NON-PUBLIC — FOR INTERNAL COMMITTEE USE ONLY

MEMORANDUM

TO: DEMOCRATIC MEMBERS AND STAFF, SENATE COMMERCE COMMITTEE
FROM: DEMOCRATIC STAFF, SENATE COMMERCE COMMITTEE
DATE: FEBRUARY 10, 2023
SUBJECT: COMMITTEE HEARING ON "BRINGING TRANSPARENCY AND ACCOUNTABILITY TO PHARMACY BENEFIT MANAGERS."

On February 16, 2023, at 10:00 AM in Room 253 of the Russell Senate Office Building, the Senate Committee on Commerce, Science, and Transportation will hold a hearing titled, "Bringing Transparency and Accountability to Pharmacy Benefit Managers." Americans are paying increasingly more for their necessary prescription medications and there is little transparency into how drug prices are determined. Pharmacy benefit managers ("PBMs") have a large role in how Americans access their medications and how much they pay, but PBMs operate out of the view of regulators and consumers.

The bipartisan "Pharmacy Benefit Manager Transparency Act of 2023," (S. 127), was introduced on January 27, 2023, by Chair Maria Cantwell (D-Wash.) and Sen. Chuck Grassley (R-Iowa), a senior member of the Senate Judiciary and Finance committees and was referred to the Commerce Committee. This hearing will address how the "Pharmacy Benefit Manager Transparency Act" will bring transparency into PBM business practices and prohibit unfair or deceptive PBM conduct that drives up costs for consumers.

WITNESSES

- **Ryan Oftebro, PharmD, FACA;** *CEO, Kelley-Ross Pharmacy Group*[1]

  Dr. Ryan Oftebro is the CEO of Seattle-based independent pharmacy Kelley-Ross Pharmacy Group. Dr. Oftebro has served as the President of the American College of Apothecaries, Board Member and Treasurer of the Polyclinic Community Health Foundation, and on the Board of Directors of the Washington State Pharmacy Association, among other positions. He also serves as a Clinical Associate professor at the University of Washington School of Pharmacy. Dr. Oftebro holds a PharmD from the University of Washington School of Pharmacy.

- **Debra Patt, M.D., Ph.D., MBA;** *Oncologist, Texas Oncology*[2]

  Dr. Debra Patt is a practicing oncologist and breast cancer specialist in Austin, Texas, and an executive vice president of cancer practice Texas Oncology with responsibilities in healthcare policy and strategic initiatives. She is an active leader in breast cancer and

[1] "Leadership Team," Kelley-Ross, available at https://www.kelley-ross.com/about/leadership-team/.
[2] "Debra Patt," Texas Oncology, available at https://www.texasoncology.com/oncologist/debra-patt.

healthcare informatics research. Her research is also in clinical decision support, predictive analytics, telemedicine, health economics and outcomes research, tools for patient symptom management and quality improvement. As an expert in healthcare policy, she has testified before Congress about protecting access to care for Medicare beneficiaries. She chairs the Council on Legislation for the Texas Medical Association and serves as the Editor in Chief of the Journal of Clinical Oncology Clinical Cancer Informatics. Dr. Patt has held numerous leadership roles in the American Society of Clinical Oncology, serves as the President of the Texas Society of Clinical Oncology, and is a clinical Professor at Dell Medical School at The University of Texas at Austin.

- **Erin Trish, PhD;** *Co-Director and Associate Professor of Pharmaceutical and Health Economics, Schaeffer Center, University of Southern California*[3]

  Erin Trish is co-director of the USC Schaeffer Center and an associate professor of pharmaceutical and health economics at the USC School of Pharmacy. In addition, she is a nonresident fellow in economic studies at the Brookings Institution and a scholar with the USC-Brookings Schaeffer Initiative for Health Policy. Her research focuses on the intersection of public policy and healthcare markets, with recent projects focused on surprise medical bills, prescription drug spending, healthcare market concentration, and healthcare reform. She has testified in the California State Assembly and presented her research at numerous federal agencies, including the Federal Trade Commission. Trish completed a postdoctoral fellowship at the USC Schaeffer Center and the Fielding School of Public Health at the University of California, Los Angeles. She received her PhD in health policy and economics from the Johns Hopkins Bloomberg School of Public Health and her BS in biomedical engineering from Johns Hopkins University.

- **Casey B. Mulligan, PhD;** *Professor in Economics, University of Chicago*[4]

  Casey Mulligan is a professor in Economics at the University of Chicago. From 2018 to 2019 he was the Chief Economist of the Council of Economic Advisers in the Trump Administration. He previously served as a visiting professor in public economics at Harvard University, Clemson University, and the Irving B. Harris Graduate School of Public Policy Studies at the University of Chicago. Dr. Mulligan has testified to both chambers of Congress, including on the employment effects of the Affordable Care Act and other welfare programs. His research covers capital and labor taxation, the gender wage gap, healthcare, Social Security, voting, and the economics of aging. Additionally, he is affiliated with the National Bureau of Economic Research, the George J. Stigler center for the Study of the Economy and the State, and the Population Research Center. He received his PhD in economics from the University of Chicago.

[3] "Erin Trish," USCMann, available at https://pharmacyschool.usc.edu/faculty/erin-trish-phd/.
[4] "Casey B. Mulligan" University of Chicago, available at https://economics.uchicago.edu/directory/casey-mulligan

EXECUTIVE SUMMARY

This memorandum covers key questions and considerations before the Committee with respect to PBMs and the associated regulatory and consumer protection landscape. It explains: (I) the role of PBMs in the prescription drug marketplace; (II) key PBM issues in the context of consumer protection; (III) federal responses and proposals regarding PBM business practices, including the "Pharmacy Benefit Manager Transparency Act of 2023"; and (IV) state regulatory and enforcement activity regarding PBMs. An appendix follows, detailing the growth in spread pricing (i.e., the differential between costs to pharmacies and costs health insurers and payers, which is retained by PBMs).

