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PHARMACY BENEFIT MANAGERS AND THE PRESCRIPTION DRUG SUPPLY CHAIN: IMPACT ON PATIENTS AND TAXPAYERS

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PHARMACY BENEFIT MANAGERS AND THE PRESCRIPTION DRUG SUPPLY CHAIN: IMPACT ON PATIENTS AND TAXPAYERS

THURSDAY, MARCH 30, 2023

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:07 a.m., in Room SD–215, Dirksen Senate Office Building, Hon. Ron Wyden (chairman of the committee) presiding.

Present: Senators Stabenow, Cantwell, Menendez, Carper, Cardin, Brown, Whitehouse, Cortez Masto, Warren, Crapo, Grassley, Cornyn, Thune, Cassidy, Lankford, Johnson, Tillis, and Blackburn.

Also present: Democratic staff: Shawn Bishop, Chief Health Advisor; Tiffany Smith, Deputy Staff Director and Chief Counsel; and Polly Webster, Senior Health Counsel. Republican staff: Kellie McConnell, Health Policy Director; Gregg Richard, Staff Director; and Conor Sheehey, Senior Health Policy Advisor.

OPENING STATEMENT OF HON. RON WYDEN, A U.S. SENATOR FROM OREGON, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The Finance Committee will come to order.

Colleagues, I am going to take just a minute to thank the members for what I believe has been a very productive work period. Our bipartisan efforts on organ transplants—thank you very much, Senator Grassley—have really paid off. We are going to have new contracting practices with much more accountability to protect the millions of Americans who depend on these organ transplants.

Senator Cardin and Senator Daines yesterday focused on dental care. Senator Crapo and both sides are working to build on our mental health work. I thought we had a very good and bipartisan housing hearing that proceeded in the middle of the work period. In my State, eight different school districts are having to buy houses to rent to teachers because there is such a housing shortage.

And finally yesterday, the investigation—a 2-year investigation by the Finance Committee—exposed massive Federal tax evasion by Credit Suisse, working with ultra-wealthy Americans, often dual citizens, who are hiding their taxes, concealing their tax obligations for years on end. So, colleagues, thanks, and it was a productive time.

This morning, we are going to continue our longstanding efforts to lower the cost of health care for taxpayers and patients. Today, the committee focuses on pharmacy benefit managers, in particular the new strategies like charging administrative fees tied to the price of a drug that these multibillion-dollar corporations have aggressively adopted in the last 4 years, since we had previously looked at PBMs.

Pharmacy benefit managers had a strong case for themselves back in the 1980s and 1990s. The original goal was to use their access to limited data to negotiate lower drug prices on behalf of their clients—insurance companies and employers.

When prescription drug coverage came to Medicare, with Part D in the 2000s, PBMs shifted into overdrive to get to a larger market and more sophisticated drugs. In recent years, it has been increasingly apparent that PBMs are using their data, their market power, and their know-how to keep prices high and pad their profits instead of sharing the benefits of the prices they negotiate with consumers in the Medicare program.

I believe this is an industry that is going in the wrong direction, and that is having a big impact on the prices that Americans pay at pharmacy counters from one end of the country to another. There are especially serious consequences for the Federal health programs that the Finance Committee oversees.

Between Medicare, Medicaid, CHIP, and the individual health insurance market, the committee oversees health coverage for more than half of all Americans, or roughly 180 million people. Prescription spending for these Americans constitutes a significant portion of the amount the United States as a whole spends on pharmaceuticals each year. That totaled $577 billion in 2021.

That is why it is so critical for the committee to examine what needs to be done to modernize the rules of the road for PBMs. Senator Crapo and I have talked about this at some length, particularly this concept of modernizing the rules, because what made sense really 34 years ago, does not look so sensible today.

So we are taking off on this hearing—as with so many of the things that I just outlined over this work period—with strong bipartisan interest, and I thank Senator Crapo for that. So what we are going to do is look at pharmacy benefit managers with a thorough eye, and take any legislative steps necessary to ensure taxpayers and patients are not getting a raw deal. The Finance Committee has a long history of tackling these big-league issues on a bipartisan basis, and the results speak for themselves.

Finally, before I turn it over to Senator Crapo, I want to illustrate just one example of PBM practices that are resulting in high prices. In a competitive market, if two products have equal quality, a business should prefer the lower-cost option.

However, oftentimes PBMs charge administrative fees to drug makers, which are calculated as a percentage of a drug's list price. That means PBMs get a higher payment if they favor higher-cost drugs. In my view, that is a clear example of these bizarre, these perverse incentives that PBMs have created that have left so many Americans fed up and outraged at the health-care system.

The consequences of this out-of-whack market are felt by taxpayers and families every time they show up at the prescription

counter. Discounts negotiated by PBMs play an important role in driving down premiums for seniors. But the games PBMs play behind the scenes also appear to be driving up drug costs for many seniors, who are forced to pay top dollar for their prescriptions at the pharmacy counter, while PBMs profit at their expense.

So we have an important opportunity today to look at the latest practices, the most current practices being employed by pharmacy benefit managers, and the impact that these tactics have on taxpayers and Americans who count on affordable medicine—affordable medicine—for a decent quality of life.

Thanks to all our witnesses.

Senator Crapo, please, and I thank you for your cooperation.

[The prepared statement of Chairman Wyden appears in the appendix.]

OPENING STATEMENT OF HON. MIKE CRAPO, A U.S. SENATOR FROM IDAHO

Senator CRAPO. Thank you very much, Mr. Chairman. I have long championed efforts to improve prescription drug access and affordability for all Americans, and I welcome the opportunity to engage in this vitally important bipartisan hearing.

Whether at the pharmacy counter, the doctor's office, or the hospital, some of the most lifesaving medications remain out of reach for far too many working families and seniors, especially in the face of persistent inflation.

Congress took a critical step toward addressing these challenges nearly 20 years ago, when we voted to enact Medicare's prescription drug benefit or Part D, leveraging market-based competition to create and protect high-quality coverage for seniors. In many ways, Medicare Part D reflects an unprecedented success story.

Coming in massively under budget, with low and stable monthly premiums and with a generic drug dispensing rate of roughly 90 percent, Part D's resilient market-oriented structure continues to ensure low-cost drug access for most seniors, even as many other medical costs have continued to skyrocket.

Stakeholders across the supply chain deserve credit for these figures and trends. That said, much has changed in the past 2 decades, and we have an obligation to both build on the aspects of Part D that work well, and to address access and affordability gaps where we find them.

In weighing and developing policy solutions, my priority is always the patient. We need to identify avenues for lowering out-of-pocket costs, increasing competition, and promoting access to lifesaving innovation, and we need to do so in a fiscally responsible manner.

Given the tremendous common ground and shared goals around this issue, I am confident that we can fulfill these objectives and deliver real results for seniors. A few major points regularly raised by Idahoans—transparency, incentives, and out-of-pocket costs—are of key importance as we hear today's testimony.

As anyone who has looked at a flow chart or a diagram of the drug supply chain can attest, the only clear thing about it is how unclear and opaque it is. We need an all-of-the-above approach to transparency that empowers consumers, plans, providers, and

pharmacies to make informed, cost-effective, and clinically appropriate decisions, as well as to practice meaningful oversight.

Policymakers also need more line of sight into the black box of drug pricing relationships and transactions, especially as we look to pursue productive reforms in the future. We also need to assess the various incentives that operate within the medication supply chain.

Ideally, we should have frameworks both within Part D and in other markets that encourage low prices through meaningful competition. Unfortunately, in too many cases, certain dynamics seem to drive list prices up, as the chairman has mentioned, even as net prices reflective of rebates and discounts decline.

The gap between list and net price has grown dramatically in recent years, keeping premiums stable but exposing some consumers to astronomical out-of-pocket costs at the pharmacy counter, particularly for uninsured patients or families relying on high-deductible health plans.

Misaligned incentives have also constrained biosimilar uptake in Part D, driving manufacturers to launch products at multiple different price points, with PBMs sometimes preferencing the option with the higher sticker price. The incentive structures at play here clearly warrant a hard look.

Americans face an out-of-pocket cost of less than $20 for 92 percent of the prescriptions filled. For the remainder, however, costs can run much higher, particularly for seniors enrolled in Part D. I look forward to discussing targeted solutions to bridge this gap without fueling premium hikes for older Americans.

With these priorities in mind, thank you to our witnesses for your being here today, and I do look forward to your testimony.

Thank you, Mr. Chairman.

[The prepared statement of Senator Crapo appears in the appendix.]

The CHAIRMAN. Thank you, Senator Crapo. And listening to you and comparing it to those five areas that I touched on where we have been working in a bipartisan way, this is especially important, because people find this at the pharmacy counter in communities all across the country. So we look forward to having the majority and minority work together.

Let me briefly introduce our witnesses. Robin Feldman, J.D. She is a national expert on drug pricing, competition, innovation, and the law. She teaches at UC College of Law, San Francisco, where she is the Arthur Goldberg distinguished professor of law. She holds the Albert Abramson 54 distinguished professor of law chair, and with apologies to Ms. Feldman and our other witnesses, I am going to be brief because I think we have so many things going on today. I think you all have wonderful backgrounds. I am just going to try to condense this a little bit.

Karen Van Nuys is next. She holds multiple positions at the Leonard D. Schaeffer Center for Health Policy and Economics, including senior fellow and the executive director of the Value of Life Sciences Innovation Program.

Lawton Robert Burns will be next. Dr. Burns is a professor of health care management, professor of management, and the James

Joo-Jin professor at the University of Pennsylvania Wharton School, with a special focus on studying health strategy.

Jonathan Levitt is with us. He is co-founder of Frier Levitt, a boutique health care law firm. He has dedicated his practice to representing pharmacies, dispensers, provider associations, manufacturers, wholesalers, and plan sponsors. We welcome him.

And Dr. Matthew Gibbs is with us, president of Capital Rx, a pharmacy benefit manager that operates with a fully transparent flat-fee dispensary. He is responsible for several core operations at Capital Rx which cut across client relations, benefit design, customer support, and clinical services.

With apologies for abbreviating all of your very distinguished backgrounds, I would just ask unanimous consent that a more complete record of their backgrounds be made a part of the record.

[The biographies appear in the appendix on p. 213.]

The CHAIRMAN. Okay, let us begin with you, Ms. Feldman.

STATEMENT OF ROBIN FELDMAN, ARTHUR J. GOLDBERG DISTINGUISHED PROFESSOR OF LAW, ALBERT ABRAMSON '54 DISTINGUISHED PROFESSOR OF LAW CHAIR, AND DIRECTOR OF THE CENTER FOR INNOVATION, UNIVERSITY OF CALIFORNIA LAW, SAN FRANCISCO, CA

Ms. FELDMAN. Thank you, Mr. Chairman and esteemed members of the committee. The supply chain for medicine is riddled with perverse incentives and marked by skyrocketing prices. Key aspects of the problem can be traced to the industry that lies at the center of drug pricing: pharmacy benefit managers, or PBMs.

Historically, PBMs were just claims processors handling the paperwork. But 15 years ago, when Medicare expanded to include prescription drugs, PBMs offered to help health plans negotiate with drug companies for better prices. But instead of prices coming down, the prices of many drugs have increased dramatically. For example, the prices of 65 common medicines have almost tripled, just during that 15-year period. Now, there are many contributing factors, but PBMs have been in the middle of it.

So how did this happen? How did PBMs, who are supposed to help bring prices down, end up driving prices higher instead? Well, rather than act as honest brokers for the health plans, PBMs have unsurprisingly acted in their own self-interest, and as it turns out, their own interests are not aligned with lower prices. Quite simply, higher prices put more dollars into a PBM's pockets.

When the sticker price goes up for a drug and the PBM negotiates a rebate, the PBM appears successful. It is a little like a department store that raises the price of a coat before putting it on sale. The markdown looks great when you walk in, but it is not.

In addition, the PBM often keeps a percentage of the rebate, so it gets to pocket more, again based on the price. Now all this might not be so bad if no one actually paid that high sticker price, but as Senator Crapo pointed out, many people do. With many plans, the out-of-pocket payment comes as a percentage of that high sticker price, and that is very difficult. Many Americans do not have prescription drug coverage, even if they do have health insurance.

Now, I mentioned raising the price of a coat before you put it on sale, but it gets worse. So, imagine if the price jump is higher than

the sale discount. That is what is happening with medicine. Between 2010 and 2017 in Medicare, prices for drugs after rebate—we are talking about after rebate—still rose 313 percent on average. So we are buying the same coat, but we are paying more and more. And a significant chunk of that increase is going to the PBMs.

Now, a PBM may be brokering deals for the health plan, but it is a very strange relationship. The PBMs refuse to give the details of the deals they are making to their own clients, the health plans. And, given the monopoly over pricing information, and the fact that only three PBMs control most of the market, PBMs are setting the terms of almost every arrangement. It is not a free and fair market.

Despite the fact that PBMs should be serving as honest brokers for the health plans, PBMs also ask drug companies for side payments. And again, those payments rise when the prices of drugs rise, and that creates perverse incentives. They vigorously deny having a fiduciary or any other type of duty to act in the best interest of the health plan and its patients.

So, at the end of the day, what do PBMs do to protect their income stream of rebates and payments? Well, PBMs stand at the center. They are the benefit managers. As well as negotiating the prices, PBMs help decide if patients will be reimbursed and how much they will be reimbursed. So, in dealing with drug companies, PBMs can offer to exclude a drug company's competitors, or to make it more difficult for patients to get the competitor's medicine. As a result, this is where we end up. Less-expensive medicines are disadvantaged, and patients are channeled into higher-priced drugs.

