The Role of Pharmacy Benefit Managers in Prescription Drug Markets

Report Prepared by the House Committee on Oversight and Accountability Staff

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Executive Summary

Pharmacy Benefit Managers' (PBMs) role as intermediaries between drug manufacturers and health insurance providers should have made them, in theory, the best positioned entities to decrease the cost of prescription drugs.[1] The three largest PBMs, CVS Caremark (Caremark), Cigna Express Scripts (Express Scripts), and UnitedHealth Group's Optum Rx (Optum Rx), control more than 80 percent of the market and are vertically integrated with health insurers, pharmacies, and providers.[2] As large health care conglomerates, some have argued that these PBMs' vertical integration with insurers and pharmacies would better position them to improve patient access and decrease the cost of prescription drugs.[3] **Instead, the opposite has occurred: patients are seeing significantly higher costs with fewer choices and worse care.**

Americans spend more today on prescription drugs than any other country, and prescription drug prices in the U.S. are more than double the cost of identical drugs in other high-income nations.[4] In 2023, the U.S. health care system spent $772.5 billion on prescription drugs, including $307.8 billion on retail drugs.[5] This mammoth spending is largely driven by a small number of high-cost products; brand name drugs accounted for 80 percent of prescription drug spending, despite the fact that 80 percent of prescriptions in the U.S. are for generic drugs.[6] Additionally, the cost of specialty drugs, which accounted for 54 percent of spending in 2023,[7] has increased more than 40 percent since 2016.[8] Patient out-of-pocket costs for prescriptions were $91 billion in 2023 alone.[9] Higher drug utilization and new drugs are also contributing to higher costs, with Americans being prescribed more and paying for more prescription drugs.[10]

This report describes the Committee on Oversight and Accountability's findings that PBMs inflate prescription drug costs and interfere with patient care for their own financial benefit.

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[1] U. S. FED. TRADE COMM'N, INTERIM STAFF REP., PHARMACY BENEFIT MANAGERS: THE POWERFUL MIDDLEMEN INFLATING DRUG COSTS AND SQUEEZING MAIN STREET PHARMACIES, 8 (Jul. 2024).
[2] Adam J. Fein, *Mapping the Vertical Integration of Insurers, PBMs, Specialty Pharmacies, and Providers: A May 2023 Update*, DRUG CHANNELS (May 10, 2023).
[3] Matthew Fiedler, Loren Adler, and Richard G. Frank, *A brief look at current debates about pharmacy benefit managers*, THE BROOKINGS INSTITUTION (Sept. 7, 2023).
[4] Andrew Mulcahy et al., *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*, RAND Corporation (2021).
[5] Eric M. Tichy, et al., *National Trends in Prescription Drug Expenditures and Projections for 2024*, 81 AM. J. OF HEALTH-SYSTEM PHARMACY 583 (2024).
[6] Sonal Parasrampuria & Stephen Murphy, *Trends in Prescription Drug Spending, 2016-2021*, Assistant Secretary for Planning and Evaluation Office of Science & Data Policy (Sept. 30, 2022).
[7] IQVIA Inst. for Human Data Science, *The Use of Medicines in the U.S. 2024: Usage and spending trends and outlook for 2028* (Apr. 2024).
[8] *Supra* note 6
[9] *Supra* note 7.
[10] CONG. BUDGET OFF., 57050, PRESCRIPTION DRUGS: SPENDING, USE, AND PRICES, 9 (Jan. 2022); *Supra* note 5.

Key Findings

- **The three largest PBMs have used their position as middlemen and integration with health insurers, pharmacies, providers, and recently manufacturers, to enact anticompetitive policies and protect their bottom line.**
  The Committee found evidence that PBMs share patient information and data across their many integrated companies for the specific and anticompetitive purpose of steering patients to pharmacies a PBM owns. Furthermore, the Committee found that PBMs have sought to use their position to artificially reduce reimbursement rates for competing pharmacies.

- **PBMs frequently tout the savings they provide for payers and patients through negotiation, drug utilization programs, and spread pricing, even though evidence indicates that these schemes often *increase* costs for patients and payers.**
  The Committee identified numerous instances where the federal government, states, and private payers have found PBMs to have utilized opaque pricing and utilization schemes to overcharge plans and payers by hundreds of millions of dollars.

- **The largest PBMs force drug manufacturers to pay rebates in exchange for the manufacturers' drugs to be placed in a favorable tier on a PBM's formulary, making it difficult for competing, lower-priced prescriptions (often generics or biosimilars) to get on formularies.**
  The Committee has found evidence that PBMs regularly place higher cost medications in more preferable positions based on their formularies, even when there are lower-cost and equally safe and effective competing options.

- **As many states and the federal government weigh and implement PBM reforms, the three largest PBMs have begun creating foreign corporate entities and moving certain operations abroad to avoid transparency and proposed reforms.**
  The Committee found that these PBMs have created group purchasing organizations (GPOs) to centralize the negotiation of rebates and fees in Switzerland and Ireland. They have also created companies in Ireland and the Cayman Islands to manufacture and market certain highly profitable generics and biosimilars. The creation of entities in locations well known for their lack of financial transparency and movement of operations that would be subject to impending regulations only heightens concerns that PBMs will do anything to avoid transparency.

- **The largest PBMs' use of tools such as prior authorizations, fail first policies, and formulary manipulations have significant detrimental impacts on Americans' health outcomes.**
  The Committee found that the use of these tools enables PBMs to slow the market uptake of cheaper generics and biosimilars. Furthermore, the Committee found that these tools often delay and negatively impact patient care.

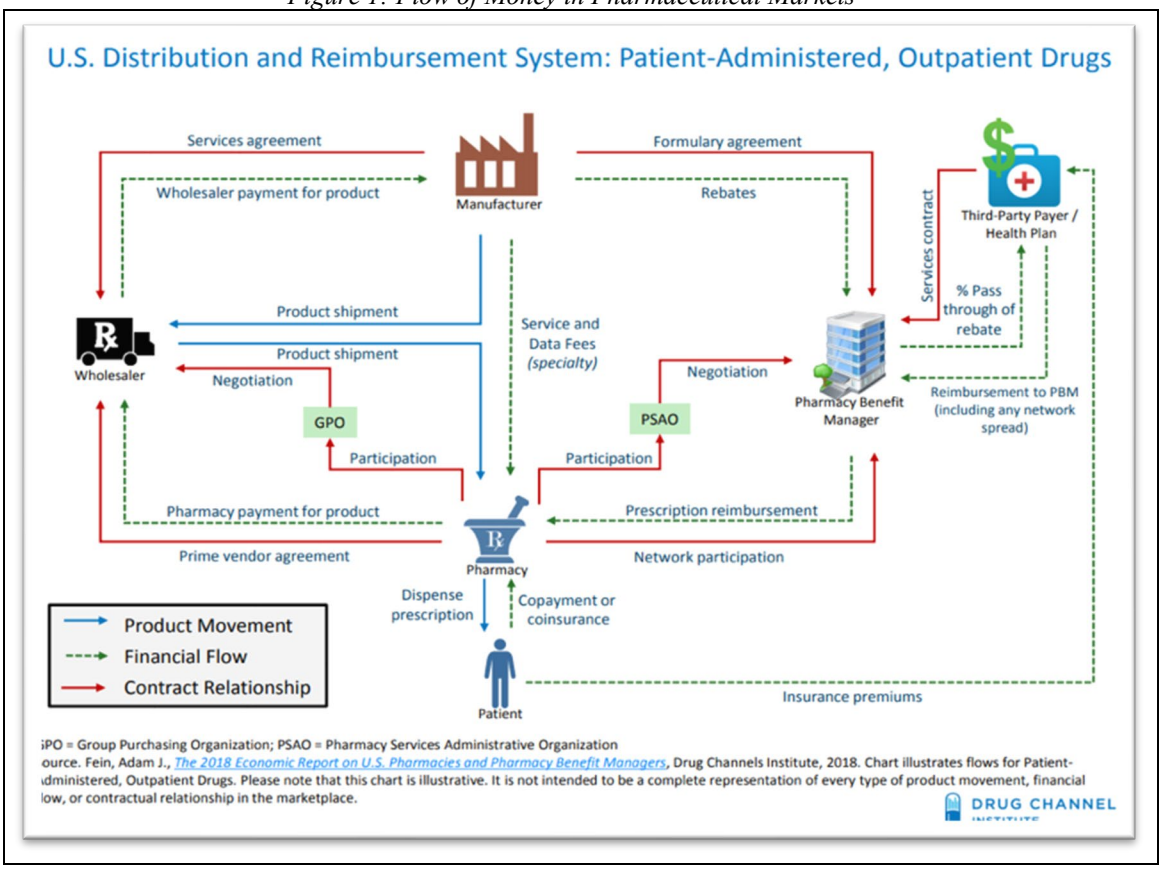
- **The anti-competitive policies of the largest PBMs have cost taxpayers and reduced patient choice.**
  The Committee found that PBMs have intentionally overcharged or withheld rebates and fees from many taxpayer-funded health programs. Additionally, the Committee found that in these taxpayer-funded health programs, PBMs use their position as middlemen to steer patients to the pharmacies they own rather than pharmacies that may have closer proximity or provide better care.

Background

I. The Role of Pharmacy Benefit Managers

PBMs are companies that manage prescription drug benefits for health insurers, Medicare Part D drug plans, self-insured employers, and other payers, such as state Medicaid programs (collectively known as "payers").[11] When they were originally created in the 1960s, PBMs functioned as passive processors of prescription drug claims.[12] However, as the pharmaceutical industry has evolved, the role of PBMs has evolved with it.[13] Today, PBMs have a more significant role and function as intermediaries between drug manufacturers, payers, and pharmacies. PBMs' central role in the pharmaceutical market is clearly observable in Figure 1:

Figure 1: Flow of Money in Pharmaceutical Markets[14]



PBMs' primary responsibilities include negotiating prices with drug manufacturers and pharmacies on behalf of payers.[15] When negotiating with a drug manufacturer, PBMs will frequently offer to place the manufacturer's drug in a lower tier on an insurance plan's

[11] *Supra* note 3.
[12] Robin J. Strongin, *The ABCs of PBMs*, NAT. HEALTH POLICY FORUM, Issue Brief, No. 749 (Oct. 27, 1999).
[13] *Id.*
[14] Brandt Dietary, *Pharmacy Benefit Manager Regulation: What Happens Now?*, Michael Best Strategies, (Jan. 14, 2019).
[15] *Supra* note 3.

formulary, making the drug more accessible to a wider range of patients; in return, the drug manufacturer will give the PBM a discount, or rebate, on the drug.[16] These rebates are frequently "calculated as a percentage of a drug's list price."[17] This creates a perverse incentive wherein PBMs prioritize more expensive drugs so they can get a larger rebate.[18]

PBMs also negotiate with individual pharmacies by offering a pharmacy a place in the plan's network, increasing the pharmacy's potential for business.[19] In return, the PBM reimburses pharmacies at a set amount for dispensing prescriptions.[20] Additionally, PBMs operate electronic systems that process prescription drug claims at the pharmacy.[21]

A PBM's compensation is determined by its business model. One such model is based on health plans paying PBMs for services directly by establishing an administrative fee contract.[22] Another route is spread pricing, where a health plan pays a PBM an agreed-upon price for each prescription that is filled and the PBM retains the difference between the health plan's price and the pharmacy's price.[23] Finally, PBMs may keep portions of manufacturer rebates as a form of compensation.[24]

II. The Current Marketplace

There are currently 66 PBMs operating in the United States; however, the three largest PBMs—CVS Caremark, Express Scripts, and Optum Rx—control approximately 80 percent of the market.[25] Collectively, the largest six PBMs collectively control approximately 96 percent of the market.[26] Moreover, the largest PBMs are now vertically integrated with health insurers, group purchasing organizations (GPOs), and retail, mail-order, and specialty pharmacies, forming a consolidated marketplace.[27] This vertical integration can be seen in Figure 2:

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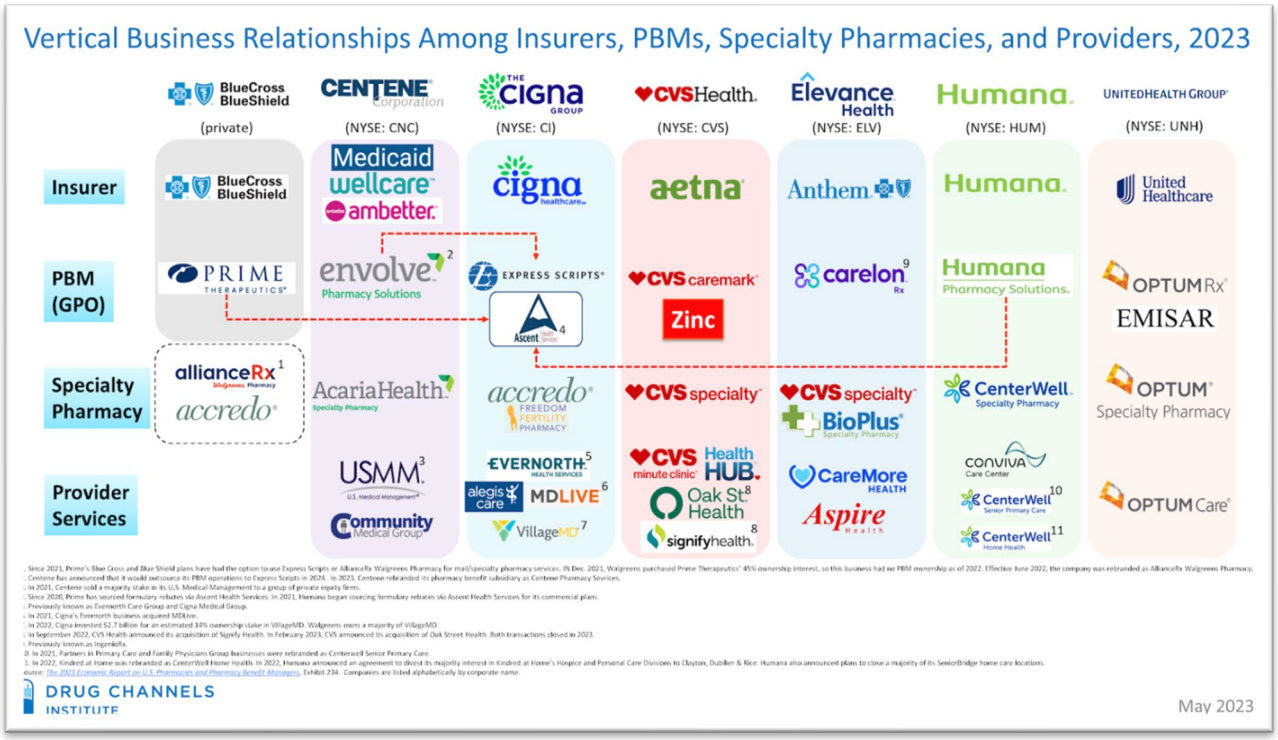
[16] *Supra* note 3.
[17] Nitzan Arad et al., *Realizing the Benefits of Biosimilars: Overcoming Rebate Walls*, DUKE UNIVERSITY MARGOLIS CENTER FOR HEALTH POLICY (March 2022). *See also* Sarah Bhatnagar, *High Drug Prices: Are PBMs the Right Target*, Bipartisan Policy Center (Feb. 02, 2023).
[18] *Id.*
[19] *Supra* note 3. .
[20] *Supra* note 3. *; see also* Press Release, Federal Trade Commission, FTC Launches Inquiry Into Prescription Drug Middlemen Industry (June 7, 2022); *see also* Hannah Rogers, Jennifer Staman, Alexander Pepper, *Pharmacy Benefit Managers: Current Legal Framework*, Congressional Research Service (November 20, 2023).
[21] *Supra* note 3. ; *see also Supra* note 20.
[22] U.S. GOV'T ACCOUNTABILITY OFF., GAO-24-106898, PRESCRIPTION DRUGS: SELECTED STATES' REGULATION OF PHARMACY BENEFIT MANAGERS, 7 (Mar. 2024).
[23] *Id.*
[24] *Id*.
[25] *Pharmacy Benefit Managers*, NAIC *available at* https://content.naic.org/cipr-topics/pharmacy-benefit-managers; *see also* Paige Twenter, *Top PBMs by 2022 market share*, BECKER'S HOSPITAL REVIEW (May 23, 2023)
[26] *Id.*
[27] *Supra* note 20.

Figure 2: Vertical Integration in PBM Markets[28]



III. The Committee's Investigation

In response to mounting concerns over the escalating cost of prescription drugs, then-Ranking Member James Comer initiated an investigation into PBMs on November 17, 2021, with the forum "Reviewing the Role of Pharmacy Benefit Managers in Pharmaceutical Markets."[29] Experts, including pharmacists, physicians, and representatives of PBMs, were able to discuss the role of PBMs in the pharmaceutical market with lawmakers and repeatedly testified to the need for greater transparency in order to determine the full extent of PBMs' tactics and their effects.

In December 2021, the Committee issued a report highlighting initial findings that large PBM consolidation has negatively impacted patient health, increased costs for consumers, forced manufacturers to raise their prices, and created conflicts of interest which distort the market and limit high quality care for patients.[30]

On March 1, 2023, Chairman Comer sent document requests related to formulary design and management, rebates, and fees to CVS Caremark, Express Scripts, Optum Rx, and the three federal agencies that oversee federal health plans: the Centers for Medicare and Medicaid Services (CMS), the Office of Personnel Management (OPM), and the Defense Health Agency

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[28] *Supra* note 2.
[29] Press Release, H. Comm. on Oversight & Accountability, PBM Forum Wrap Up: Greater Transparency, Further Congressional Review Needed to Lower Drug Prices (Nov. 17, 2021).
[30] Staff Report, H. Comm. on Oversight and Reform, *Report: A view from Congress: Role of Pharmacy Benefit Managers in Pharmaceutical Markets*, 117th Cong. (Dec. 10, 2021).

