary out of pocket costs are often based on the list price of a drug rather than the price net negotiated rebates. Without more transparency as to the scope and terms of the financial arrangements that PBMs have with manufacturers, it is virtually impossible to know if PBMs' current formulary designs maximize cost savings for Part D and its enrollees or for PBMs themselves.

PBMs and pharmacies

On pharmacies, the construction of narrow networks and competition from PBM owned pharmacies may place significant competitive pressure on sole proprietorship and community pharmacies.⁵⁴ This may reduce these pharmacies revenue base or impose additional costs on these medical providers and create challenges for consumer access, especially for some vulnerable populations and rural communities.

Moreover, PBMs may engage in spread pricing policies, in which a PBM pays a pharmacy a lower amount than they report to a health plan for a dispensed prescription. This behavior imposes costs on health plans, include state Medicaid programs. ⁵⁵ The difference between what the PBM pays the pharmacy and what the plan pays the PBM for the same prescription is pocketed by the PBM and can result in substantial earnings. In addition, because contracts between PBMs and pharmacies are proprietary, State Medicaid agencies and other payers often cannot verify the amount of spread pricing. If spread pricing is not appropriately monitored and accounted for, plans may not be aware of the spread amount included in pharmacy costs and may negotiate separate administrative payments to PBMs without knowing how much PBM profit is already built into the pharmacy costs as spread pricing. State Medicaid agencies and health plans may use these inflated pharmacy costs in setting premium rates and payments to managed care organizations if they delegate coverage responsibility. If a payer increases its capitated payments to

⁵² https://www.finance.senate.gov/imo/media/doc/A%20Tangled%20Web.pdf

⁵³ National Academies of Sciences, Engineering, and Medicine. 2018. *Making Medicines Affordable: A National Imperative*. Washington, DC: The National Academies Press. https://doi.org/10.17226/24946.

⁵⁴ Most prescription drugs are dispensed through large pharmacy chains. According to Drug Channels, the top seven companies operating pharmacies—CVS Health, Walgreens Boots Alliance, Cigna, UnitedHealth Group, Walmart, Kroger, and Rite Aid—accounted for 70% of U.S. prescription dispensing revenues in 2022. The top 15 pharmacies accounted for more than 75% of total dispensing revenues from retail, mail, long-term care, and specialty pharmacies. See https://www.drugchannels.net/2023/03/the-top-15-us-pharmacies-of-2022-market.html.

⁵⁵ Royce TJ, Kircher S, Conti RM. "Pharmacy Benefit Manager Reform: Lessons from Ohio." JAMA. 2019 Jul 23;322(4):299-300.

managed care organizations (such as state Medicaid MCOs or Medicare Part C) based on a rate setting influenced by inflated pharmacy costs, it increases the cost of the benefit.⁵⁶

PBMs have been found to overcharge state Medicaid programs in Ohio, Kentucky, Illinois, and Arkansas more than \$415 million once spread pricing schemes were discovered. It is difficult to determine the full extent and the impact of these practices, however they likely result in taxpayers paying more for prescription drugs than needed.⁵⁷

PBMs and drug makers

The reaction of drug makers to the business model of PBMs also presents tradeoffs.

The rebates offered by drug makers competing in the arena set by PBMs may offset increases in list prices. Such behavior creates disconnections between the list prices set by drug makers and the actual transacted prices for branded prescription drugs, such as documented by many reports (see *Figure 18*).

Figure 18. Trends in branded drugs' list prices, net prices, and patient out of pocket costs 2013 through 2022.



Source: IQVIA Institute, Mar 2023; CMS National Health Expenditures (NHE), Mar 2022.

Notes: Includes COVID-19 vaccines and therapeutics. IQVIA audits include measures of sales at Wholesaler Acquisition Cost (WAC) or list prices. Additionally, the IQVIA Institute has analyzed company reported net revenues for a sample of companies and products and projected a total market estimate (see Methodology section). Payer net spending reflects the total amounts spent by payers for medicines in both retail and non-retail settings, including all insurance types, and cash paying patients, offset by the estimates of rebates or payments which reduce payer responsibility. Payer net spending is derived from an analysis of CMS NHE data, IQVIA audited sales, and IQVIA estimates of manufacturer invoice-level and net revenue. Payer net spending has been estimated to include non-retail drug spending which is otherwise not reported by CMS. Patient out-of-pocket costs are derived from IQVIA audited measures of pharmacy out-of-pocket costs and informed by IQVIA audited non-retail sales and CMS NHE out-of-pocket costs share of non-retail healthcare costs. Due to lag times in reporting. CMS-derived measures are projections for 2022 while IQVIA-derived metrics are actual.

