

A View from Congress:

**Role of Pharmacy Benefit
Managers in Pharmaceutical
Markets**



December 10, 2021

Report Prepared by the House Committee on Oversight and Reform Minority Staff

Table of Contents

Table of Contents	2
Executive Summary	3
Background	6
PBM Impact on Patient Care.....	7
PBMs’ Anticompetitive and Fraudulent Behavior	10
Legislative Landscape.....	12
117th Congress	13
<i>Lower Costs, More Cures Act of 2021 (H.R. 19 - Republican sponsorship)</i>	13
<i>Pharmacy Benefit Manager Accountability Study Act of 2021 (H.R. 1829)</i>	13
<i>Improving Transparency to Lower Drug Costs Act of 2021 (H.R. 3682)</i>	13
<i>Pharmacy DIR Reform To Reduce Senior Drug Costs Act (H.R. 3554)</i>	13
<i>Ensuring Seniors Access to Local Pharmacies Act of 2021 (H.R. 2608)</i>	14
<i>Insulin Cost Reduction Act (H.R. 5623)</i>	14
<i>Stop Stalling Access to Affordable Medications (H.R. 2883)</i>	14
<i>Preserve Access to Affordable Generics and Biosimilars Act (H.R. 2891)</i>	14
<i>Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act (H.R. 2884)</i>	15
<i>Prescription Pricing for the People Act (S. 1388)</i>	15
116th Congress	15
<i>Prescription Drug Pricing Reduction Act of 2020 (S. 4199)</i>	15
<i>Encouraging Innovative Benefit Design to Lower Costs for Seniors Act (S. 3013)</i>	15
<i>Drug Price Transparency in Medicaid Act of 2019 (H.R. 5281)</i>	15
<i>Insulin Price Reduction Act (H.R. 4906)</i>	15
<i>Competition Prescription Act of 2019 (H.R. 3947)</i>	16
<i>Lower Health Care Costs Act (S. 1895)</i>	16
<i>Pharmacy Benefit Manager Accountability Study Act of 2019 (H.R. 3223)</i>	16
<i>More Efficient Tools to Realize Information for Consumer Act (H.R. 2296)</i>	16
<i>Public Disclosure of Drug Discounts and Real-Time Beneficiary Drug Cost Act (H.R. 2115)</i>	16
<i>Prescription Drug Price Transparency Act (H.R. 1035)</i>	17
<i>Phair Pricing Act of 2019 (H.R. 1034)</i>	17
<i>PBM Transparency in Prescription Drug Costs Act (H.R. 5304)</i>	17
Conclusion	17
Appendix.....	19

Executive Summary

Americans spend more on prescription drugs—about \$1,200 per person—than any other country.¹ Total spending on prescription drugs in the United States is also growing,² rising to \$369.7 billion in 2019.³ Although prescription drug prices account for only roughly 10 percent of overall healthcare spending, Americans pay more out-of-pocket for prescription drugs than for hospital care or health insurance.⁴

For years, congressional Democrats have attacked brand-name pharmaceutical companies over pricing issues, claims of excessive profits, and tactics to maintain market share. In seeking to cast these companies as the sole villains in the drug cost debate, they disregard the benefits they provide the public in the form of treatments and cures, such as the three effective COVID-19 vaccines developed through Operation Warp Speed. In their focus on manufacturers, Democrats also ignore an important factor in the prescription drug debate: the practices of Pharmacy Benefit Managers (PBMs).

PBMs manage and administer prescription drug benefits on behalf of private companies and public programs such as Medicare and Medicaid. They act as middlemen in the marketplace, negotiating with health insurers, pharmaceutical manufacturers, pharmacies, and other entities with the supposed objective of driving down costs.

Costs, however, have been rising. In the past decade, a time period which coincides with the consolidation of the PBM market, drug prices have risen three times faster than inflation and patient out-of-pocket costs have risen 53 percent.

Why did this happen? During the course of this review, Committee Republicans discovered the following key findings:

- 1. PBM practices impact patient health.** In some circumstances, PBMs require prior authorization before a patient is approved for a given prescription. Sometimes there are lengthy delays for such prior authorizations, and patients can suffer – or even die – while they wait. PBMs also engage in fail first practices, in which a drug must either prove ineffective or intolerable for the patient before they can opt for different drug. In some cases, patients have to fail first on a far more expensive option, even if cheaper alternatives exist. Why? Because the PBM has a financial incentive to force the patient onto a more expensive option.

¹ Robert Langreth, *Drug Prices*, Bloomberg, (Sep. 16, 2020), <https://www.bloomberg.com/quicktake/drug-prices>.

² *A Look at Drug Spending in the U.S.: Estimates and Projections from Various Stakeholders*, PEW CHARITABLE TRUSTS (Feb. 27, 2018), <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/02/a-look-at-drug-spending-in-the-us>.

³ *National Health Expenditure Data: NHE Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 16, 2020), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet>.

⁴ Yusra Murad, *As Drug Prices Soar, Policymakers Eye Dose of Government Intervention*, MORNING CONSULT (Dec. 20, 2018), <https://morningconsult.com/2018/12/20/drug-prices-soar-policymakers-eye-dose-government-intervention/>.