LEGAL ISSUE

Currently, the Federal Trade Commission ("FTC") is authorized by Section 5 of the Federal Trade Commission Act, (15 U.S.C. 45) to take enforcement action against businesses that engage in unfair or deceptive acts or practices. When the FTC brings an action under Section 5, the court determines whether the conduct is unfair or deceptive.

While the FTC currently can bring an action against PBMs for unfair or deceptive practices, the court may ultimately decide that the PBM practices are unfair or deceptive. The Pharmacy Benefit Manager Transparency Act of 2023 makes it clear that spread pricing and arbitrary post-sale fees and clawbacks are unfair and deceptive. The law will also allow the FTC to seek civil penalties for the initial violation.[5]

The current drug market is opaque PBMs' transactions are conducted through contracts that are black boxes so no one knows the amount or rebates, where the rebates flow, and how much pharmacies are reimbursed. This opaque market has allowed PBMs to extract revenue from the prescription drug market without consumers, other market participant, or policymakers being able to see what value they add to the market or what the true market conditions are.

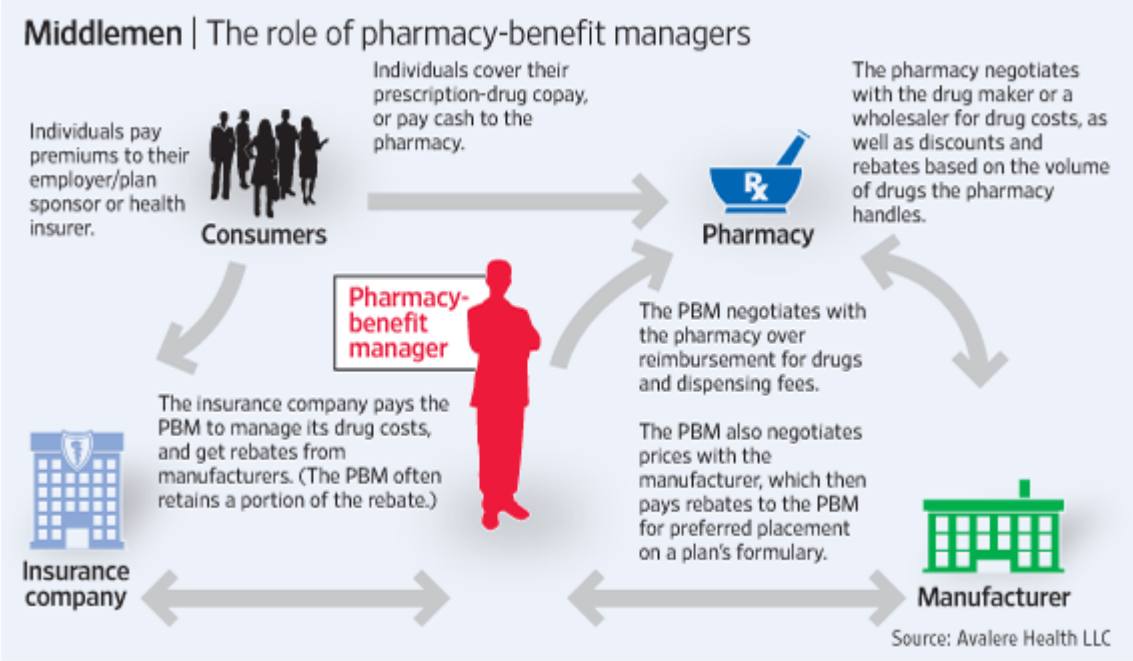
The Pharmacy Benefit Manager Transparency Act will require PBMs to report information that has not been publicly available, such as the amount of clawbacks from pharmacies, the amount of any spread the PBM retained, and changes to formulary placement. This transparency will give needed insight into the market to discourage manipulation and facilitate further policymaking regarding PBM and the prescription drug market.

BACKGROUND ON PBMS

PBMs administer prescription drug benefits on behalf of health insurers and payers, including employers, state Medicaid agencies, and commercial insurers that provide employer-sponsored

[5] Under the FTC Act, the FTC is authorized to seek civil monetary penalties if the business knowingly violated an FTC rule or an existing FTC cease and desist order. Congress can authorize civil penalties on the first violation, such as violations of the COVID-19 Consumer Protection Act, Pub. L. No. 116-260, Title XIV, § 1401(c)(1).

insurance and government-sponsored coverage.[6] PBMs negotiate drug prices with pharmaceutical manufacturers on behalf of health insurers and payers, which gives them immense bargaining power with manufacturers seeking favorable formulary placement.[7] A formulary is a tiered list of covered drugs, decided by a PBM. Favorable formulary placement by a PBM means, for example, that a drug may be easier to prescribe, which gets the manufacturers' products to more patients and means more revenue for manufacturers. PBMs use their bargaining power to obtain rebates from manufacturers on behalf of their insurer and payer clients, ostensibly to lower drug costs for consumers.[8] The following illustration shows PBMs' role in the prescription drug supply chain:



PBMs act as prescription drug middlemen for more than 266 million Americans.[9] There are 66 PBM companies,[10] but consolidation in the PBM industry has resulted in three companies controlling around 80 percent of the PBM market—CVS Caremark represents 34 percent of total adjusted claims (CVS purchased Aetna in 2018), Express Scripts (owned by Cigna) accounts for 25 percent, and OptumRx (a subsidiary of UnitedHealth) claims 21 percent.[11] Other companies make up the rest of the market: Humana has 8 percent, Prime has 6 percent, MedImpact has 4 percent, and other PBMs account for the remaining 3 percent of market share.[12] In addition to