(DHA).[31] Since then, the Committee has received and reviewed more than 140,000 pages of documents. Additionally, the Committee has held two hearings regarding PBMs[32] and marked up and favorably reported H.R. 6283, the Delinking Revenue from Unfair Gouging (DRUG) Act, which would apply to the Federal Employees Health Benefits Act (5 U.S.C. §§ 8901 et seq.).[33]

PBMs' Anticompetitive Behavior

> *"A recent poll by Morning Consult showed that in March 2023…85 percent of Americans are concerned that PBMs are overcharging for prescription medicines and pocketing the difference as profit. In that survey, 88 percent of Democrats and 88 percent of Republicans shared that concern … I think we have a mandate from the American people to investigate.*"[34] **– Rep. Raja Krishnamoorthi (D-Ill.)**

The PBM industry has experienced significant consolidation and vertical integration over the last few decades.[35] In 1995, five PBMs controlled 80 percent of the market; by the 2010s, CVS Caremark, Express Scripts, and Optum Rx dominated 80 percent of the market.[36] CVS Health Corporation, a healthcare company, owns both CVS Caremark, a PBM, CVS Pharmacy, a retail pharmacy chain, and CVS Specialty, a specialty pharmacy. Cigna, a large healthcare company, owns Express Scripts, a PBM, and Express Scripts Pharmacy, a mail-order pharmacy. UnitedHealth Group, another large healthcare company, owns both Optum Rx, a PBM, and an Optum Specialty Pharmacy.

[31] Press Release, H. Comm. on Oversight & Accountability, Comer Launches Investigation into Pharmacy Benefit Managers' Role in Rising Health Care Costs (Mar. 1, 2023).
[32] *The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part I: Self-Interest of Healthcare?*: *Hearing Before H. Comm. on Oversight & Accountability*, 118th Cong. (May 23, 2023); *The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part II: Not What the Doctor Ordered*: *Hearing Before H. Comm. on Oversight & Accountability*, 118th Cong. (Sept. 19, 2023).
[33] Delinking Revenue from Unfair Gouging Act, H.R.6283, 118th Cong. (2023).
[34] *Supra* note 32.
[35] T. Joseph Mattingly II & David Hyman, *Pharmacy Benefit Managers History, Business Practices, Economics, and Policy*, JAMA HEALTH FORUM (Nov. 3, 2023).
[36] Andrew Lautz, *How Pharmacy Benefit Managers Impact Taxpayers and Government Spending*, NATIONAL TAXPAYERS UNION (Jan. 23, 2023).

Figure 3: Vertical Relationships within PBM Markets[37]

[37] *Supra* note 2.

"It is possible to operate a PBM, restrain costs for the employer and taxpayers while still providing the best pharmacy care available. But changes must be made to require greater transparency and allow for greater competition for this to happen."[38] **– Greg Baker, CEO, AffirmedRx**

I. Pharmacy Networks

PBMs administer pharmacy networks, typically comprised of independent community and chain pharmacy providers as well as specialty pharmacies and physician-dispensing facilities associated with medical practices.[39] Establishing these networks is a key function of PBMs, and they utilize this function to "steer" patients to the pharmacies they control.[40] Each of the big three PBMs own their own pharmacies, disincentivizing negotiation, enabling benefitting from higher prices, and hurting their competition by reducing patients' pharmacy choices.[41]

"My wife and I bought the local pharmacy with an SBA loan… What I hoped could be and can be a great opportunity for my community is in peril..." [42] – **Kevin Duane, PharmD, pharmacist and owner of Panama Pharmacy, Jacksonville, Florida**

Anticompetitive practices make it difficult for unaffiliated chain and independent community pharmacies to survive. PBMs reimburse independent and unaffiliated chain pharmacies at low rates and charge retroactive fees.[43] Retroactive fees are often arbitrary and can be levied weeks to months after a prescription is processed.[44] Even though a pharmacy may be in-network, extraneous PBM fees add up, often costing a pharmacy more to fill a prescription than it is reimbursed.[45] Due to the market share of the three largest PBMs, pharmacies are often faced with choosing between accepting fees or not serving patients.

Community and independent pharmacies are struggling to keep up. Dr. Duane testified before the Committee that his pharmacy "cannot negotiate any aspect of [their] contracts with [PBMs] in any meaningful type of fashion."[46] Additionally, Dr. Duane explained:

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[38] *Supra* note 32.
[39] *Supra* note 22.; *see also* Specialty Drug Dispensing for Physician Offices, McKesson, https://www.mckesson.com/specialty/drug-purchasing-and-management/dispensing-services/.
[40] Interim Staff Report, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, U.S. FEDERAL TRADE COMMISSION (July 2024) *available at* https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; *see also Reviewing the Role of Pharmacy Benefit Managers in Pharmaceutical Markets Forum, House Comm. On Oversight and Reform Minority*, 117th Congress. (Nov. 17, 2021).
[41] *Supra* note 2.
[42] Press Release, H. Comm. on Oversight and Accountability, Comer Announces First Hearing on Pharmacy Benefit Managers' Role in Rising Health Care Costs (May 16, 2023).
[43] Stacy Mitchell, *How the FTC Protected the Market Power of Pharmacy Benefit Managers*, ProMarket, (Feb. 19, 2021).
[44] Nat'l Ass'n of Chain Drug Stores, DIR Fees, *available at* https://www.nacds.org/dir-fees/.
[45] *PBM Reform: It's Time for Washington to Protect*, WSPA *available at* https://www.wsparx.org/page/PBM.
[46] *Supra* note 32.

"The outsized role PBMs take in the pharmacy space has caused many problems for our patients and our practice. The three largest PBMs control 80 percent of the market today, which means patients are forced by PBMs into using a certain pharmacy, often one owned and operated by the PBM, or they may be forced to get their drugs through the mail even though they want a pharmacist face-to-face in their community. Patients and their doctors have virtually no say in what drugs are used, since the PBM essentially forces which drugs can be used – not because a drug is better or worse, but because the PBM can make more money from it."[47] **– Kevin Duane, PharmD, pharmacist and owner of Panama Pharmacy, Jacksonville, Florida**

These practices have sometimes violated state law, leading to enforcement actions and legal settlements. In January 2022, CVS Caremark agreed to pay $4.8 million to the Oklahoma Insurance Department for alleged violations of Patient's Right to Pharmacy Choice Act.[48] In March 2023, Ohio Attorney General Dave Yost sued Express Scripts, Prime Therapeutics and five other PBMs for colluding to keep drug prices high and to exclude competing pharmacies from their networks by forcing them to accept drug reimbursement rates "far below what they have to pay for these drugs" and pay "exorbitant 'administrative' fees."[49]

II. Retroactive Fees

"[Independent pharmacies] can be the center of a community. We are more than just providing medication for people… We can help on things that they can't get into right away with their physicians. [Rising PBM fees are] huge. Indescribable amount of chaos. We cannot adequately plan because of the amount of money that is taken back are" [50] **– Kevin Duane, PharmD, pharmacist and owner of Panama Pharmacy, Jacksonville, Florida**

Direct and Indirect Remuneration (DIR) fees are retroactively levied on pharmacies for prescriptions purchased under Medicare Part D benefits. DIR fees were intended in Medicare Part D to ensure accurate reporting and payment for the actual cost of a drug and avoid over-reimbursement by the government.[51] Instead, DIR fees are an avenue for PBMs and plan sponsors to claw back or charge back pharmacies after a reimbursement claim has been

[47] *Supra* note 32.
[48] Oklahoma Ins. Dep't, Press Release, *OID Reaches $4.8 Million Settlement Agreement with CVS Caremark for Alleged Violations of the Patient's Right to Pharmacy Choice Act, Dependent on Federal Court Decision* (Jan. 20, 2022).
[49] News Release, Ohio Attorney General, Yost Sues Express Scripts, Prime Therapeutics and 5 Others, Blaming Exorbitant Drug Prices on Their Collusion (Mar. 27, 2023).
[50] *Supra* note 32.
[51] DIR Fees, Frier Levitt Attorneys at Law, *available at* https://www.frierlevitt.com/what-we-do/pharmacy-law/dir-fees/#:~:text=PBMs%20typically%20utilize%20DIR%20fees,adjustments%2C%E2%80%9D%20or%20similar%20names

submitted.[52] Retroactive fees are being manipulated by PBMs to increase profits and introduce vast uncertainty for pharmacies that are hit with unpredictable fees that result in negative reimbursement rates.[53]

Figure 4: Illustration of DIR Fees' Impact on Pharmacy Business Operations[54]

One way that PBMs penalize competing independent and specialty pharmacies is by basing DIR fees on opaque performance ratings, which are based on retail medication therapy management and chronic disease management.[55] For example, PBM rating systems grant higher performance ratings to pharmacies that frequently dispense generics and "maintenance medications" for chronic conditions such as hypertension or diabetes.[56] As such, specialty pharmacies, like in-house oncology clinics, receive low performance ratings and therefore higher DIR fees.[57] In July 2022, Aids Healthcare Foundation (AHF) sued Express Scripts alleging they manipulated Medicare star ratings to ensure pharmacies get unfairly low scores, allowing

[52] Pharmacy Direct and Indirect Renumeration (DIR) Fees: Recommendations for Reforms to Benefit Patients, Pharmacists, and Government, McKesson, *available at* https://www.mckesson.com/globalassets/mckesson/documents/about-mckesson/public-affairs/reining-in-pharmacy-dir-fees
[53] *Supra* note 51.
[54] *Supra* note 52.
[55] True North Political Solutions, *White Paper: DIR Fees Simply Explained*, PHARMACY TIMES (Oct. 25, 2017).
[56] *Id.*
[57] *Id.*

Express Scripts to "claw back" Medicare benefits from pharmacies. According to AHF, Express Scripts was engaged in 14 different violations across nine states.[58]

> "*According to the government, these [Direct and Indirect Remuneration (DIR)] fees increased by 107,400 percent from 2010 to 2020. This is a travesty. You know what PBM really stands for? It stands for Pretty Big Markups. We've got to stop this."* **– Rep. Raja Krishnamoorthi (D-Ill.)**

In 2017, CMS released a fact sheet about the rise in DIR fees reported in recent years and its impact on net drug costs.[59] According to CMS, higher DIR fees lead to higher out-of-pocket spending.[60] DIR fees do not translate to cost-savings for Medicare beneficiaries, as they are not reflected in the negotiated price that determines patient cost-sharing.[61] Similarly, DIR fees do not save taxpayers money since CMS is reimbursing the drug's negotiated price, rather than the price after DIR fees are applied.[62] Additionally, higher out-of-pocket drug costs increase Medicare plan liability as beneficiaries spend more towards their plan's out-of-pocket maximum.[63] After out-of-pocket spending reaches a certain point ($8,000 in 2024), beneficiaries enter the catastrophic coverage phase.[64] Once a beneficiary falls under catastrophic coverage, Medicare is responsible for all covered drugs for the remainder of that year.[65]

On May 3, 2023, CMS provided guidance for Medicare Part D sponsors on reporting DIR data for contract year 2022.[66] In the guidance, CMS highlighted concerns that risk-sharing payments and adjustments, including all rebates, subsidies, and post-payment incentives, related to supplemental coverage of Part D drugs were not being reported as DIR.[67] It is important that DIR data be reported to CMS accurately, as it determines payment reconciliation for costs incurred by Part D sponsors for Part D drugs, net DIR fees.[68] Under the new guidance, CMS defines DIR broadly as "discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-priced services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal action, and other price concessions or similar benefits."[69] The 2024 DIR reporting guidance for contract year 2023 contained no substantive changes from the previous year's guidance.[70]

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[58] Paige Minemyer, *AIDS Healthcare Foundation Sues Express Scripts over Medicare 'Clawbacks'*, FIERCE HEALTHCARE (Jul. 14, 2022).
[59] Fact sheet, Ctrs. for Medicare & Medicaid Servs., Medicare Part D – Direct and Indirect Remuneration (DIR) (Jan. 19, 2017).
[60] *Id.*
[61] *Id.*); *see also* U. S GOV'T ACCOUNTABILITY OFF., GAO-23-105270, MEDICARE PART D: CMS SHOULD MONITOR EFFECTS OF REBATES ON PLAN FORMULARIES AND BENEFICIARY SPENDING (Sept. 5, 2023).
[62] *Supra* note 59.
[63] *Id.*
[64] *Id.*
[65] *Id.*
[66] Ctrs. for Medicare & Medicaid Servs., Final Medicare Part D DIR Reporting Guidance for 2022 (May 3, 2023).
[67] *Id.*
[68] *Id.*
[69] *Supra* note 66.
[70] *Id.*

In 2022, CMS promulgated a final rule impacting pharmacy price concessions for Medicare Advantage (Part C) and Medicare Prescription Drug Benefit (Part D) effective January 1, 2024.[71] The final rule mandates that all price concessions (including DIR fees) be included in the "negotiated" final price that is paid by patients at the pharmacy counter, rather than being retroactively charged.[72] The rule was intended to provide greater transparency for patients and pharmacies and "lower total beneficiary out-of-pocket costs," according to CMS.[73] However, instead of benefiting pharmacies and patients, the rule has resulted in PBMs withholding pharmacy reimbursement and reducing reimbursement rates below the cost of the medication.[74] The reduced reimbursement is understood to be in response to the PBMs' inability to collect retroactive DIR fees.[75] While the implementation of the rule is still ongoing, the initial impacts indicate that PBMs are simply moving towards replacing DIR fees with reduced reimbursements for competitor pharmacies and not reducing the price of drugs at the pharmacy counter.[76]

While CMS' DIR reporting guidance and final rule were a step towards eliminating unpredictable retroactive fees, these actions do not remove unfair fees entirely, nor increase transparency into PBM fee policies. Rather, DIR fees are instead applied to the point-of-sale price paid by Medicare beneficiaries rather than being assessed on the pharmacy weeks or months after a prescription is filled.[77] As a result, Medicare beneficiaries' out-of-pocket costs increase, and pharmacies are underwater on the cost of dispensing certain drugs. The Department of Health and Human Services (HHS) Inspector General (IG) is currently auditing CMS to determine if Part D sponsors are submitting accurate DIR reporting data to Medicare.[78]

III. Steering Patients to Pharmacies owned by PBMs

> "*PBMs use a variety of methods to steer patients away from unaffiliated pharmacies. They create differential cost-sharing structures and arbitrary lists, such as specialty and aberrant drug lists, among other schemes, to limit independent pharmacies' access to patients."*[79] **– Hugh Chancy, RPh, Owner, Chancy Drugs Pharmacy, Georgia**

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[71] Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 87 Fed. Reg. 27,704 (May 9, 2022) (42 C. F. R. § 417, 422, 423).
[72] *Id.*
[73] Maia Anderson, *'This is an Emergency': Trade Group Warns Nearly a Third of all Independent Pharmacies Will Go Extinct Because of a CMS Rule*, FORTUNEWELL (Mar. 30, 2024).
[74] *Report for February 2024 Survey of Independent Pharmacy Owners/*Managers, NCPA, *available at* https://ncpa.org/sites/default/files/2024-02/Feb2024-DIRsurvey.Exec%20Summary.pdf
[75] Letter from Community Oncology Alliance to Hon. Chiquita Brooks-LaSure, Adm'r, Ctrs. for Medicare & Medicaid Servs. (Feb. 21, 2024), *available at* https://assets.mycoa.io/1709818057048_COA_CMS_Letter_ESI-UnreasonableREimbursementTerms_FINAL_Redacted_Sanitized.pdf
[76] *Id.*
[77] *Supra* note 66.
[78] U.S. Dep't of Health & Human Servs. Off. of Inspector Gen., Workplan, Part D Sponsors Reporting of Direct and Indirect Renumerations, *available at* https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000249.asp.
[79] *Supra* note 32.