Although the pharmaceutical supply chain is a complex system, the overview of these aspects of the problem can be summarized fairly simply. PBMs are able to exploit their role at the center to extract dollars and channel the system into higher-priced drugs. That is the core of the problem.

Thank you, and I look forward to your questions.

[The prepared statement of Ms. Feldman appears in the appendix.]

The CHAIRMAN. Well said.

Let us go next to Dr. Van Nuys.

STATEMENT OF KAREN VAN NUYS, Ph.D., SENIOR FELLOW, LEONARD D. SCHAEFFER CENTER FOR HEALTH POLICY AND ECONOMICS; AND EXECUTIVE DIRECTOR, VALUE OF LIFE SCIENCES INNOVATION PROGRAM, UNIVERSITY OF SOUTHERN CALIFORNIA, LOS ANGELES, CA

Dr. VAN NUYS. Thank you, Chairman Wyden, Ranking Member Crapo, and honorable members of the committee. Thank you for the opportunity to testify today about the practices of pharmacy benefit managers.

My name is Karen Van Nuys, and I am an economist and a senior fellow at the Leonard D. Schaeffer Center for Health Economics at the University of Southern California. The opinions I offer here today are my own and build on previous statements and publications.

At the Schaeffer Center, we have been studying prescription drugs for over a decade, and we are among the first research institutions to quantify the role of intermediaries in that market. PBMs provide important and much-needed services to drug companies, insurers, employers, and patients, and sit in the middle of nearly every financial transaction.

This position provides them with extraordinary information access and leverage. As has been widely reported, the PBM industry has become larger and more vertically integrated. Four out of five U.S. prescriptions are now handled by the top three PBMs. While their size may allow them to negotiate lower drug prices, it also positions them to suppress competition and raise drug costs.

Which of these two possibilities prevails is ultimately an empirical question that our research seeks to answer. Estimating money flows in this market can be challenging, because much of the needed data is opaque to outsiders. That said, drug price researchers have been conducting these studies that shine slivers of light into the dark corners of the system. From these glimpses, we can assemble a collage of the overall picture, and here are some things we have learned in assembling that collage.

First, in some circumstances, PBMs raise drug costs. We compared what Medicare paid for the most common generic drugs with what those same prescriptions would have cost cash-paying members at Costco. We found that Medicare could have saved $2.6 billion in 2018 on just 184 drugs if they had been purchased without insurance at Costco. Somehow, involving the PBM and the health plan in the transaction increased drug costs by 21 percent.

Second, in some branded markets, when PBMs negotiate savings from manufacturers, they do not always pass those along to patients and taxpayers. My Schaeffer colleagues and I studied the money flows from U.S. insulin sales between 2014 and 2018. While PBMs negotiated a 31-percent reduction in net payments to manufacturers, the total amount spent per unit of insulin barely budged. Instead, intermediaries, including PBMs, were capturing those savings. In 2014, intermediaries were taking 31 out of every 100 dollars spent on insulin. Five years later, they were claiming $53, more than half. PBM's share alone grew 155 percent in 5 years.

PBMs use commercial tactics like copay clawbacks, spread pricing, and strategic formulary placement to do this. This leads to perverse outcomes, including patients' copays exceeding the cost of the drug on one in four prescriptions, and plans paying on average 31-percent markups for generic scripts.

PBMs motivate manufacturers to compete for formulary placement through rebates. PBMs often keep a share, leading them to prefer drugs with higher rebates. So manufacturers offer higher rebates, raising list prices to accommodate them. Consequently, this form of competition pushes prices up rather than down, and formularies can end up favoring the highest- not lowest-cost drug.

High list prices have real consequences for patients. Those without insurance may pay list prices directly; those with insurance may still be exposed in the deductible phase or through coinsurance payments. Passing rebates through to health plans creates its own problems for patients. Health plans may use them to lower premiums, but this decreases the effective generosity of cov-

erage. It transfers resources from sick patients to healthy beneficiaries.

Finally, the current rebate-focused price negotiation process can generate counterintuitive formulary designs. For example, researchers found that 72 percent of Medicare formularies place at least one branded product on a lower cost-sharing tier than its generic. Some biosimilar manufacturers are finding that it is easier to get biosimilars with high list prices and high rebates onto formularies compared to identical products with lower prices.

While it is true that PBMs provide valuable services, the lack of transparency in the transactions they control, the misaligned incentives that govern their behavior, and vertical consolidation in the PBM industry should be concerning to us all. Increased transparency that gives market participants more equal footing in price negotiations would help level the playing field, and stricter reporting requirements for more granular transaction data would allow regulators to analyze specific markets and tactics, identify problems more quickly, and provide us with more targeted solutions.

Thank you. I look forward to your questions.

[The prepared statement of Dr. Van Nuys appears in the appendix.]

The CHAIRMAN. Thank you for your testimony. We are serious about this.

Dr. Burns?

STATEMENT OF LAWTON ROBERT BURNS, Ph.D., MBA, JAMES JOO-JIN KIM PROFESSOR, PROFESSOR OF HEALTH CARE MANAGEMENT, WHARTON SCHOOL, UNIVERSITY OF PENNSYLVANIA, PHILADELPHIA, PA

Dr. BURNS. Well, good morning. Thank you, Chairman Wyden and Ranking Member Crapo, for inviting me to speak. My name is Robert Burns. I am a professor of health care management and strategy at the Wharton School.

One part of my research focuses on the entire health-care ecosystem. I have taught the introductory course on the entire healthcare system for over 35 years. I am beginning to understand it, so I understand everybody's frustration. I put it into a textbook which was published 2 years ago. It covers not only the life sciences side, pharma, and biotech, but also the providers: the insurers—both public and private—and then the employers. And it provides a big picture of what goes on with health care.

I think you need to understand that big picture of the ecosystem to understand some of the dynamics that you are focusing on here today. Another part of my research does a deep dive into what we call the supply chain, and I look at both the institutional and retail supply chains in health care. I have written two books on these topics, and I have been studying them since the 1990s.

This past fall, I published a 650-page book just on the PBMs and the GPOs, basically trying to "demystify" their roles in the healthcare system. To paraphrase Mark Antony in Act III of Shakespeare's *Julius Caesar,* "I come here today not to praise the PBMs, but to bury some concerns about them."

The CHAIRMAN. And you said you wrote 590 pages about PBMs?

Dr. BURNS. And 650 pages on GPOs and PBMs.

The CHAIRMAN. That almost equals, Senator Grassley, the report that you and I did. I think we have a close competition. Excuse me for interrupting. It is not going to count against your time.

Dr. BURNS. My remarks today focus on three topics. First, just the role of intermediaries: health intermediaries and health-care-linked buyers and sellers. Health care is full of them. They are not well-understood or appreciated. No course is taught on these critters, and I liken them to the Rodney Dangerfield of health care. They get absolutely no respect.

Worse yet, they are considered the whipping boys—in other words, the people who take the rap and get spanked for the evil doings of others. I spent 25 years studying these intermediaries, starting with the HMOs in the 1990s, the GPOs in the early 2000s, and then more recently the PBMs. They all take the rap. They are all blamed for all the ills in health care.

My first book on GPOs and the institutional supply chain taught me a lot about these intermediaries. We have been down this road before, and to quote President Harry Truman, "The only thing new in the world is the history we don't know." So that is why I have devoted so much time to these things.

I believe there is a lot of smoke but not as much fire as people think. I take my readers through an exercise in critical thinking, looking at the allegations that you have seen everywhere, and then I get my students to ask the question, "Is what I just heard really true?"

A historical analysis—this is one of the tools I use—shows that PBMs serve the interests of health plans and the ERISA plan sponsors who utilize them. The PBMs are agents. They are not rogue actors in the health-care system. They exert leverage over manufacturers in terms of the volume, trading off higher volumes for a lower unit cost.

They have used a lot of the same contracting tools for decades, once you consult the historical record. One thing that should alleviate some concerns here is that their business models have been changing over the last 5 to 10 years. They no longer rely on rebates the way they used to, and I think what they are relying on now is the dispensing of specialty pharmaceuticals, and we ought to reserve some time today to talk about the role of specialty pharmaceuticals in the rising prices for Medicare Part D seniors, because it is a huge role.

You ought to know that manufacturers do not like intermediaries like PBMs. Very few people like intermediaries like PBMs, and basically that is because they are using leverage to extract price concessions from everybody. The name of the game in this area is trade-offs. You are trading off volume for price, access for price, things like that. You cannot have it all.

But the PBMs are clearly instruments of trying to extract leverage from the manufacturers. Yes, there has been some consolidation of the PBMs, but it is a competitive market, and if you look carefully, everybody in health care is consolidating, not just the PBMs. I think the problem that we face in this sector is no or little competition in the specialty pharmacy area.

The second part of my report focuses on the rebates or what we call the gross-to-net disparities. Rebates basically reflect the dif-

ference between the gross and the net price. Research shows, if you look carefully, that the rebates do not drive increases in list price.

A lot of factors drive that gross-to-net disparity. A lot of factors drive the rise in the list prices charged by manufacturers. Some of those drivers are found in Federal legislation and Federal contracting dynamics.

The second thing to recognize is that those rebates flow increasingly to the health plans, who are the people that the PBMs are agents for. They do not flow to the PBMs as much, and I think Part D and Medicaid policies encourage manufacturers to raise their list prices, as well as to increase their launch prices, where I think a lot of the attention ought to focus.

Finally, there are a lot of issues about rising out-of-pocket costs in Medicare Part D. That occurs primarily in the catastrophic phase, and that is driven primarily by the high cost of specialty pharmaceuticals.

The CHAIRMAN. We are going to have to move on.

Dr. BURNS. I will stop.

[The prepared statement of Dr. Burns appears in the appendix.]

The CHAIRMAN. Great; thank you very much.

Okay, let us see. Mr. Levitt?

STATEMENT OF JONATHAN E. LEVITT, CO-FOUNDING PARTNER, FRIER LEVITT ATTORNEYS AT LAW, PINE BROOK, NJ

Mr. LEVITT. Chairman Wyden, Ranking Member Crapo, and members of the Senate Finance Committee, thank you for inviting me to testify here today about PBMs. I am a trial lawyer with the law firm of Frier Levitt. I represent stakeholders in the drug supply chain—most importantly, independent, retail, and specialty pharmacies.

I have been trying cases against PBMs for the last 20 years. I am here at my own cost. The six largest PBMs control 96 percent of the Nation's prescription drug market, and adversely impact all stakeholders in the drug supply chain, including patients, pharmacies, plan sponsors, and taxpayers.

As with all Americans, Medicare and Medicaid and employer groups are at the mercy of PBMs and their vertically integrated health-care conglomerates. These top PBMs are driving independent pharmacies out of business; creating pharmacy deserts, especially in rural areas; fueling drug list prices higher for all Americans; and delaying and denying treatment for the sickest Americans, including those with serious diseases like cancer.

In my written testimony, I have provided information on all PBM tactics that adversely impact the stakeholders. During these opening remarks, I address how PBMs fuel drug prices and extract the DIR fees from pharmacies. While drug manufacturers set drug prices, the growing gap between the list price of drugs and the actual net price is due to rebates that PBMs extract from manufacturers for preferential formulary placement and tiering treatment.

Americans pay their copay based on the list price of drugs, not the net price. Thus, patients pay dramatically increased, artificially inflated costs for drugs. PBMs, through their sister companies, siphon a huge percentage of the list price of drugs as profits to CVS

Health, Cigna, and UnitedHealth, all of whom own little-known companies called rebate aggregators.

Today, two of these PBM-owned rebate aggregators are located outside the United States. Cigna, which owns Express Scripts, owns Ascent Health, located in Switzerland. UnitedHealth, which owns OptumRx, also owns Emisar, the rebate aggregator located in Ireland.

Just this week, the Attorney General in Ohio filed a lawsuit against Cigna for using, in his own words, "a little-known Switzerland-based company to illegally drive up drug prices and ultimately push those higher costs onto patients, who rely on lifesaving drugs such as insulin."

Now let me make a few comments on DIR fees, the direct and indirect remuneration that PBMs extract from pharmacies. PBMs extracted $12.6 billion in 2021 in post-point-of-sale DIR fees from retail and specialty pharmacies. These performance fees are supposed to be based on legitimate adherence metrics that measure how well a pharmacy has kept a patient on the physician's prescribed drug regimen.

However, especially in the case of specialty pharmacies, PBM adherence methodologies are designed to cheat pharmacies and are shrouded in secrecy. Pharmacies are unable to audit PBMs on the accuracy of their DIR fee calculations. PBMs provide no adherence data, and pharmacies are unable to challenge PBMs out of fear of retaliation.

CMS will eliminate DIR fees in 2024, but the problem is not eliminated. PBMs and their affiliated Medicare Part D plans will compensate for the lost DIR fee revenue, which is very profitable, by drastically reducing pharmacy reimbursement.

Case in point: in 2024, Express Scripts will slash pharmacies' reimbursement rates to rates that are worse than the time when DIR fees existed. The other top PBMs are likely to follow, which will drive more pharmacies out of business. However, given that PBMs own their own affiliated mail-order pharmacies, the largest specialty pharmacies, and giant chain pharmacies, PBMs do not care if they drive independents out of business. PBMs will make money one way or the other.