Report: The Use of Medicines in the U.S. 2023: Usage and Spending Trends and Outlook to 2027. IQVIA Institute for Human Data Science, April 2023.

Moreover, evidence suggests that these offsets off sets are not complete. In Medicare Part D, the differential between list prices set by branded drug makers and the costs borne by beneficiaries and taxpayers exists and has been growing over time (see *Figure 18*).

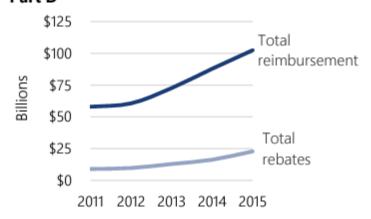
⁵⁶ CMS Press Release, "CMS Issues New Guidance Addressing Spread Pricing in Medicaid, Ensures Pharmacy Benefit Managers are not Up-Charging Taxpayers." Available at https://www.cms.gov/newsroom/press-releases/cmsissues-new-guidance-addressing-spread-pricing-medicaid-ensures-pharmacy-benefit-managers-are-not. Accessed on August 18, 2022.

⁵⁷ Catherine C. "State report: Pharmacy middlemen reap millions from tax-funded Medicaid." The Columbus Dispatch, (2018), https://stories.usatodaynetwork.com/sideeffects/state-report-pharmacy-middlemen-reap-millionsfrom-tax-funded-medicaid/. See also Gillespie L. "Pharmacy Middlemen Overcharged Medicaid \$123.5 Million, State Says." 89.3 WFPL, (Feb. 23, 2019), https://wfpl.org/pharmacy-middlemen-overcharged-medicaid-123-5million-state-says/. See also Liss S. "Centene reaches \$72M settlement with Illinois, Arkansas for alleged Medicaid overcharges". HealthcareDrive, (Oct. 1, 2021), https://www.healthcaredive.com/news/centene-72msettlement-illinois-arkansas-overcharge-Medicaid-medicines/607535/

Indeed, a recent OIG report⁵⁸ found that after accounting for rebates, Part D reimbursement still increased 62 percent from 2011 to 2015 (see *Figure 19*). Total rebate dollars for all brand-name drugs in Part D more than doubled (a 155 percent increase) across the 5 years, from \$9 billion in 2011 to \$23 billion in 2015. Despite the substantial growth in rebates, the gap between total reimbursement and total rebates increased from 2011 to 2015. Therefore, total rebate-adjusted reimbursement under Part D still increased 62 percent, from \$49 billion in 2011 to \$80 billion in 2015. In addition, the percentage of brand-name drugs for which manufacturers paid rebates decreased. OIG found that total reimbursement for all brand name drugs in Part D increased 77 percent from 2011 to 2015, despite a 17 percent decrease in the number of prescriptions for these drugs. After accounting for manufacturer rebates, reimbursement for brand name drugs in Part D still increased 62 percent from 2011 to 2015.

Figure 19. The gap between total reimbursement and total rebates increased each year for brand-name retail prescription drugs covered under Medicare Part D.

Exhibit 3: From 2011 to 2015, the gap between total reimbursement and total rebates increased each year for brand-name drugs in Part D



Source: OIG analysis of Medicare Part D data, 2011 to 2015.

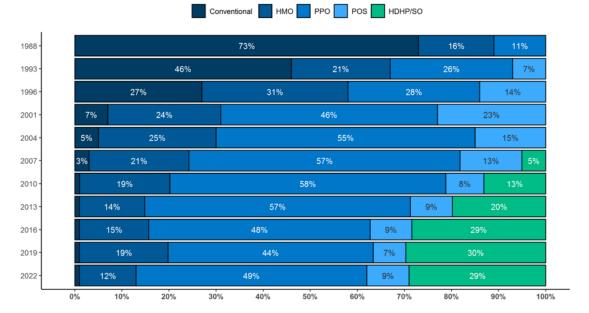
This activity also directly impacts the out-of-pocket payments consumers paid for such drugs. It may also have the most perverse effect on the millions of commercially insured patients in high deductible health plans and the uninsured (see *Figure 20*).

Figure 20. Distribution of health plan enrollment for covered workers, by plan type, 1988-2022

-

⁵⁸ https://oig.hhs.gov/oei/reports/OEI-03-15-00080.asp

Figure 10
Distribution of Health Plan Enrollment for Covered Workers, by Plan Type, 1988-2022



NOTE: Information was not obtained for POS plans in 1988 or for HDHP/SO plans until 2006. See the Survey Design and Methods section from the 2005 Kaiser/HRET Survey and the 2021 KFF Survey for a discussion of weighting changes.