2. **PBMs use their market leverage to increase their profits, not reduce costs for consumers.** PBMs control which medications are included on a given health plan’s formulary, or the list of drugs that plan agrees to cover. Drug manufacturers agree to discounts, or pay rebates, in order to get their products placed more favorably on formularies. But the savings from the discounts and rebates do not make their way down to the consumer; they go to the PBMs’ bottom line.
3. **Drug manufacturers actually raise their prices due to PBMs.** As PBMs demand larger and larger rebates or discounts, manufacturers offset these reductions by raising the “list” prices for their drugs. PBMs encourage this practice because they pocket the higher rebates received from higher priced drugs.
4. **PBMs own their own pharmacies, which creates conflicts of interest, hurts competition, and distorts the market.** Another key function of PBMs is to establish a network of pharmacies from which plan beneficiaries can get their prescriptions filled. However, the three largest PBMs—CVS Caremark, Express Scripts, and Optum Rx—own their own pharmacies. They also control 80 percent of the market. But they are not the only ones – smaller PBMs own their own pharmacies too. PBMs “steer” patients to the pharmacies they control, making it difficult for independent pharmacies to survive. PBMs also reimburse unaffiliated pharmacies at low rates and charge a number of fees to independent pharmacies. These retroactive fees can be for just participating in the network, or they can be tied to performance metrics, such as pharmacy refill rates, error rates, or audit rates, which the PBM establishes. These retroactive fees add up – sometimes it costs a pharmacy more to fill a prescription than it is reimbursed. For specialty pharmacies, they accrue fees based on irrelevant metrics.
5. **Rebates are not the only way PBMs drive up costs.** A list price is like the sticker price on a car: few people actually pay that amount. Higher list prices still drive-up costs, even if that’s not the actual cost patients are paying. Insurance premiums and copayments are based on list prices. PBMs engage in a number of questionable practices, one of which is spread pricing, in which PBMs pay a pharmacy a lower amount than they report to a health plan sponsor. The PBM pockets the difference. Sometimes they get caught – PBMs have overcharged state Medicaid programs in Ohio, Kentucky, Illinois, and Arkansas more than \$415 million once spread pricing schemes were discovered.⁵ It is difficult to determine the full extent of the impact of these practices, but it is always the American taxpayer who loses.

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

- 6. Greater transparency is necessary to determine the extent of the damage PBMs' tactics are having on patients and the marketplace.** Without insight into PBM practices, it is difficult to determine the extent to which these practices are damaging pharmaceutical markets.
- 7. There are twenty-two Republican and bipartisan legislative solutions which could provide meaningful reform and lower prescription drug costs for Americans.**

Unlike Democrats, Ranking Member James Comer and House Republicans are not ignoring PBMs; they are taking steps to investigate the entire prescription drug marketplace. On November 17, 2021, Ranking Member Comer held a forum on “Reviewing the Role of Pharmacy Benefit Managers” (herein “the forum”) where lawmakers heard from experts, pharmacists, physicians, and PBMs about the role PBMs play in the rising cost of prescription drugs. At the forum, House Republicans heard significant testimony on the need for greater transparency in pharmaceutical markets to determine the extent of the damage PBMs' tactics are having on patients and the marketplace.

As the forum and this report highlights, House Republicans continue to conduct oversight over the entire prescription drug market to help reduce the costs of prescription drugs for all Americans. This report also describes twenty-two legislative solutions which could provide meaningful reform and lower prescription drug costs for Americans.

Background

PBMs are companies that manage prescription drug benefits for insurers, Medicare Part D drug plans, self-insured employers, and other payers, such as state Medicaid programs (collectively known as “payers”).

Originally, PBMs functioned as passive processors of prescription drug claims at the retail pharmacy level. However, today PBMs are more active intermediaries, or middlemen, in the U.S. health care system. PBMs negotiate on behalf of payers with drug companies for discounts on drugs in the form of rebates. Additionally, PBMs administer pharmacy networks, typically comprised of retail and chain store pharmacy providers, as well as pharmacies or physician dispensing facilities associated with medical practices (collectively in this document, all are referred to as “pharmacy providers”).