I have taken depositions of PBM executives and insurance executives, and I have asked questions such as, "What do you do with the $12 billion of DIR fees that you take from pharmacies? Does any of it go back to Medicare or to patients?"

The answers to these questions that I have gotten under oath from these executives are really staggering. I would love to share those answers, but PBM gag clauses and protective orders in these cases prevent me from doing so. I truly hope Congress can shine more transparency on PBMs and pass meaningful legislation for the benefit of all Americans.

I welcome your questions. Thank you.

[The prepared statement of Mr. Levitt appears in the appendix.]

The CHAIRMAN. Thank you very much, Mr. Levitt.

Dr. Gibbs?

STATEMENT OF MATTHEW GIBBS, Pharm.D., PRESIDENT, CAPITAL Rx INC., NEW YORK, NY

Dr. GIBBS. Thank you, Chairman Wyden, Ranking Member Crapo, and members of the Finance Committee. First and foremost, I am a pharmacist. I have been in the PBM industry for a very long 24 years, serving in various leadership roles. I am currently serving as a member of the executive team at Capital Rx, a disrupter PBM in the market.

We must first take a step back to truly understand how the PBM situation developed. Since PBMs emerged in the 1980s and 1990s, they have played a vital role in the overall supply chain. PBMs connect all pharmacies in the U.S. via a single uniform communication logic.

This logic allows pharmacies from single-store ownership to multistore chain operations to communicate safety edits, drug-to-drug interactions, disease-to-drug interactions, and patient payment information. This happens within milliseconds and is arguably the most efficient transaction in all of health care.

In the early 2000s, PBMs started to grow in scale, while at the same time brand drug inflation increased. PBMs began to negotiate directly with pharmaceutical manufacturers on rebates for preferred product placement on the PBMs' formularies. Rebates quickly became the lifeblood of every PBM. With this development came a web of complex layers of rebate payment definitions, which became impossible for any employer or government entity to track.

The market then shifted in an arguably suspicious direction, choosing consolidation over innovation. It is no secret to anyone on this committee that 70 to 80 percent of the PBM market is controlled by three major organizations. Each of these is either owned by or owns a major insurance carrier.

PBMs also own dispensing assets, mail-service pharmacies, and specialty home delivery, and in certain circumstances even a retail chain. Fortunately, the Federal Trade Commission is now examining these market concerns.

Most critical is the fact that nearly all PBMs utilize a less-than-efficient pricing benchmark. This benchmark is known as average wholesale price, or AWP. This was the pricing source that was part of a class action lawsuit that required the majority of publishers of AWP to stop before September 2011.

There was hope in the market that, at the time, a new industry benchmark would emerge. Unfortunately, every PBM migrated back to AWP through another available index, and it now is again the market standard. State fee-for-service Medicaid plans, however, were no longer going to leverage AWP, so they relied on CMS to develop a new acquisition cost benchmark called National Average Drug Acquisition Cost or NADAC.

It is based on survey data from retail pharmacies that report their invoiced acquisition cost at the drug level to CMS. NADAC is published on a free public website, while AWP—remembering that is the industry standard—is a fee-based subscription service.

So how is Cap Rx different, and why am I the only PBM meeting with you today? Capital Rx is set up to change the way drugs are priced and patients are cared for to create enduring social change. We are over 1 million members strong across all payer types. Our

pricing model abandons the traditional AWP index and utilizes NADAC as the primary benchmark, and we have a single ledger model that is easily understood by our payers.

The best way to describe the problem in the market is to give you an everyday example. If you go in the pharmacy to pick up an over-the-counter product, you quickly see the prices in front of you and you know what you are going to pay when you get to the register. But when you go to the back, and you go to the pharmacy to pick up your prescription, you spin the roulette wheel and cross your fingers and hope for the most affordable price that month.

It does not have to be this way, and it is a direct result of the AWP being manipulated by PBMs. The ask is simple: every drug should have a price that is accessible to every American at any time.

Traditional PBMs have trained everyone to believe that drug pricing is unstable, using complex proprietary algorithms to lower their contractual reimbursements to pharmacies, while at the same time not returning those savings to the payers or the patients.

And while Medicare limits this practice to some extent, most commercial and managed Medicaid contracts still allow it to continue. One solution is to use NADAC as a publicly available price and the source of truth for drug costs. Is it perfect? No. Is it fundamentally better than the industry standard? Absolutely.

I will leave you with this final message. I have worked my entire career to drive transparency into the pharmacy supply chain. We are at a pivotal moment in history where we can finally change what is broken and bring rational drug level pricing to the American people.

Compulsory NADAC reporting from all retail, mail order, and specialty pharmacy home deliveries will drive competition and bring meaningful cost insights to payers and patients alike.

Thank you, Chairman Wyden, Ranking Member Crapo, and the committee, for your time on this crucial issue.

[The prepared statement of Dr. Gibbs appears in the appendix.]

The CHAIRMAN. All right. Colleagues and guests, we are about to start votes. Two points. One, we are just going to keep this moving. It is such an important topic, and Senator Crapo and I will figure out a way to do it.

The first four questioners will still be the first four questioners, though in a somewhat different order because Senator Stabenow has to get to a Forestry hearing, and she has been very patient, has a great interest.

Senator Stabenow?

Senator STABENOW. Thank you very much, Mr. Chairman and Ranking Member, and thank you to all of you. This is a really important hearing, and I very much appreciate your courtesy as well.

I have long been involved in issues around rising prices of prescription drugs, as many of our colleagues have, and I mean this is, bottom line, about lifesaving medicine. It is about people's life and their health, and I would say it is hard to find something more serious than whether or not people can afford the medicine that they need. And unfortunately, we know that for decades Americans have been paying the highest prices in the world, which makes no

sense. And when we look at prices three times higher as in many countries, I mean, it is just—it makes absolutely no sense.

One of the lifesaving drugs we have tried to tackle, and we are tackling, is insulin, and we know that prices have tripled in the last decade, with insulin costs going up 800 percent more than in other developed countries. So we have now put a cap of $35 per month for someone on Medicare.

It is a good start. Drug companies that make insulin are now appearing to move in this direction, but there is a lot more to do—Medicare negotiation and so on. I know the Lowest Price Act, which was signed into law in 2018, banned PBMs from blocking pharmacists from telling patients how they could pay less money for a prescription if they paid out of pocket. They were not allowed to tell people that.

So that was just one of many, many bad practices. So let me get to today. PBMs have said that their purpose is to negotiate lower prices. I said, when we had a group of PBMs in front of us a couple of years ago, we should call them "PBNs," because they are pretty bad negotiators, if that is what they are supposed to be doing.

So, I would first ask Ms. Feldman, can you discuss in more detail the PBMs' practices that have led Americans to pay the highest prices in the world?

Ms. FELDMAN. Thank you. When PBMs channel patients into higher-priced drugs, then the prices rise for everyone in the system.

Fair and efficient markets do not work that way. Patients should be encouraged to buy the drug with the lower sticker price. That entire system is how we end up with some of the highest prices in the world for the same drugs that other developed countries are purchasing.

Senator STABENOW. Thank you very much.

And, Mr. Levitt, you talked about the DIR fees, and I share your great concern both for those independent pharmacies and so on, but also for beneficiaries. So could you talk more about how the DIR fees harm the sickest people in the system, and could you give us more details? We are talking about people who have cancer or other serious diseases, and how they are affected by these fees.

Mr. LEVITT. Thank you. It is true that the sickest are the most harmed, because I will say PBMs have made the argument that when we collect all these rebates and also fees from pharmacies, we are able to lower the premium. That is actually true, that the premium is lowered—and for those who never use their prescription drug card, they pay the lower premium.

But for the sickest Americans, those, for example, with cancer, when they go to the pharmacy counter, as has been stated, they pay the maximum copay. They go into the donut hole, and then they go into catastrophic coverage—all of them, anyone who is on a specialty drug.

So those patients who use their medication, they pay the most. And also, the government does. In the catastrophic coverage phase, the PBM insurance company pays the least. Manufacturers and the government pay more, and so do patients. So the sickest patients are the biggest losers.

Senator STABENOW. Thank you.

Mr. Chairman, thank you again, and the ranking member, for holding this hearing. This is a very important piece of how we are going to really make medicine in America affordable for people. I would just add we, as taxpayers, pay for basic research that creates these drugs, which I am happy to do, and it is an important piece of what happens.

But it is public dollars, and then when we end up paying the highest prices in the world, this does not equate. This does not work, and I am so glad we are tackling this.

The CHAIRMAN. And thanks for all your leadership in these issues, Senator Stabenow. I hope everybody picked up on the point Mr. Levitt just made to Senator Stabenow, and that is, you can do phenomenally well in the prescription drug system as long as you never need medicines. If you do not need medicines, everything works out well.

Senator Crapo?

Senator CRAPO. Thank you very much, Mr. Chairman.

When we talk about the need for greater transparency in the drug supply chain, that term can and should mean a few different things. It means transparency for plans, who need to select the best PBM option and conduct effective oversight. But it also means transparency for consumers in choosing a plan, as well as for providers in choosing the most cost-effective, clinically appropriate medication to prescribe.

We also know from experience that any effective transparency policy needs to drive down rather than increase costs, and that credible trade secrets warrant protection. With these considerations in mind, I will start with you, Mr. Levitt and Dr. Van Nuys, in that order.

What specific and concrete policy steps should we take to improve transparency under the Medicare Part D system for patients and plan sponsors, as well as for providers and pharmacies? I would ask you to be as succinct as you can, because I want to have a few other answers as well.

Mr. LEVITT. So, to speak very succinctly, I think that the process for the government to take that would be the most practical and the most effective would be to create a true rebate safe harbor. So that would mean that it would be transparent, that PBMs could legally take a rebate fee or an administrative fee, but it would be limited to 3 percent, 4 percent, 5 percent, not 50 percent. So I think a very practical rebate safe harbor would be a big change.

Senator CRAPO. Okay, go ahead. Were you going to add something?

Mr. LEVITT. I was just going to add, from the patient perspective, the Medicare Plan Finder is where patients go to look and see their copay. The Medicare Plan Finder does not reveal that patients are paying a copay based on that list price of the drug instead of the net price after rebates and after DIR fees.

Senator CRAPO. All right; thank you.

Dr. Van Nuys?

Dr. VAN NUYS. Thank you, yes. You heard from Dr. Gibbs in his opening statement about how helpful the National Average Drug Acquisition Cost data are to his business model, but they are also helpful to researchers like us.

I think one action that the Federal Government can take is to create similar pricing series that are collected regularly, standardized, averaged, and posted publicly just like NADAC is. That would help.

But those series are not on the acquisition cost, which is the cost that pharmacies pay to wholesalers, but at other points in the distribution system—so, for example, the prices that are the reimbursements that pharmacies are receiving from pharmacy benefit managers, or the prices that health plans are paying their pharmacy benefit managers to settle claims.

If we had similar aggregated—so, not disclosing any confidential information—if we had similar consistent benchmarks and measures in those points of the distribution system, people like Dr. Gibbs could use them in their business negotiations, researchers like me and regulators could know more about how prices are moving throughout the system. I think that would be a big help.

Senator CRAPO. All right; thank you very much.

Dr. Gibbs, what would your answer to that question be?

Dr. GIBBS. Well, I feel as if Dr. Van Nuys quoted me, but I would say it is very similar. We are using a pricing index everywhere—Medicare, managed Medicaid, commercial—off of AWP, and it literally has nothing to do with the price of a drug. So I do not know if people understand that in most, if not all, Medicare contracts, you pay the average cost of all drugs.

That is your guarantee. Drugs do not have a price. You do not know the price of generic Lipitor. You pay a price based on all generics' average over a year. We do not buy any products like that in our economy. We have accepted it in the drug business. And until we get rid of the fundamental issue of these average benchmarks that are not related to drug costs, we can do all these other great, creative things around rebates, transparency, but when the cost basis is not reflective of actual cost, it is not going to be worth it. We have to change that.

Senator CRAPO. Well, thank you very much.

I have a number of other questions that basically ask for solutions, and I am not going to have time to get into those. So I am going to yield my time back to the chairman.

But I would like to ask you all—I will tell you, we will be submitting questions for the record to you, and I ask you to really pay a lot of attention to these questions, because we need the kind of expertise and guidance that you can give to us to help us put together the right solutions here.

The CHAIRMAN. And I second Senator Crapo's request. We want to make this a bipartisan effort in this committee. So please, treat Senator Crapo's questions like mine and everyone else's. We have got to get moving on this.

My first question to you, Ms. Feldman, is that in 2021, Senator Grassley and I released what was, really, a landmark report, reviewing contracts between the three biggest PBMs and insulin manufacturers. One of the findings was that the manufacturers often paid PBMs administrative fees for services—for example, for providing data—and PBMs made billions of dollars every year off these fees.

The report also found that these administrative fees are often based on a drug's list price. So, preferring a higher-priced drug by placing it on an advantageous lower formulary tier can make more money for the PBM, yet higher costs for patients and taxpayers.

Question: doesn't the PBMs' practice of preferring higher-priced drugs raise patient costs and overall drug spending?

Ms. FELDMAN. Yes, of course. When patients are channeled into higher-priced drugs, the prices rise. With the system you have just described, the problem is that the person negotiating on behalf of the patient should not be getting paid by the other side. It is a conflict of interest. It is a problem, and it pushes those prices higher.

When that payment is based on a higher price for the drug, it undermines the negotiation entirely.