PBMs limit patients' abilities to choose their pharmacies. The three largest PBMs each own retail, mail-order, and specialty pharmacies that are "preferred" in-network under the pharmacy benefit.[80] PBMs steer patients to pharmacies they own by various means, including: (1) preventing patients from receiving 90-day prescriptions at competing pharmacies; (2) abusing data received by the PBM to target patients with highly profitable medications; (3) only covering specialty medications if they are dispensed from a particular pharmacy; and (4) charging patients higher copays at competing pharmacies to incentivize patients to use the PBM owned pharmacy.[81] Anticompetitive behavior harms patients and independent community pharmacies, increasing drug prices for patients, employers, and government payers.[82]

PBM efforts to steer patients have resulted in significant recent litigation including in April 2022, the Minnesota Department of Commerce initiated an enforcement action against CVS Caremark for violations of the Pharmacy Benefit Manager Act, seeking to fine the company $1.25 million. The Department alleged CVS Caremark violated state laws protecting patient choice by requiring patients to fill maintenance medications at CVS retail pharmacies or Caremark-owned mail-order pharmacies.[83] The State of Oklahoma is in active litigation against the Pharmaceutical Care Management Association (PCMA), the trade association for PBMs, attempting to uphold the state's ability to prevent PBMs from, amongst other things, steering patients to PBM-affiliated pharmacies over competing pharmacies.[84] The case is presently being appealed to the Supreme Court. A bipartisan group of 32 Attorneys General have filed an amicus brief urging the Supreme Court to take up the case and overrule the Tenth Circuit's decision that states are unable to regulate PBMs.[85]

According to the Pharmacists Society of the State of New York, PBMs use various tactics, most of which they contractually prohibit competing pharmacies from doing, to entice patients to use PBM-owned pharmacies for long-term maintenance prescriptions.[86] At their mail-order pharmacies, PBMs will offer patients a 90-day prescription for the price of 60 days while prohibiting a local community pharmacy from offering patients the same price.[87] The Committee's investigation found examples of outreach to patients in which the PBM will claim to save the patient 29 percent against the local pharmacy, even though that competing pharmacy's copays are set by the PBM.[88]

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[80] Press Release, Fed. Trade Comm'n, FTC Deepens Inquiry into Prescription Drug Middlemen (May 17, 2023).
[81] *Supra note 32*.; *see also Supra* note 30.; *see also Supra* note 42.
[82] Letter from B. Douglas Hoey, CEO, Nat'l Community Pharmacists Ass'n, to Hon. Lina Khan, Chair, Fed. Trad Comm'n (May 23, 2022).
[83] *State moves to fine CVS/Caremark for patient protection law violations*, NAT'L CMTY PHARMACISTS ASS'N (Apr. 29, 2022).
[84] Press Release, The Office of Minnesota Attorney General, Attorney General Ellison Leads Effort Asking Supreme Court to rule on States' Authority to Regulate Pharmacy Benefit Managers (June 10, 2024).
[85] Brief on Petition for a Writ of Certiorari to the U.S. Ct. of App. for the Tenth Cir., et al. as Amici Curiae Supporting Petitioners, *Pharm. Care Mgmt. Ass'n v. Mulready*, 78 F.4th 1183 (10th Cir. 2023). *available at* https://ncdoj.gov/wp-content/uploads/2024/06/Mulready-v.-PCMA-Amicus-Brief-Certiorari.pdf
[86] *PBM Basics*, Pharmacists Society of the State of New York, Inc., *available at* https://www.pssny.org/page/PBMBasics.
[87] *Id.*
[88] Express Scripts Fifth Production, ESI00012629 (Oct. 27, 2023) (on file with Comm.).

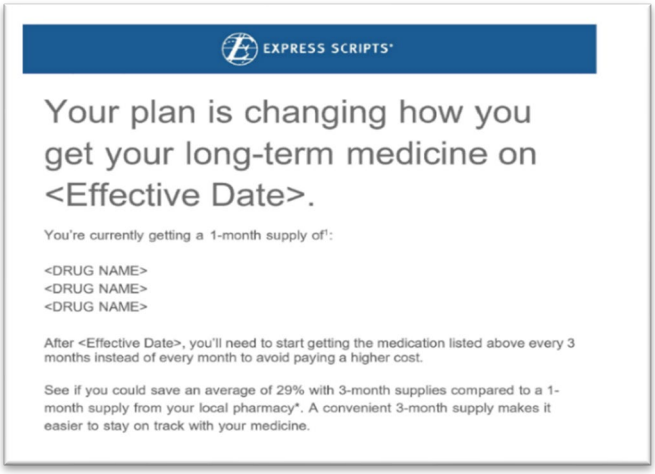
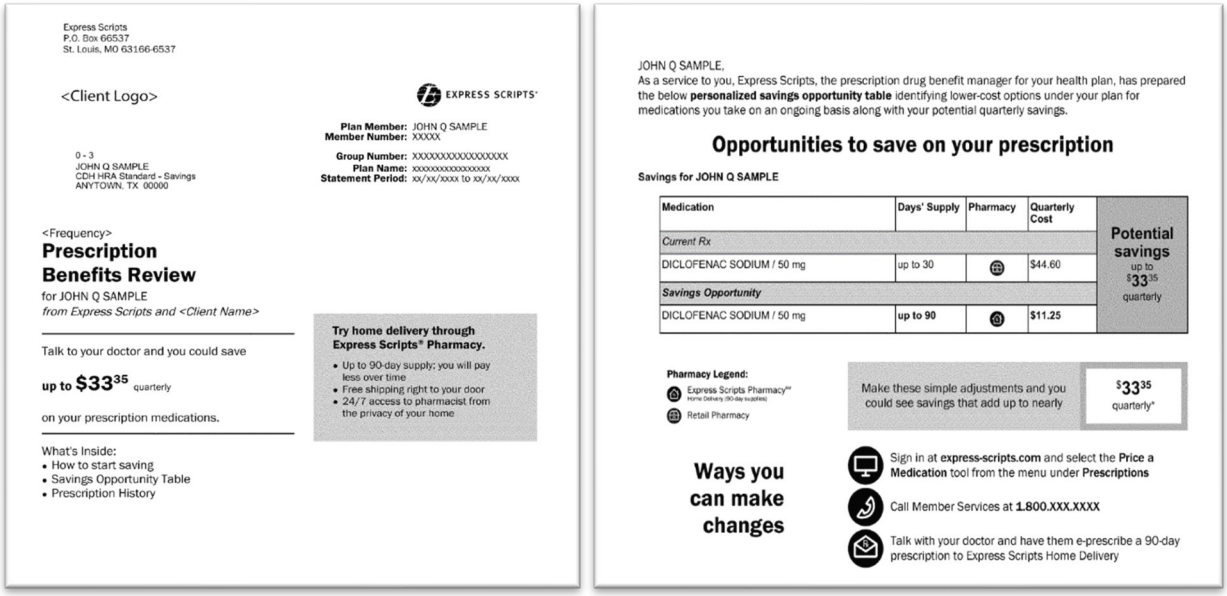


Figure 5: Express Scripts patient outreach for 90-day prescription[89]

Further, the Committee found examples of outreach templates that PBMs use to incentivize patients to use PBM-owned pharmacies. Below is an example of a letter that would go out to a patient urging them to move their prescription to Express Scripts' mail-order pharmacy by providing patients the ability to save money and get more of the medication at once.[90] While this is made to appear to benefit the patient, what it is instead doing in practice is limiting a patient's ability to choose their own pharmacy. Express Scripts can allow a competing brick-and-mortar pharmacy to offer the medication for the same or a lower price and 90-days instead of 30-days, and simply let the patient choose which pharmacy they want to use based on higher quality care or ease of use. But Express Scripts does not do so. Instead, they use their position as middlemen to shift long-term maintenance prescriptions to the pharmacies they own.

[89] *Id.*
[90] Express Scripts Fifth Production, ESI00012638-ESI00012645 (Oct. 27, 2023) (on file with Comm.).

Figure 6: Express Scripts directing patient to Express Scripts Pharmacy[91]

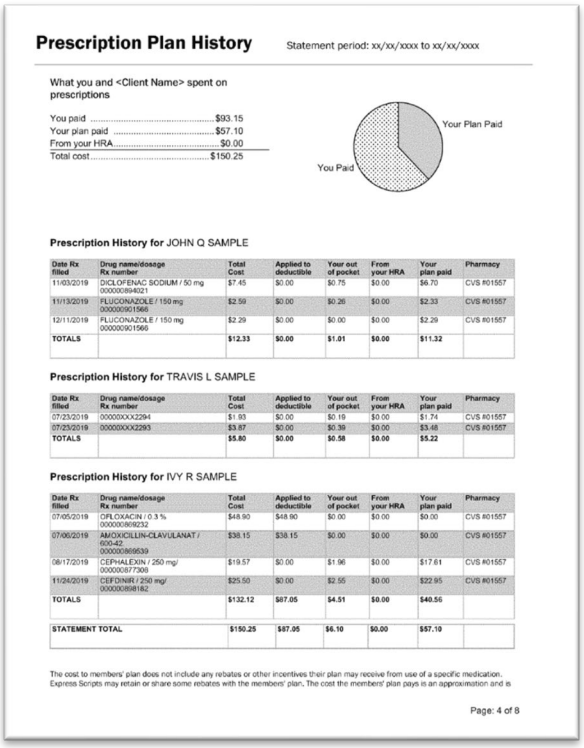


PBMs not only steer patients to mail-order pharmacies for long-term maintenance drugs but they also specifically target patients with higher cost medications. A recent review commissioned by the Washington State Pharmacy Association found that filling prescriptions through mail-order pharmacies in the State of Washington cost payers and patients more, despite being touted as a savings benefit.[92] This analysis found that in Washington, generic prescriptions filled by mail-order cost more than three times higher and branded drugs three to six times higher than if they were filled at traditional pharmacies.[93] Alarmingly, branded mail order drugs cost roughly 35 times higher than those filled by independent pharmacies.[94] An audit of Florida's Medicaid managed care program found that PBM anticompetitive practices that guide patients toward PBM-owned pharmacies charged higher prices on specialty drugs than if they were filled at a competing pharmacy.[95]

Below is another example from Express Scripts illustrating just a small portion of the data the three large PBMs have access to for any patient who uses them to manage their pharmacy benefit:

[91] *Id.*
[92] Jared S. Hopkins, *Mail-order drugs were supposed to keep costs down. It's doing the opposite*., WALL ST. J. (Jun. 25, 2024).
[93] *Id.*
[94] *Id.*
[95] 3 Axis Advisors, *Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis*, 126 (Jan. 27, 2020).

Figure 7: Express Scripts utilizing patient data to urge the patient to stop using competing pharmacy[96]



Prescription Plan History Statement period: xx/xx/xxxx to xx/xx/xxxx

What you and <Client Name> spent on prescriptions

You paid $93.15
Your plan paid $57.10
From your HRA $0.00
Total cost $150.25

Prescription History for JOHN Q SAMPLE

Date Rx filled	Drug name/dosage Rx number	Total Cost	Applied to deductible	Your out of pocket	From your HRA	Your plan paid	Pharmacy
11/03/2019	DICLOFENAC SODIUM / 50 mg 00000894021	$7.45	$0.00	$0.75	$0.00	$6.70	CVS #01557
11/13/2019	FLUCONAZOLE / 150 mg 00000901566	$2.59	$0.00	$0.26	$0.00	$2.33	CVS #01557
12/11/2019	FLUCONAZOLE / 150 mg 00000901566	$2.29	$0.00	$0.00	$0.00	$2.29	CVS #01557
TOTALS		**$12.33**	**$0.00**	**$1.01**	**$0.00**	**$11.32**	

Prescription History for TRAVIS L SAMPLE

Date Rx filled	Drug name/dosage Rx number	Total Cost	Applied to deductible	Your out of pocket	From your HRA	Your plan paid	Pharmacy
07/23/2019	00000XXX2294	$1.93	$0.00	$0.19	$0.00	$1.74	CVS #01557
07/23/2019	00000XXX2293	$3.87	$0.00	$0.39	$0.00	$3.48	CVS #01557
TOTALS		**$5.80**	**$0.00**	**$0.58**	**$0.00**	**$5.22**	

Prescription History for IVY R SAMPLE

Date Rx filled	Drug name/dosage Rx number	Total Cost	Applied to deductible	Your out of pocket	From your HRA	Your plan paid	Pharmacy
07/05/2019	OFLOXACIN / 0.3 % 00000809232	$48.90	$48.90	$0.00	$0.00	$0.00	CVS #01557
07/06/2019	AMOXICILLIN-CLAVULANAT / 600-42 00000869639	$38.15	$38.15	$0.00	$0.00	$0.00	CVS #01557
08/17/2019	CEPHALEXIN / 250 mg/ 00000877306	$19.57	$0.00	$1.96	$0.00	$17.61	CVS #01557
11/24/2019	CEFDINIR / 250 mg/ 00000898182	$25.50	$0.00	$2.55	$0.00	$22.95	CVS #01557
TOTALS		**$132.12**	**$87.05**	**$4.51**	**$0.00**	**$40.56**	
STATEMENT TOTAL		**$150.25**	**$87.05**	**$6.10**	**$0.00**	**$57.10**	

The cost to members' plan does not include any rebates or other incentives their plan may receive from use of a specific medication. Express Scripts may retain or share some rebates with the members' plan. The cost the members' plan pays is an approximation and is

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Express Scripts not only has the name of a prescription a patient uses but also identifies the costs, which they determine, to the patient. This enables the PBM to undercut the competing pharmacy for maintenance medications or push patients with high-cost medications to the PBM owned pharmacy.

Specialty medications are generally used to treat rare and complex health problems and often require specialized storage and dispensing that is closely supervised by a provider. However, there is no widely accepted definition of a specialty medication. OptumRx policy documents reviewed by the Committee state that specialty pharmacies are necessary for highly complex medications.[97] According to testimony, PBMs "create differential cost-sharing structures and arbitrary lists, such as specialty and aberrant drug lists," to shift certain, generally highly profitable, medications to PBM owned pharmacies.[98]

Further, documents and testimony indicate that PBMs only view the specialty pharmacies they own as necessary for treating patients. When a non-PBM affiliated specialty pharmacy can fill a specialty prescription, PBM coverage tactics shift patients to their affiliated specialty pharmacies, even when it delays or interrupts patient care.[99] In oncology and rheumatology treatment, it is common for providers to prescribe high-cost intravenous drugs that are

[96] *Supra* note 90.
[97] Optum Rx Second Production, ORX-COA-00005477 (May 3, 2023) (on file with Comm.).
[98] *Supra* note 32.
[99] Joyce Frieden, *PBM specialty pharmacy requirement hurting patients, specialists say*, MEDPAGE TODAY (Aug. 23, 2022).

administered under the provider's supervision. In some instances, PBM specialty pharmacy requirements have forced providers to delay treatments by requiring a prescription to be sent to the PBM's specialty pharmacy first before it can be shipped to the provider clinic to be administered.[100] This can result in delays of weeks or more. These delays, combined with the limited formulary mandates, effectively decide which therapy is best for a sick patient and removes decision-making authority from both providers and patients. Medical providers, not PBMs, know what treatments are best for their patients and the best venue in which to receive them.

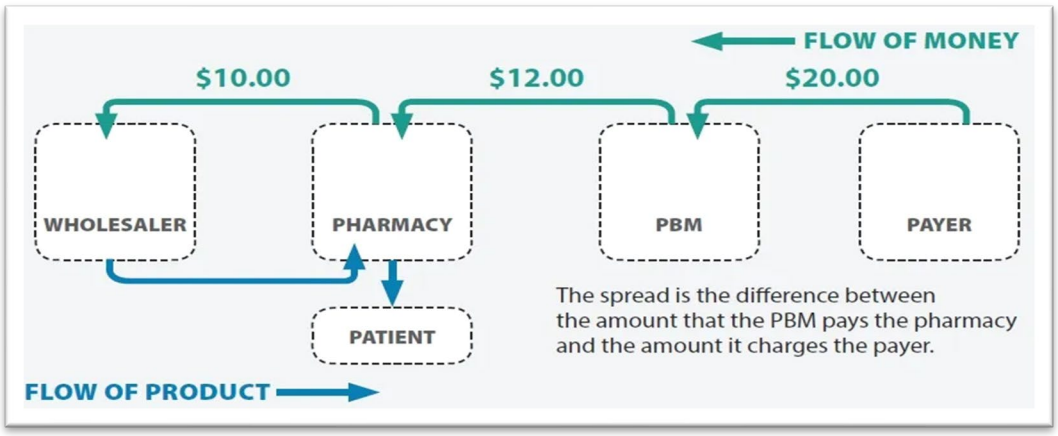
Spread Pricing

> ***Rep. LaTurner:*** *"We have seen examples of PBMs engaging in spread pricing. Where the PBM charges more than what they reimburse the pharmacy and then pocket the difference. In my home of Kansas, accusations of this practice were recently settled for $26.7 million dollars… Do you believe that additional transparency in the price setting of drugs important?"*
>
> ***Mr. JC Scott, CEO, Pharmaceutical Care Management Association:*** *"Yes transparency can be helpful."*[101]

PBMs regularly engage in spread pricing, a practice where the PBM charges payers more than what the PBM reimburses the pharmacy, and the PBM pockets the difference, or "spread."[102] Spread pricing is a common way that PBMs earn revenue.[103] In Figure 8 below, the PBM charges the payer $20 for a prescription but only pays $12 to the pharmacy. The PBM keeps the $8 spread as profit, and often does not disclose the spread to the payer or pharmacy.[104]

[100] *Id.*
[101] *Supra* note 32.
[102] Spread Pricing 101, National Community Pharmacists Association *available at* https://ncpa.org/spread-pricing-101 (last accessed Sept. 1, 2023)
[103] Supra note 36.
[104] Todd Mizeski and Conor R. McCabe, *Proposed Congressional Bill Seeks to Ban Spread Pricing in State Medicaid Plans*, FRIER LEVITT (April 12, 2023).