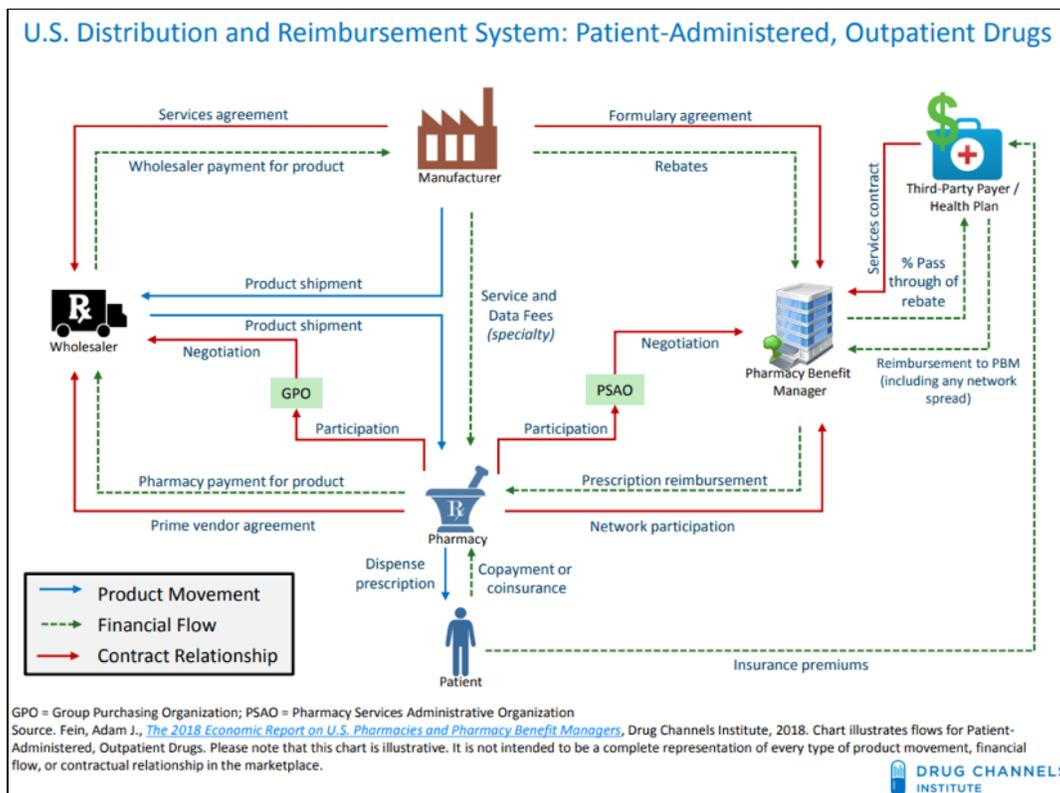


Figure 1: Flow of Money in Pharmaceutical Markets⁶

The PBM industry has significantly consolidated in the last 10 years resulting in the three largest PBMs (in order)—CVS Caremark, Express Scripts, and Optum Rx—controlling an

⁶ Brandt Dietary, *Pharmacy Benefit Manager Regulation: What Happens Now?*, Michael Best Strategies, (Jan. 14, 2019), <https://michaelbeststrategies.com/2019/01/14/pharmacy-benefit-manager-regulation-what-happens-now/>.

estimated 80 percent of the prescription drug market in this country.⁷ Further, these major PBMs and even smaller PBMs, own and operate their own retail and/or mail-order pharmacies. Due to this vertical and horizontal consolidation, experts have expressed concerns that PBMs' monopoly power no longer benefits payers and patients.⁸

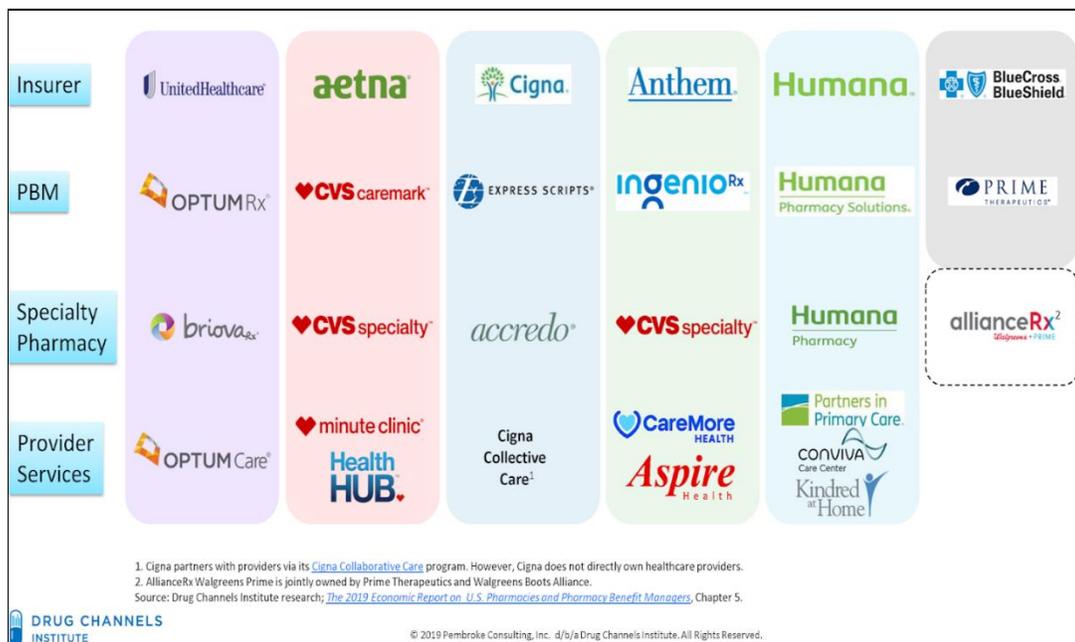


Figure 2: Vertical Integration in PBM Markets⁹

PBM Impact on Patient Care

PBMs negotiate and administer the list of prescription drugs covered, also known as a formulary, by commercial insurance plans and Medicare Advantage. PBMs' control over formularies enables them to seek higher rebates from pharmaceutical companies in exchange for better positioning on the formulary.¹⁰ At the forum, Dr. Madelaine Feldman, president of the

⁷ Josh Mader, *Pharmacy Benefit Managers: Market Landscape and Strategic Imperatives*, Hiro, (2021), <https://www.hirc.com/PBM-market-landscape-and-imperatives>.

⁸ Paige Minemyer, *Senate hearing puts spotlight on debate over consolidation in PBM market*, Fierce Healthcare, (Apr. 11, 2019), <https://www.fiercehealthcare.com/payer/senate-hearing-puts-spotlight-debate-over-consolidation-pbm-market>.

⁹ Adam Fein, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?*, Drug Channels Institute, (Dec. 12, 2019), <https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html>.

¹⁰ Deirdre Macbean, *How high prescription drug rebates can derail pharmacy benefit plans*, Health Partners, <https://www.healthpartners.com/plan/blog/prescription-drug-rebates-and-pbms/>.

Coalition of State Rheumatology Practices, and Rep. Diana Harshbarger (R-Tenn.) discussed PBMs' tactics to steer patients to higher priced drugs:¹¹

Dr. Feldman: Rebates do play into step therapy. Often times, I have to choose a drug that is more expensive before I can get to the less expensive drug ... Take the example of the \$10,000 metastatic prostate cancer therapy drug available on the formulary. You must step through the \$10,000 drug before you can get to the \$350 drug...