The CHAIRMAN. You are being way too logical for a lot of the ways the Federal Government does business, and I appreciate it.

Dr. Van Nuys, for you: your research suggests that PBMs may be overcharging their health plan clients for generic medicines, including Medicare Part D plans. One of your studies found that Medicare was overcharged by $2.6 billion for generic medicines in 2018 alone, compared to Costco's pricing for the same drugs.

A separate Harvard study backs up your findings. They found Medicare would have saved $3 billion in 2020 if Part D plans were charged the same prices that Mark Cuban's Cost Plus Drugs company charged us for generics. This is all factually correct thus far; is that correct?

Dr. VAN NUYS. Yes.

The CHAIRMAN. Okay. Now, it is no secret that big PBMs can be effective negotiators when there is competition between drug manufacturers. It is hard to believe they are not getting as good a deal, if not better, than Costco or Mark Cuban. So I want to finish up with a specific example.

CivicaScript is a nonprofit pharmaceutical manufacturer. They sell a generic prostate cancer drug for $160. The average price that the PBMs are charging the Part D plans for the exact same drug is over $3,000. Just let that all sink in a little bit—the difference between generic prostate cancer drugs for $160; PBMs are charging Part D $3,000. Yet Civica cannot get the big three PBMs to cover their drug, which is a tiny fraction of what they are doing their business with.

So as a result, Part D plans—and consequently patients and taxpayers—for this drug, this specific drug in this specific case, they are facing a markup of nearly 2,000 percent. Is that right?

Dr. VAN NUYS. The math?

The CHAIRMAN. Yes.

Dr. VAN NUYS. Oh, I trust your math, yes.

The CHAIRMAN. Yes, correct. So, colleagues, we are going to enter this letter into the record from CivicaScript. It provides more details on the issue. But the example that we have cited with a generic prostate cancer drug, we are talking about a markup of almost 2,000 percent. So something is way out of whack here, all right?

[The letter appears in the appendix beginning on p. 211.]

The CHAIRMAN. One last question for you, Dr. Van Nuys. Why do PBMs appear to be charging such high prices to their health plan clients for these medicines?

Dr. VAN NUYS. I think the short answer is, because they can. Lack of transparency in these markets allows PBMs to pay the pharmacy one reimbursement and then charge the plan a different price for that same prescription and keep the difference, which is the spread.

And because plans cannot see what the pharmacy has been paid, they do not know when they are being overcharged. It is that kind of lack of transparency that certainly is driving what happened with the Costco study that we did. I suspect that is also going on in the CivicaScript example you just cited.

In the CivicaScript example, there is also this added complexity of the PBM owning the specialty pharmacy that is dispensing it. That is a different issue, but also related to your question.

The CHAIRMAN. So let me close with this, and my time is just about up. This sounds like a really bad news discussion for patient costs and spending under Medicare. Is that your assessment as well?

Dr. VAN NUYS. Yes, I agree.

The CHAIRMAN. Because we have got to figure out how to hold down costs in America. We have got to figure out how to strengthen Medicare. Senator Crapo and I talk about this often. In this committee, colleagues, the late Senator Hatch worked with us, and I think Senator Grassley remembers as well. We built the CHRONIC Care bill.

We are interested in finding ways for people to get good-quality care, and to make it more affordable. We have just gotten a snapshot in time of just how the consumer gets fleeced under these kinds of PBM practices, and how that really ripples right through to Medicare, which picks up so many of these bills. And we just cannot afford to do business this way and meet the challenge of Medicare in our time.

Senator Grassley?

Senator GRASSLEY. Mr. Chairman, thank you for continuing this committee's work on PBMs. Something ought to get done this Congress, considering the fact that there is already a bill out of Judiciary, a bill out of Commerce. Senator Sanders is talking about getting a bill out of the HELP Committee. The House committee is already working on this issue.

I believe it is our duty to understand how the pharmaceutical supply chain is working, and what we can do to improve it. In 2019, this committee held a hearing with PBM executives, and we worked to advance a bipartisan bill to shed more light on PBMs and drug companies. The Inflation Reduction Act took big steps to reduce drug prices, but there are approximately 30 provisions in the Grassley-Wyden bill still not law that would establish more accountability in the drug pricing world, including for PBMs.

The current drug price system is so opaque that it is easy to see why there are many questions about PBM motives and practices. In 2018, I pressed the Federal Trade Commission to investigate PBMs. Last year, the FTC began studying PBMs, and I am not waiting—we cannot wait for FTC to issue their report.

The Judiciary and Commerce Committees have passed PBM bills that I am working on with Senator Cantwell. Senator Cantwell is also on this committee. The Prescription Pricing for the People bill requires the FTC to study pharmaceutical intermediaries, including vertical integration, and issue a report and recommendations to Congress within 1 year. This bill has passed the Judiciary Committee on a voice vote. The PBM Transparency Act has advanced out of the Commerce Committee with a bipartisan vote of 18 to 9. This bill puts sunshine on PBMs and saves taxpayers $740 million.

I pursued bipartisan legislation, held hearings, and conducted oversight. In the Grassley-Wyden 2-year investigation into insulin price-gouging, we found that that PBM scheme encourages drug makers to spike the drug list price in order to offer greater rebates, and in turn secure priority placement on covered meds, and all at the expense of many patients.

This especially impacts those who are uninsured, underinsured, and on high-deductible plans. Recently three insulin manufacturers announced that they were lowering the list price on their insulin products. I believe the key way that we can solve high prescription drug prices is to have more transparency.

One of the panelists talked about PBMs being scapegoats. I think they have created their own scapegoat environment, because of lack of transparency. If you want people to understand what you are doing and you are playing a very important role in this whole business of getting pills from the manufacturer to the consumer, then why not have transparency, and then you do not have any problems with the public not understanding what you are doing?

So, my one and only question will be to Dr. Van Nuys and Mr. Levitt. The Cantwell-Grassley PBM Transparency Act requires transparency reporting to shine sunlight on prices and fees. Why is PBM transparency important to ensuring taxpayers and patients are getting the lowest drug prices possible?

Dr. VAN NUYS. I think transparency is an essential first step, because it gives researchers like me, regulators like the Federal Government, the opportunity to understand the bigger picture. But more importantly, that kind of transparency is actually going to provide participants in the markets with information about the true prices that they are facing.

When they have information about the true prices that they are facing, they can make better economic decisions, and they can choose the highest-value opportunity. So I think it is an important first step. I think it will help in at least those two ways.

Senator GRASSLEY. Mr. Levitt?

Mr. LEVITT. Thank you. It is our contention, based on information we have seen in litigation and how we studied the market, that there is a huge percentage of the list price of a drug that is retained by the PBM and the PBM rebate aggregator. Transparency would shine the light on that.

It is okay if PBMs make some money, but if it is 20 or 30 percent of the list price of a drug, that is a problem. If we are able to shine that transparency on those rebates, we can actually lower the list price of drugs for all Americans. Pharmaceutical companies could literally charge less and earn the same net price. Plan sponsors including the government, Medicare and Medicaid, and private em-

ployers could pay a lower price for drugs, and pharmacies could stay in business because they could get a reasonable reimbursement rate.

The CHAIRMAN. I thank my colleague, and next is Senator Cornyn.

Senator CORNYN. Thank you, Mr. Chairman. This is an extraordinary panel, and there is so much complexity here that I am going to join Senator Crapo in sending you some specific questions about solutions. I am not sure what the right metaphor is. I have heard you talk about the system being riddled with perverse incentives.

Sometimes the PBM is called the "black box," and I have heard us talk about transparency. I start with the fundamental proposition that our pharmaceutical industry is entitled to a return on their investment for their risk-taking, and that we are the beneficiary of that from the public health standpoint.

The fact that the American and the international pharmaceutical industry can come up with Operation Warp Speed in an incredible amount of time and save millions of lives, is something to be celebrated.

Conversely, I do believe that there is a lot of gamesmanship going on in the industry. Maybe that is an understatement for all of you here. So again, I do not know what the right metaphor is—whether it is a Rubik's Cube, or a shell game, or whatever you want to call it—but transparency, as many of you have said, seems to be an important part of getting the right answer.

But I cannot help but feel like this is by design, the complexity and the difficulty of actually determining what is the price of the drug. Dr. Gibbs, you talked about the importance of setting that standard. So I am very interested in getting some specific proposals, and of course Senator Grassley and others have talked about transparency.

But it strikes me that without transparency, the market cannot work. Dr. Van Nuys, do you agree with that?

Dr. VAN NUYS. Wholeheartedly, yes.

Senator CORNYN. I mean, I am not an economist. I am a recovering lawyer, but it seems to me that this whole area is rife with gamesmanship. We have even had examples of drugs that have had as many as 100 different patents, so-called patent thickets, and product-hopping and other gamesmanship by the industry, to try to maximize price.

Again, I do not begrudge the industry making a return on their investment, and I know it is highly risky. But I do object to the gamesmanship and the playing of a rigged system. So, Dr. Van Nuys, why is it that Costco can charge so much less for the same drug?

Dr. VAN NUYS. Again, I am going to go back to transparency. I think that because, in a cash market, there is no third-party payer, there is no spread. The PBM is not charging a spread, and so Costco does not have to pass those costs on to the patient.

Senator CORNYN. I am not—I usually do not gamble when I go to Las Vegas, but sometimes they talk about the spread. This sounds like it is one big gambling operation.

Dr. VAN NUYS. I am not sure whether it is gambling, but it is a way for PBMs to capture money inside that distribution process, yes.

Senator CORNYN. And, Dr. Gibbs, you talked about the mechanism that you have used to try to provide more transparency and sort of a standard price that people can operate from, because we lack the basic information to understand the system and this whole——

Mr. Levitt has talked about all the "do not disclose" statements and the confidential settlements and things like that that prohibit him from telling us what he knows about this system. But what impact do you think your company and the way you are operating in terms of the business model, compared to Amazon or Mark Cuban's Cost Plus Drugs—what promise does that have to lead us out of this terrible mess?

Dr. GIBBS. Sure. Thank you, Senator, for your question. I would say our goal is and always has been to bring transparency options, regardless of channels.

Senator CORNYN. You want to make money too though, don't you?

Dr. GIBBS. Correct. I mean we are—we are a startup. We started in 2018, and we are not profitable yet. We are getting there, and it——

Senator CORNYN. I do not think Amazon was either for the first period of time.

Dr. GIBBS. Exactly, exactly. And using a price index like NADAC, which is published by CMS—they actually do the survey to the pharmacies. And by making it more robust so it is not voluntary—today it is a voluntary survey—and getting better responses to that will lead us to the actual drug cost.

And then you can have your nuance of Costco, Mark Cuban, and a person can actually go in and look, and actually be informed of what the real price is once and for all. Today, with all the dynamics, from PBM spread to stores having different usual and customary fees, to membership programs that all the stores have, it has created this quagmire for a person to really know what they are going to pay.

The only way is to level set. The good news is, we have the tools already. We just need to enforce them.

Senator CORNYN. Well, Dr. Burns, I appreciate your scholarly work, but the fact it took you 650 pages or so to explain PBMs and GPOs I think speaks volumes about where we are.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Cornyn.

Next would be Senator Cardin.

Senator CARDIN. Thank you, Mr. Chairman, and let me thank you for calling this hearing. I want to thank our panelists. Put me down on the comments that you made in the opening. I strongly support greater transparency.

The rebate systems seem to be leading to the wrong types of incentives. Higher-cost drugs are priority over lower-cost drugs, and quite frankly, I do not know who holds the pharmacy benefit managers accountable for any public responsibility.

I think that is the challenge. We, the taxpayers, are the largest payers and consumers of pharmaceutical products, and yet the pharmacy benefit managers that play a critical role in this are really not accountable to us. To me, that is the major challenge.

So, I do not know how we get a handle on the accountability issue, but let me mention one area that has been one of my major areas of concern. We have many low-cost drugs that are very important in our health-care system, infusion drugs, that are in short supply.

I have heard specifically of examples where patients were denied the protocol care because the drugs were not available. These are low-cost drugs that in the richest country in the world, that spends the most on pharmaceutical products—to me it is outrageous that these drugs are not in adequate supply.

Now, you would think the pharmacy benefit managers that are negotiating on behalf of the companies' coverage for drugs would have leverage to make sure that low-cost drugs are available. But it does not seem to be the case, and this past year we added more drugs to the shortage-of-supply list than we ever have in the past.

So how can we modify our system to make sure that we have adequate supplies, and how can the pharmacy benefit managers be engaged in that process? Who wants to take a shot at that? Please.

Dr. BURNS. Well, there are Federal reports that the major problem with drug shortages is not PBMs; it is with the manufacturers, and I am not here today to bash the manufacturers. But oftentimes, those shortages are driven by manufacturing problems and compliance problems in the plants operated by those manufacturers. That is the source of the problem, number one.

The source of the problem number two is, sometimes we just do not have enough manufacturers there, such that one could pick up the slack if one of the other manufacturers' production goes down.

Senator CARDIN. I agree with you that the primary responsibility is with drug manufacturers and their profit motives. If they cannot make enough on a particular drug, they are going to use that capacity for other purposes.

But I would just argue that pharmacy benefit managers are a huge part of the pharmaceutical chain here, and they could use their leverage in regard to pharmaceutical manufacturers. I would suggest also that the group purchasing organizations that are setting up could also add to the number of drug shortages because of the pricing here.

So there is part of what they are setting up, to me, that makes the problem more challenging. Yes, did you want to respond, Mr. Levitt?