[6] United States Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising cost of a Century Old Drug*, Staff Report, at 29 (Jan. 14, 2021) ("Senate Finance Committee Staff Report").
[7] *Id.*
[8] *Id.*
[9] *The Value of PBMs*, Pharmaceutical Care Management Association (PCMA), available at https://www.pcmanet.org/value-of-pbms/
[10] *Pharmacy Benefit Managers*, National Association of Insurance Commissioners (NAIC) (April 11, 2022), available at https://content.naic.org/cipr-topics/pharmacy-benefit-managers
[11] Pharmacy Benefit Managers: Market Landscape and Strategic Imperatives," Health Industries Research Companies (HIRC) (2022), available at https://www.hirc.com/PBM-market-landscape-and-imperatives.
[12] *Id.*

consolidation, the PBM industry is vertically integrated in that health insurance companies and pharmacy chains own PBMs.[13,14]

PBMs' revenue comes from: (1) service fees charged to pharmacies, insurers, and manufacturers; (2) prescription processing fees; (3) mail-order pharmacy charges; (4) up-charging drugs; and/or (5) pocketing rebates.[15] The PBM business is astoundingly profitable; the three top PBMs owners are Fortune 500 companies—as of 2021, CVS Health was number four with $7.2 billion in profits, UnitedHealth Group was number five with $15.4 billion in profits, and Cigna was number 13 with $8.5 billion in profits.[16,17]

I. The Role of PBMs in the Market for Prescription Drugs

PBMs were created in the 1960s when insurance companies began offering prescription drugs as a health plan benefit to control drug spending.[18] In the early 1980s, as the U.S. generic drug industry grew, PBMs saw financial incentive in transitioning consumers from brand-name prescriptions to generic drugs. At first, this worked well to control costs for consumers, but market consolidation, lack of transparency, and questionable business practices have turned the tables and given PBMs too much power over the market for prescription drugs.[19]

PBMs work in conjunction with drug manufacturers, wholesalers, pharmacies, and health insurance providers but play no direct role in the physical distribution of prescription drugs. PBMs occupy a place in the middle of the supply chain that is largely invisible to consumers. PBMs develop and maintain lists of covered medications on behalf of health insurers and payers, use their leverage to negotiate rebates and discounts from drug manufacturers, and contract directly with individual pharmacies to reimburse them for drugs dispensed to consumers.[20]

---

[13] Senate Finance Committee Staff Report, at 31.

[14]Concentration in the PBM market may result in unfair practices for consumers. For example, a group of HIV/AIDs patients sued PBM CVS Health for requiring them to fill their CVS-Caremark-administered prescriptions at CVS locations, or pay full list price for their medication. *See, e.g.*, *John Does v. CVS Health Corp. et al*, Class Action Complaint, No. 2:18-cv-01280 (N.D. Cal. Feb. 16, 2021), available at https://s3.documentcloud.org/documents/4383141/John-Doe-HIV-AIDS-vs-CVS.pdf

[15]Jack Du, "Pharmacy Benefit Management (PBM) Industry," Investopedia, January 27, 2022, available at: https://www.investopedia.com/articles/markets/070215/what-pharmacy-benefit-management-industry.asp.

[16] Fortune, *Fortune 500* (2021), available at https://fortune.com/fortune500/2021/search/

[17] It has been reported that more than 40 percent of CVS's operating income comes from its PBM line of business. Lungreth, Ingold, & Gu, *The Secret Drug Pricing System Middlemen Use to Rake in Millions*, Bloomberg (Sept. 11, 2018), available at https://www.bloomberg.com/graphics/2018-drug-spread-pricing/

[18] *Pharmacy Benefit Managers*, NAIC, supra n. 5.

[19] Harper, *Cigna's $54 Billion Purchase of Express Scripts Could Upend the Prescription Drug Market*, Forbes (March 8, 2018) available at https://www.forbes.com/sites/matthewherper/2018/03/08/cignas-54-billion-purchase-of-express-scripts-could-upend-the-prescription-drug-market/?sh=1f42d1ff2306; *see also* Dayen, *The Hidden Monopolies that Raise Drub Prices*, The American Prospect (Spring 2017), available at https://prospect.org/health/hidden-monopolies-raise-drug-prices/

[20] *Pharmacy Benefit Managers and Their Role in Drug Spending*, The Commonwealth Fund (April 22, 2019), available at https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending#2

PBMs handle negotiations and payments within the supply chain, sitting between manufacturers, insurance plans, and pharmacies. PBMs do not distribute or dispense drugs, instead they negotiate with drug manufacturers how much their health insurer or payer clients will have to pay for drugs prescribed to the subscribers of the health plans (the consumers). The price concessions the PBMs negotiate are called rebates. PBMs also negotiate the reimbursement rates pharmacies will be paid when a consumer fills a prescription. The payments from the health plans to the manufacturers, and the payments to pharmacies for prescriptions flow through PBMs. The PBM is the only party that knows what the others are paying or being paid.[21]

II. Questionable PBM Conduct That Affects Drug Cost and Access

A. Formulary Placement and Rebates

PBMs develop formularies (lists of covered drugs) on behalf of health insurers and payers. To get their drug placed on a formulary, pharmaceutical manufacturers provide rebates to PBMs, some of which the PBMs keep, some of which are passed on to insurers and payers. PBMs create tiers within formularies and tier placement affects how much patients pay for the drug in co-pays or co-insurance.[22] Manufacturers will pay higher rebates to PBMs for preferred formulary placements (e.g., placement in a tier that does not require pre-authorization) or to have the only drug of its class placed on a formulary.[23]