Kaiser/HRET Survey and the 2021 KFF Survey for a discussion of weighting Granges.

SOURCE: KFF Employer Health Benefits Survey, 2018-2022; Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 1999-2017; KPMG Survey

Employer-Sponsored Health Benefits, 1993 and 1996; The Health Insurance Association of America (HIAA), 1988.

This behavior also undermines transparency in our system, as the difference between list prices and transacted prices can grow under these incentives. ^{59,60} the policy trends in our system to improve transparency and more closely align reimbursements with actual prices paid for medical care provision.

Economic theory suggests drug makers offer rebates off their list prices to compete in the arena PBMs create and maintain between drug makers and that PBMs will tend to place the higher list-price drug in the preferred formulary tier. This can be managed when list prices for drugs are set by external parties (such as based on value assessments in Europe or generic drugs for which prices are set through competition and state and health plan mac lists). However, as described above in the U.S., list prices of branded drugs are set by drug makers without any bounds. When drug makers have the absolute power to set their list prices and enter brand-brand competition with other drug makers through the PBM arena, shadow pricing behavior may occur. Shadow pricing is a practice in which would-be competitor drug makers follow each other's price increases. The House Oversight Committee⁶¹ See as an example the pricing practices of Abbvie and Amgen for their products Humira and Enbrel *Figure 21*.⁶²

https://oversight democrats.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf

⁵⁹ https://www.gao.gov/prescription-drug-

spending #: ``: text = For %20 example %2C%20 retail %20 prescription %20 drug, other %20 countries %20 for %20 prescription %20 drugs.

⁶⁰ https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2023

⁶² The Oversight Committee report notes, "AbbVie and Amgen also engaged in shadow pricing for their products Humira and Enbrel. One Amgen pricing committee presentation prepared in May 2016 described Amgen's pricing strategy for Enbrel: "Price increase strategy is to follow AbbVie's price increases." In December 2017, while approving a planned 4.9% Enbrel price increase for the end of the year, Amgen's then-Executive Vice President and Head of Global Commercial Operations told his team, "[Y]ou have authorization to proceed with a competitive price increase for Enbrel—should Humira pull the trigger at any point."

Figure 21. Evidence of Shadow Pricing Practices by Drug Makers Documented by the House of Representatives Oversight Committee, 2022.

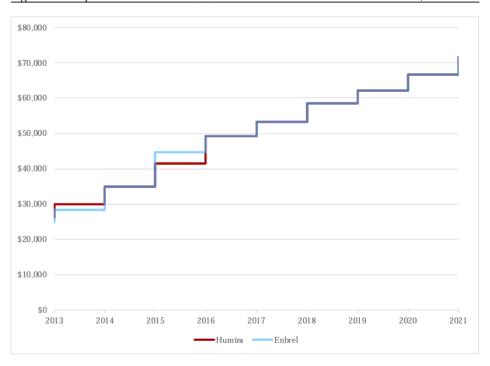


Figure 8: Comparison of Humira and Enbrel Prices for Annual Course of Treatment, 2013-2021

Faced with strong incentives to compete in the PBM arena on rebates, drug makers may also choose to undermine the formulary incentives by threatening PBMs through the offer of bundled rebates across drugs they sell.⁶³ This behavior on the one hand may reduce prices paid for drugs, but on the other hand may reduce competition between drug makers, reducing access to drugs by patients and physicians. This may be particularly perverse when it impacts the entry and competition of generics and biosimilars.

PBMs and horizontal consolidation

I am also worried about the market tendency to consolidate because of these practices.

In my research, I have noted the ubiquity of most favored nation (MFNs) clauses in contracts between PBMs and health plans. ⁶⁴ MFNs guarantee each health plans contracting with a PBM that they will share in lower prices PBMs are able to extract from drug makers. ⁶⁵ From a theoretical perspective, MFNs in the is context, create a contracting extension that lead to weaker formulary incentives where the copay in the preferred tier exceeds marginal cost. Under these circumstances, horizontal mergers between PBMs

⁶³ See GAO-23-105270, MEDICARE PART D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending
And Lawton Robert Burns. The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs (Palgrave Macmillan, 2022).
64 Conti RM, Frandsen B, Powell ML, Rebitzer JB. "Common Agent or Double Agent? Pharmacy Benefit Managers in the Prescription Drug Market."
National Bureau of Economic Research Working Paper Series No. 28866, May 2021. Available at http://www.nber.org/papers/w2886.
See also Lawton Robert Burns. The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs (Palgrave Macmillan, 2022).
65 Certain federal regulations also build MFN-style guarantees into the purchase of prescription drugs insured by Medicaid or acquired by hospitals. These MFN guarantees threaten formulary efficiency by introducing a contracting externality. If one PBM secures a lower net price for a branded prescription drug through aggressive formulary incentives, the drug maker must also lower the net price for the other PBMs who have MFN guarantees.