Mr. LEVITT. Yes, I think that it is true. Manufacturers should be making these short-supply drugs. But I think one of the things that PBMs can do in a more moral control of the formulary, is to put these low-cost drugs on the formulary, encourage manufacturers to make these by giving them a fair return, and giving the pharmacies a fair return for dispensing some of these drugs.

Senator CARDIN. I agree. It seems to me that, as I see it, the PBMs have ignored this issue, and in some cases have made it worse because of the way that they have organized their pricing. So, it encourages the pharmaceutical manufacturers to do what

they are doing today, rather than trying to provide a different avenue so that we can deal with the shortages.

We have some legislation here to deal with the shelf life of drugs and to make it easier, and some incentives to add capacity for lower-cost drug manufacturing. So, we are doing some things on the supply side.

But when you look at the profits that are being made, both at the manufacturer level and at the benefit manager level, to me it is shocking that there is not an attention to the patient who needs these drugs.

Thank you, Mr. Chairman.

The CHAIRMAN. I thank my colleague.

Senator Cassidy is next.

Senator CASSIDY. Dr. Burns, it's like no one is talking to you, man, so I would like to talk to you. We have several academics on, and if you read Ms. Feldman and Dr. Van Nuys, you are thinking, are you all from the same planet, right? You seem to be—so let me just ask about some things that Dr. Van Nuys puts in her testimony and have your response.

In 2019 before patents were due to expire, Gilead introduced an authorized generic version of Harvoni that was going to lower out-of-pocket cost by $2,500, but it never made it to several PBMs' formularies. The patients continued to pay top dollar, even though there was a generic that was available. I think I summarized that correctly, Dr. Van Nuys.

Now, that would look like something which is an abuse of a PBM, by a PBM. What would you say to that, Dr. Burns?

Dr. BURNS. Well, one has to look at the incentives in Medicare Part D plans, and the incentives there are to get the beneficiary through all of the various coverage phases into the catastrophic phase, where the government picks up almost all of the tab and the health plan pays very little.

So it is the health plans who have an incentive for the patients to move through those coverage plans, such that their liability is diminished when the patient hits the catastrophic phase. It is not the PBM; it is the health plan that the PBM is an agent for.

Senator CASSIDY. So you are saying that the health plan would be instructing the Part D PBM in order to put that formulary so as to move the person into the catastrophic phase most rapidly?

Dr. BURNS. Well, the health plans run the Part D plans. They are not instructing the PBM to run the patient——

Senator CASSIDY. So, it still sounds like a little bit of a collusion. If you have an insurance company that owns, in whole, the PBM company, and they are telling them, listen, we want to offload our responsibility, so stick it to the patient buying the drug and move them into—that is what you are saying, huh?

Dr. BURNS. Not necessarily, because that vertical integration that you have talked about with the health plans owning the PBMs, that is mostly recent, okay. Up until 2018, the only health plan that owned a PBM——

Senator CASSIDY. Yes, but I think what we are describing is still a recent phenomenon, at least until that was capped.

Mr. Levitt, you are shaking your head. You are waving your hand. You are like jumping up and down, but be concise.

Mr. LEVITT. I thought I was being more subtle than that, but yes. I mean the PBMs, and the insurance companies are one in the same, and there is no firewall. So UnitedHealth owns Optum. Cigna owns Express Scripts, and CVS owns Caremark and SilverScript.

So to the extent—that was an accurate statement. These health plans want the patient to have a higher-cost drug to move through the coverage phases to get to the catastrophic.

Senator CASSIDY. So I think what you are saying is that we have to actually broaden our view. The PBM is merely an agent for the insurance company that is willing to foist cost upon both the consumer and upon the Federal taxpayer, in order to maximize their profit?

Mr. LEVITT. That is right, but——

Senator CASSIDY. Let me stop you, because I have limited time.

Dr. Van Nuys, now recent legislation has changed the dynamic of the Medicare Part D incentive. Theoretically, there is no longer a reward for sticking it to the patient and moving her into the catastrophic. Would you expect that which Dr. Burns, I think it is fair to say—I do not know if "minimizes" is the right word but seems to give less importance to—how do you think this is going to impact it?

Dr. VAN NUYS. I will start by saying I am not sure, but I do think that it could alleviate some of the issues. I do not know. We will have to see how it plays out to understand.

Senator CASSIDY. And, Dr. Burns, coming back to you, I think you are quoting Weinstein-Schulman's data when you, in your testimony, say that people are inferring that the higher list price, even though net price is minimally rising, that they are inferring that that is related to the fees, the rebates, et cetera.

Seems like a pretty good inference to me. And so, knowing that that high list price is what the person, the patient in her deductible, is going to pay, they are still extracting more money from the Medicare beneficiary, a lot more money. Your thoughts on that?

Dr. BURNS. Sure. Research, as well as my own study of some of these drugs, shows that the list price goes up because the manufacturers can get away with it.

Senator CASSIDY. Now the Schulman article or articles, and the Schulman-Weinstein most recently, show that the list price grows, I do not know, 2.7 percent, whereas the—I am sorry. List price will grow 5 percent and net price is growing 1.7 percent. Now, that is not the manufacturer; in fact, there is a depressive effect. Others have noted that this is costing manufacturers a fair amount of money. So I am not sure. So where would you come from?

Dr. BURNS. Well, the manufacturer is setting that list price, and then the PBMs act as agents on the health plan to negotiate down that price——

Senator CASSIDY. No. That list price is a negotiation between the rebate and the net price. In fact, I think I know that the manufacturers do not report, as a profit, the list price. They only report the net price, which tells me that that is all they are counting on, and the rebate, the price between the list and the net, is that which the PBM is demanding for where they put it on a tier, etcetera. Would you dispute that?

Dr. BURNS. Well, the PBM demands that, in order to get on the formulary, and then demands a bigger rebate in order to get a more favored position on that formulary. And then the PBM translates or passes along those rebates to the health plan. The issue is what the health plans do with that money, not the PBMs.

Senator CASSIDY. I am way over, but I will say that the lack of—the opaqueness of it is, I think, what people are concerned about, because we do not know the entirety of that is going back to the payer. It may be going back to the integrated insurance company, but we do not know that it is going back to Google, Exxon, Deloitte and Touche, or you know, Performance Contracting in Louisiana.

Dr. BURNS. And what I would say is——

The CHAIRMAN. To be continued, Senator Cassidy. Important points.

Senator Menendez is next, followed by Senator Carper and Senator Thune.

Senator MENENDEZ. Mr. Levitt, pharmacy benefit managers are key players, or should be, in alleviating patients' financial burden at the pharmacy counter, as they frequently set patients' out-of-pocket costs based on a drug's list price. The higher the list price, the more the patient pays, an obvious burden.

Less obvious, but equally concerning, is that PBMs benefit significantly from high list prices and have no incentive to choose lower-priced drugs to drive down patient costs. PBMs extract rebates from manufacturers based on list price in exchange for a manufacturer's drug receiving formulary placement.

Those rebates are passed on to plans that employ them, but almost never to patients, and manufacturers also pay distributors, group purchasing organizations, and specialty pharmacies percentage fees that are based on the list price. The patient gets nothing.

So, under the current structure, PBMs make more money when a drug's list price increases, while patients bear the financial burden. Conversely, if a manufacturer lowers the list price, PBMs stand to lose money while patients benefit.

So, Mr. Levitt, do you agree that it would be better for patients if the supply chain was delinked from list prices, so that patients' out-of-pocket costs were based on net prices?

Mr. LEVITT. Yes. There is absolutely no doubt that patients would do better paying a copay based on that lower price, based on the drug benefit structure of almost all plans.

Senator MENENDEZ. And let me ask you, would patients be better off if PBMs and other supply chain entities were paid flat fees for the services they provide?

Mr. LEVITT. Absolutely they would, as long as it is a reasonable flat fee.

Senator MENENDEZ. Now, Humira treats people who are afflicted with crippling rheumatoid arthritis. This critical medicine can cost patients more than $80,000 a year. It should be good news to consumers that Humira biosimilars are being launched, which should make the treatment more affordable for patients who desperately need it.

But because the economic incentives to PBMs are completely skewed, the biosimilar drugs launch with two different prices: one with a high list price and a large rebate; one with a low list price

and a lower rebate. So take another look at this chart. We know PBMs favor the high list price in order to obtain larger rebates, even though the patient would pay significantly less if PBMs selected the drug with the lower list price.

So is it true, Mr. Levitt, that the current structure incentivizes PBMs to select higher-cost drugs to the detriment of patients?

Mr. LEVITT. Yes, Senator, it does, and it is often to the detriment of the patient, because sometimes there is a better drug on formulary that does not pay as much of a rebate that would be better for the patient.

Senator MENENDEZ. You know, the Pharmacy Care Management Association, which represents the PBMs, includes research on their website that states, and I quote, "High list prices hurt patients who must pay these prices. If list prices were lower, out-of-pocket payments based on list prices would be lower and more affordable."

It rocked my mind when I read this. So if the PBMs themselves acknowledge lower list prices would help patients at the pharmacy counter, why would they still place preference on a higher list price product, when a drug company has given them a better option for their patients?

Mr. LEVITT. Because they have established this architecture in the system, where they have these rebate aggregators that we believe are secretly siphoning a lot of that rebate out and not giving it back to the plan or the consumer.

Senator MENENDEZ. Thank you.

Now finally, as a result of mergers and acquisitions in recent years, CVS Caremark, Express Scripts, and OptumRx now control approximately 80 percent—80 percent—of all U.S. prescription drug claims. This level of concentration gives these PBMs market power over data, drug coverage, and contracting—80 percent.

The hyper-consolidation, with little to no regulatory oversight, creates inappropriate negotiating leverage that discourages competition and makes it difficult to achieve transparency, affordability, and timely access for patients. So, Mr. Levitt, how does the consolidation in the PBM market impact costs for patients, and what sort of regulation and oversight is needed to protect consumers?

Mr. LEVITT. I think, first of all, this massive power influence over physicians, which is a problem—we want physicians to act independently. I think some of the things Congress could do to lower drug prices would be to create more transparency, as has been discussed a lot, but also a safe harbor for rebates.

If PBMs want to earn a rebate, to keep money, it should be at an amount defined by the government. I think that would help lower drug prices.

Senator MENENDEZ. Thank you. Thank you, Mr. Chairman. I appreciate that Mr. Levitt's from New Jersey, his sock wear.

The CHAIRMAN. I noticed.

Senator MENENDEZ. It looks like he may have graduated from North Carolina at one point.

The CHAIRMAN. All right. Next will be Senator Carper and Senator Thune, and I thank my colleagues for their patience, and when we start voting, we are going to keep everything going.

Senator Carper?

Senator CARPER. Thank you, Mr. Chairman. Welcome everyone. Nice to see you all.

I am from Delaware, born in West Virginia, grew up in West Virginia, but I am privileged to represent the people of Delaware here for quite a while now.

We are proud in Delaware, especially with being the first State to ratify the Constitution. And in the Constitution, you may recall—in the preamble of the Constitution it starts with these words: "We the people of the United States, in order to form a more perfect union." It does not say in order to form a perfect union, but a more perfect union.

Out of that, I take the idea that everything we do, we can do better, and we need to do better. That includes the way we deliver health care: to cover more people, to do it in a cost-effective way, harness market forces where we can to provide better health care.

I will just say, there are four questions that I ask when I am considering, among other things, how to make pharmaceuticals more available to people, to make sure that they are getting the drugs that they need at a reasonable cost.

But I ask four questions in this room, and one of those is, given an idea, I say, what is the effect on patients, how does it affect patients? Then I ask, how will this affect taxpayers? What are the budget implications of what is suggested to us? The third question I ask is, a particular answer or idea, does it foster innovation? Does it diminish innovation? And the last question I ask is, does a particular idea simplify or make more complex an already complex situation, as you know?

And with that in mind, I am going to ask, not a question for all of you. I am going to pick on Dr. Karen Van Nuys, and I would appreciate your response to this.

Again, one of my guiding principles—and I just mentioned it is the first one—is, in terms of pharmaceuticals, the work that we do here with respect to prescription drugs—one of my first questions is, how does it affect patients at the counter in terms of their pocketbooks?

That is why I previously cosponsored something called Creating Transparency to Have Drug Rebates Unlocked, and you bet there is an acronym for all that. It is C, capital C, through, T-H-R-U (C–THRU). And it is led by Senator Wyden, and would have ensured that cost savings from rebates provided by drug manufacturers would be passed on to patients.

At the same time, sometimes lowering costs in one part of our health-care market, as you know, can cause another—it is like squeezing a balloon; it pops out some place else.

But here is my question, Dr. Van Nuys. Can you share with us briefly your thoughts on how we can better ensure that rebate cost savings are passed down to patients at the counter, while also managing costs for our Federal Government? And is there a narrow or maybe an incremental way to go about this so we can balance these trade-offs? Thank you.

Dr. VAN NUYS. Thank you, Senator. Let's see. As you know, it is hard to lower patient out-of-pocket costs without impacting premiums and squeezing the balloon in one place and having it bulge in another.

And so one of the solutions or avenues to help would be to take some of the savings that we have identified, right, that $2.6 billion that Medicare was overpaying for low-cost generic drugs in 2018, and figure out ways to take that money out of the current system and get it to patients for out-of-pocket relief or so we can lower premiums. We can do a lot of things with that.

We had—my coauthor Erin Trish and I—an op-ed in *The Washington Post* this week about taking those low-cost generic drugs out of the benefit, so that we do not run it through this process that adds 21 percent to their cost.