Figure 8: Spread Pricing Instituted by PBMs[105]



I. Medicaid and Private Health Insurance

> *"Another harmful, anticompetitive tactic employed by PBMs is spread pricing, which refers to the difference between how much a PBM reimburses the pharmacy for a drug and the higher price they turn around and charge the plan for the same prescription. For years, community pharmacists have said that PBMs have been playing spread pricing games, contributing to higher drug costs to the detriment of patients and the taxpayer-funded programs the PBMs are supposed to serve."*[106] – **Hugh Chancy, RPh, Owner, Chancy Drugs Pharmacy, Georgia**

In spread pricing schemes, the payer can include private health insurance plans or, in the case of Medicaid, the government.[107] Most state Medicaid programs function as managed care programs which pay a monthly rate per enrolled member to contracted managed care organizations (MCOs).[108] The MCOs then reimburse the provider for health services under the terms of a Medicaid contract.[109] MCOs often contract with PBMs to manage prescription drug

[105] Ed Silverman, *Spread Pricing: From Largely Unknown to Much Scrutinized and Criticized*, MANAGED CARE (Sept. 2019) *available at* https://lsc-pagepro.mydigitalpublication.com/publication/?i=613323&article_id=3460622&view=articleBrowser.
[106] *Supra* note 32.
[107] *Supra* note 102.
[108] Hannah Maniates, *Why did they do it that way? Understanding Managed Care*, Nat'l Assoc. of Medical Dirs. (Jan. 22, 2024).
[109] *Id.*

benefits.[110] Spread pricing occurs when "a PBM charges an MCO more for a drug than the amount a PBM pays a pharmacy," and the PBM pockets the difference.[111]

PBMs frequently tout the savings they provide for payers and patients through negotiation, drug utilization programs, and drug discounts. However, there are numerous instances where state auditors have found significant spread pricing schemes that increase costs for payers and patients.[112] Multiple states have subsequently audited their Medicaid programs due to concerns about spread pricing amid high Medicaid drug costs.[113] In 2018, the Ohio Attorney General found that Centene Corp., while managing Ohio's Department of Medicaid prescription drug program, engaged in spread pricing and cost the state program nearly $225 million.[114] Ohio brought a lawsuit against Centene, who ultimately agreed to pay $88.3 million to the state.[115] Since that lawsuit, Centene has paid nearly $1 billion in 18 states over spread pricing schemes.[116] Centene had long contracted with CVS Caremark as its PBM and recently moved to Express Scripts.[117] In another audit, the HHS IG found that PBMs in the District of Columbia improperly kept $23.3 million in spread pricing from 2016-2019.[118] In November 2022, Express Scripts agreed to pay $3.2 million to settle claims that they overcharged Massachusetts' workers' compensation insurance system for prescription drugs.[119]

Due to its cost to taxpayers, several states have taken steps to prohibit spread pricing in Medicaid managed care programs and congressional lawmakers have introduced multiple bills that would prohibit spread pricing.[120] The Congressional Budget Office (CBO) estimates that eliminating spread pricing in Medicaid managed care organizations, as outlined in the Lower

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[110] *Medicaid MCO PBM Pricing,* U.S. Dep't of Health and Human Services OIG a*vailable at* https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000434.asp#:~:text=Managed%20care%20organizations%20(MCOs)%20contract,drug%20benefits%20on%20their%20behalf

[111] Catherine Candisky, *State Report: Pharmacy Middlemen Reap Millions from Tax-funded Medicaid*, THE COLUMBUS DISPATCH (2018) *available at* https://stories.usatodaynetwork.com/sideeffects/state-report-pharmacy-middlemen-reap-millions-from-tax-funded-medicaid/; s*ee also* *Supra* note 110.

[112] Eric Pachman & Antonio Ciaccia, *The cancerous design of the U.S. drug pricing system*, 46Brooklyn (Jul. 2018); *see also* U. S. DEP'T OF HEALTH & HUMAN SERVS. OFF. OF INSPECTOR GEN., THE DISTRICT OF COLUMBIA HAS TAKEN SIGNIFICANT STEPS TO ENSURE ACCOUNTABILITY OVER AMOUNTS MANAGED CARE ORGANIZATIONS PAID TO PHARMACY BENEFIT MANAGERS, A-03-20-00200 (Mar. 16, 2023).

[113] U.S. DEP'T. OF HEALTH & HUMAN SERVICES OFF. OF INSPECTOR GEN., A-03-20-00200, THE DISTRICT OF COLUMBIA HAS TAKEN SIGNIFICANT STEPS TO ENSURE ACCOUNTABILITY OVER AMOUNTS MANAGED CARE ORGANIZATIONS PAID TO PHARMACY BENEFIT MANAGERS (March 2023).

[114] News Release, Ohio Attorney General's Office, Centene Agrees to Pay a Record $88.3 Million to Settle Ohio PBM Case Brought by AG Yost (June 14, 2021); *see also* Supra note 36.

[115] *Id.*

[116] James Drew, *Centene PBM Settlement with South Carolina raises total payout to $964.8M*, ST. LOUIS BUS. J. (Jan. 4, 2024).

[117] Raghav Mahobe & Leroy Leo, *Centene to Cut Costs with New Pharmacy Benefit Manager, Shares Jump*, Reuters (Oct. 25, 2022).

[118] *Supra* note 113.

[119] Brendan Pierson, *Express Scripts to Pay $3.2 Mln to Settle Massachusetts Overcharge Claims*, REUTERS (Nov. 7, 2022).

[120] Erin Slifer and Alyssa Llamas, *Bipartisan Congressional Support for PBM Reform Grows*, THE COMMONWEALTH FUND (June 21, 2023).

Costs, More Transparency Act of 2023,[121] would reduce federal spending by $1.1 billion over ten years.[122]

II. Impacts on Pharmacies

Problems with spread pricing also manifest in pharmacy networks where PBMs can require patients to use PBM-owned or affiliated "preferred" pharmacies with more favorable reimbursement contracts.[123] Due to PBMs' role as middlemen reimbursing competing pharmacies for dispensing drugs, PBMs can reimburse pharmacies they own more than they reimburse competing pharmacies, such as community and independent pharmacies.[124] In a healthy market this would typically result in the competing pharmacies simply contracting with other PBMs, they are unable to do so because of the consolidation.[125] Therefore, community and independent pharmacies are left with no choice but to contract with PBMs, otherwise, they could not serve their customers and remain in business.[126] The contracts between PBMs and independent and community pharmacies are opaque and often designed to hurt a competing pharmacy's business, sometimes leading to business closure.[127]

Express Scripts' contracts beginning in 2024 instituted indefinite reimbursement rates for Medicare Part D participants, meaning that there is no contractual guarantee for consistent reimbursements for a drug.[128] For example, Express Scripts' average reimbursement on branded specialty drugs for cancer treatments to independent community oncologists is less than the cost of acquiring the drug, by an average of between 22 and 26 percent less than average wholesale price.[129] As a result, pharmacies are absorbing up to 11.5 percent of a drug's cost to dispense high-cost, life-saving treatment to patients.[130] Independent pharmacies are taking a loss to dispense medications to save patient's lives. They have no way to know what the reimbursement rates will be on a given day for a given medication, and they have no accountability measures to determine if their reimbursement rates are the same as competing pharmacies or pharmacies owned by the PBMs. Neither these pharmacies, nor their patients, know what the PBM is charging their clients on these medications.

Between 2010 and 2018, roughly 6 percent of independent pharmacies closed in the United States.[131] Furthermore, the Rural Policy Research Institute "found that reimbursements [to pharmacies] under the cost of [a drug's] acquisition led to the closure of 1,231 independent pharmacies in rural areas between 2003 and 2018. As a result, 630 rural communities

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[121] H.R.5378 - 118th Congress (2023-2024): Lower Costs, More Transparency Act (2023).
[122] CONG. BUDGET OFF., ANSWERS TO QUESTIONS FOR THE RECORD FOLLOWING A HEARING ON HEALTH CARE SPENDING (Mar. 22, 2024), *available at* https://www.cbo.gov/publication/60133.
[123] Supra note 80; *see also* *Supra* note 86; PBM Abuses, Nat'l Cmty. Pharmacists Ass'n, *available at* https://ncpa.org/sites/default/files/2020-12/pbm-business-practices-one-pagers.pdf.
[124] *Supra* note 86.
[125] *Id.*
[126] *Id.*
[127] Arthur Allen, *What to know about the drug price fight in those TV ads*, NPR (July 7, 2023).
[128] *Supra* note 75.
[129] Express Scripts as Primary Plan Name – 2024, Average Script – Branded Specialty Drugs (Documents on file with the Comm.).
[130] *Id.*
[131] *Supra* note 123.

nationwide that had at least one retail pharmacy in 2003 had zero retail pharmacies in 2018."[132] In urban areas, 1 in 8 pharmacies closed between 2009 and 2015 due to "lower-than-cost reimbursements in the Medicaid and Medicare programs, disproportionately affecting independent pharmacies and low-income neighborhoods."[133] When independent pharmacies close, patients are forced to travel further or pay more to receive their medications.

Rebates and Fees

> "*When PBMs pursue varying rebate agreements with plan sponsors, coverage of generics is delayed and patients suffer as a result. These delays in coverage restrict patient access to lower-cost generics and expose patients to unnecessarily high cost-sharing, even though lower-cost alternatives are available*."[134] – Craig Burton, Executive Director, Biosimilars Council

Drug rebates are partial refunds, or "after-the-fact payments, usually calculated as a percentage of a drug's list price" paid by the drug manufacturers to PBMs.[135] CVS Caremark reports on its formularies that it "may receive rebates, discounts, and service fees from pharmaceutical manufacturers for certain listed products."[136] Rebates for prescription medications were first provided safe harbor in 1987 when Congress amended the Anti-Kickback Statute and directed the Secretary of HHS to immunize certain practices from prosecution and create guardrails to prevent abuse.[137] Thereafter, the Secretary of HHS delegated this authority to the HHS IG, who promulgated rules delineating the safe harbors and appropriate guardrails.[138] After significant litigation and confusion in the 1990s, the HHS IG revised the rule to what it remains today.[139] The system these regulations have created allow retrospective rebates to be conditioned on a PBM manipulating the market to shift market share to one medication over another, even if those medications are less expensive.[140] PBMs have argued that these rebates are vital to driving down the cost of prescription drugs,[141] however spending on prescription drugs has increased nearly every year since.[142]

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[132] *Id.*
[133] *Id.*
[134] *Supra* note 32.
[135] *Supra* note 17.
[136] *See e.g.*, CVS Caremark First Production, CCM00000023 (March 31, 2023) (on file with Comm.).
[137] Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. 100-93, 101 Stat. 680 (1987).
[138] 57 FR 3330, Federal Register, *available at* https://www.federalregister.gov/citation/57-FR-3330.
[139] 42 C.F.R. 1001.952(h)(4), Code of Federal Regulations (July 09, 2024), *available at* https://www.ecfr.gov/current/title-42/chapter-V/subchapter-B/part-1001/subpart-C/section-1001.952
[140] Thomas R. Barker & Ross Margulies, *The History of Rebates in the Drug Supply Chain and HHS' Proposed Rule to Change Safe Harbor Protection for Manufacturer Rebates*, Foley Hoag LLP (Apr. 2019).
[141] *Prescription Drug Rebates*, PCMA *available at* https://www.pcmanet.org/prescription-drug-rebates.
[142] *Prescription Drug Expenditure in the United States From 1960 to 2022,* Statista, *available at* https://www.statista.com/statistics/184914/prescription-drug-expenditures-in-the-us-since-1960

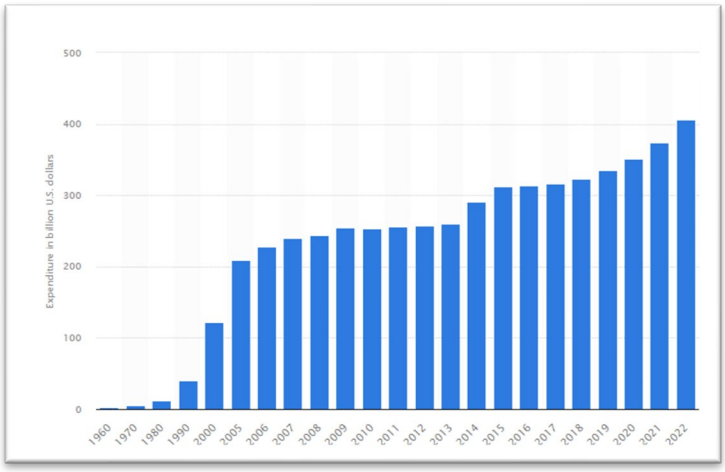

Figure 9: Prescription Drug Expenditure in the United States from 1960-2022[143]

The largest PBMs have significantly more leverage when negotiating rebates compared to smaller PBMs and should be able to command higher rebates.[144] PBM rebate retention rates vary by company and contract. The result should be greater savings for patients who receive benefits from these PBMs. However, this does not appear to be the case. The image below shows how much it costs to purchase a 30-day supply of a generic chemotherapy drug, Imatinib, from Cost Plus Drugs versus CVS. Purchasing this drug from Cost Plus Drugs instead of CVS saves a patient or health insurance company hundreds of thousands of dollars each year.

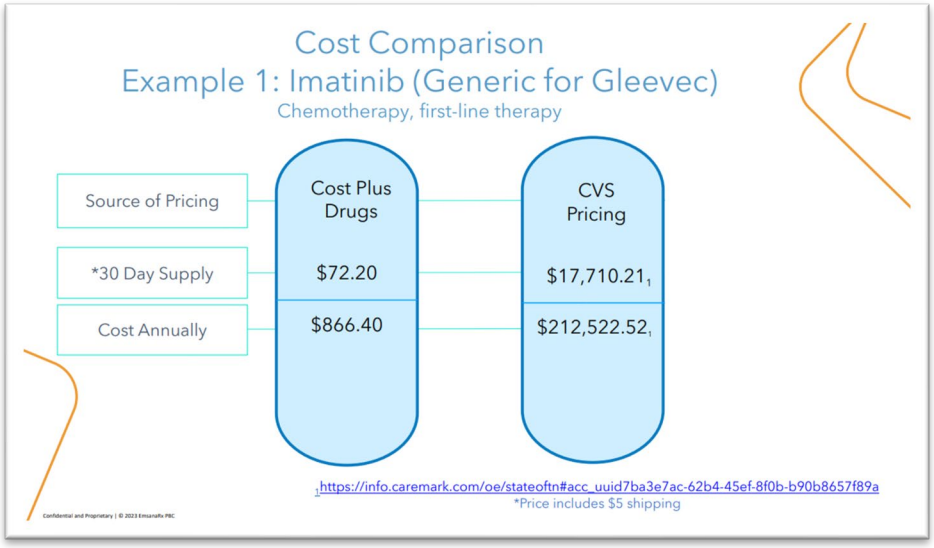

Figure 10: Cost Comparison between Cost Plus Drugs and CVS Pricing for Imatinib[145]

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[143] *Id.*

[144] S. FIN. COMM., STAFF REPORT, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (Jan. 14, 2021).

[145] Greg Baker, *Written Testimony: Role That Pharmacy Benefit Managers (PBMs) Play in the Pharmaceutical Market* (May 23, 2023) *available at* https://oversight.house.gov/wp-content/uploads/2023/05/AffirmedRx-Testimony-to-the-House-Committee-on-Oversight-and-Accountability-May-2023.pdf

In 2020, a University of Southern California study found a direct correlation between rebate increases and manufacturer price increases: a $1 increase in rebates corresponds with a $1.17 increase in drug list price, "suggest[ing] that rebates do play a role in increasing list prices."[146] During a September 2023 Committee hearing, Representative Grothman (R-Wis.) discussed the role of rebates on insulin affordability with Lori Reilly, Chief Operating Officer, Pharmaceutical Research and Manufacturers of America:[147]

> ***Rep. Grothman:*** *Insulin has been a growing concern for Americans. How have PBM practices such as rebate negotiations impact the affordability of insulin for patients with diabetes?*
>
> ***Ms. Reilly:*** *The net price of insulin has actually decreased… But most patients haven't felt that, again, because PBMs insist on charging patients a full list price of the medicine and not the negotiated rate. The typical insulin has a rebate of about 84 percent, which is 84 percent lower than what patients are being asked to pay. The PBMs have not had an interest in putting lower priced insulin on the market.*

An alternative PBM market has emerged that provides a more transparent and cost-saving alternative to traditional PBM business model. Like a traditional PBM, transparent PBMs provide employers, plan sponsors, and insurers with access to prescription drug benefits for their clients. However, transparent PBMs have clear pass-through business models which provide more direct, clear contracts; frequent opportunities for the client to audit the PBM; fair copays; almost no limitations on client's access to PBM data; and 100 percent pass-through of rebates.[148] Instead of relying on rebates and mark-ups, many Transparent PBMs' derive their revenue from flat administrative fees, removing the conflicts of interest that can drive up the costs of prescriptions.[149] As a result, transparent PBMs are very effective at negotiating rebates and discounts with drug companies that result in reduced out-of-pocket costs for patients. For example, Transparency Rx, a coalition of Transparent PBMs, provides clients with 163 percent savings on high blood pressure and heart medications, 184 percent savings on medications for Type 2 diabetes, and 195 percent savings on statin drugs for cholesterol, compared to traditional PBMs.[150] With transparent contract terms, access to information, and the ability to audit the PBM, payers can verify that they are not paying hidden fees and are actually receiving the PBMs' promised cost-savings.[151]

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[146] *Supra* note 17.
[147] *Supra* note 32.
[148] Rx Preferred Benefits, Pharmacy Benefits Management, *available at* https://rxpreferred.com/solutions/pbm-services; *see also* Alliance of Community Health Plans, A Unique Approach: Transparent PBMs (Apr. 5, 2019), *available at* https://achp.org/wp-content/uploads/PBM-Infographic_4.5.19.pdf
[149] *Id.*
[150] Transparency Rx, Transparency Bridges Gaps, *available at* https://transparency-rx.com
[151] *Supra* note 148.