Because PBMs retain a share of the rebate, they have an incentive for manufacturers to keep list prices high, and because manufacturers need PBMs to gain formulary access, manufacturers will not set drug prices too low, or lower the prices, because of concerns that PBMs will react negatively to the reduced rebate.[24] This has been a source of debate between drug manufacturers and PBMs where the manufacturers have argued that they must raise list prices for drugs to pay the rebate and PBMs have contended that they have been passing a larger share of the rebates to insurers.[25]

A 2020 white paper published by the USC Schaeffer Center for Health Policy and Economics concluded that there is a near one-to-one relationship between rising rebates and increasing list prices for branded prescription drugs.[26] This finding supports the notion that PBMs' demands for rebates are at least partly responsible for increasing list prices for drugs.[27] Consumers may bear these high prices if their cost-sharing is based on a percentage of the list price or if they are

[21] *Pharmacy Benefit Managers*, NAIC, supra n. 9.
[22] Senate Finance Committee Staff Report, at 31.
[23] *Id.* at 40.
[24] *Id.* at 89.
[25] *Pharmacy Benefit Managers and Their Role in Drug Spending*, The Commonwealth Fund (April 22, 2019), available at https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending#2
[26] Sood, Ribero, Ryan, & Van Nuys, *The Association Between Drug Rebates and List Prices*, USC Schaeffer Center for Health Policy & Economics (Feb. 11, 2020) available at, https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/
[27] *Id.*

among the 25 percent of Americans who have high-deductible health plans, who pay more for their prescriptions for a longer period of time before they meet the higher deductible.

PBMs also have an incentive to prioritize high-priced (or highly rebated) drugs over drugs that are more cost effective. This has been cited as the reason tier placement has been used to favor on-patent brand-name drugs over less expensive (i.e., potentially generic) drugs that are just as clinically useful.

In addition to rebates, PBMs charge drug manufacturers "rebate administration fees" for tracking the rebates owed to the insurers and payers and providing claims data that the drug companies use to gauge their market share. Like rebates, these fees are based on a percentage of the drug prices (2 percent to 5 percent of product sales).[28]

B. Spread Pricing

Another role PBMs play in the prescription drug market is reimbursing pharmacies for the drugs they dispense to consumers who receive drug benefits from an insurer or payer. Spread pricing occurs when the PBM charges the insurer a higher price for a drug than it reimburses the pharmacy, and the PBM retains the difference.

Spread pricing is most common with generic drugs, which make up about 90 percent of all prescriptions dispensed in the United States because generics are a way to keep drug costs under control for insurers and payers.[29] Insurers and payers, including Medicaid and Medicare Part D, are paying millions to PBMs because of spread pricing.

In an investigative report, *Bloomberg* journalists examined the prices of 90 of the best-selling generic drugs used by Medicaid managed-care plans. For the 90 drugs, which included more than 500 dosages and formulations, PBMs and pharmacies skimmed off $1.3 billion of the $4.2 billion the Medicaid insurers spent on the drugs in 2017. And this is only for Medicaid insurers—other payers may not have access to the data necessary to determine what they are paying as a result of spread pricing. Examples of spread pricing are set forth in the Appendix. The lack of transparency in the PBM market, discussed below, makes spread pricing possible.

C. Post-sale clawbacks of pharmacy reimbursements

PBMs apply or enforce several post-sale fees on pharmacists that increase their profit margin (and consequentially reduce pharmacy profits). One such fee is the direct and indirect remuneration ("DIR") fee, which was originally created by the Center for Medicare and Medicaid Services ("CMS") to provide visibility into the true cost of drugs provided through

[28] *Id.* at 8; *see also* Walker, *Drugmakers Point Finger at Middlemen for Raising Drug Prices*, The Wall Street Journal (Oct. 3, 2016), available at https://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336.

[29] Lungreth, Ingold, & Gu, *The Secret Drug Pricing System Middlemen Use to Rake in Millions*, Bloomberg (Sept. 11, 2018), available at https://www.bloomberg.com/graphics/2018-drug-spread-pricing/.

Medicare Part D, ensure accurate payments to plan sponsors, and reduce the financial burdens on Medicare Part D beneficiaries and plan sponsors.[30]

While DIR is a part of Medicare Part D, the way PBMs have leveraged DIR to their advantage is not a necessary part of Medicare Part D. PBMs (and insurance plans) have imposed DIR fees on pharmacies through the use of plan performance assessments, which are imposed on pharmacies after the point-of-sale. These payments to the PBM are known as "clawbacks" and can be assessed months after the sale of the medication to the consumer. Often, the performance measures are unknown, unpredictable, inconsistent, and outside of a pharmacy's control. CMS has reported that DIR fees grew more than 107,400 percent between 2010 and 2020, much of which occurred after 2012 when the use of performance-based payment arrangements between Medicare Part D sponsors or PBMs and pharmacies became more prevalent.[31] DIR fees increase consumer costs because they are not always passed back to the consumer.

Another post-sale fee that PBMs assess is a brand effective rate ("BER") or generic effective rate ("GER"). This is a contractual rate set by PBMs for reimbursement for generic drugs. The contractual reimbursement is a percentage of the drug's average wholesale price and measured at the aggregate PSAO level. When the aggregate reimbursement to pharmacies falls below the contracted effective rate, the PBM will assess the pharmacy for the "overpayment" and claw back the reimbursement. This clawback frequently happens at the end of a calendar year, after the drug was authorized and dispensed to the consumer.[32] It has been reported that one PBM, OptumRx, demanded GER recoupment from pharmacies for claims submitted two years earlier.[33] As with DIR fees, it is unclear whether these fees are passed back to the consumer or the insurance plan or payer.

D. Lack of Transparency

The pharmaceutical pricing structure is opaque. And because PBMs are in the middle of all the transactions, they are they only entities with all the information about the real price for prescription drugs.