Right now, 21 percent is going to intermediaries. There are much better things we can be doing with that money: helping patients, helping taxpayers, helping the domestic supply industry, and helping innovation.

Senator CARPER. That is a very good answer. Yes, so go ahead and then I will—my time will expire, but go ahead, please.

Ms. FELDMAN. I believe there are three key areas that are really worth focusing on to try to bring sanity here.

Senator CARPER. Yes, ma'am.

Ms. FELDMAN. One is to clarify that the PBMs have a duty to the health plans and the patients they represent. The second is to ensure transparency, so the market can operate—price and price term transparency. And the third is to ensure that patients get the benefit when they choose a cost-effective drug, so that when the drug has a lower sticker price and the patient chooses it, the patient pays less.

Senator CARPER. Great. I am going to ask the men—I have to go. I address the men on the panel. If you agree with what she just said, those three, raise your right hand.

[No hands raised.]

Senator CARPER. If you agree with two of them, raise your right hand.

[No hands raised.]

Senator CARPER. How about one? All right. Well, we will come back, and we will let the guys have their discussion later on. Thank you. Thanks very much.

The CHAIRMAN. Thank you, Senator Carper.

Senator Thune?

Senator THUNE. Thank you, Mr. Chairman.

I would say, if we were starting over, I would blow up this whole model of the supply chain, because I think it is an antiquated model. I believe the free market works when there is competition. But you have so much vertical integration, so much consolidation of market power, and no transparency, as has been pointed out a lot of times already.

And I just—this to me makes no sense, and I have tried to study this supply chain and how this drug pricing works in this country, and I just—it is incredibly complex. There is not any other product that we buy in the market that has such a complicated and antiquated way of getting products to the consumer.

I say that as just an observation and something that I hope we can work on. But I know that these, some of these issues are embedded in a system that has been in place for a long time. But I would start over.

Let me start—I have a question having to do with the 340B program, which is critical to South Dakota hospitals, and, Mr. Levitt, if you could speak to this. I often hear concerns from South Dakota pharmacists, hospitals, and health centers when it comes to engaging the PBMs, especially on the 340B program.

The dynamics of 340B are complicated as well. There is a lot going on with contract pharmacies right now, but it is important that the program continues to serve its intended purpose of helping our hospitals and health centers support their communities. So, could you talk about the impact of PBMs' practices on hospitals and health centers in the 340B program?

Mr. LEVITT. Thank you, Senator. I think nowhere in the drug supply chain is the influence of vertically integrated health-care companies with PBMs—and with what they call third-party administrators in the 340B program—more troubling.

The whole idea of 340B is to get 50 percent of the drug costs as a profit back to the hospitals like the ones in South Dakota. But what really happens? You have PBMs that take maybe a DIR fee of 5 percent or 10 percent. So that 50-percent profit that is supposed to go to hospitals in your State is taken by PBMs.

PBMs also own a third-party company that manages the 340B program. Those third-party companies might take out another 10 percent. So now, of that 50-percent profit that was supposed to help with indigent care in South Dakota, 15 percent is gone.

Then you have the PBMs that own pharmacies and specialty pharmacies, and they act as contract pharmacies, as you mentioned, for the covered entities in your State, and they might take out another 10 percent or maybe more. So, at the end of the day, the 340B program is completely frustrated by PBMs, their specialty pharmacies, their retail pharmacies, and by their third-party administrators.

Senator THUNE. Let me—I want to direct this question to you too, Mr. Levitt. But we talked a little, you hit a little bit on independent pharmacies, but I also hear concerns from pharmacists in South Dakota regarding their retroactive direct and indirect remuneration fees, and this is something that CMS took a step toward providing more certainty on in their final rule last year by incorporating these fees in a negotiated rate.

However, I know that pharmacies continue to have concerns about low reimbursement rates from PBMs, and we need to ensure that our independent pharmacies remain viable, serve patients, while also ensuring that the Medicare program is a good steward of taxpayer dollars by promoting value and rewarding quality.

In your submission to the committee, you discussed the current performance metrics for pharmacies, some of which you state may not benefit pharmacies or patients. How do we incentivize or reward those pharmacies that are providing high-quality care to patients?

Mr. LEVITT. The current system that PBMs use, the metrics that they use for medication adherence—there is no oversight. One of the Senators talked about accountability. CMS has absolutely no idea how these big insurance companies for the Medicare Part D program are evaluating adherence. It does not incentivize physicians that dispense drugs, or pharmacies.

The solution might be CMS becoming more active in understanding how adherence is judged, so that the pharmacies that are truly doing well, serving patients, can get benefited more.

Senator THUNE. Good; thank you.

Mr. Chairman, I am about out of time, so I will—I have one question I would like to submit for Mr. Gibbs for the record, dealing with the things that you are doing in terms of technology and some of the ideas that you have that hopefully could impact in a positive way the price that consumers are paying at the counter. So I will submit that one for the record. But thank you, Mr. Chairman.

The CHAIRMAN. I thank my friend. I just want to say before he goes, I think there is no question that if you were starting over today, literally starting from scratch, nobody would go out and set up what we are dealing with now. And that is part of our challenge, and we are going to make it bipartisan, and that is what Senator Crapo and I have been talking about. I look forward to working with him.

Senator Tillis is next.

Senator TILLIS. Thank you, Mr. Chair. I thank you all for being here.

I spent most of my career in management consulting, supply chain optimization, strategic resources—all things that are relevant to this topic. For the last 8 years, I have been trying to get use cases that I could follow through the entire process, from the investigational new drug, to the new drug application, clinical trials, the manufacturing of product, going to the PBMs, going through the insurers, the health-care providers. And in 8 years I have not had anybody in this value chain willing to step up and go through the whole process. That suggests to me, Dr. Burns, that there is a lot of smoke. We just do not know exactly where the fires are.

But I do, for one, think that we have some use cases where the PBMs are likely to be guilty of some of the fires. I think right now we probably have people across the country viewing this committee kind of like a Super Bowl watch party. You have PBMs watching it; they are going to get hammered today. You have the other people watching it, probably cheering. But every once in a while, a statement is going to be made going, "Whoa! We have a dysfunction here."

I look at health-care policy pretty simply. To me, there are three critical success factors: how are you going to improve access, how are you going to improve outcomes, and how are you going to reduce costs? And until we get transparency in the entire process, we are not going to make headway here.

The other thing I would like to do, Mr. Chair, is have a hearing at some point where past members, past or current members who passed bills, have to sit where you are, and the industry and all the people in the supply chain get to ask you questions about what you were thinking. They may have been a good idea, but a lot of the restrictions that we have are congressionally mandated. So, we have to look in the mirror if we are going to solve this problem.

Pfizer launched a rheumatoid arthritis drug at a lower cost than the originator drug. A PBM placed a high price, high rebate on the formulary. Gilead authorized generic versions of a branded hep-C

drug. They found that nearly half of Part D plans covered the branded versions, but the authorized generics were specifically launched to reduce patient cost. By the end of 2020, less than 20 percent of Medicare patients received either.

Mylan launched a generic version of a lifesaving cancer drug for two price points. This PBM placed the high price, high rebate drug on the formulary. Sandoz, biosimilar, same sort of outcome: higher price, higher rebate on the formulary. Amgen with Humira, widely prescribed drug, similar story.

Teva, lifesaving cancer drug, similar story. AbbVie, same story. These are examples, some of them widely prescribed drugs, that make no sense in terms of the ultimate cost and the availability of it. I said in a committee hearing, last week I believe, with Mr. Becerra—I said I think everybody in the value chain needs to be at the table to take a haircut.

Now the question is, if we do it right, that haircut will probably look more similar to Dr. Gibbs. If we do it wrong, somebody in the value chain is going to get a haircut very similar to Mr. Levitt. And, Mr. Levitt, I appreciate you being here, because if we get this right, you are going to have fewer clients going forward, and I think you will be okay with that.

But this is another thing that 5 minutes cannot simply allow me to drill down on with somebody who has written 600 pages. That is the CliffsNotes version of all that we need to understand to get this policy right.

But you reminded me of an experience I had going into a controlled burn, when you said there is a lot of smoke, but you cannot see the fire. When you go in a controlled burn on a house, you have to put your hand on the firefighter ahead of you, because you are not going to see him the minute you enter the house. But there is a fire, and my guess is there are, in some segments of the supply chain, big ones that are going to be difficult to bear out, others where we can have some hits, the singles and doubles, and get something done.

But I am telling the industry, everybody in the supply chain, there is no rational basis for us not to have use cases so we can figure out the root causes of the problem, and it is not as simple as any one. You have to go through this and figure out what their value add is.

I think over time the PBMs have morphed; there is a lot of vertical integration now, a number of things that we have to look at if we are serious about coming up with a bipartisan proposal for solving this. Now I would like to reserve the right to speak with you all individually, because I think your expertise requires far more attention than I can give you in the remaining 6 seconds. So, thank you for being here.

The CHAIRMAN. I thank my colleague, and as we talked about yesterday, I am very much looking forward to working with him on this.

Senator Brown is next.

Senator BROWN. Thank you, Mr. Chairman.

Senator Tillis, thank you for your comments. I heard about the last two-thirds of them. Thank you for that. With the Inflation Re-

duction Act, we stood up to big pharma and dark money and finally began to take action to bring down the cost of prescription drugs.

I thank the chairman for his leadership on that. I have been working on this my whole career, pushing for Medicare price negotiations, pushing to crack down on drug company price-gouging. Their lobbyists rarely lose. They lost this time. We are seeing the same kind of actions with railroad lobbyists fortunately.

We can build on that success to lower prices further by reforming DIR fees. It is an impenetrable system of fees most people have never heard of that makes it harder for local pharmacies—we all hear from them often—to serve Ohioans who count on them every day.

Fees are so exorbitant in some cases, they force people's community pharmacy out of network or to close altogether. I called the administration last year to finalize its DIR fee reform proposal to help lower drug costs for seniors. CMS has acted to protect seniors' pocketbooks, but there are other problems with these fees that the rule does not touch.

Mr. Levitt, for you: what other actions should Congress take to better protect consumers and local businesses they count on by addressing DIR fees or any new practices PBMs are starting because of the CMS rule?

Mr. LEVITT. I think that there is some current law that applies to Medicare Part D. Terms and conditions in Medicare Part D are supposed to be reasonable and relevant. But PBMs think that they can pay below cost to pharmacies and still get away with it. Their argument is, "Look, we have 68,000 pharmacies in our network. If it was not reasonable, they would all drop out."

But they are dropping out. So I would like CMS to clarify some current guidance. The guidance that says, "reimbursement rates must be reasonable," I would like CMS to clarify to PBMs that that means that the reimbursement rate actually must be reasonable.

Senator BROWN. Thank you.

Another concern I have with DIR fees is that pharmacies are paid or forced to pay based on quality measures.

That sounds great, but I also hear from pharmacists in Ohio these measures are often inconsistent, sometimes just do not make sense. Some pharmacies, as I think you know from your head nod, Mr. Levitt, learn about these quality measures only after it is too late to address them. Elaborate on that, would you?

Mr. LEVITT. Sure. These DIR fees are based on performance. They are supposed to be based on the performance of pharmacies. But 50 percent of DIR fees plus are paid by specialty pharmacies, and the PBMs do not know how to measure adherence for specialty drugs.

I think they do it intentionally wrong. Sometimes they do it themselves instead of outsourcing adherence. If we had more time, I could give you specific examples. But I think CMS has no idea how these PBMs are judging adherence. I think CMS should take a look.

We sometimes ask the PBMs in depositions, "Have you gone to CMS and asked them whether you are doing adherence measurements correctly?" There is no communication between CMS and

these big PBMs on DIR fees, including on the net reimbursement rate after the DIR fee.

Senator BROWN. Thank you.

One of the biggest problems with our whole prescription drug system—and I think all five of you know this—is how opaque it is. Just a few companies dominate each part of the supply chain, which is far more convoluted than it needs to be, always frankly, to the benefit of the big drug companies.

Even the experts are mostly guessing about what is happening behind closed doors at the pharmaceutical companies, again all to their benefit. I am proud that my State is in some ways taking the lead in tackling some of these problems. Ohio is getting some $100 million in overcharges back from PBMs.

Earlier this week, we sued one of the mysterious group purchasing organizations, GPOs, that are owned by PBMs and used to take dollars from the pockets of people who simply need their medications. It is unacceptable that these shadowy, secretive entities have so much power over people's health care.

Mr. Levitt, talk for the last couple of minutes—how do GPOs operate? How do they contribute to the drug cost problem for everyday Americans?

Mr. LEVITT. So, every single manufacturer that wants to get their drug onto a PBM's list of drugs that the PBM makes available to their big plan sponsors, has to pay a rebate to get on formulary. So PBMs use that, that formulary, as a tool to extract dollars from manufacturers. Sometimes if a manufacturer might resist, they might say that they do not want to pay a rebate, the PBM says, "We are not going to put you on formulary. Or maybe we will, but we are going to make your copay Tier 3, which means no one is going to want to buy your drug. Or we might use step edits or prior authorization, so that physicians have a very tough time getting your drug onto formulary."

So these rebate aggregators, no one knows how much money they actually take out of the system. So, to be clear, these rebates that are collected by PBMs are not fully turned over to the plan sponsors, or maybe even to the government. They are retained in the middle.

Senator BROWN. Thank you.