I. Formulary Manipulation and Abuse

> "*Lack of transparency and the complexity of rebates and fees can make it difficult for plan sponsors to assess whether they are fully benefiting from all price concessions that PBMs negotiate on their behalf*."[152] **– Lori Reilly, Chief Operating Officer, Pharmaceutical Research and Manufacturers of America**

PBMs are responsible for developing formularies, which are lists of drugs that are covered under a health insurance plan.[153] Formularies are typically divided into four tiers, with Tier 1 including generic drugs and having the lowest copay, and Tier 4 including unique or specialty drugs (e.g., chemotherapy) with the highest out-of-pocket cost.[154] Since these tiers differ in their cost-sharing amounts, beneficiaries are encouraged to use drugs on the lower tiers when possible.[155] Drug manufacturers have a clear financial incentive to secure access on a plan sponsor's formulary: being included on a formulary, especially in a lower tier, means that more people will have access to the manufacturers' drugs at lower costs.[156] For health conditions and diseases, like diabetes, that can be treated by several similar drugs, it is even more important for a manufacturer to be covered on a formulary.[157]

The Committee found evidence that while each PBM conducts an extensive review of the safety and clinical efficacy of a medication when designing its formularies, each PBM places strong considerations on the financials of a medication when determining what tier to place the medication. For clarity, these financials do not automatically prioritize medications that are lower costs for plans or patients, but instead prioritize the financial benefit a PBM can obtain by placing the medication in a more desirable tier.

Optum Rx designs its formularies by starting with its National Pharmacy & Therapeutics Committee (P&T), which consists of physicians and pharmacists, not employed by Optum Rx, who "evaluate existing and emerging drugs based on scientific evidence, and review and appraise those drugs in an unbiased and evidenced-based way. A drug's cost plays no role in the P&T Committee's clinical review, only becoming relevant after the P&T Committee has identified drugs in a particular therapeutic class that are clinically effective and should be covered."[158] According to a P&T Committee charter, drugs are selected and sorted on the Optum Rx formulary based on "economic considerations" only after safety, efficacy, and therapeutic need have been established."[159]

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[152] *Supra* note 32.
[153] *Supra* note 144.
[154] Understanding Drug Tiers, PATIENT ADVOCATE FOUNDATION, https://www.patientadvocate.org/explore-our-resources/understanding-health-insurance/understanding-drug-tiers/.
[155] *Supra* note 59.
[156] *Supra* note 144.
[157] *Id.*
[158] Letter from Michael D. Bopp, Partner, Gibson, Dunn & Crutcher LLP, to James Comer, Chairman, H. Comm. on Oversight & Accountability (March 15, 2023).
[159] Optum Rx Second Production, ORX-COA-00005226-ORX-COA-00005235 (May 3, 2023) (on file with Comm.).

After the P&T Committee has met and provided, Optum Rx turns to the Formulary Management Committee and Business Implementation Committee.[160] The Formulary Management Committee is described as an internal leadership group that "makes recommendations on the placement of an FDA-approved prescription drug to an assigned tier" and whether any exclusion programs, and utilization management programs such as prior authorization, quantity limits, and step therapies, that have been recommended by the P&T Committee should be applied.[161] The Formulary Management Committee's recommendations include considerations of "clinical, economic, and pharmacoeconomic evidence on a heterogeneous population, including information from the Optum Rx P&T Committee and supporting financial analyses."[162] Whereas the P&T Committee meetings are transparent and open to the public,[163] the Formulary Management Committee is not, despite its role in considering "financial effect…to set final formulary tiering."[164] After the Formulary Management Committee recommendations are made, the decisions are sent to the Business Implementation Committee and implemented into plan policies.[165]

Express Scripts works with payers to design formularies and gives its clients the option to use one of Express Script's standard formularies or create a custom formulary.[166] Its most popular formulary, the Express Scripts National Preferred Formulary, is used by clients that cover 21 million people. Clients covering an additional 4 million lives utilize one of Express Scripts' other standard formulary options.

Express Scripts uses a process to develop formularies that incorporates three Committees: the Therapeutic Assessment Committee, the National P&T Committee, and the Value Assessment Committee.[167] The process starts with the Therapeutic Assessment Committee, consisting of "clinical pharmacists and physicians who are employed by Express Scripts," which reviews scientific literature and data[168] on new medications and then makes a formulary placement recommendation to the P&T Committee.[169] The P&T committee, comprised of "practicing physicians and pharmacists not employed by Express Scripts," reviews formulary placement for all new and old medications.[170] Thereafter these recommendations go to the Value Assessment Committee, consisting of "Express Scripts' employees from formulary management, product management, finance, and clinical account management."[171] The Value

[160] Optum Rx Second Production, ORX-COA-00002078- ORX-COA-00002087 (May 3, 2023) (on file with Comm.).
[161] Optum Rx Second Production, ORX-COA-00005268- ORX-COA-00005276 (May 3, 2023) (on file with Comm.).
[162] *Id.*
[163] Optum Rx Second Production, ORX-COA-00005321 (May 3, 2023) (on file with Comm.).
[164] Optum Rx Second Production, ORX-COA-00005323 (May 3, 2023) (on file with Comm.).
[165] *Supra* note 160.
[166] Letter from Christopher J. Armstrong, Partner, Holland & Knight, to James Comer, Chairman, H. Comm. on Oversight & Accountability (Mts arch 16, 2023).
[167] Express Scripts First Production, ESI00000001-ESI00000005 (April. 6, 2023) (on file with Comm.).
[168] "The drug evaluation documents include, at a minimum: a summary of the pharmacology, safety, efficacy, dosage, mode of administration, and the relative place in therapy of the medication under review compared to other pharmacologic alternatives." *Id.*
[169] *Id.*
[170] *Id.*
[171] *Id.*

Assessment Committee considers the "value of drugs by evaluating the net cost, market share, and drug utilization trends of clinically similar medications," and has the authority to designate a medication as "include" or "exclude" from all formularies, not on the basis of whether it benefits patients, but the economics of the medication.[172] While the P&T Committee can ignore a recommendation by the Value Assessment Committee for inclusion or exclusion, the Committee did not receive documents illustrating that the P&T does so.[173] Instead, evidence suggests that decisions were often made based on the economics of a medication, rather than its benefit to patients or affordability.[174]

CVS Caremark develops and reviews formularies in a similar manner to Optum Rx and Express Scripts. The Trade Relations Group first submits formulary recommendations to the Formulary Review Committee, who in turn submits template formularies to the P&T Committee.[175] All CVS Caremark template formularies are reviewed and approved on a quarterly basis.[176] Additionally, 11 percent of CVS Caremark's clients choose to use a custom formulary.[177]

The Formulary Review Committee is an internal CVS Caremark committee responsible for evaluating business factors that can affect a formulary, such as utilization trends, the potential impact of generic drugs or drugs slated to become available over the counter, brand and generic pipeline, line of business, plan sponsor cost, applicable manufacturer agreement, and the potential impact on members.[178] For example, "when an A-rated generic becomes available, it is typically considered preferred and…encouraged."[179] The Formulary Review Committee takes these factors and uses them to make business recommendations to the P&T Committee, and the P&T Committee must approve all recommendations before they can be included on a formulary.[180]

The P&T Committee is an advisory body independent of CVS Caremark and is comprised of nineteen physicians and three pharmacists; the twenty-two members are not employees of CVS Caremark.[181] The P&T Committee is "supported by the CVS Caremark Clinical Formulary Department," which houses clinical pharmacists who prepare drug monographs and therapeutic class reviews based on a clinical literature review.[182] The P&T Committee bases its decisions on "scientific evidence, standards of practice, peer-reviewed

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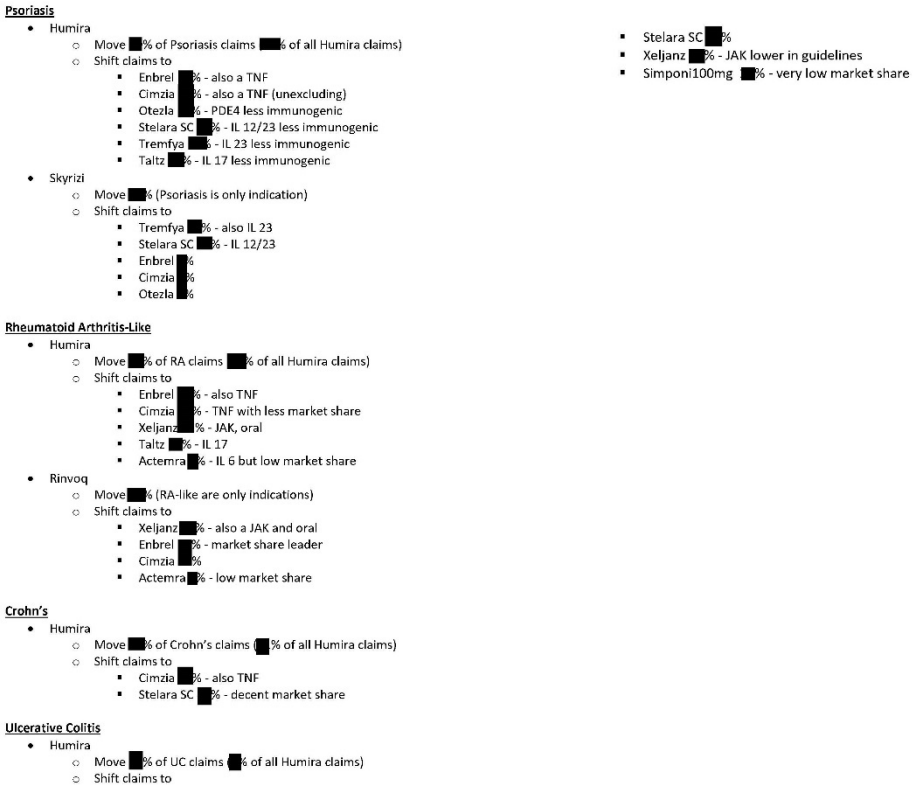
[172] *Id.*
[173] *Id.*
[174] Express Scripts First Production, ESI00000266 (April. 6, 2023) (on file with Comm.).; – Januvia (peptidase-4 inhibitor), test strips, insulin, ESI00000271 Multiple Sclerosis (Aubagio, Tecfidera, Gilenya, Mayzent
[175] Letter from Nicholas L. McQuaid, Partner, Latham & Watkins, to James Comer, Chairman, H. Comm. on Oversight & Accountability (July 14, 2023).
[176] *Id.*
[177] Letter from Nicholas L. McQuaid, Partner, Latham & Watkins, to James Comer, Chairman, H. Comm. on Oversight & Accountability (May 10, 2024).
[178] CVS Caremark Seventh Production, CCM00024472 (Dec. 29, 2023) (on file with Comm.).
[179] CVS Caremark Seventh Production, CCM00024473 (Dec. 29, 2023) (on file with Comm.).
[180] *Supra* note 178.
[181] *Supra* note 178.; *see also* CVS Caremark Seventh Production, CCM00024470-CCM00024471 (Dec. 29, 2023) (on file with Comm.).
[182] CVS Caremark Seventh Production, CCM00024471 (Dec. 29, 2023) (on file with Comm.).

medical literature, accepted clinical practice guidelines, and other appropriate information."[183] CVS Caremark works to make sure that the P&T Committee does not have access to or consider information regarding CVS Caremark's "rebates, negotiated discounts, or net costs."[184]

PBMs also maintain exclusion lists, which are drugs that are not included on formularies.[185] For example, in 2021, Express Scripts excluded approximately 400 drugs from its formularies.[186] When a drug is excluded from a formulary, it will not be covered by the insurer.[187] This forces patients to either switch to another drug, potentially affecting health outcomes, or pay out-of-pocket, which is often unsustainable.[188]

One example of PBM market manipulation was evident in documents reviewed by the committee which indicate that Express Scripts was discussing how to shift patients from medications going off patent exclusivity to other high-cost medications:

Figure 11: Express Scripts internal document indicating how they would shift claims to more lucrative medications[189]



[183] *Id.*
[184] *Id.*
[185] *Supra* note 144.
[186] *Supra* note 144.
[187] *Id.*
[188] *Id.*
[189] Express Scripts Eighth Production, ESI00012723-00012724 (June. 14, 2024) (on file with Comm.).

PBMs often claim that the threat of exclusion or the benefit of being a "preferred" product typically allows them to extract greater rebates from manufacturers.[190] While this may be the case, the Committee found that PBMs often choose higher cost medications for their formularies costing patients more at the counter, employers more to subsidize their prescription drug plans, and taxpayers more for federal health care programs. In reviewing standard formularies for 2020, 2021, and 2022, from the three largest PBMs, the Committee found 300 examples, which can be found in the Appendix to the report, of the three largest PBMs preferring medications that cost at least $500 per claim more than the medication they excluded on their formulary. While some of these decisions likely have valid clinical reasons, the sheer quantity and dramatic increase in costs highlight the priority of PBMs.

In total, the Committee identified more than 1000 examples of medications that, according to Medicare Part D data, would have been less expensive had the excluded medication been given preference or simply able to compete on a level playing field.

II. Rebates Effects on Biosimilars and Competition

> *"There is significant evidence from the [Office of the Inspector General], [Federal Trade Commission], [Government Accountability Office], of a number of different practices that PBMs utilize that make it harder for companies to reduce the list price of their medicines…* The Wall Street Journal *noted just this past week that [PBMs] often overcharge. So I believe there is a pattern of behavior that has been well documented that demonstrates the large challenges that exist with PBMs that is not to the benefit of patients but to the detriment."* **– Lori Reilly, Chief Operating Officer, Pharmaceutical Research and Manufacturers of America**

Drug rebate payments are a PBM negotiation tool used to promote utilization of expensive brand drugs.[191] Rebates paid to PBMs are typically a percentage of a drug's list price, so PBMs have an incentive to select more expensive drugs for formulary status.[192] A January 2023 report released by the Association for Accessible Medicines (AAM) revealed that PBMs block patient access to lower-cost generic drugs in favor of higher priced brand drugs with high rebates.[193] PBMs also have a financial incentive to promote the use of expensive medications and encourage drug list-price increases in order to increase their profits. [194] Drug manufacturers are increasing drug list prices to satisfy PBMs' demands for higher rebates. [195] New generic

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[190] *PBM Tools Will Save Health Plan Sponsors and Consumers More than $1 Trillion on Prescription Drug Costs*, PCMA, *available at* https://www.pcmanet.org/pbm-tools.
[191] Deirdre MacBean, *How high prescription drug rebates can derail pharmacy benefit plans*, HEALTHPARTNERS *available at* https://www.healthpartners.com/plan/blog/prescription-drug-rebates-and-pbms (last accessed: May 16, 2023).
[192] Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs,* YALE LAW & POLICY REVIEW, Vol. 38 (Jan. 1, 2019).
[193] *Study Finds Middlemen Increasingly Block Patient Access to New Generics*, ASS'N FOR ACCESSIBLE MEDICINES (Jan. 23, 2023) *available at* https://accessiblemeds.org/resources/press-releases/middlemen-block-patient-access-new-generics.
[194] *Supra* note 192.
[195] *Id.*

drugs are experiencing historically slow adoption by patients directly resulting from PBM coverage decisions to prefer higher priced drugs with high rebates over lower list price drugs. [196] During the Committee's second hearing on PBM practices, Representative Gary Palmer (R-Ala.) discussed the negative impact of PBM rebates on the availability of prescription drugs with Craig Burton, Executive Director of the Biosimilars Council.[197]

> ***Rep. Palmer:*** *So, what you are saying is rebates have a negative impact on patients?*
>
> ***Mr. Burton:*** *Yes, sir.*
>
> ***Rep. Palmer:*** *So, what you are saying to the Committee is that this price setting could impact the availability of certain generic drugs… This is a confusing game that is being played. What I don't want to get lost in all this is that the patient is not the number one concern here.*
>
> ***Mr. Burton:*** *I think that's right… There seems to be an assumption that a general brand drug will just stay on the market. That isn't the case.*

Biologics can be used to treat a myriad of illnesses, such as psoriasis, diabetes, and cancer.[198] They are also some of the costliest prescriptions dispensed in the United States.[199] Only two percent of Americans use biologics, yet they account for approximately 40 percent of prescription drug spending.[200] A less expensive alternative to biologics are biosimilars, a type of biologic medicine that "is highly similar to a biologic medicine already approved by the FDA" and which "have no clinically meaningful differences from the [biologic]."[201] They are analogous to generic drugs: a biosimilar is to a biologic what a generic drug is to a brand name drug.