Many of the inputs to drug prices are determined in behind-the-scenes pricing deals that PBMs initiate or are involved in.[34] Rebates can obscure the actual cost of drugs if manufacturers increase their prices to cover the rebates. Spread pricing can obscure the cost of drugs because the insurer will have no idea how much less a PBM is reimbursing a pharmacy compared to what

[30] 42 C.F.R. § 423.308

[31] Centers for Medicare & Medicaid Services, Department of Health and Human Services, Notice of Proposed Rule, *Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs*, 87 Fed. Reg. 1842, 1910 (Jan 12, 2022).

[32] *What Pharmacies Should Know About DIRs, GERs, and BERs*, AmerisourceBergen (Aug. 18, 2021), available at https://www.amerisourcebergen.com/insights/pharmacies/what-pharmacies-should-know-about-dir-fees-and-ger-and-ber-recoupments.

[33] *Pharmacy Alert: History and Status of Generic Effective Rate*, Frier Levitt (Feb. 7. 2020), available at, https://www.frierlevitt.com/articles-publications/service/pharmacylaw/pharmacy-alert-history-and-status-of-generic-effective-rate/.

[34] Turner, *Price Transparency Is Critical to Drug Pricing Solutions*, Forbes (July 11, 2017), available at https://www.forbes.com/sites/gracemarieturner/2017/07/11/price-transparency-is-critical-to-drug-pricing-solutions/?sh=4e9cf300204a.

the insurer is paying for the drug. Post-sale fees obscure drug costs when they are not returned to the insurer or consumer. Insurers cannot make informed decisions about their PBM contracts when they do not have good information about the price of the drugs for which they are paying.

III. Federal responses and proposals regarding PBM business practices

A. Federal response

The federal government has taken a number of actions aimed at curbing PBM practices that result in higher costs for consumers and taxpayers. In 2018, by passing S. 2554, Congress prohibited health plans from including "gag orders" in their contracts with pharmacy networks that would ban pharmacists from disclosing to consumers if a drug would cost less if they paid for it out-of-pocket rather than under their insurance plan and required them to ensure that PBMs acting on their behalf do not include gag orders.[35]

In November 2021, the Biden administration published interim final rules requiring health plans to submit healthcare spending information to the government, including prescription drug rebates, fees, and other remuneration paid by drug makers.[36]

The FTC has initiated a study into PBM practices, including whether PBMs set prices to unfairly favor PBM-affiliated pharmacies at the expense of independent pharmacies.[37]

B. Select Legislative Proposals

A number of bills have been introduced in Congress to curb PBM practices and bring more transparency into the prescription drug market. Bills introduced Congress include:

118th Congress Legislative Proposals:

- *Pharmacy Benefit Manager Transparency Act of 2023*, S.127. This bill—reintroduced, incorporating changes from the Commerce Committee markup during the 117th Congress—would prohibit PBMs from: (1) charging a health plan or payer a different amount for a prescription drug than it reimburses the pharmacy where the PBM retains the difference; (2) arbitrarily, unfairly, or deceptively reducing or, clawing back a pharmacy reimbursement payments; or (3) arbitrarily, unfairly, or deceptively increasing fees or lowering reimbursements to pharmacies to offset reimbursement changes in federally-funded health plans. PBMs would be exempt from liability if they: (1) return 100 percent of any price concessions to a health plan or payer; or (2) provide full disclosure of the cost, price and reimbursement of prescription drugs to health plans and

[35] Patient Right to Know Drug Prices Act, S. 2554, 115th Congress (2018), https://www.congress.gov/bill/115th-congress/senate-bill/2554
[36] *See supra* n.27.
[37] *FTC Launches Inquiry Into Prescription Drug Middlemen Industry*, Federal Trade Commission (June 7, 2022), available at https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

pharmacies; all fees markups, and discounts they charge or impose on health plans and pharmacies; or the aggregate remuneration fees they receive from drug makers to health plans, payers, and federal agencies. It would prohibit an individual from knowingly reporting false or misleading PBM-related information to a federal department or agency.

The bill would also require PBMs to file an annual report with the FTC aggregating: (1) differences between the amounts received from health plans and payments to pharmacies for prescription drugs; (2) fees charged to and amounts clawed back from reimbursements to pharmacies; (3) explanations of cost, copay, coinsurance, or deductible increases or reimbursement rate decreases for a prescription drug; and (4) differences between reimbursements/charges to affiliated and nonaffiliated pharmacies. The FTC would have to submit annual reports to relevant committees regarding complaints received by, reports filed with, actions brought by, and open investigations or inquiries by the FTC, surrounding PBMs. Within a year of enactment, the FTC would also be required to submit a report addressing the policies, practices, and role of PBMs regarding formulary design or placement.

The bill includes whistleblower protections and would allow the FTC and state attorneys general to enforce its provisions, including by seeking civil penalties for each violation.

In the 117th Congress, the *Pharmacy Benefit Manager Transparency Act of 2022,* S. 4293, was reported favorably out of Committee on June 22, 2022, with an amendment in the nature of a substitute.

- *Prescription Pricing for the People Act of 2023*, S. 113, This bill—reintroduced from the 117th Congress— would require the FTC to study the role of intermediaries in the pharmaceutical supply chain and provide Congress with policy recommendations. Introduced by Senator Grassley with 10 co-sponsors (seven Republicans, four Democrats) on Jan. 26, 2023. The Judiciary Committee considered the bill on Feb. 9, 2023, where was reported favorably on a voice vote.