The CHAIRMAN. I thank my colleague, and I appreciate the fact we have been working on these issues for a long time. And I would just say to my colleagues, these are complicated issues. There are questions of transparency and accountability. You always know whose side Senator Brown is on. Senator Brown is always on the side of the working families and the senior citizens.

I told the story the other day about how we got the price-gouging penalties, finally, and we are already starting to see breaks for consumers. We have the poster kids for these drugs like Humira, and we are starting to see price reductions. I thank my colleague for all his good work.

I understand Senator Whitehouse, in his usual magnanimous way, is saying that he would like Senator Cortez Masto to go first.

Senator CORTEZ MASTO. Thank you; I appreciate that. First of all, let me just reiterate what my colleagues have said. This is a great panel, and I hope this is one of many discussions we are hav-

ing, because it takes more than 5 minutes to really dive into the issues here. So I appreciate everyone being here.

I also want to thank our chairman and Senator Crapo, not only for holding this hearing, but really the work that we have done historically in this committee together, to lower drug prices for so many across the country, and continue to do.

Today, I am introducing legislation called the Lower Drug Costs for Families Act, and what it will do is penalize pharmaceutical companies for increasing the price of their drugs faster than the rate of inflation, for patients in both the private health insurance market as well as Medicare. I think that is so important. It is what we are talking about today.

We have heard PBMs often prefer higher-priced drugs to reap in administrative fees—we have heard that today—on the percentage of a drug's price. We know that health plans have incentives to limit overall drug spending. We have seen that as well, and we have also heard that PBMs get paid, both by their health plan clients and by the drug companies they negotiate with. This raises serious questions as to whether PBMs are serving the best interest of their clients, including union health funds.

Obviously, transparency is key. That is what we are hearing about. But, Dr. Gibbs, let me ask you this, because you note in your testimony that Capital Rx has both financially and clinically aligned interests with its clients.

As a PBM working with union payers, I am curious about your perspective here as well. How is your PBM model different, and what does that mean for the patients?

Dr. GIBBS. Thank you, Senator, for your question. We work off what is called a single ledger model. We do not have to keep two separate sets of books, which have been referred to in many different aspects here today. What we reimburse the pharmacies is what we bill our clients. What we receive from pharmaceutical contracts is passed back to our clients, 100 percent.

Where that can be validated is with the Consolidated Appropriations Act. PBMs had to report their third-party margin spread at retail. They had to report their rebates that were retained on specific clients. So the data is now there as of January 31st of this year.

I do not know what the Department of Labor or CMS intends to do with that. But that will shine the first light on what PBMs are making in this space, and I proudly put zeros in both of those columns.

Senator CORTEZ MASTO. Yes. And so, can I ask you, what else should we be learning from your model that you have not heard today, that we have not discussed, that we should be aware of?

Dr. GIBBS. I think first and foremost is the fact that the supply chain is complex because the basis is wrong. The fact that at wholesale acquisition cost, which is kind of the starting point of drug pricing, when we actually serve a pharmacy, their price is lower than that.

It does not make sense. The pharmacy does not buy lower than the wholesaler. So that should tell us right away that we are starting off at a place that is nonsensical, and until we fix that, every-

thing else we are talking about is gray noise. We have to fix the cost basis of drug pricing in this country.

Everything ties to that. Rebates tie to WAC. Wholesaler price ties to WAC. AWP goes to pharmacy sometimes. So, until that is all defined and revealed and becomes transparent, the rest of the fixes are going to continue to be on a spiral, in my opinion.

Senator CORTEZ MASTO. Thank you. And you know, it is true in Nevada, like every other State, where I am hearing from Nevadans, from our patients, from our pharmacies, all on the same issue.

So it is not something that is unique to any one State. We have to figure this out, and I so appreciate the conversation today. I look forward to more of it so we can really address this issue, and I am going to yield the remainder of my time to my good colleague here.

Thank you.

Senator CRAPO. Senator Whitehouse?

Senator WHITEHOUSE. Thank you, Senator Crapo. Thank you, Senator Cortez Masto, and thank you all for being here.

There is an obvious logic that Dr. Gibbs represents here, of having PBMs as an organized counterweight to the power of the pharmaceutical industry, which otherwise dominates. The danger is that a pharmacy benefit manager, once they are interposed between the pharmaceutical company and the customer, can become just a toll taker, or just a self-dealer, and extract more money out of the transactions than any market principle would justify.

It gets a little bit worse than that, because if they are going that way, there is also the prospect that either through coordination or just through happy coexistence, the pharmaceutical companies can artificially inflate their prices to get paid more. That allows pharmacy benefit managers to get a bigger share of the savings that are, at this point, fake savings.

The pharmaceutical industry is happy because it is making more money. The PBMs are happy because they are making more money. Nobody is blowing the whistle on the initial price being a phony, because the PBMs who are supposed to fight the initial price are actually in on the economics of the transaction, and the consumer once again takes it in the neck.

So I am very interested in following up on what more in the way of transparency and guard rails we can do to prevent those behaviors and highlight them when they happen. Mr. Levitt is a lawyer. I am particularly interested in where you think some of our agencies might have a more robust role than they are presently exercising, like for instance our friends at the Department of Justice. And I will ask you about that in a minute, and give you the closing words.

But I also want to point out that—as I sort of step back and observe this phenomenon of concern about pharmacy benefit managers—while it is possible that big pharma and big PBMs are orchestrating high prices that they can share, they are not doing their jobs about proper pricing.

I think there is also a bit of competition going on here, and that big pharma would like nothing more than to have the American concern about their prices be diverted to concern about PBM behavior, so that we take our eye off the ball of how big pharma is pricing its products.

I think the window we created in the Inflation Reduction Act to actually start real negotiations and get a bit of a better look under the hood is going to help cure that problem. But I urge all of my colleagues not to take our eye off the ball of pharma pricing as we look into the question of PBM behavior. And with that, Mr. Levitt, back to you on where you think the executive branch of government could be operating more effectively in this space, and how.

Mr. LEVITT. I think PBMs, for one of the things they do—they earn, it has been called an administrative fee and a data fee—there is a safe harbor for those fees. There is a law about that. In order to be safe in that harbor, these PBMs are supposed to follow the rules, and they are not following the rules, because these are percentage-based fees that they are taking.

I also think the executive branch should take a look at the Medicare bids submitted by these prescription drug plans. We talked a lot here about the different pricing. There was a cancer drug mentioned that was a couple of thousand dollars versus a generic—a nonprofit company had a generic that was a couple of hundred dollars.

I think that when you bid, when these prescription drug plans bid Medicare, somebody should look at those bids. They should compare to things like Mark Cuban's Cost Plus Drugs, or this private company that has very cheap drugs.

So I think looking at safe harbors, looking at the bids, and I think that DOJ absolutely should take a look at rebate aggregators, to see just how much money is being pulled out, especially when it relates to Medicare Part D.

Senator WHITEHOUSE. When you say take a look at the Medicare bids, you are meaning a very practical look comparing what the bid is for this particular drug in isolation against similar drugs or treatments—or perhaps other bids that they have made in other places, just to give a reality check that it is for real?

Mr. LEVITT. Exactly.

Senator WHITEHOUSE. Okay. Thank you very much.

Thanks, Chairman Crapo.

Senator CRAPO. Thank you.

Senator Lankford?

Senator LANKFORD. Thanks. Thanks for the marathon that you all are on at this point today. You are crossing the 2-hour mark of us pummeling you with questions. Let me pummel you with a few more on this.

Mr. Levitt, I am going to come back to you because you are sufficiently warmed up there on it, and it is the issue of tiering that has come in. This is an area that I have been working on for a while. The drug companies complain about the PBMs until they cooperate with them for tiering. When it is time for a drug to go generic, once the generic is about to be released, the PBM and the branded drug, they negotiate together some way to get a higher rebate fee if they will put the generic drug on the branded tier.

That means the copay for the consumer is more, and it also is a higher cost for Medicare at that point. This has been an issue. They are literally driving generic companies out and driving the prices higher for the consumer. At the same time, the PBM will

come back and say, "We are negotiating to get better prices for the consumer," when they are actually not. Where am I wrong on this?

Mr. LEVITT. I can see no fault in any of that logic.

Senator LANKFORD. Okay. So how do we, how do we solve this?

Mr. LEVITT. Earlier we talked about accountability. I am not sure who is looking at these formularies. I mean, if it is a Medicare formulary, I think CMS has outsourced Medicare to these private companies—completely outsourced, with very little oversight. So I think that CMS should look hard at this tiering issue you talked about.

Also, honestly, in this self-funded plan space, I think big employer groups need to more carefully examine what their contracts say and what PBMs are doing.

Senator LANKFORD. Okay. I would also—let me add one more element as well. There have been some studies and some conversations about what PBMs do to independent pharmacies, especially with the DIR fees, with the new quality basis that they literally invent every month or quarter.

They will retroactively change all their requirements on them. But it has been remarkable to me how many independent pharmacists have told me the same crazy story, that they get a change in quality, they get a drive-down in price, and then within about 2 weeks, they will get a call from one of the PBM-owned pharmacies saying, "Hey, we are trying to expand into your area. Would you like to merge into our pharmacy? Would you like to become one of us?"

So my challenge is in a couple of ways. What PBMs are doing, I believe, is actually driving our independent pharmacies and our rural pharmacies into submission or gone from there, and that is a real problem.

The second thing we have seen is, even VA recently cooperating with a PBM to basically cut off thousands of rural pharmacies around the country and say, "You are no longer going to do VA benefits. You have to do mail order through our PBM to be able to do it," which will kill our pharmacies.

Have you seen this as just independent stories, or has anyone seen this as an actual trend that is going on?

Mr. LEVITT. The story told about PBMs aggressively auditing an independent pharmacy and then offering to buy that pharmacy, I have seen that for 10 years. I have seen that trend.

The irony also, Senator, is that when PBMs buy these pharmacies, they are literally buying them with their own money, because PBMs have the DIR fees that are pure profit, and it has fueled this proliferation of PBMs buying up pharmacies.

The thing about the VA and TRICARE, I think—you know, I looked at those. Whatever information is public about the TRICARE bid I was able to see. There were two PBMs that bid for the TRICARE business. That is one of the biggest contracts in the country. I cannot figure that out, but someone has got to look at that.

Senator LANKFORD. That is worth a follow-up from there. The question is out there always. When we talk to any of the PBMs and we say we need greater transparency—we need to know more about the pharmacy reimbursement, the manufacturer rebates, we

need that—their response is always the same: "Well, that is going to hurt the consumer. If we give you greater transparency, the consumer is going to be hurt." Now, we never get an answer of what that really means. Where are they coming from on that, and does it really hurt the consumer if there is greater transparency in the PBMs? I will let anyone answer that who wants to be able to answer that. Dr. Burns?

Dr. BURNS. Well, there is plenty of research that shows when you start mandating transparency, especially of prices, there is always a danger of collusion among the people who are revealing those prices. So you always have to watch out for that.

And studies show that a lot of the transparency movement, which has been going on for 20 years, has not really benefited consumers, because most consumers do not know what to do with the information.

Senator LANKFORD. Right. The challenge that we have is, obviously, the consumer is paying a higher price, and we all know it. The spread pricing is real; we all know it. The percentages that are being paid is a very real issue. The rebates are not going back to the consumer.

We all know all those things, and any time we try to step in and say, "Okay, so let us provide some transparency to find out how many dollars are there," they are like, "Oh, that is going to hurt the consumer," as if everything they are already doing is not hurting the consumer. But suddenly that piece becomes oh, that is going to be bad for the consumer.

So this is an issue I am glad this committee is taking on. I am glad you all are here. We have a lot more work to do. We discussed this 4 years ago and have done nothing about it so far. I am grateful to the Biden administration and CMS in some of the things that they are currently doing on DIR fees to step in, but it is not far enough.

And we have some additional work to do in this area. So I appreciate all the preparation that you all made for this hearing. I am grateful we are having it. Thank you all.

Senator CRAPO. Thank you.

Senator Warren?

Senator WARREN. Thank you, Mr. Acting Chair.

So last year, Congress passed the Inflation Reduction Act, which finally gives HHS the authority to negotiate drug prices for a select number of high-priced brand-name drugs. This is a significant achievement, and one that drug companies paid their lobbyists about $150 million to avoid. That is one of the signals that it probably will have some effect.

Despite these wins, there is more that we need to do to reduce exorbitant drug prices for all Americans, and that includes taking a hard look at the pharmacy benefit managers that we have been talking about, the PBMs that negotiate discounts from manufacturers on behalf of insurance plans, putting upward pressure on list prices.

But we also cannot lose sight of the ways that drug companies continue to abuse our intellectual property laws to drive out competition, to jack up prices, and to protect their profits. So, in a competitive market, we would expect to see a lot of patent applications

for new drugs as companies race to invent the next blockbuster product.

Professor Feldman, does that describe the patent landscape for pharmaceuticals right now?

Ms. FELDMAN. Senator, that is not really what we are seeing right now. Companies are largely recycling and repurposing existing drugs today. To cite one study, 78 percent of the drugs associated with new patents are not new drugs coming on the market; they are existing ones.

Senator WARREN. Wow.

Ms. FELDMAN. We are seeing a lot of churn.

Senator WARREN. So, think about that. More than three out of four new patent applications for pharmaceuticals are for existing drugs, which means adding new patents for things like new formulations or manufacturing methods, or even certain restrictions on a drug, but not actually for new drug compounds, new drugs into the field.