One self-employed, self-insured woman who has atrial fibrillation always paid the same price and signed the same contract every year. Now the drug costs \$500 ... that is because another manufacturer came in with a bigger price concession and kicked her drug to a higher tier.

Rep. Harshbarger: You know what that's called? That's called pay-to-play.

Finding: PBM practices impact patient health.

PBMs increasingly use tactics such as prior authorizations, fail first step therapy, and other utilization management tools to dictate what treatment patients with cancer and other serious diseases can receive.¹² Prior authorizations occur when PBMs determine whether a prescribed treatment will be covered, often when there is a lower-cost alternative or concerns that the treatment may not be safe for a patient based on the patient's health conditions.¹³ Fail first step therapies are when PBMs require a patient to fail on a medication. Failure is indicated by the patient experiencing significant side effects, such as nausea and vomiting resulting in trips to the emergency room prior to being able to take another medication.¹⁴ Mr. Ted Okon, the executive director of the Community Oncology Alliance, recounted a story about a patient attempting to get a cancer drug from the PBM but was delayed for two months due to PBM prior authorization and steering practices.¹⁵ A week after being admitted to hospice, the patient finally got the drug she needed but died a week later.¹⁶

Finding: PBMs use their market leverage to increase their profits, not reduce costs for consumers.

¹¹ *Reviewing the Role of Pharmacy Benefit Managers in Pharmaceutical Markets Forum*, House Comm. On Oversight and Reform Minority, (Nov. 17, 2021), https://www.youtube.com/watch?v=X_HQesUKCHU.

¹² *Supra* n. 6.

¹³ *What is Prior Authorization*, Cigna, (2021), <https://www.cigna.com/individuals-families/understanding-insurance/what-is-prior-authorization>.

¹⁴ *Lecture Series Explores "Fail First" Approach to Cutting Cancer Costs*, Assoc. of Comm. Cancer Cent. (Nov. 27, 2019), <https://www.accc-cancer.org/acccbuzz/blog-post-template/accc-buzz/2019/11/27/lecture-series-explores-fail-first-approach-to-cutting-cancer-costs>.

¹⁵ *Supra* n. 11.

¹⁶ *Id.*

While these tactics were originally designed to drive patients toward lower cost or more effective treatments, they enable PBMs to shift patients to medications with higher rebates causing higher list prices.¹⁷ At the forum, Dr. Madelaine Feldman outlined how healthcare plans contract with PBMs to construct formularies and drive patients to more expensive drugs.¹⁸ She noted the “kickbacks” from drug companies to PBMs are “enormous” and savings are not passed on to patients.¹⁹

Finding: Drug manufacturers raise their prices due to PBMs.

According to a study by the University of Southern California Schaeffer Center, a \$1 increase in rebates equates to a \$1.17 increase in list price.²⁰ As the table below shows, for six drug companies reporting, list prices have all increased while “net” prices—net of rebates and discounts given to PBMs and insurers—have decreased in five of the six cases cited. At the forum, Dr. Erin Trish, the co-director of the USC Schaeffer Center, testified these hidden rebates allow PBMs to hide cost savings from patients and charge them more than their fair share.²¹

Brand-Name Drugs, Change in List vs. Net Price, by Company, 2020

Company	[A] Average list price change	[B] Average net price change	[A] - [B] Gross-to-net difference	Average reduction from list price
Eli Lilly and Company	+3.4%	-5.3%	-8.7%	-60.0%
Janssen	+3.8%	-5.7%	-9.5%	-53.0%
GlaxoSmithKline	+3.2%	-0.7%	-3.9%	n.a.
Merck & Co	+3.1%	+0.9%	-2.2%	-45.5%
Novartis	+3.7%	-0.2%	-3.9%	-46.8%
Sanofi	+0.2%	-7.8%	-8.0%	-54.0%
Unweighted average	+2.9%	-3.1%	-6.0%	-51.9%

Source: Drug Channels Institute analysis of company reports

Published on Drug Channels (www.drugchannels.net) on April 14, 2021.



Figure 3: List Price vs. Net Price comparison²²

¹⁷ *Supra* n. 14.

¹⁸ *Supra* n. 11.

¹⁹ *Id.*

²⁰ Neeraj Sood, et. al, *The Association Between Drug Rebates and List Prices*, USC Schaeffer Cent., (Feb 11, 2020), <https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/>.

²¹ *Supra* n. 15.

²² Adam Fein, *Gross-to-Net Bubble: Net Prices Drop (Again) at Six Top Drugmakers*, Drug Channels Institute, (Apr. 14, 2021), <https://www.drugchannels.net/2021/04/gross-to-net-bubble-update-net-prices.html>.

Despite dramatically increasing rebates, the cost of prescription drugs have risen three times faster than inflation over the past decade even after the discounts provided to PBMs.²³ The reason for this is, that by driving list prices higher, PBMs are also driving patient out-of-pocket costs higher, particularly for innovative new medications.²⁴ According to the Journal of the American Medical Association, from 2010-2016, list prices rose 129 percent for 14 medications with the highest drug expenditures.²⁵ During the same time, patient out of pocket costs increased 53 percent and insurance payments to PBMs for those drugs increased 64 percent after rebates and discounts.²⁶ At the forum, Rep. Buddy Carter (R-Ga.) highlighted this issue:

Rep. Carter: They collect nearly half of what patients spend on prescription drugs. Can you justify the value of PBMs at such great cost?"