<u>Select 117th Congress Legislative Proposals:</u>

- *Build Back Better*, H.R. 5376, would require insurers and PBMs to provide plan sponsors with a biannual report on drugs dispenses, costs, member out-of-pocket spending and other information.
- *Reduced Costs and Continued Cures Act*, H.R. 5260, would amend titles XI, XVIII, and XIX of the Social Security Act to lower prescription drug prices in the Medicare and Medicaid programs, improve transparency related to pharmaceutical prices and transactions, lower patients' out-of-pocket costs, and ensure accountability to taxpayers. It was introduced by Senator Peters and five Democrat co-sponsors on September 14, 2021.

- *Prescription Pricing for the People Act of 2021*, S. 1388, would require the FTC to study the role of intermediaries in the pharmaceutical supply chain and provide Congress with policy recommendations. Introduced by Senator Grassley with eight co-sponsors (six Republicans, two Democrats) on July 29, 2021.
- *Pharmacy Benefit Manager Accountability Study Act of 2021*, H.R. 1829, would require the Government Accountability Office to report on the role of pharmacy benefit managers in the supply chain and recommend legislative actions to lower the cost of prescription drugs. The measure was also introduced in the Senate (as S. 298) by Senator Blackburn and cosponsored by Senator Braun on February 8, 2021.
- *Drug Price Transparency Act of 2021*, S. 1523, would amend title IX of the Social Security Act and title XXVII of the Public Health Service Act to establish requirements with respect to prescription drug benefits, including by ensuring that reduction in prices to PBMs are reflected in the price for consumers. Introduced by Braun with two Republican co-sponsors on April 21, 2021.
- *Drug Price Transparency in Medicaid Act of 2021*, H.R. 6101, would amend title XIX of the Social Security Act to improve transparency and prevent the use of abusive spread pricing and related practices in the Medicaid program. Introduced by Carter with three Republicans and one Democrat co-sponsors on December 1, 2021.
- *Lower Costs, More Cures Act of 2021*, H.R. 19, would provide reforms with respect to the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, and the Food and Drug Administration. Introduced by Representative Rodgers with 124 cosponsors (124 Republicans) on April 21, 2021.

IV. State regulatory and enforcement activity regarding PBMs

State policymakers and law enforcement officers have taken action to curb the PBM practices listed above.

A. State laws

All states and the District of Columbia have used their regulatory authority over insurance carriers or their authority as administrators of their state Medicaid program to curb these PBM practices to some degree.[38] States also have enacted laws requiring PBMs to obtain a license to operate in the state.[39] Some states have enacted laws that prohibit or regulate spread pricing and laws requiring PBMs to report pricing and rebate information to promote transparency.[40]

---

[38] *See State Policy Options and Pharmacy Benefit Managers (PBMs)*, National Conference of State Legislatures, available at https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx

[39] As of August 2019, 27 states required PBMs to obtain a license. *New PBM Laws Reflect States' Targeted Approaches to Curb Prescription drug Costs*, National Academy for State Health Policy (Aug. 12, 2019), available at https://www.nashp.org/comparison-state-pharmacy-benefit-managers-laws/#:~:text=Comparison%20of%20State%20Pharmacy%20Benefit%20Managers%20Laws%20,%20%20%E2%9C%93%20%2029%20more%20rows%20.

[40] *See id*; *see supra* n. 32.

B. State enforcement actions

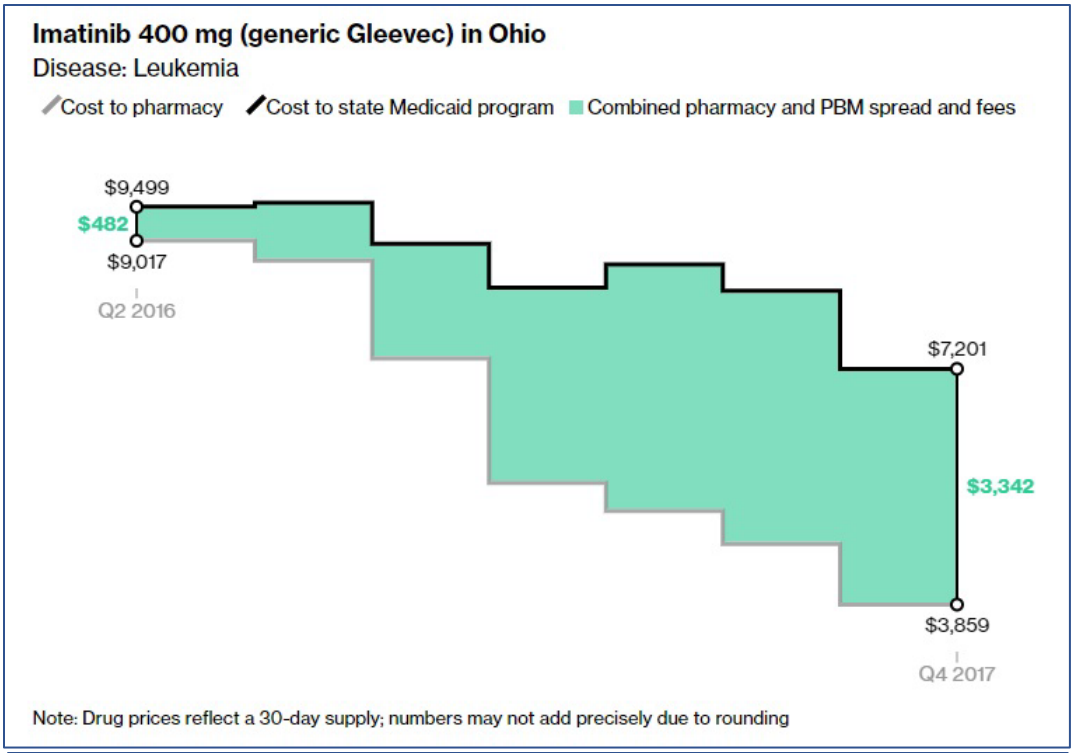
Several state attorneys general have sued PBMs for various practices. For example, on April 13, 2022, the Louisiana Attorney General sued OptumRx for inflating the price of prescription drug charges in the state's Medicaid program, including by spread pricing and by clawing back money from pharmacies without passing it back to the state.[41] In October of 2021, Centene Corporation, a large seller of Medicaid health plans, paid $71.2 million to settle a lawsuit by Illinois and Arkansas that its PBM subsidiary submitted inaccurate bills to the state Medicaid programs and failed to disclose discounts; and settled a similar lawsuit with Ohio and Mississippi for $143 million in June of 2021.[42]