A consequence of rebates and exclusion lists is that they create a barrier to market entry for biosimilars.[202] Biosimilars are often excluded from a formulary or are listed on higher tiers of the formulary, which makes them more expensive for plans and patients.[203] For example, Amgen, a biotechnology company, recently launched Amjevita, the first non-interchangeable biosimilar of Humira.[204] The company launched both a high-list, high-rebate version of the drug and a low-list, low-rebate version of the drug. Most PBMs and plan sponsors have opted for the

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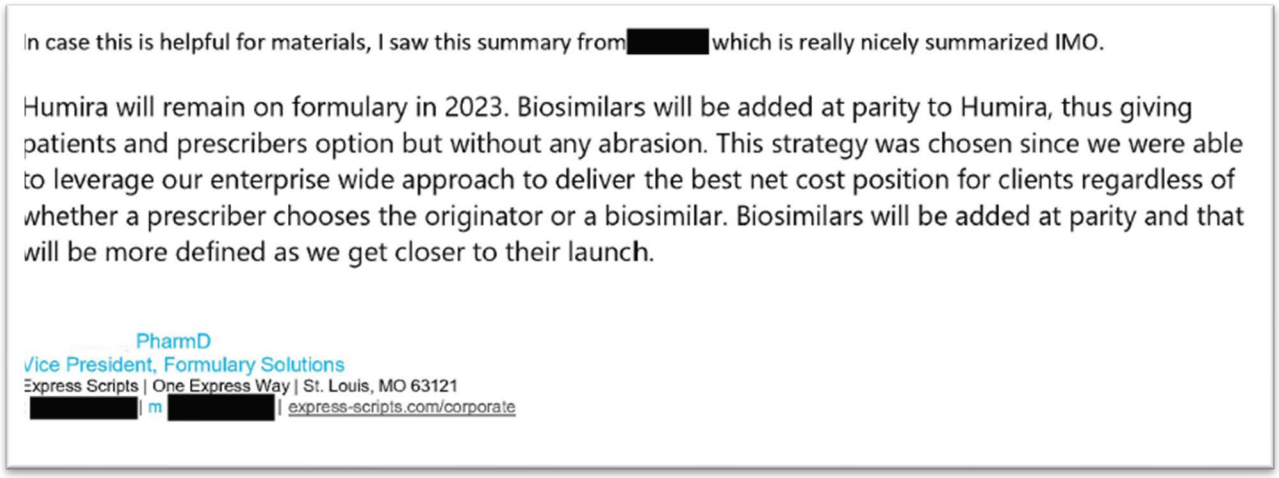
[196] *Supra* note 193.
[197] *Supra* note 32.
[198] *Overview for Health Care Professionals*, U.S. FOOD & DRUG. ADMIN. (last updated Dec. 13, 2022) *available at* https://www.fda.gov/drugs/biosimilars/overview-health-care-professionals.
[199] Biosimilars Handbook, BIOSIMILARS COUNCIL *available at* https://www.biosimilarshandbook.org/patient-learning-track.
[200] *Id.*
[201] Biosimilar Basics for Patients, U.S. Food & Drug Admin. (last updated Aug. 10, 2023).
[202] *Supra* note 17.
[203] Laura Joszt, *Margaret Rehayem: Rebates Remain Influential and a Barrier to Biosimilar Adoption for Employers*, AJMC (Apr. 28, 2023).
[204] Leigh Ann Anderson, *Is Amjevita Interchangeable with Humira?,* DRUGS.com (last updated Apr. 30, 2024).

high-list, high-rebate version.[205] The adoption of higher priced versions of drugs will garner higher rebates for PBMs while patients end up paying more out-of-pocket and taxpayers pay more in government run programs such as Medicare and TRICARE.[206]

This practice is not reserved for taxpayer funded health care programs. In emails reviewed by the Committee, staff at Express Scripts highlighted that their account teams should not discuss Humira with their clients "due to rebate impact with Abbvie."[207] These emails also expose that even though PBMs have the market power to negotiate when a biosimilar comes on the market, their negotiations do "not translat[e] to savings or value worth moving against the innovator."[208] In fact, for plan year 2023, as biosimilars to Humira come to market, Express Scripts used its market power to offer biosimilars at the same price as Humira.[209]

Figure 12: Email from Express Scripts VP for Formulary highlighting that biosimilars would be offered at the same price as Humira[210]



In case this is helpful for materials, I saw this summary from [redacted] which is really nicely summarized IMO.

Humira will remain on formulary in 2023. Biosimilars will be added at parity to Humira, thus giving patients and prescribers option but without any abrasion. This strategy was chosen since we were able to leverage our enterprise wide approach to deliver the best net cost position for clients regardless of whether a prescriber chooses the originator or a biosimilar. Biosimilars will be added at parity and that will be more defined as we get closer to their launch.

[redacted] PharmD
Vice President, Formulary Solutions
Express Scripts | One Express Way | St. Louis, MO 63121
[redacted] | m [redacted] | express-scripts.com/corporate

These comments raise questions as to why they are unable to extract savings from manufacturers when PBMs exert control over the market. In this case, Express Scripts used its market power to keep all net prices the same, therefore exacting a higher rebate while keeping list prices, and therefore the patient's copay, higher.

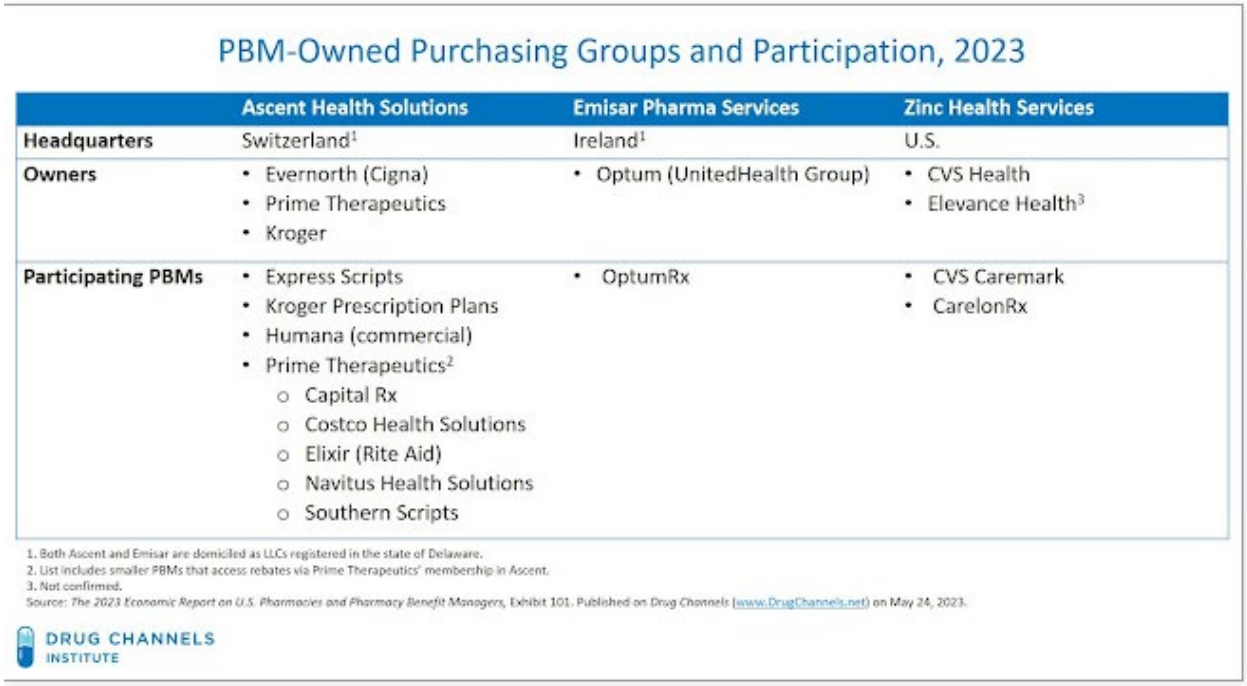
III. PBMs' creation of foreign business entities to hide rebates and fees

In the past five years the three largest PBMs have created group purchasing organizations (GPOs) and moved to centralize negotiation with pharmaceutical manufacturers for rebates and

[205] Adam J. Fein, *The Warped Incentives Behind Amgen's Humira Biosimilar Pricing – And What We Can Learn from Semglee and Repatha,* DRUG CHANNELS (Feb. 7, 2023).
[206] *Id.*
[207] Express Scripts Eight Production, ESI00012756 (June. 14, 2024) (on file with Comm.).
[208] Express Scripts Eight Production, ESI00012766 (June. 14, 2024) (on file with Comm.).
[209] Express Scripts Eight Production, ESI00013648 (June. 14, 2024) (on file with Comm.).
[210] *Id.*

fees.[211] These organizations are not only providing negotiation services for these three PBMs but also for many smaller PBMs as well.[212] On its face this seems like a move which would enable the PBMs to better leverage their and other PBM's negotiating powers to obtain steeper drug discounts.[213] However, two of the three GPOs were formed in foreign countries known for their lack of financial transparency and low tax rates. Express Scripts created the GPO Ascent Health Services (Ascent), based in Switzerland and Optum Rx created Emisar Pharma Services (Emisar), based in Ireland.[214]

Figure 13: PBM-owned Group Purchasing Organizations and PBM Participation[215]



PBM-Owned Purchasing Groups and Participation, 2023

	Ascent Health Solutions	Emisar Pharma Services	Zinc Health Services
Headquarters	Switzerland[1]	Ireland[1]	U.S.
Owners	• Evernorth (Cigna) • Prime Therapeutics • Kroger	• Optum (UnitedHealth Group)	• CVS Health • Elevance Health[3]

Participating PBMs	• Express Scripts
	• Kroger Prescription Plans
	• Humana (commercial)
	• Prime Therapeutics[2]
	  ○ Capital Rx
	  ○ Costco Health Solutions
	  ○ Elixir (Rite Aid)
	  ○ Navitus Health Solutions
	  ○ Southern Scripts
		• OptumRx	• CVS Caremark
			• CarelonRx

1. Both Ascent and Emisar are domiciled as LLCs registered in the state of Delaware.
2. List includes smaller PBMs that access rebates via Prime Therapeutics' membership in Ascent.
3. Not confirmed.

Source: *The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Exhibit 101. Published on Drug Channels (www.DrugChannels.net) on May 24, 2023.

DRUG CHANNELS INSTITUTE

Why have these PBMs created GPOs based abroad, when they could easily have created them in the United States? According to reports, Express Scripts' motivations for basing Ascent in Switzerland was likely for "[t]ax efficiency" and to "[l]everage GPO safe harbor rules to avoid rebate reform and enable Express Scripts to collect GPO admin fees."[216] Similarly, experts believe that Optum Rx's decision to base Emisar in Ireland was because they stood "to lose a lot if they got regulated on rebates…[c]reating another organization that's offshore, they can protect their interests."[217] It appears that the PBMs created these entities with the sole intent to limit transparency and avoid regulations on rebates.

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[211] Adam J. Fein, *Five (or Maybe Six?) Reasons that the Largest PBMS Operate Group Purchasing Organizations*, DRUG CHANNELS (May 24, 2023).
[212] *Id.*
[213] *Id.*
[214] *Id.*
[215] *Id.*
[216] Adam J. Fein, *Drug Channels News Roundup, May 2019: Express Scripts' New GPO, More on Amazon/PillPack, a BS Update, and Vegas Video*, DRUG CHANNELS (May 30, 2019).
[217] Deborah Abrams Kaplan, *PBMs are Creating GPOs, and Stirring Debate as to Why*, MHE Publication (June 12, 2022).

These are not the only foreign entities PBMs use to avoid scrutiny. In 2021, Cigna created Quallent Pharmaceuticals, a wholly owned subsidiary based in the Cayman Islands,[218] which "sources select pharmaceuticals from U.S. Food and Drug Administration (FDA)-approved pharmaceutical manufacturers."[219] Last year, CVS Health created Cordavis, a wholly owned subsidiary based in Dublin, Ireland[220], which is being used to "commercialize and/or co-produce biosimilar products…for the U.S. pharmaceutical market."[221] The location of these subsidiaries raise significant questions about the purpose of their creation, in particular whether their foreign domicile is intended to prevent transparency and enable PBMs to retain hidden rebates and keep patient costs high.

PBMs' Impact on Patient Care

> *"Unfortunately, the PBM preferred drug is often not the best drug for a patient but the most profitable drug for the PBM… Treatment delays, denials, and fueling drug costs is the PBM hell my patients and I live in every day. The top PBMs have such leverage that they do what they want."*[222] **– Dr. Miriam Atkins, Oncologist, Augusta Oncology**

PBMs' anticompetitive behaviors have significant implications for Americans' health because of the financial incentives to force patients into more expensive medications. New-to-market generic drugs are experiencing historically slow adoption by patients directly resulting from PBM coverage decisions.[223] The delays are driven by PBM's choice to prefer higher priced drugs with high rebates over lower list price generic drugs.[224] Dr. Miriam Atkins, a medical oncologist in Augusta, Georgia, testified before the Committee in May 2023, stating that she must challenge PBMs "to get [her] patients [the] evidence-based, lifesaving treatment they need."[225]

> ***Chairman Comer:*** *Dr. Atkins, do you think a patient is more likely to take a cancer drug if a drug is $72 or $17,000?*
>
> ***Dr. Atkins:*** *$72 for sure.*

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[218] Adam J. Fein, *What's Behind CVS Health's Novel Vertical Integration Strategy for Humira Biosimilars* (Sept 06, 2023); *see also* https://www.quallentpharmaceuticals.com/ ("60 Nexus Way, P.O. Box 30997, Grand Cayman Ky1-1204, Cayman Islands")
[219] *About Us,* Quallent Pharmaceuticals *available at* https://www.quallentpharmaceuticals.com/about-us.
[220] *Who We Are*, *About Us, Meet Our Team,* Cordavis, *available at* https://www.cordavis.com
[221] *Supra* note 216. ; *see also CVS Health Launches Cordavis,* PR Newswire *available at* https://www.prnewswire.com/news-releases/cvs-health-launches-cordavis-301908281.html
[222] *Supra* note 32.
[223] *Supra* note 193.
[224] *Supra* note 193.
[225] *Supra* note 32. (statement of Dr. Miriam Atkins, AO Multispecialty Clinic).

Chairman Comer: *So would you agree that insane prices on vital medication like this are killing people?*

Dr. Atkins: *Yes.*[226]

PBM practices not only impact patients' pocketbooks, but also their health. PBMs use tactics like prior authorization and fail first requirements, also known as step therapy, which can prevent or delay patients from accessing the medicines they need.[227] According to the American Medical Association (AMA) a prior authorization is a requirement by a PBM that a physician get approval from the PBM for the prescription they prescribed.[228] AMA states that prior authorizations "can lead to negative clinical outcomes."[229] Fail first policies require patients to try and fail on a medicine preferred by their insurer and PBM before the originally prescribed medicine is covered.[230] PBMs justify these methods to "control costs and enhance safety by ensuring that patients do not use more expensive treatments when less expensive but equally effective therapies are available."[231]

As part of the Committee's investigation, Caremark, Express Scripts, and OptumRx cumulatively produced thousands of pages of formularies and narrative letters explaining how each PBM crafts its formularies. Within these PBM's formularies they specifically delineate certain tiers or certain medications for prior authorization. Fail first is generally not as clearly identifiable in a formulary but can be found by looking at the lists of medications used to treat a specific disease. When there is only one medication on the lowest tier, with other competing brand name medications on higher tiers, it is designed for a patient to use the medication on the lowest tier until they fail, then they can be approved to use medications on higher tiers. The Committee found countless examples in each formulary of medications that have been designated for prior authorization or that appear to be designated as fail first medications.

Apply prior authorization or fail first policies to certain medications can harm patients by restricting necessary care unless the patient can pay for the prescription out of pocket.[232] Additionally, lengthy delays for prior authorizations can cause suffering or even death as patients wait for PBMs to approve life-saving medications their doctors prescribe.[233] PBMs enact these policies to manipulate the market share of certain medications to get higher rebates from pharmaceutical manufacturers at the expense of patients. Patient health should not be compromised for PBM profits.

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[226] *Supra* note 32.
[227] Katie Koziara, *New data show insurers and PBMs increase barriers to care*, PhRMA (Dec. 2, 2021),
[228] Sara Berg, *What Doctors Wish Patients Knew About Prior Authorization*, AMA (Sep. 11, 2023).
[229] Sara Berg, *What Doctors Wish Patients Knew About Prior Authorization*, AMA (Sep. 11, 2023).
[230] *Supra* note 227.
[231] Geoffrey Joyce, et al, *Medicare Part D Plans Greatly Increased Utilization Restrictions on Prescription Drugs, 2011-20*, HealthAffairs (Mar. 2024).
[232] *Id.*
[233] Aaron Tallent, *Oncologists Say Prior Authorization is Causing Delays in Care*, OBR ONCOLOGY (Mar. 25, 2022); *What is Prior Authorization*, CIGNA (2021); Kevin B. O'Reilly, *1 in 3 doctors has seen prior auth lead to serious adverse event*, AMA (Mar. 29, 2023).

One positive the Committee identified while reviewing PBM care initiatives was that PBMs protect patients' health and safety by checking for medication interactions and identifying when patients may be taking a medication in an inappropriate manner. As middlemen, PBMs have access to all patient data and are therefore able to identify when a patient gets multiple of the same medication in a short time period, thus enabling them to identify potential misuse of a medication for both the patient and their physician. PBMs are also able to identify how medications may interact with one another in a way that could injure a patient. This is not an uncommon occurrence as many patients, particularly elderly patients, receive care from multiple different physicians and pharmacies.