internalize this externality. The result is more efficient (stronger) formulary incentives where the copay in the preferred tier is set closer to marginal cost. PBMs are now huge entities that are much larger by various metrics than their negotiating counterparts up and down stream in the us medical care system, such as health plans or drug makers (see *Figure 22*).

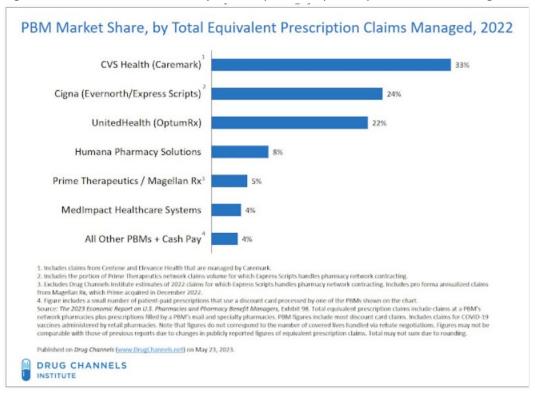


Figure 22. PBM market share, by total equivalent prescription claims managed, 2022.

The horizontal consolidation among PBMs has tradeoffs. While it may generate higher rebates extracted from drug makers, it also reduces competition between these important intermediaries in our system, reduces incentives for transparency, which in turn reduces the ability for health plans and their beneficiaries to shop for PBMs services. This market organization may also not facilitate the sharing of rebates with plans/employers or patients. ^{66,67,68} Indeed, the distribution of efficiency gains is determined by competition in the market for PBM services. ⁶⁹ When PBMs are highly concentrated, efficiency gains resulting from formularies accrue to PBMs rather than consumers or drug makers.

PBMs and vertical consolidation with health plans

⁶⁶ Drug Channels. "Employers are Getting More Rebates Than Ever – But Sharing Little with Their Employees". (January 18, 2018). Available online at: https://www.drugchannels.net/2018/01/employers-are-getting-morerebates-than.html.

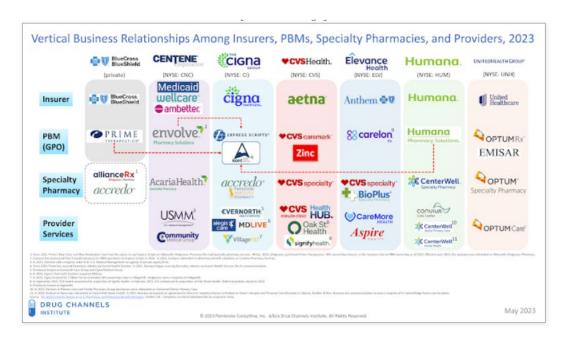
⁶⁷ Bai G, Sen A, Anderson G." Pharmacy *Benefit Managers, Brand-Name Drug Prices, and Patient Cost-Shari*ng," Annals of Internal Medicine 168(6) (2018): 436-437.

⁶⁸ Feldman W, Rome B, Raimond V, et al. 'Estimating Rebates and Other Discounts Received by Medicare Part D". JAMA Health Forum 2(6) (2021): e210626

⁶⁹ https://www.drugchannels.net/2023/05/the-top-pharmacy-benefit-managers-of.html

In my research, I have noted that each PBM operating in the U.S. act as a common agent for many health plans. ⁷⁰ This creates tradeoffs – more volume increases PBMs leverage to negotiation with drug makers, ⁷¹ but more plans with contracts requiring MFNs undermines the ability of PBMs to obtain price concessions from drug makers and creates a problem for each plan-PBM relationship. Specifically, the challenge arises because PBMs cannot pass off deeper price concessions to larger or more restrictive plans because MFNs prohibit them from doing so. This creates conditions under which larger plans may want to capture the full benefit of the PBM for themselves. Indeed, one potential explanation for the vertical consolidation we have observed in the U.S. market (see *Figure 23*) is related to these incentives.

Figure 23. Vertical relationships among insurers, PBMs, specialty pharmacies, and providers, 2023.