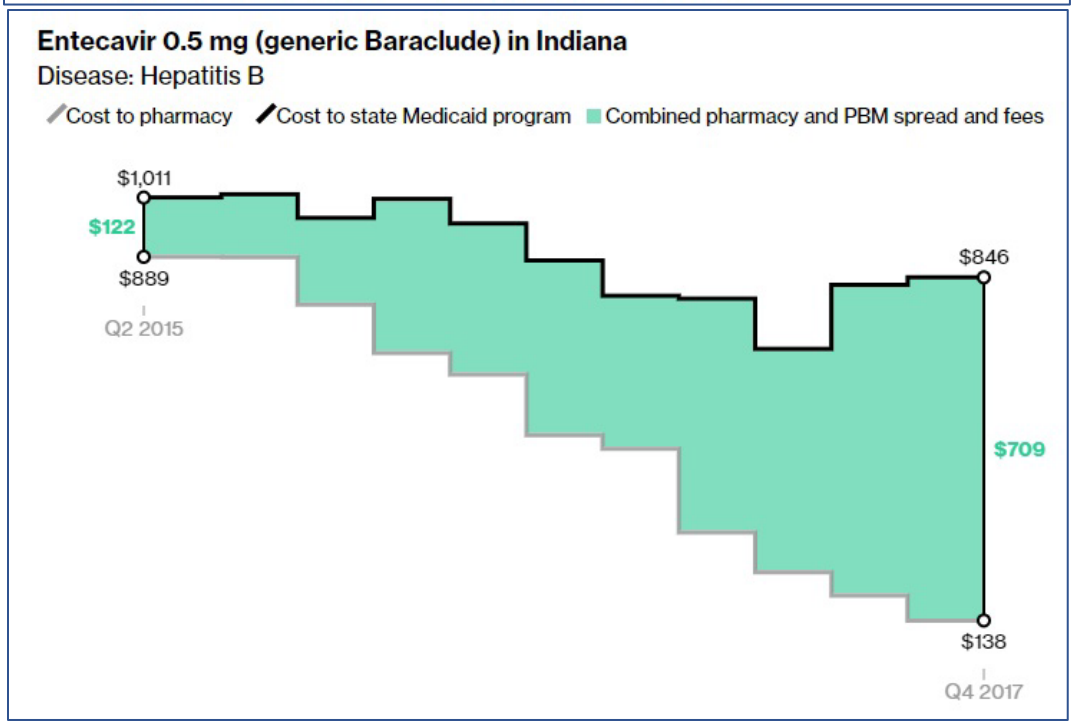
APPENDIX

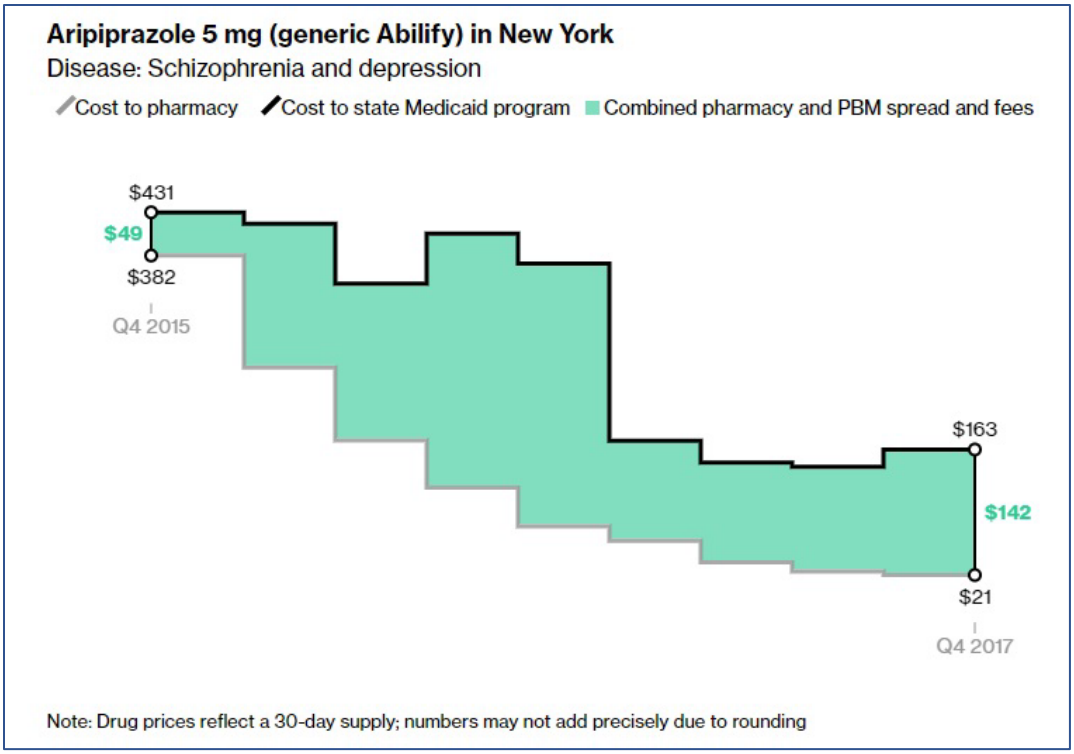
In an analysis of pharmacy and middleman markups in Medicaid plans around the country, Bloomberg found big spreads on dozens of drugs, and evidence that the spreads are growing. For many widely used generic drugs, state insurance plans are collectively paying millions of dollars in fees to private companies. For example, Frahm's South Side Drug bought pills from distributors, and dispensed prescriptions to the Wapello County jail.[43] In turn, the pharmacy got reimbursed for the drugs by CVS Health Corp., which managed the county's drug benefits plan. As he compared the newspaper notice with his own records, and then with the county's, Frahm saw that for a bottle of generic antipsychotic pills, CVS had billed Wapello County $198.22. But South Side Drug was reimbursed just $5.73.