Figure 14: Identifying potential concerns with a patient's prescriptions[234]

Prescription History

Date of Service	Drug Description	Strength	Quantity	Days Supply
10 08 22	CLONIDINE HCL	0.3 MG	270	90
10 05 22	FARXIGA	10 MG	30	30
09 29 22	AMLODIPINE BESYLATE	10 MG	90	90
09 14 22	METOPROLOL TARTRATE	100 MG	180	90
08 29 22	FLUTICASONE PROPIONATE	50 MCG	48	90
08 21 22	SPIRONOLACTONE	50 MG	90	90
08 18 22	LOSARTAN POTASSIUM	100 MG	90	90
08 11 22	LOSARTAN POTASSIUM	100 MG	30	30
08 02 22	METFORMIN HCL	500 MG	180	90
08 02 22	CLONIDINE HCL	0.3 MG	270	90
08 01 22	SPIRONOLACTONE	50 MG	30	30

Impacts on Federal and State Health Care Programs

In addition to their effects on patients' health, PBMs' anticompetitive practices directly affect American taxpayers. As Mr. Greg Baker, CEO of AffirmedRx, testified before the Committee, "PBMs are not constrained by any obligation to be transparent on their pricing or methodology… this problem is also costing taxpayers significantly since some of the biggest health plans in the country are run by local and state entities."[235]

I. Federal Employee Health Benefits (FEHB)

FEHB is the largest employer-sponsored group health insurance program in the United States, covering more than 8 million federal employees, retirees, and family members.[236] FEHB

[234] Express Scripts Seventh Production, ESI00012672 (Feb. 14, 2024) (on file with Comm.).
[235] *Supra* note 32.
[236] FEHB Handbook, , U.S. Office of Personnel Management (last visited July 11, 2024), *available at* https://www.opm.gov/healthcare-insurance/healthcare/reference-materials/fehb-

enrollees typically share the cost of their health insurance with the federal government as the employer; the government's portion of premiums paid is set by law, and the enrollee is responsible for paying the difference.[237] The government's contribution can be paid out of agency appropriations or other funds available for the payment of salaries.[238]

A March 2024 report by the Office of Personnel Management (OPM) IG found that a FEHB plan, the American Postal Workers Union Health Plan, was overcharged nearly $45 million by Express Scripts, who had been contracted by the Health Plan to provide pharmacy benefits for enrollees from contract year 2016 through 2021.[239] This overcharge was due to Express Scripts not passing through all discounts, credits, and rebates that were required by the contract.[240] Under the contract's PBM Transparency Standards, Express Scripts was required and failed to send pass-through transparent drug pricing from retail pharmacy claims, remit several drug purchasing discounts from drugs filled by Express Scripts' own mail order pharmacy warehouses and specialty pharmacies, return retail pharmacy claim transaction fees that it was credited, share drug manufacturer rebates, and share a portion of FEHB's drug manufacturer rebates with FEHB and the health plan.[241] Specifically, a large portion of the rebates collected by Express Scripts and its rebate aggregator, Ascent, were not passed through "due to lower rebate percentages agreed to internally between [Express Scripts] and Ascent, thereby allowing Ascent to keep the portion of rebates that [the OPM IG is] questioning."[242]

This instance was not the only time that Express Scripts has been found to overcharge an FEHB plan. In February 2023, the OPM IG audited Group Health Incorporated's FEHB pharmacy operations for contract years 2015 through 2019.[243] The IG found that FEHB was overcharged approximately $15 million because Express Scripts did not pass through all the discounts, credits, rebates, and administrative fees that were required in Express Scripts' contract.[244]

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handbook/#:~:text=It%20is%20the%20largest%20employer,family%20members%2C%20and%20former%20spouses

[237] Cost of Insurance, U.S. Office of Personnel Management(last visited July 11, 2024), *available at* https://www.opm.gov/healthcare-insurance/healthcare/reference-materials/reference/cost-of-insurance/.

[238] *Id*.

[239] U.S. OFF. OF PERSONNEL MGMT. OFF. OF INSPECTOR GEN., OFF. OF AUDITS, REPORT NO. 2022-SAG-029, FINAL AUDIT REPORT: AUDIT OF THE AMERICAN POSTAL WORKERS UNION HEALTH PLAN'S PHARMACY OPERATIONS AS ADMINISTERED BY EXPRESS SCRIPTS, INC. FOR CONTRACT YEARS 2016-2021 (Mar. 29, 2024).

[240] *Id*.

[241] *Id*.

[242] *Id*.; *see also* Terence Park, Dae Y. Lee, *OIG Audit of Federal Employee Pharmacy Benefits Plan Reveals Express Scripts Retained $44.9 Million in Overpayments and Unreported Rebates*, FRIER LEVIT ATTORNEY AT LAW (May 15, 2024).

[243] U.S. OFF. OF PERSONNEL MGMT. OFF. OF INSPECTOR GEN., OFF. OF AUDITS, REPORT NO. 1H-08-00-21-015, FINAL AUDIT REPORT: AUDIT OF GROUP HEALTH INCORPORATED'S FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM PHARMACY OPERATIONS AS ADMINISTERED BY EXPRESS SCRIPTS, INC. FOR CONTRACT YEARS 2015 THROUGH 2019 (Feb. 16, 2023).

[244] *Id*.

II. Medicare

Unlike Medicare Parts A and B, which are administered by Medicare, Medicare Parts C (commonly called Medicare Advantage) and D are administered by private health insurance companies.[245] Medicare Part D provides prescription drug benefits to enrollees,[246] while Medicare Part C is an alternative to Medicare Parts A and B which frequently includes Part D prescription benefit coverage.[247] According to GAO, Part D plan sponsors used PBMs to provide 74 percent of drug benefit management services in 2016.[248] As more vertical integration has occurred, it is likely that even more than 74 percent of plan sponsors use PBMs to manage their prescription drug benefit.

CVS reported that Medicare Part D plans are required to cover at least two drugs per therapeutic class and "substantially all" drugs in these six categories: anticonvulsants, antidepressants, antineoplastics, antiretrovirals, antipsychotics, and immunosuppressants.[249] Mandating coverage in these six areas can lead to differences in pricing between government plans and commercial plans because it "reduces the incentives for manufacturers to offer meaningful discounts…because manufacturers know plan sponsors must cover their drugs in these classes.[250] Caremark alleges that coverage mandates lead to higher costs for CMS and Part D enrollees compared to other types of plans.[251]

PBMs have also been accused of overcharging the federal government with regard to Medicare. In May 2017, the Department of Justice filed a lawsuit against UnitedHealth Group, which owns Optum Rx, alleging the company overcharged the government by more than $1 billion through its Medicare Advantage plans by submitting invalid diagnosis data. The case is still ongoing. [252] In December 2019, CVS and it's Omnicare business were sued by the Department of Justice over alleged fraudulent billing of Medicare and other government programs for outdated prescriptions for disabled and elderly individuals.[253] In September 2023, Cigna Group, Express Scripts' parent company, agreed to pay $172,294 to resolve allegations that it violated the False Claims Act by submitting and failing to withdraw inaccurate and

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[245] *Center for Medicare Advocacy*, Part D/ Prescription Drug Benefits *available at* https://medicareadvocacy.org/medicare-info/medicare-part-d/; *Understanding Medicare Advantage Plans*, MEDICARE *available at* https://www.medicare.gov/Pubs/pdf/12026-Understanding-Medicare-Advantage-Plans.pdf
[246] *Id*.
[247] *Supra* note 245.
[248] U.S. GOV'T ACCOUNTABILITY OFF., GAO-19-498, MEDICARE PART D: USE OF PHARMACY BENEFIT MANAGERS AND EFFORTS TO MANAGE DRUG EXPENDITURES AND UTILIZATION (Jul 15, 2019).
[249] Letter from Nicholas L. McQuaid, Partner, Latham & Watkins, to James Comer, Chairman, H. Comm. on Oversight & Accountability (Aug. 28, 2023).
[250] *Id.*
[251] *Id.*
[252] United States of America et al v. Unitedhealth Group incorporated et al, no. 1:2022CV00481 - document 138 (D.D.C. 2022), Justia Law, https://law.justia.com/cases/federal/district-courts/district-of-columbia/dcdce/1:2022cv00481/240495/138/ (last visited May 21, 2024).
[253] Rebecca Pifer, *CVS Long-Term Care Pharmacy Sued by DOJ Over Fraudulent Prescribing Practices*, HEALTHCARE DIVE (Dec. 17, 2019).

untruthful diagnosis codes for its Medicare Advantage Plan enrollees to increase Cigna Group's payments from Medicare.[254]

In the Appendix to this report, the Committee identified more than 300 examples of the three largest PBMs preferring medications that cost at least $500 per claim more than the alternative medication they excluded on their formulary. When this information is applied to the Medicare program, the Committee estimates that these decisions cost taxpayers billions per year.

III. Medicaid

Medicaid is frequently delivered through a Managed Care Organization (MCO).[255] PBMs usually serve as third party administrators to an MCO, which contracts with a state's Medicaid program to manage its prescription drug benefits.[256]

Over the years, PBMs have repeatedly been found to overcharge Medicaid. In September 2014, CVS agreed to pay $6 million to settle allegations that it knowingly failed to reimburse Medicaid for prescription drug costs.[257] Furthermore, in 2017 alone, PBMs and their pharmacies made as much as $4.2 billion by improperly engaging in spread pricing and charging the Medicaid program more than they were reimbursing pharmacies.[258]

As previously mentioned in this report, although PBMs frequently tout the savings they provide for payers and patients, there are numerous instances where state auditors have found significant spread pricing schemes that increase costs for payers and patients.[259] PBMs have been caught overcharging Medicaid programs in Ohio, Kentucky, Illinois, and Arkansas by more than $415 million.[260]

Subsequently, multiple states have audited their Medicaid programs because of concerns about spread pricing amid high Medicaid drug costs and brought lawsuits against the PBMS, alleging that the PBM overcharged the state's Medicaid program.[261] In 2018, the Ohio Attorney General investigated Centene Corp. and found that it engaged in spread pricing while managing Ohio's Department of Medicaid prescription drug program and cost the state program nearly $225 million.[262] Ohio sued Centene, who ultimately agreed to pay $88.3 million to the state.[263]

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[254] United States ex rel. Cutler v. Cigna Corp., et al., No. 3:21-cv-00748 (M.D. Tenn.) United States Department of Justice (2023) *available at* https://www.justice.gov/opa/pr/cigna-group-pay-172-million-resolve-false-claims-act-allegations (last visited May 14, 2024)
[255] Elizabeth Hinton & Jada Raphael, *10 Things to Know About Medicaid Managed Care*, KFF (May 1, 2024).
[256] *Supra* note 249.
[257] Jonathan Stempel, *CVS' Caremark Unit Settles U.S. False Claims Allegations*, REUTERS (Sep. 26, 2014)
[258] Robert Langreth, David Ingold, Jackie Gu, *The Secret Drug Pricing System Middlemen Use to Rake in Millions*, BLOOMBERG (Sep. 11, 2018).
[259] *See e.g. Supra* note 112.); *see also Id.*
[260] *Supra* note 111; *see also* Lisa Gillespie, *Pharmacy Middlemen Overcharged Medicaid $123.5 Million, State Says*, LOUISVILLE PUBLIC MEDIA (Feb. 23, 2019); *see also* Samantha Liss, *Centene Reaches $72M Settlement with Illinois, Arkansas for Alleged Medicaid Overcharges*, HEALTHCARE DIVE (Oct. 1, 2021).
[261] *Supra* note 113.
[262] *Supra* note 114.; *see also* Supra note 36.
[263] *Supra* note 114.

Since that lawsuit, Centene has paid nearly $1 billion in 18 states over spread pricing schemes.[264] Centene had long contracted with Caremark as its PBM and recently moved to Express Scripts.[265] In another audit, the HHS IG found that PBMs in the District of Columbia improperly kept $23.3 million in spread pricing from 2016-2019.[266] In November 2022, Express Scripts agreed to pay $3.2 million to settle claims that they overcharged Massachusetts' workers' compensation insurance system for prescription drugs.[267]

Due to its cost to taxpayers, several states have taken steps to prohibit spread pricing in Medicaid managed care programs and congressional lawmakers have introduced multiple bills that would prohibit spread pricing.[268] The CBO estimates that eliminating spread pricing in Medicaid managed care organizations, as outlined in the Lower Costs, More Transparency Act of 2023,[269] would reduce federal spending by $1.1 billion over ten years.[270]

IV. TRICARE

In 2019, a suit was filed against Express Scripts after a whistleblower alleged the company defrauded the federal government and vendors out of billions of dollars through the delivery of unnecessary prescription drugs to military personnel.[271] In October 2022, it was announced that TRICARE beneficiaries would lose access to approximately 15,000 independent pharmacies due to contract changes between Express Scripts and the Defense Health Agency.[272] Consequently, U.S. service members and veterans have encountered difficulties trying to access their prescriptions in a timely manner and at their preferred pharmacies.[273]

At the Committee's first PBM hearing in May 2023, multiple Congressmen expressed their concerns about TRICARE to Kevin Duane, PharmD, a pharmacist and owner of an independent pharmacy in Jacksonville, Florida, home to multiple military facilities and thousands of TRICARE beneficiaries.[274] In dropping independent pharmacies, TRICARE beneficiaries are encountering significant hurdles when trying to access their prescriptions. Representative Andy Biggs (R-Ariz.) and Dr. Duane discussed the impact of PBM pharmacy networks on our nation's service men and women:[275]

> ***Rep. Biggs:*** *Have PBMs made it more difficult for veterans and service members to access prescription drugs in a timely manner?*

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[264] *Supra* note 116.
[265] *Supra* note 117.
[266] *Supra* note 113.
[267] *Supra* note 119.
[268] *Supra* note 120.
[269] *Supra* note 121.
[270] *Supra* note 122.
[271] *Around the nation: Lawsuit Alleges PBM's 'Refill Pill Mill' Defrauded Government*, ADVISORY BOARD (Jun. 23, 2022); *PBM Faces Suit Over Alleged 'Refill Pill Mill' Scheme*, NAT'L CMTY PHARMACISTS ASS'N (Jun. 29, 2022).
[272] *TRICARE changes force 15,000 pharmacies out of network*, The American Legion (Oct. 27, 2022).
[273] Jake Stofan, *INVESTIGATES: Veterans forced to wait for hours in long lines at NAS Jax pharmacy,* Action News Jax (May 23, 2023).
[274] *Jacksonville Florida Military Bases*, Military.com *available at* https://www.military.com/base-guide/jacksonville-florida-military-bases.
[275] *Supra* note 32.

Dr. Duane: *Absolutely.*

Representative Pat Fallon (R-Tex.) engaged with Greg Baker, CEO of AffirmedRx, to discuss the impact of Express Scripts' decision to reduce pharmacy benefits for TRICARE members:[276]

> ***Rep. Fallon:*** *In the Fall of 2022, Express Scripts announced they would be reducing prescription reimbursements for 10 million TRICARE members. Additionally, 15,000 primarily rural and independent pharmacies were then dropped from the TRICARE network. That is particularly concerning to me since I represent 10 rural counties… How does this impact access and competition? It was reported that Express Scripts removed rural staples like Walmart, Kroger, and Sams Club in favor of CVS, of course a pharmacy that is owned by one of the other Big Three. Do you find it harder to compete in the market?*
>
> ***Mr. Baker:*** *We absolutely do.*
>
> ***Rep. Fallon:*** *If we are removing competition from TRICARE networks, how does that improve service and lower costs?*
>
> ***Mr. Baker:*** *It does not do either of those things.*

Impacts of Recent Policy Proposals

I. Anti-kickback Rebate Rule

Medicare Part D rebates were shielded in the 1990s from the federal anti-kickback statutes under safe harbor protections because they were thought to be passed through to Medicare patients and lower out-of-pocket costs.[277] At the conclusion of Trump Administration, CMS finalized a rule curbing the use of rebates in Medicare Part D to pass along manufacturer rebates to patients.[278] However, patient out-of-pocket costs typically do not reflect rebates that are paid directly from drug manufacturers to PBMs and instead reflect coinsurance and copays based on the often inflated list price of the drug.[279] Instead, this rule provided safe harbor

[276] *Id.*
[277] Jeff Lagasse, *Updated: Trump-era rebate rule for Medicare Part D on hold until 2023*, HEALTHCARE FINANCE (Feb. 1, 2021).
[278] Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 85 Fed. Reg. 76,666 (Nov. 30, 2020) (to be codified at 42 C.F.R. pt. 1001).
[279] 85 Fed. Reg. 76,666 (Nov. 30, 2020) (to be codified at 42 C.F.R. pt. 1001).

provisions for rebates applied to drugs as they are dispensed at the pharmacy counter, thereby encouraging drug manufacturers, PBMs, and plan sponsors to lower drug costs for patients.[280]

Additionally, the rule would have increased PBM transparency by allowing safe harbor provisions for PBM service fees only under the conditions that PBMs report their compensation via written agreements with drug manufacturers, conduct services in compliance with state and federal law, be paid fair market value compensation for PBM services, and submit annual written disclosures to drug manufacturers that are made available to HHS.[281] The implementation of this rule was delayed to January 1, 2032, by a provision within the Inflation Reduction Act of 2022 (IRA).[282] The rebate rule, while promising for lowering out-of-pocket drug costs, must be implemented carefully to ensure that the benefits of manufacturer discounts do not accumulate to PBMs and are instead passed through to patients.