Mr. Ciaccia: No.²⁷

Dr. Erin Trish testified that greater transparency is needed in the marketplace and PBMs should be required to share savings with consumers and plans.²⁸

PBMs drive list prices higher while seeking larger rebates, forcing patients to pay higher costs at the pharmacy counter. As a result, insurers paid more and passed those costs on to patients through increased premiums.²⁹ President Trump implemented the "Lowering Prices for Patients by Eliminating Kickbacks to Middlemen" Executive Order which required all rebates to be passed through to patients driving down patient copays.³⁰ Democrats have included in their so-called Build Back Better plan a repeal of this Executive Order, which will enable PBMs to retain their large rebates and increase costs for seniors at the pharmacy counter.³¹

PBMs' Anticompetitive and Fraudulent Behavior

Finding: PBMs own their own pharmacies, which creates conflicts of interest, hurts competition, and distorts the market.

Through multiple mergers, every large PBM now owns and operates mail-order and specialty pharmacies, and some own retail pharmacy locations as well.³² By owning and operating pharmacies that are competing with other pharmacies they negotiate with, it creates a

²³ Jeff Lagasse, *Drug prices rose three times faster than inflation over the last decade, even after discounts*, Healthcare Finance, (Mar. 04, 2020), <https://www.healthcarefinancenews.com/news/drug-prices-rose-three-times-faster-inflation-over-last-decade-even-after-discounts>.

²⁴ Eric Yang, et. al, *Changes in Drug List Prices and Amounts Paid by Patients and Insurers*, JAMA Network, (Dec. 9, 2020), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2773825>.

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Supra* n.11.

²⁸ *Id.*

²⁹ Exec. Order No. 13939, (2020). *See also Supra* n. 20.

³⁰ *Id.*

³¹ Terry Wilcox, *'Build Back Better' plan to repeal rebate rule would saddle seniors with higher drug costs*, Washington Times, (Nov. 16, 2021), <https://www.washingtontimes.com/news/2021/nov/16/build-back-better-plan-to-repeal-rebate-rule-would/>.

³² *Supra* n. 14.

destructive incentive to negotiate in bad faith with competing pharmacies because it benefits the PBMs financially. They use their position as middlemen to implement policies to steer patients to their own pharmacies and hurt their competition. At the forum, Ms. Tiffany Jones, assistant general counsel at SenderraRx, told lawmakers “every single PBM engages in steering every single day for every single patient,” referencing PBMs steering patients to pharmacies which they own and operate.³³ Mr. Kim Caldwell, who testified on behalf of the Pharmaceutical Care Management Association, reiterated how common it is for PBMs to steer patients to their own pharmacies when he stated that he “gets calls at [his] house too, someone wanting [him] to get [his] prescription somewhere else” and it “happens on a regular basis. Why is that? It’s part of doing business, I suppose.”³⁴

Finding: Rebates are not the only way PBMs drive up costs.

PBMs can also cut reimbursements to competing pharmacies while simultaneously charging public health plans significantly higher fees.³⁵ Mr. Antonio Ciaccia, the CEO of 46Brooklyn Research, told the panel, at the forum, that PBMs engage in a tactic called spread pricing, “where the PBM pays the pharmacy low, bills the plan sponsor high, and pockets the difference.”³⁶ As a result, PBMs have been able to pocket three to six times the going rate for their services.³⁷

In Ohio, CVS Caremark and OptumRx charged Ohio Medicaid \$223.7 million more than it actually paid to pharmacies.³⁸ In Kentucky, PBMs paid competing pharmacies \$123.5 million less than they charged the state Medicaid program in 2018 alone.³⁹ In October 2021, Centene agreed to a settlement with Arkansas and Illinois to pay \$72 million for overcharging their state Medicaid programs for prescriptions.⁴⁰

Overcharging state Medicaid programs is not the only way PBMs use their position as middlemen for their own benefit. In the Medicare Part D program, PBMs use a mechanism called direct and indirect remuneration (DIR) to clawback a percentage of the reimbursement for a medication that was paid to a pharmacy.⁴¹ These clawbacks have risen to an estimated \$9.1

³³ *Supra* n. 11.

³⁴ *Id.*

³⁵ Stacy Mitchell, *How the FTC Protected the Market Power of Pharmacy Benefit Managers*, ProMarket, (Feb. 19, 2021), <https://promarket.org/2021/02/19/ftc-market-power-pharmacy-benefit-managers/>.

³⁶ *Supra* n. 11.

³⁷ *Id.*

³⁸ Catherine Candisky, *State report: Pharmacy middlemen reap millions from tax-funded Medicaid*, The Columbus Dispatch, (2018), <https://stories.usatodaynetwork.com/sideeffects/state-report-pharmacy-middlemen-reap-millions-from-tax-funded-medicaid/>.

³⁹ Lisa Gillespie, *Pharmacy Middlemen Overcharged Medicaid \$123.5 Million, State Says*, 89.3 WFPL, (Feb. 23, 2019), <https://wfpl.org/pharmacy-middlemen-overcharged-medicaid-123-5-million-state-says/>.

⁴⁰ Samantha Liss, *Centene reaches \$72M settlement with Illinois, Arkansas for alleged Medicaid overcharges*, HealthcareDrive, (Oct. 1, 2021), <https://www.healthcaredrive.com/news/centene-72m-settlement-illinois-arkansas-overcharge-Medicaid-medicines/607535/>.