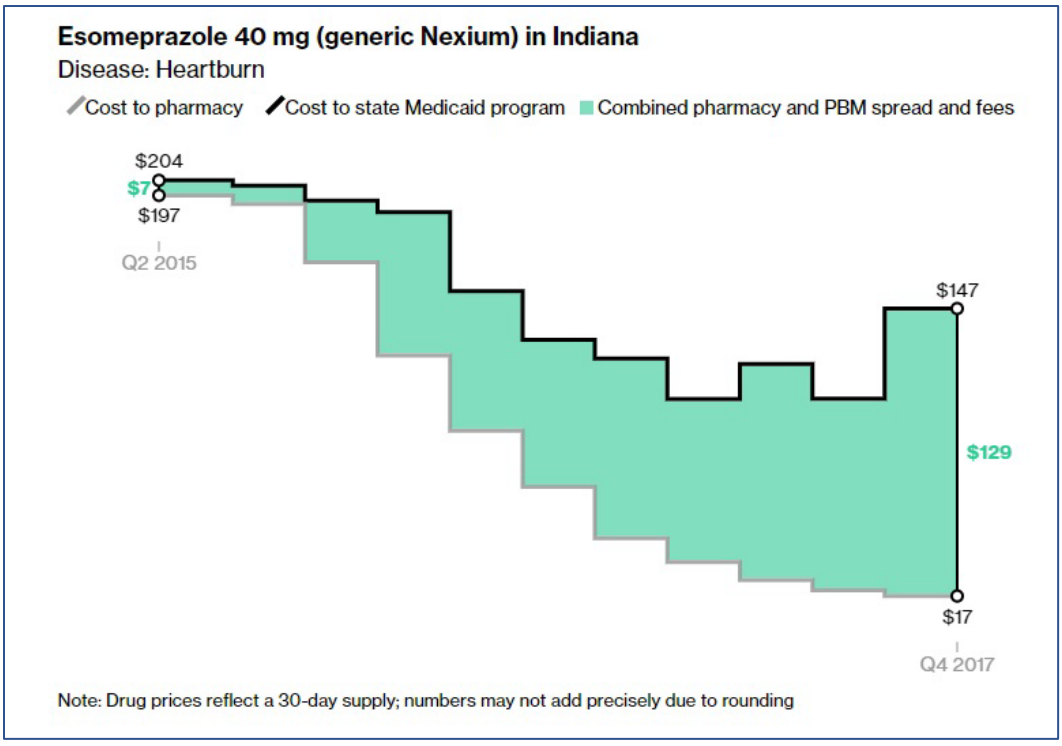
In line with Frahm's analysis, Bloomberg examined the prices of 90 of the best-selling generic drugs used by Medicaid managed-care plans.[44] For the 90 drugs analyzed, which includes more than 500 dosages and formulations, PBMs and pharmacies siphoned off $1.3 billion of the $4.2 billion Medicaid insurers spent on the drugs in 2017.

[41] *State of Louisiana v. OptumRx and United Healthcare of Louisiana*, C-717848, East Baton Rouge Parish (April 12, 2022), available at http://www.ag.state.la.us/Files/Article/13028/Documents/FileStampedPetitionOptum.pdf
[42] https://ncpa.org/newsroom/qam/2021/10/04/centene-shell-out-71-million-settle-pbm-overpayments-suit#:~:text=The%20lawsuits%20stemmed%20from%20allegations%20that%20Envolve%2C%20Centene%27s,fees%2C%20according%20to%20an%20announcement%20of%20the%20settlement.
[43] https://www.bloomberg.com/graphics/2018-drug-spread-pricing/
[44] https://www.bloomberg.com/graphics/2018-drug-spread-pricing/


Imatinib 400 mg (generic Gleevec) in Ohio
Disease: Leukemia
Cost to pharmacy
Cost to state Medicaid program
Combined pharmacy and PBM spread and fees
$9,499
$482
$9,017
Q2 2016
$7,201
$3,342
$3,859
Q4 2017
Note: Drug prices reflect a 30-day supply; numbers may not add precisely due to rounding


Entecavir 0.5 mg (generic Baraclude) in Indiana
Disease: Hepatitis B
Cost to pharmacy
Cost to state Medicaid program
Combined pharmacy and PBM spread and fees
$1,011
$122
$889
Q2 2015
$846
$709
$138
Q4 2017


Aripiprazole 5 mg (generic Abilify) in New York
Disease: Schizophrenia and depression
Cost to pharmacy
Cost to state Medicaid program
Combined pharmacy and PBM spread and fees
$431
$49
$382
Q4 2015
$163
$142
$21
Q4 2017
Note: Drug prices reflect a 30-day supply; numbers may not add precisely due to rounding


Esomeprazole 40 mg (generic Nexium) in Indiana
Disease: Heartburn
Cost to pharmacy
Cost to state Medicaid program
Combined pharmacy and PBM spread and fees
$204
$7
$197
Q2 2015
$147
$129
$17
Q4 2017
Note: Drug prices reflect a 30-day supply; numbers may not add precisely due to rounding