While there are potential efficiencies with vertical consolidation between PBMs and health plans, there may also be potential perverse impacts. ⁷² We find that a large PBM acting as an agent for many payers can internalize the contracting externality created by MFNs and so enhance market efficiency. But to the extent that large, common-agent PBMs reduce market competition, the resulting efficiency gains will accrue to PBMs rather than consumers or producers and consequently, reduce how sensitive a drug maker's rebate offer will be to any one PBM's formulary design. This will indeed result in lower rebates, but the main consequence is PBM formularies will not be so generous, and patients may pay more out of pocket. In short, MFNs can increase patients' out-of-pocket costs for drugs.

Vertical consolidation between health plans and PBMs likely has other consequences. Burns notes that such integration also potentially signals that PBMs may focus increasingly more on the specialty pharmacy

⁷⁰ https://www.drugchannels.net/2023/05/mapping-vertical-integration-of.html

⁷¹ As Lawton Burns has noted, vertical integration may have important, positive consequences for competition. According to analysts, one outcome of this vertical integration will be more aggressive price competition among health plans and PBMs. This could come about by the merging parties' bundling of medical and pharmacy benefits, which would entail a diminution of carve-out contracts between employers and PBMs for just the pharmacy benefit. This would put pressure on the margins of the freestanding PBMs, because vertically integrated insurers would discount their in-house PBM's services to win the combined business. Any stand-alone PBM contracts would need to lower prices to remain competitive. See Lawton Robert Burns. *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs* (Palgrave Macmillan, 2022).

⁷² Brot-Goldberg Z, Che C, Handel B. "*Pharmacy Benefit Managers and Vertical Relationships in Drug Supply: State of Current Research.*" NBER Working Paper Series (April 2022).

business for their profitability and, conversely, focus increasingly less on retained rebates.⁷³ PBMs have passed along a much greater share of these rebates to health plan sponsors over the past decade, from 75% in 2013 to 90% in 2018. According to some PBM industry presentations, rebates apply to 70% of their branded pharmacy scripts, which in turn account for only 10% of total scripts. Rebates have also diminished in importance due to Medicare's growing share of retail prescription drug spending (from 18% in 2006 to 30% in 2017) and the low amount of rebates retained by PBMs in their relationships with Medicare Part D plans.

Gray et al examines the extent and impact of PBM-health plan vertical consolidation in Medicare Part D plans. ⁷⁴ They find evidence that vertical integration between PBMs and insurers increased dramatically in the Medicare Part D market with the market share of vertically integrated plans increasing from about 30% to 80% between 2010 and 2018. Vertical integration between a health plan and the PBM did not result in lower premiums for beneficiaries of the integrated plan. Furthermore, they show that rising vertical integration may have led to the market exit of standalone PBM competitors, which could explain rising premiums for Medicare beneficiaries at non-vertically integrated plans. ⁷⁵

The existence of MFNs in PBM contracts with health plans does allow smaller plans and employers to get better deals from drug makers than they otherwise would without the pooling with the larger plans the PBM offers. However, with vertical consolidation between PBMs and larger plans, smaller plans and employers may have even less ability to understand the benefits and costs of PBMs, and shop accordingly. This is important to note because self-insured plans account for around two-thirds of enrollment in employer plans, and consequently it is still frequently the case that the PBM and the ultimate payer are different entities even where PBMs and insurers are integrated.⁷⁶

Growing vertical integration between health plans and PBMs will likely reduce the transparency of freestanding PBMs' financial results.⁷⁷ This may also create challenges with medical loss ratio reporting by health plans covering Medicare Part D beneficiaries and beneficiaries enrolled in Medicare Advantage (Part C) plans.^{78,79}

⁷³ Lawton Robert Burns. The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs (Palgrave Macmillan, 2022).

⁷⁴ Gray C, Alpert AE, Sood N. "Disadvantaging Rivals: Vertical Integration in the Pharmaceutical Market." NBER Working Papers 31536, 2023. National Bureau of Economic Research.

⁷⁵ Gray et al found studied the vertical acquisition of Catamaran (a PBM) with United (a health plan) in 2015.

⁷⁶ https://www.kff.org/report-section/ehbs-2022-section-10-plan-funding/

⁷⁷ Lawton Robert Burns. The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs (Palgrave Macmillan, 2022).

⁷⁸ CMS, "CMCS Informational Bulletin: Medical Loss Ratio (MLR) Requirements Related to Third-Party Vendors." Available at

https://www.medicaid.gov/federal-policy-guidance/downloads/cib051519.pdf. Accessed on August 18, 2022.

⁷⁹ https://www.brookings.edu/articles/a-brief-look-at-current-debates-about-pharmacy-benefit-managers/