⁴¹ Adam Fein, *Pharmacy DIR Fees Hit a Record \$9 Billion in 2019 – That’s 18% of Total Medicare Part D Rebates*, Drug Channels Institute, (Feb. 13, 2020), <https://www.drugchannels.net/2020/02/pharmacy-dir-fees-hit-record-9-billion.html>.

billion in 2019, roughly 18 percent of the total Medicare Part D spending.⁴² While these clawbacks were originally intended to enable PBMs to accurately report pharmacy rebates and price concessions, they have grown dramatically to enable PBMs to create a negative reimbursement in certain cases.⁴³ At the forum, Ms. Tiffany Jones said far more oversight through law and regulation is necessary.⁴⁴ She said more protections need to be in place to provide a robust network of specialty pharmacies for patients, end the practice of patient steering, and prohibit pharmacy direct and indirect remuneration clawbacks.⁴⁵

This means a PBM is not only taking back all of what the PBM paid the pharmacy for the prescription, but also clawing back part or all the patient's copay.⁴⁶ When the result of a DIR fee is a negative reimbursement, that copay is not returned to the patient, instead, PBMs retain those fees. At the forum, Dr. Jonathan Grider, owner of the Lake Cumberland Pharmacy in Russell Springs, Kentucky, explained to lawmakers how PBMs' anticompetitive practices harm independent pharmacies and the patients they serve in their communities.⁴⁷ He highlighted the dire situation small pharmacies face: "Once this discussion is completed, I'll be back at the pharmacy making PBMs more money."⁴⁸ Due to ambiguity in reporting requirements, it is unclear what percentage of those fees the Medicare program receives.⁴⁹

Finding: Greater transparency is necessary to determine the extent of the damage PBM tactics are having on patients and the marketplace.

Legislative Landscape

At the forum on "Reviewing the Role of Pharmacy Benefit Managers in Pharmaceutical Markets," Ranking Member Comer called on witnesses to provide solutions to Congress to reform PBMs and lower prescription drug costs for patients.⁵⁰ Two witnesses provided important feedback:⁵¹

Dr. Trish: To reduce or mitigate the concerns for patients, we need to share rebates with patients at the point of sale. It makes no sense that their cost sharing does not reflect the true net costs of these drugs and they are the ones suffering from paying higher out of pocket spending.

⁴² *Id.*

⁴³ *White Paper: DIR Fees Simply Explained*, Pharmacy Times, (Oct. 25, 2017), <https://www.pharmacytimes.com/view/white-paper-dir-fees-simply-explained>. See also *DIR Fees*, Frier Levitt, <https://www.frierlevitt.com/what-we-do/pharmacy-law/dir-fees/>.

⁴⁴ *Supra* n. 11.

⁴⁵ *Id.*

⁴⁶ *Supra* n. 43.

⁴⁷ *Supra* n. 11.

⁴⁸ *Id.*

⁴⁹ Nicole Kruczek, *Easy Reading: Direct and Indirect Remuneration Fees*, Pharmacy Times, (Jul. 21, 2020), <https://www.pharmacytimes.com/view/easy-reading-direct-and-indirect-remuneration-fees>.

⁵⁰ *Supra* n. 11.

⁵¹ *Id.*

Ms. Jones: Transparency is the most important tool. Patients aren't able to afford their drugs, independent pharmacies aren't able to service those patients in the networks because PBMs are taking so much money ... Where is the money going? Let's also have regulations in place that don't allow them to side-step the laws in place.

This report seeks to continue this conversation by highlighting legislative proposals in the House of Representatives and Senate that provide meaningful PBM reform and lower prescription drug costs for Americans.

Finding: There are twenty-two Republican and bipartisan legislative solutions which could provide meaningful reform and lower prescription drug costs for Americans.

117th Congress

Lower Costs, More Cures Act of 2021 (H.R. 19 - Republican sponsorship)

This bill requires the Centers for Medicare & Medicaid Services (CMS) to publish certain information, as reported by PBMs, relating to generic dispensing rates, drug discounts and rebates, and payments between PBMs, health plans, and pharmacies.

Pharmacy Benefit Manager Accountability Study Act of 2021 (H.R. 1829)

This bipartisan bill requires the Government Accountability Office (GAO) to report on the role of PBMs in the pharmaceutical supply chain and recommend legislative actions to lower the cost of prescription drugs. The report must address the use of rebates and fees, the average prior authorization approval time, and the use of step therapy within the 10 largest PBMs.

Improving Transparency to Lower Drug Costs Act of 2021 (H.R. 3682)

This bipartisan bill requires CMS to publish certain payment information regarding PBMs and prescription drugs. Specifically, CMS must publish certain information, as reported by PBMs, relating to generic dispensing rates, drug discounts and rebates, and payments between PBMs, health plans, and pharmacies, in accordance with specified confidentiality requirements.

Pharmacy DIR Reform To Reduce Senior Drug Costs Act (H.R. 3554)

This bipartisan bill establishes certain requirements for PDPs and the prices of covered drugs under the Medicare prescription drug benefit. Specifically, the bill requires price concessions, payments, and fees that are negotiated with a pharmacy to be included in a drug's negotiated price, excluding incentive payments, and for this price to be provided at the point of sale. Additionally, PDPs must report price concessions or incentive payments that are made after payment for covered drugs at the point of sale, including by contracted intermediaries, to the pharmacy at least annually. CMS must establish standardized pharmacy performance measures with respect to incentive payments and price concessions; such measures must account for all pharmacy types, including specialty pharmacies, and focus on patient health outcomes and other targeted areas.

Ensuring Seniors Access to Local Pharmacies Act of 2021 (H.R. 2608)

This bipartisan bill establishes several requirements for PDPs under the Medicare prescription drug benefit. Specifically, the bill requires PDPs to allow any pharmacy located in a health professional shortage area, a medically underserved area, or a rural area to be included as an in-network pharmacy if the plan already has other in-network pharmacies in the same area. The bill also establishes certain standards for PDPs regarding pharmacy reimbursements and related disclosures. Among other things, the bill prohibits PDPs from reimbursing a pharmacy in an amount that is less than the amount the PBM reimburses an affiliated pharmacy (i.e., a pharmacy that has a shared ownership interest with the PBM) for the same services.