II. Medicare Price Negotiation

The passage of the IRA permitted CMS to negotiate the prices of certain prescription drugs covered under Medicare Part D.[283] Only those drugs that have been in the marketplace for several years without competition are eligible for negotiations.[284] In August 2023, the first ten drugs selected for negotiation were announced, including drugs frequently used to treat common health conditions such as diabetes, heart failure, and blood clots.[285] Several manufacturers of these medications, including AstraZeneca, Bristol Myers Squibb, Janssen Biotech, and Merck have filed lawsuits against HHS to stop the negotiation process.[286] As of July 2024, there are approximately 10 outstanding lawsuits which challenge CMS' ability to negotiate drug prices: 1 in Texas, 1 in Illinois, 1 in Ohio, 1 in Connecticut, 1 in D.C., 1 in Delaware, and 4 in New Jersey.[287] The lawsuits allege various constitutional violations, including an argument that price negotiation amounts to an illegal taking of a product without just compensation because "it allows Medicare to obtain manufacturers' patented drugs without paying fair market value under the threat of serious penalties."[288]

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[280] 85 Fed. Reg. 76,666 (Nov. 30, 2020) (to be codified at 42 C.F.R. pt. 1001).
[281] *Supra* note 278.
[282] Margaux J. Hall et al., *Congress paves the way for drug pricing reforms with passage of the Inflation Reduction Act of 2022*, ROPES & GRAY (Aug. 12, 2022).
[283] Press Release, U.S. Dept. of Health and Human Services, HHS Selects the First Drugs for Medicare Drug Price Negotiation (Aug. 29, 2023).
[284] Tami Luhby, *Drugmakers want to stop Medicare from negotiating prices. Here's what you should know*, CNN (June 16, 2023).
[285] Press Release, The White House, FACT SHEET: Biden-Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation (Aug. 29, 2023).
[286] Joseph Choi, *5 things to know about the first 10 drugs chosen for Medicare negotiation*, THE HILL (Aug. 29, 2023).
[287] O'Neill Institute for National and Global Health Law, Georgetown University Law Center, Health Care Litigation Tracker: Inflation Reduction Act, *available at* https://litigationtracker.law.georgetown.edu/issues/inflation-reduction-act/ (last visited Jul. 10, 2024).
[288] *Supra* note 286;*see also Supra* note 284.

The Administration's action threatens to negatively impact patients by increasing launch prices for new medications.[289] In August 2022, the CBO determined that "the inflation-rebate and negotiation provisions would increase the launch prices for drugs that are not yet on the market relative to what such prices would be otherwise."[290] Additionally, analysts suggest that pharmaceutical companies will attempt to counter limits on future price increases by launching new drugs at higher prices and raising prices on existing drugs under the guise of inflation.[291] Unfortunately, ZS Associates, a consulting firm with a focus on global healthcare, predicts that higher launch prices will most harshly affect treatments for cancer and other rare diseases because the IRA could restrict price increases.[292]

There are also concerns that government price setting will chill research and development (R&D) and reduce patient access as pharmaceutical companies shift R&D from drugs that are most necessary to those not beholden by U.S. price controls.[293] Additionally, price caps may discourage venture capital investment in pharmaceutical development as future pay-off will decrease.[294] In August 2022, the Association for Accessible Medicines (AAM) and the Biosimilars Council expressed disappointment with the IRA, stating it "replace[d] competition – the only proven way to provide patients relief from high brand drug prices – with a flawed framework for government price setting that will chill the development of, and reduce patient access to, lower-cost generic and biosimilar medicines."[295] Research conducted at the University of Chicago found that price controls would increase healthcare spending by $50.8 billion over 20 years, culminating in 135 fewer drugs, which in turn would result in "a loss of 331.5 million life years in the U.S., 31 times as large as the 10.7 million life years lost from COVID-19 in the U.S. to date."[296] Already, 22 drugs and 36 research programs have been discontinued by manufacturers since the passage of the IRA.[297]

Furthermore, the Biden Administration has failed to demonstrate that Americans will not experience challenges accessing treatments and long wait-times. The Chamber of Commerce argues that patients in countries with similar price control policies have access to fewer treatments and must wait longer to get those treatments and contends that the Administration has

[289] Jared S. Hopkins, *A New U.S. Law Aims to Reduce Drug Prices. But First, It Might Raise Them.,* THE WALL STREET JOURNAL (Jan. 14, 2023).
[290] Press Release, Energy and Commerce Committee, House Ways and Means Committee, and Senate Finance Committee, Democrats' Drug Price-Setting Scheme Dismantles Medicare's Promise, Undermines Seniors' Health (Aug. 29, 2023) (citing Letter from Phillip L. Swagel, Dir., Congressional Budget Off., to Hon. Jason Smith, Ranking Member, H. Comm. on the Budget (Aug. 4, 2022).
[291] *Id*. (citing to Jared S. Hopkins, *A New U.S. Law Aims to Reduce Drug Prices. But First, It Might Raise Them.,* THE WALL STREET JOURNAL (Jan. 14, 2023).
[292] *Supra* note 289.
[293] Brooke Masters, *The world will need to stop piggybacking on US pharma*, FINANCIAL TIMES (Sept. 1, 2023).
[294] *Id.*
[295] Press Release, Association for Accessible Medicines, AAM Statement on Senate Passage of Inflation Reduction Act (Aug. 7, 2022).
[296] *Supra* note 290.; Christina Smith, *The Inflation Reduction Act Will Raise Drug Costs and Reduce Cures*, Citizens Against Government Waste (Aug. 5, 2022).
[297] Life Sciences Investment Tracker, incubate *available at* https://lifesciencetracker.com.

failed to conduct research or analysis on the impact on access that America's seniors will face due to the IRA.[298]

[298] Press Release, U.S. Chamber of Commerce, U.S. Chamber: Biden Administration Rushes to Implement Drug Price Control Scheme, Failing to Examine the Negative Side Effects for Seniors (Aug. 28, 2023),

Legislative Reforms

Amid the complex concerns with PBMs' anticompetitive tactics that drive up healthcare costs for Americans, federal and state governments are advancing policy solutions to increase transparency and prohibit unfair business practices.

I. Federal reforms

Both chambers of Congress have proposed reforms in the 118th Congress that tackle problems discussed in this report with the current nature of the PBM market. These proposals include stopping retroactive DIR fees, setting reimbursement and rate floors, delinking PBM compensation from the price of a medication, standardizing performance measures for pharmacies, eliminating narrow definitions of specialty drugs that turn patients away from preferred pharmacy towards that of the PBM, stopping compulsory mail-order for patients, and expanding in-network pharmacy coverage. Bipartisan legislative proposals in the House of Representatives and Senate are at various stages of the legislative process and share the same goal of improving transparency in the PBM market to save taxpayers and patients money.

Proposed legislation in the 118th Congress includes:

- *Delinking Revenue from Unfair Gouging (DRUG) Act (H.R. 6283)* creates certain requirements for PBMs that contract with a carrier offering health benefits plans offered under the FEHB program, including de-linking policies and prohibitions on spread pricing and patient steering. Earlier this year, the House Committee on Oversight and Accountability favorably reported the DRUG Act with bipartisan support.[299]

- *Lower Costs, More Transparency Act (H.R. 5378)* passed the House of Representatives on December 11, 2023, with overwhelming bipartisan support.[300] This legislation requires a variety of transparent pricing disclosures from medical providers, as well as mandating that PBMs semiannually report to health plan sponsors information including spending, rebates, and fees associated with covered plan drugs. If this bill becomes law, PBM contracts will be required to allow health plan fiduciaries to audit certain claims and cost information to improve transparency. For PBM arrangements under Medicaid, pass-through pricing models are required and spread pricing is prohibited.[301] According to CBO, H.R. 5378 would produce net savings of $715 million and generate $4.3 billion in revenue by 2033.[302]

- *Pharmacy Benefit Manager Transparency Act of 2023 (S. 127)* prohibits PBMs from engaging in certain practices when managing the prescription drug benefits under a

[299] *Supra* note 33.
[300] *Supra* note 121.
[301] *Id.*
[302] Cong. Budget Off., Cost Estimate – Estimated Direct Spending and Revenue Effects of H.R. 5378, the Lower Costs, More Transparency Act (Dec. 8, 2023), *available at* https://www.cbo.gov/system/files/2023-12/hr5378-DS-and-Revs_12-2023.pdf.

health insurance plan, including charging the plan a different amount than the PBM reimburses the pharmacy. The bill also prohibits PBMs from arbitrarily, unfairly, or deceptively (1) clawing back reimbursement payments, or (2) increasing fees or lowering reimbursements to pharmacies to offset changes to federally funded health plans. S. 127 was reported out of the Senate Committee on Commerce, Science, and Transportation in March 2023.[303]

- *Medicare PBM Accountability Act (H.R. 5385)* amends Title XVIII of the Social Security Act (Medicare Program) to establish PBM extensive reporting requirements with respect to prescription drug plans and Medicare Advantage Prescription Drug (MA-PD) plans under Medicare Part D. H.R. 5385 was reported favorably by the House Energy and Commerce Committee in December 2023.[304]

- *PBM Reporting Transparency Act (S. 2493)* requires the Medicare Payment Advisory Commission (MedPAC) to submit two reports to Congress on arrangements with pharmacy benefit managers with respect to prescription drug plans and MA–PD plans.[305] The first report requires (1) a description of trends, including high-level averages and totals for each of the types of information submitted; (2) an analysis of any differences in agreements and their effects on plan enrollee out-of-pocket spending and average pharmacy reimbursement, and any other impacts; and (3) any recommendations the Commission determines appropriate. The second report must describe any changes with respect to the information in the first report over time, together with any other recommendations deemed appropriate by MedPAC.

- *Protecting Patients Against PBM Abuses Act (H.R. 2880)* establishes requirements for Medicare pharmacy benefit managers (PBMs) with respect to remuneration, payments, and fees. Specifically, it restricts PBMs that are under contract with plans under the Medicare prescription drug benefit or Medicare Advantage from (1) receiving income for their services other than flat dollar amount service fees; (2) basing any service fees on the prices of covered drugs or any associated discounts, rebates, or other remuneration; (3) charging plan sponsors for ingredient costs or dispensing fees in amounts that are different than what is reimbursed to the pharmacy; or (4) reimbursing network pharmacies for less than that what is reimbursed to PBM-affiliated pharmacies. Such PBMs must also report on the difference between certain costs for drugs on the plan's formulary and those that are not on the formulary but are therapeutically equivalent. PBMs must also report certain information regarding rebates and fees they receive from drug manufacturers. CMS must publish this and other information that is currently reported by PBMs online. H.R. 2880 was reported favorably by the House Committee on Energy and Commerce in December 2023.[306]

[303] S.127 - 118th Congress (2023-2024): Pharmacy Benefit Manager Transparency Act of 2023 (2023).
[304] H.R.5385 - 118th Congress (2023-2024): Medicare PBM Accountability Act (2023).
[305] S.2493 - 118th Congress (2023-2024): PBM Reporting Transparency Act (2023).
[306] H.R.2880 - 118th Congress (2023-2024): Protecting Patients Against PBM Abuses Act (2023).

- *Pharmacy Benefit Manager Sunshine and Accountability Act (H.R. 2816)* expands and otherwise modifies reporting requirements for PBMs. Current law requires PBMs contracting with plans under the Medicare prescription drug benefit or plans that are offered on state health insurance exchanges to report certain information regarding rebates, fees, and other related information. The bill applies these requirements to PBMs that contract with private health insurers, and it expands these requirements to include more specific information relating to prices and fees, such as rebates that the PBM receives from drug manufacturers that are not passed through to other entities and the highest and lowest rebate percentages the PBM receives among all its contracts. The bill also requires HHS to annually post the information reported by PBMs on its website.[307]

- *Pharmacy Benefits Manager Accountability Act (H.R. 2679)* establishes reporting requirements for PBMs. The bill's requirements include PBMs reporting annually to plan sponsors certain information about the amount of prescription drug copayment assistance funded by drug manufacturers, a list of covered drugs billed under the plan during the reporting period, and the total gross and net spending by the health plan on prescription drugs during the reporting period. In addition, PBMs must submit specified elements of the report (e.g., the total gross spending on prescription drugs) to the Government Accountability Office (GAO). With this information, GAO must report on the pharmacy networks of plans or PBMs, including whether such networks under common ownership (i.e., vertical integration) with the plans or PBMs are designed to encourage plan enrollees to use network pharmacies over other pharmacies.[308]

II. State reforms

Congress may also draw legislative solutions from the success of state-level PBM reforms, as states also act to remedy the anticompetitive nature of the PBM market. States are the primary regulator of private health insurance and all 50 states have enacted some level of PBM reform since 2017.[309]

The most commonly enacted PBM provision, passed in 44 states, prohibits PBMs from instituting contracts with pharmacies that prevent a pharmacy or pharmacist from disclosing accurate pricing information to patients.[310] The next most common legislative provision, passed in 30 states, limits the amount a patient is required to pay for their medication through manufacturer rebates or coupons and requires a patient pay the lesser of published costs for a particular drug.[311] Other state-level PBM reforms include:[312]

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[307] H.R.2816 - 118th Congress (2023-2024): Pharmacy Benefit Manager Sunshine and Accountability Act (2023).
[308] H.R.2679 - 118th Congress (2023-2024): Pharmacy Benefits Manager Accountability Act (2023).
[309] Nat'l Acad. for State Health Policy, *State Pharmacy Benefit Manager Legislation* (last updated Nov. 7, 2023), *available at* https://nashp.org/state-tracker/state-pharmacy-benefit-manager-legislation/
[310] *Id.*
[311] *Supra* note 309.
[312] *Id.*

- Requiring PBM licensure/registration
- Requiring PBMs to report rebate or other information to the state
- Establishing Maximum Allowable Costs (MAC) list requirements
- Prohibiting discrimination against 340B-covered entities
- Prohibiting claw backs/retroactive denials
- Establishing reimbursement requirements
- Preventing or prohibiting spread pricing
- Creating regulations for the state or a contracted party's audit of a PBM
- Creating regulations for a PBM's audit of a pharmacy
- Requiring PBMs to share rebate or other information to health plans
- Requiring a PBM to have a fiduciary duty to insurers
- Banning patient steering

GAO recently released a report highlighting five states' laws regulating PBM drug pricing and pharmacy payments. Most importantly, the GAO study identified that states enacting these types of reforms are most successful when regulators have "broad state regulatory authority" and "robust enforcement powers" to rely on, in addition to legislative authority.[313] In this report, notable state-level reform areas enacted in Arkansas, California, Louisiana, Maine, and New York include: [314]

- *Fiduciary or other "duty of care" requirements*: Fiduciary duty to act in the best interest of the health plan or other entity to which the duty is owed and act in "good faith" or "fair dealing."

- *Drug pricing and pharmacy reimbursement*: Limiting PBMs' use of manufacturer rebates and their ability to pay pharmacies less than they charge health plans (i.e., engage in spread pricing).

- *Transparency*: Requiring PBMs to be licensed by and/or registered and report certain information such as drug pricing, fees, and amounts of rebates received and retained.

- *Pharmacy network and access requirements*: Prohibiting discrimination against unaffiliated pharmacies and limiting patient co-pays charged by PBMs.

As these laws go into effect, greater transparency and increased competition in the healthcare market is expected to lead to pass-through cost savings for payers and patients. Texas has unique insight into the true "cost" of PBMs because its Department of Insurance requires PBMs to file annual reports on rebates, fees, and other payments.[315] In 2023, PBMs operating in Texas reported receiving $2.2 billion in manufacturer rebates, of which $91 million were retained as revenue, $2.07 billion were passed on to issuers (payers), which PBMs often own,

[313] *Supra* note 22.
[314] *Id.* .
[315] Adam J. Fein, *Texas Shows Us Where PBMs' Rebates Go*, DRUG CHANNELS INST. (Aug. 9, 2022).

and only $15 million were passed through to enrollees (patients).[316] This type of reporting for just one state's PBM revenues is an example of how better transparency measures can hold companies accountable for what they are charging payers and patients.

[316] TEX. DEP'T OF INSURANCE, 2023 PRESCRIPTION DRUG COST TRANSPARENCY REVIEW: PHARMACY BENEFIT MANAGERS (last updated May 31, 2024), *available at* https://www.tdi.texas.gov/reports/life/2023-pharmacy-benefit-managers.html

Conclusion

PBMs function as middlemen in the pharmaceutical market, situated between health insurers, drug manufacturers, and pharmacies. Their primary responsibilities include negotiating prescription drug prices with drug manufacturers and pharmacies on behalf of payers, the creation and maintenance of formularies and pharmacy networks, reimbursing pharmacies for dispensing prescriptions, and the operation of the electronic systems that process prescription drug claims at retail pharmacies.

With these roles, PBMs are ideally positioned to influence the price of prescription drugs. They should be able to decrease the cost of prescription drugs and improve Americans' health, but that has not occurred. Instead, the opposite has happened: the cost of prescription drugs has increased every year since 2005, patients have fewer choices for which pharmacies they want to use, and physicians are forced to prescribe specific PBM preferred medications which are often more expensive.

The Committee has found PBMs' anticompetitive tactics, implemented by PBMs to protect their profit margins, are often the driving force behind these decisions. Because a PBM's compensation is determined by which business model their clients choose, PBMs are incentivized to implement practices such as spread pricing and steering patients to PBM-owned pharmacies. The largest PBMs have also developed a business model where they can force drug manufacturers to pay high rebates for the manufacturer's drug to be placed in a favorable formulary tier while excluding competing, lower-priced prescriptions such as generics or biosimilars. Other tactics, such as prior authorizations and fail first, harm Americans by delaying or preventing their access to life-saving medications. These tools allow PBMs to slow the market uptake of cheaper generics and biosimilar alternatives to brand-name drugs which serves to keep the cost of prescription drugs high.

As governments have begun to examine PBMs closely and increase transparency in the marketplace, Caremark, Optum Rx, and Express Scripts have begun to create foreign corporate entities to obscure their operations and prevent them from being subject to proposed transparency reforms in the United States.

The Committee's findings indicate that the present role of PBMs in prescription drug markets is failing and requires change. Congress and states must implement legislative reforms to increase the transparency of the PBM market and ensure patients are placed at the center of our health care system, rather than PBMs' profits.