Insulin Cost Reduction Act (H.R. 5623)

This bipartisan bill would ban the use of rebates for insulin in the Part D marketplace unless those rebates are passed on directly to the consumer, which would lower costs at the pharmacy counter for insulin. The bill also makes cost sharing based off the price after rebates (net price), rather than the list price, which will reduce patient's deductibles and co-pays.

Stop Stalling Access to Affordable Medications (H.R. 2883)

This bipartisan bill makes it an unfair method of competition to submit an objectively baseless petition to the Food and Drug Administration (FDA) in an attempt to interfere with a competitor's application for market approval of a drug. The bill authorizes the Federal Trade Commission to sue an individual or entity that submits such a petition to the FDA. A party found liable in such a lawsuit shall be subject to civil penalties, such as a fine of up to \$50,000 for each day that the FDA spent reviewing the baseless petition.

Preserve Access to Affordable Generics and Biosimilars Act (H.R. 2891)

This bipartisan bill authorizes the Federal Trade Commission (FTC) to initiate proceedings against parties to any agreement resolving or settling a patent infringement claim in connection with the sale of a drug or biological product. Such an agreement is presumed to have anticompetitive effects and is a violation of this bill if the filer of the generic drug or biosimilar application receives anything of value and agrees to limit or forego research, development, manufacturing, marketing, or sales of the generic drug or biosimilar. An agreement is exempted if the only consideration granted to the generic manufacturer is (1) the right to market its product prior to the expiration of any statutory exclusivity, (2) a payment for reasonable litigation expenses, or (3) a covenant not to sue on any claim that the generic drug or biosimilar infringes a patent. An agreement is also exempt if the agreement's pro-competitive benefits outweigh the anticompetitive effects.

Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act (H.R. 2884)

This bipartisan bill limits in certain instances the number of patents that the manufacturer of a biologic drug can assert in a lawsuit against a company seeking to sell a biosimilar version of that drug.⁵²

Prescription Pricing for the People Act (S. 1388)

This bipartisan bill requires the FTC to report about anticompetitive practices and other trends within the pharmaceutical supply chain that may impact the cost of prescriptions drugs. The FTC also must provide recommendations to increase transparency in the supply chain and prevent anticompetitive practices.

116th Congress

Prescription Drug Pricing Reduction Act of 2020 (S. 4199)

This Republican bill requires CMS to publish certain information, as reported by PBMs, relating to drug discounts and rebates, and payments between PBMs, health plans, and pharmacies.

Encouraging Innovative Benefit Design to Lower Costs for Seniors Act (S. 3013)

This Republican bill allows PDP sponsors under the Medicare prescription drug benefit to offer additional plans in a region. Specifically, CMS must update guidance to allow prescription drug plan (PDP) sponsors to offer up to four plans in a region; CMS may also set a greater limit, as appropriate. PDP sponsors may offer up to two additional plans beyond this limit if the PDP sponsor ensures that, under at least one of the plans, PBMs do not receive any remuneration unless at least 10 percent of price reductions received from drug manufacturers are reflected at the point-of-sale or otherwise used to reduce beneficiary cost-sharing.

Drug Price Transparency in Medicaid Act of 2019 (H.R. 5281)

This bipartisan bill requires pass-through pricing models, and prohibits spread pricing, for payment arrangements with PBMs under Medicaid. The bill also extends funding for retail pharmacy surveys and requires additional information with respect to price concessions, dispensing fees, and survey participation to be made publicly available.

Insulin Price Reduction Act (H.R. 4906)

This bipartisan bill prohibits health insurance plan issuers and PBMs from receiving rebates or discounts for insulin from manufacturers who certify that its current insulin list price has been reduced to an amount no greater than what the list price was for the same insulin on July 1, 2006. This restriction does not apply to discounts provided to insurance plan holders at retail sale or to flat-rate fees for service paid to PBMs. Further, insurance plans are prohibited from applying a deductible to insulin that has received such price certification. A manufacturer may certify insulin prices by submitting to the Department of Health and Human Services (HHS) data about

⁵² A biologic drug is produced through natural processes or isolated from natural sources. A biosimilar version is substantially similar to the original biologic, which is the reference product, and is often marketed as a less expensive alternative.

the list price of any insulin the manufacturer has produced since January 1, 2000, and by setting the current list price for an insulin product at the 2006 rate.

Competition Prescription Act of 2019 (H.R. 3947)

This Republican bill prohibits sponsors of Medicare Part D PDPs from reducing a payment to a pharmacy after a claim without defect has been submitted by such pharmacy. The bill establishes requirements for pricing standards for PBMs under Medicare and other federal prescription drug benefit programs. Starting in 2025, the bill removes the cap on rebates paid by manufacturers of outpatient prescription drugs under Medicaid.

Lower Health Care Costs Act (S. 1895)

This bipartisan bill makes a series of changes relating to health care coverage, costs, and services. Among other things, the bill limits prices that PBMs may charge health insurers or enrollees for prescription drugs, based on prices paid by PBMs to pharmacies.

Pharmacy Benefit Manager Accountability Study Act of 2019 (H.R. 3223)

This bipartisan bill requires GAO to study the role of PBMs with respect to federally facilitated exchanges, including the role of PBMs in pharmaceutical supply chains, the competition among PBMs, and the use of rebates and fees by PBMs in such exchanges.

More Efficient Tools to Realize Information for Consumer Act (H.R. 2296)

This bipartisan bill requires prescription drug manufacturers to report, and HHS to publish, specified information related to prescription drug pricing and the pharmaceutical supply chain. Specifically, HHS must publish reports submitted by drug manufacturers that include the percentage of any wholesale drug price increase that is greater than 10 percent in one calendar year (or 25 percent over three consecutive years), an explanation for the price increase, and other data. HHS must enter agreements with other agencies, research organizations, and public and private health insurers to share data submitted to HHS by drug manufacturers about the identity and quantity of drug sample requests by health practitioners. HHS also must publish online aggregate data reported by PBMs, including the percentage of prescriptions provided by mail-order, rate that generic versions of drugs are dispensed, and aggregate discounts, rebates, or price concessions negotiated. The bill requires the FTC to report about potentially anticompetitive practices by PBMs such as steering patients to certain pharmacies or designing price formulas that increase the market share of higher priced drugs, among other information.

Public Disclosure of Drug Discounts and Real-Time Beneficiary Drug Cost Act (H.R. 2115)

This bipartisan bill requires CMS to publish certain payment information regarding PBMs and prescription drugs. Specifically, CMS must publish certain information, as reported by PBMs, relating to generic dispensing rates, drug discounts and rebates, and payments between PBMs, health plans, and pharmacies, in accordance with specified confidentiality requirements. The bill also provides statutory authority for certain provisions of the CMS rule titled "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses," published on May 23, 2019. The rule requires, in part, Medicare PDP sponsors to implement an electronic, real-time benefit tool that is capable of integrating with at least one prescriber's electronic prescribing system or electronic health record. The tool must provide prescribers with

patient-specific, real-time formulary and benefit information, including information regarding cost-sharing, formulary alternatives, and utilization management requirements. The rule would take effect January 1, 2021.

Prescription Drug Price Transparency Act (H.R. 1035)

This bipartisan bill establishes additional requirements for PDPs under Medicare and Medicare Advantage, as well as health insurance carriers under the Federal Employees Health Benefits Program, relating to the methodology of payments to pharmacies and the use of PBMs. Specifically, such PDPs and carriers must disclose specified information to pharmacies regarding applicable standards for reimbursement that are based on drug costs, including the sources used to update such standards. Additionally, such PDPs and carriers may not contract with PBMs that require, or that provide an incentive for, plan enrollees to use pharmacies that have a shared ownership interest with the PBM.

Phair Pricing Act of 2019 (H.R. 1034)

This bipartisan bill requires that certain negotiated prices for covered drugs under the Medicare prescription drug benefit be disclosed at the point-of-sale. Specifically, negotiated prices offered under a PDP must be disclosed at the point-of-sale; the disclosed price must include specified adjustments, payments, and fees that are negotiated with the pharmacy (e.g., dispensing fees) by the PDP sponsor or PBM. Additionally, CMS must establish certain quality measures for PDP sponsors to use when determining incentive payments and adjustments (e.g., performance payments) to pharmacies.

PBM Transparency in Prescription Drug Costs Act (H.R. 5304)

This bill will mandate quarterly reports on the costs, fees and rebate information associated with PBMs' contracts ensuring that employers know the true costs of the services that they are paying for—passing on savings to consumers. States, local governments, organizations and businesses use PBMs to negotiate lower drug prices for the individuals on their health insurance plans.

Conclusion

Americans spend more on prescription drugs than any other country and they pay more out-of-pocket for prescription drugs than hospital care or health insurance. The cost of prescription drugs is still rising as it has consistently over the past decade, placing an ever-increasing financial strain on many Americans. Yet, instead of taking a holistic approach to investigating the causes of this continual rise, House Democrats have chosen to attack pharmaceutical companies that have brought innovative and life-saving medications to market, including three incredibly successful COVID-19 vaccines.

House Republicans are investigating the players at the center of the prescription drug marketplace—the PBMs. PBMs' position in the market makes them a focus for Congress when examining areas of needed reform.

Ranking Member Comer held a forum with House Republicans to take the first step to review the tactics and role of PBMs in pharmaceutical markets, finding PBMs' anticompetitive

tactics are driving up prescription drug costs and harming patients. These ongoing tactics warrant greater transparency into this industry and congressional action to provide meaningful reform to drive down prescription drug costs. While Democrats are unwilling to take action to address these concerns, there are several Republican proposals in the House and Senate that could provide real relief to millions of Americans struggling with the costs of their prescription drugs.

Appendix

Ranking Member James Comer has taken the first step to investigate the entire prescription drug marketplace holding a forum on “Reviewing the Role of Pharmacy Benefit Managers” with House Republicans, where lawmakers heard from experts, pharmacists, physicians, and PBMs about the role PBMs play in the rising cost of prescription drugs. The witness panel included:

- Dr. Jonathan Grider, PharmD: Owner of Lake Cumberland Pharmacy in Russell Springs, Ky.
- Dr. Erin Trish, PhD: Co-Director of the USC Schaeffer Center, Assistant Professor, Department of Pharmaceutical and Health Economics, USC School of Pharmacy
- Mr. Antonio Ciaccia: Chief Executive Officer, 46Brooklyn Research
- Dr. Madelaine Feldman, MD, FACR: President of the Coalition of State Rheumatology Practices and Past Chair of the Alliance for Safe Biologic Medicines
- Mr. Kim Caldwell, RPh: Principal at Texas Star Healthcare Consulting, on behalf of the Pharmaceutical Care Management Association
- Ms. Tiffany Jones, JD: Vice President of Regulatory Affairs and Assistant General Counsel at SenderraRx
- Mr. Ted Okon, MBA: Executive Director of the Community Oncology Alliance