So let us say that a drug company manufactures a pill and the patent for this pill is just about to expire. Instead of facing competition, the company decides it will make the delayed release version of the drug, so that it goes into effect just a little while after the pill is ingested. Even though it is the exact same drug, the company patents the new formulation and then removes the original from the market. Ms. Feldman, could that restart the clock on the drug's monopoly protections?

Ms. FELDMAN. Yes. That would effectively restart the clock.

Senator WARREN. Okay. So drug companies use these tricks, and a lot of others, to keep their monopolies and keep pushing prices higher and higher and higher. Now the Inflation Reduction Act exempts drugs from Medicare negotiation for the first 7 or 11 years, depending on the kind of drug, following that initial approval.

Recognizing the potential for gaming, CMS has issued guidance saying it will use the earliest approval of all the formulations of a drug to determine its eligibility for the program. Professor Feldman, without this step, could drug companies use these patent tricks to ensure that their drugs never become eligible for the Medicare negotiation provision in the IRA?

Ms. FELDMAN. Product hopping is a serious concern with regulations like that. The CMS guidance is a very important step for ensuring that companies cannot evade the impact of the law by simply changing the packaging of the drug or shifting from 20 milligrams to 40 milligrams.

Senator WARREN. Wow. Well, you know, we must ensure that drug companies do not rely on tricks in order to avoid competition. I support this step from CMS. I am glad to hear that you do. But the administration can do more to limit patent abuses without Congress, and they can do it for a wider range of drugs than just the handful of drugs that are currently subject to Medicare negotiations.

We need to scrutinize the PBMs, but using existing administrative tools to end abusive drug company monopolies would give patients faster, broader relief from high drug prices.

Thank you.

The CHAIRMAN. Have you completed your time?

Senator WARREN. I have.

The CHAIRMAN. All right.

Senator Blackburn?

Senator BLACKBURN. Thank you, Mr. Chairman, and thank you all for being here today.

I want to return to this issue of patient steering. I think that—and I know that Senator Lankford touched on that, and I constantly hear from Tennesseans how frustrated they are with the PBMs.

You know, in all transparency, I would do away with the PBMs. I think they are unnecessary, and when patients are being steered, when patients are not able to reap the benefit of that reduced price and they continue to pay higher prices, it is something that is very difficult.

I looked at the Ohio suit. I think, Mr. Levitt, your testimony had referenced that, and I know Kroger's chief medical officer lives in Nashville. You know, when they cannot turn a profit and the PBMs have muddied the process and they are pushing that business offshore, I think that it is difficult.

Mr. Levitt, let me come to you on that. Let's talk for a little bit on what this does to Medicare and Medicaid, when you have this steering that is going on, because you have people in rural Tennessee that this is happening to, and then they have no access. So I would love to hear just a touch from you on that. Time is limited.

Mr. LEVITT. Under Medicare Part D, there is a Federal "any willing provider" law, that is——

Senator BLACKBURN. That is my next question, so let's go ahead and hit that, because you know, we have any willing provider in Tennessee, which limits the PBMs. And so, should we just blanket that federally?

Mr. LEVITT. Yes. It is good Federal law, and Tennessee, you have actually passed one of the strongest State any willing provider laws in the country, which is phenomenal for practices and pharmacies in your State. The steering is terrible, particularly for sick patients, the sickest patients like cancer patients.

We have examples in your State where a patient who has the choice to go to the oncologist that they want to get the drug from, is steered to a PBM-owned specialty pharmacy, and then they just get this oral oncolytic, which is a dangerous drug, in the mail. It is terrible for patient care.

Senator BLACKBURN. Well, we think it is too, and we think that any willing provider has helped in so many instances.

Let us continue down this same chain, because with a lot of our community health centers, what we hear is that the PBMs get in here and it really compromises the availability of pharmaceuticals and cramps the community health centers on patient care, and I would love to hear you comment for a moment on that.

Mr. LEVITT. Are these Federally Qualified Health Centers?

Senator BLACKBURN. Yes, and community health centers in rural areas, yes.

Mr. LEVITT. I am not an expert on the Federally Qualified Health Centers.

Senator BLACKBURN. Okay. Well, with our community health centers in rural areas, does anybody else want to weigh in on that because—go ahead, Ms. Feldman.

Ms. FELDMAN. Sure. I just want to talk about what is happening with the community pharmacies.

Senator BLACKBURN. Yes.

Ms. FELDMAN. One of the techniques we have talked about in the hearing is clawbacks; so with that, the PBM actually asks for money back from the pharmacy. Sometimes the pharmacist loses money on the transaction. Now if a PBM owns the pharmacy, money is just going from one pocket into the other; it does not matter. But for a community pharmacist, it can drive them out of business. These are the types of techniques that are reducing the number of community pharmacies we have and limiting patient choice and access to medicine.

Senator BLACKBURN. Well, and also what we are seeing is because PBMs have a role, what is happening is, we have lessened the 340B programs. That is something that when you have 230 health centers, community health centers, in your State, and you have the PBMs stepping in, it hurts the 340B programs that they have, because basically you are taking those savings away.

I know there has been a lot of talk about vertical integration today, and we have monitored that. I will tell you, we are quite concerned about what we see there, because any time you have another step in that vertical integration, what you end up seeing is higher prices for consumers, and then you have less access, and it convolutes the market.

So, thank you all for being here today.

Thank you, Mr. Chairman.

The CHAIRMAN. All right. I understand that Senator Johnson is either on his way or he would like to have us to hold for him. All right, let us—is Johnson's staff here? Is that the desire of the Senator? Okay. Well then, I will kind of jump the wrap-up and give you kind of my thoughts here about what we would like to work with you all on, and put it this way.

I am heading back to Oregon in a few hours, and then over the next 10 days or so I am going to be having town hall meetings across my State, primarily in rural areas. We have them open to all. You can ask anything you want. I have had 1,045 of them in my time in office. It is something I pledged in every county every year, to throw open the doors.

People care a whole lot about this matter of getting mugged at the pharmacy counter. They do not get it, and they look at the prices around the world, and several of my colleagues compared them to other countries, and they certainly do not get all the medical lingo that we have been speaking about today. Rebates, DIR fees, putting things in hoppers, or hopping around or some such thing; people do not get that kind of thing. But they do understand these examples where what you are seeing just defies common sense and fairness. Whatever it was, a couple of hours ago, I cited this example of Civica and how it affects Part D, which is Medicare, you know.

I am one of the people who voted for Part D. I got a lot of flak for voting for Part D. I thought it was important to get started, be-

cause it covered people and helped people, but clearly has not done enough for cost containment. What we were told again a couple of hours ago is Civica, a nonprofit, sells a generic prostate drug for $160.

The average price that PBMs charge Medicare Part D plans for the exact same drug is over $3,000, and yet Civica cannot get the big three PBMs to cover the drug. So that means that people on Medicare and taxpayers are paying for medicine that is marked up almost 2,000 percent.

So, I am going to take that home, and I am going to go into these rural communities, bright red politically, and they are going to want something done about this. They are going to want something done about this. I think while I wait for my colleague and I am wrapping this up, I would be interested—we can go down the panel.

What do you think—if you could do one thing going forward, just one thing to end something that is so unconscionable, you know, taxpayers, seniors facing a 2,000-percent markup—and this is not kind of some abstract theory, this is what we were given as an example, to highlight today how Medicare Part D gets hammered.

Medicare is our flagship health program, and we have a lot of challenges in demographics, given the number of people who turn 65 every day. So, we will wait for Senator Johnson, but I think I would be interested——

We will start with Ms. Feldman, but everybody, as we wrap up after 3 hours, everybody take a crack at your idea, because I can tell you what we are going to do during our work period at home. Our staffs, Democratic and Republican, are going to be talking among themselves so we can see if we can go from the constructive discussion with all of you and with the members, and really come up with practical steps for what to do.

So why don't you all just go right down? You have one crack at dealing with that outrageous example of the nonprofit versus what PBMs charge Medicare, and then when Senator Johnson comes, we will break for that. We will start with you, Ms. Feldman, and we will go down the row.

Ms. FELDMAN. Sir, may I offer you one other example to take back to your constituents?

The CHAIRMAN. Yes. But I think I would rather get——

Ms. FELDMAN. To the one.

The CHAIRMAN. Yes. I would rather get—here comes Senator Johnson.

Ms. FELDMAN. Ahh.

The CHAIRMAN. And that gives you more time to think, okay? Senator Johnson is going to use his time for questions, and then I will not be doing any more speechifying, other than to hear your response to what I asked.

Senator Johnson?

Senator JOHNSON. Thank you, Mr. Chairman. Thank you for holding this hearing. This has been fascinating. I wish I could have spent more time here, but I did hear the testimony.

Dr. Burns, I always like starting out with the macro, okay? Let us take a look at the overall industry.

The latest information I have according to the AMA, in 2021 we spent about $4.3 trillion on health care. Is that——

Dr. BURNS. We are over $4 trillion, that is correct.

Senator JOHNSON. And also, about $577 billion on pharmaceuticals—gross total?

Dr. BURNS. It depends on how you measure retail versus institutional.

Senator JOHNSON. So what do you think the number is?

Dr. BURNS. Well, if you look just at the retail numbers that come out of CMS, people will say, well, it is about 10 percent, 11 percent of health-care spending. But if you throw in the institutional side of it, the drugs that are used in hospitals, you could get up to 15 or 16 percent of national health care.

Senator JOHNSON. So about a half-trillion dollars or somewhere in the ballpark. What do you think the after-tax profitability in total of that amount is?

Dr. BURNS. Well, it varies by sector. There are——

Senator JOHNSON. I understand. But I mean in total, would you say—again, total industry after-tax profitability probably averages about 5 percent. Well, let us say with drugs more, maybe it might be 10 percent.

Dr. BURNS. Why not? The pharmaceutical companies and the medical device companies clean up.

Senator JOHNSON. Okay. So would it be——

Dr. BURNS. They are in the low 20-percent range.

Senator JOHNSON. Okay. So again, I am talking about after tax, because let us face it——

Dr. BURNS. Sure.

Senator JOHNSON [continuing]. The tax the government collects goes right back into our coffers as well.

Dr. BURNS. Yes.

Senator JOHNSON. So, but let us say it is 20 percent on a half-trillion dollars. That is about $100 billion on a total spend in health care of about $4.3 trillion. So we are talking somewhere 2, 2½ percent in terms of profitability of the drugs, in terms of our overall health-care spending.

I make the point because it is easy for us to zero in on a particular problem. Again, I think PBMs—this is a really interesting hearing, okay? But if you eliminate all the profitability and all the incentives for creating new drugs, you have not really made a dent in our health-care spend. Is that pretty accurate?

Dr. BURNS. Well, the real issue now facing the Part D plans and their beneficiaries is the high-cost specialty drugs, for which there are no competitors, and that is where the elderly are getting creamed——

Senator JOHNSON. Right.

Dr. BURNS [continuing]. In terms of their out-of-pocket cost. What we need there is more competition among those sorts of manufacturers.

Senator JOHNSON. There you go. Do we not also need more consumer involvement? I think, Dr. Gibbs, you were talking in your testimony that unlike every other product—and that may be a little bit too broad—but like almost every other product in our economy, we do not know what things cost in drugs. And again, I think that

is a generally true statement, but I guess I would argue that the reason for that is because of the third-party payer system, where consumers pay about 10 percent of all of our goods and services in health care—10 percent.

Nobody cares what any of this stuff costs. If they did, you would have price transparency just through the marketplace; correct? I mean, does anybody want to disagree with that? How about the attorney who sues these guys?

Dr. BURNS. I would totally agree with it, and if everybody's covered by insurance—and more than 90 percent of the population are—they do not really care about the cost.

Senator JOHNSON. So the solution, again—you know, I would argue the biggest problem with PBMs is we have Medicare and their formularies, and it makes it so unbelievably complex. I am an accountant, okay? I actually understand numbers. I understand. I have had people try to explain this to me like Professor Burns. You have written books on this stuff, and you are just sort of kind of getting your arms around this, okay?

Markets are complex. If you let in the competitive market system with consumers participating in it, you will get price transparency just as a natural part of it, as opposed to trying to suss it out through government regulations, which we have been trying to do, and it just does not work.

Dr. BURNS. Well, as I wrote in the textbook I published 2 years ago, consumers and consumer literacy just have not shown up yet.

Senator JOHNSON. So we do want drug companies to produce new molecules to save lives. I mean, we want that R&D. So there has to be a profit motive in there. One thing that I found out during the pandemic is how completely unlevel the playing field is between generics and the patentable drugs.

Part of the problem is, now it has to be random control trials as the only standard. They will not accept observational meta-analysis of that. So the playing field is totally tipped towards patentable drugs.

So all these molecules that are there, doctors oftentimes cannot use. And of course we found with some generic drugs that, in my experience working with the doctors worked really well in COVID, were not allowed, and I am highly concerned. I have actually—I am the author of Right to Try. I have also authored another bill now, Right to Treat.

It should not be necessary, but can I get just your opinion in terms of allowing doctors to use their medical judgment? Something like 20 percent of all drugs are prescribed off label. That is how you get generic drugs more readily used, more looked at by the medical profession, and hopefully with more observational studies to prove their efficacy or if there are problems with them.

I mean, we have got to produce research on generics and try and use those as much as possible. Does anybody want to argue with that?

Dr. BURNS. I totally agree. The last thing you want to do is second-guess what the doctors are doing at the bedside or the point of care. The thing I would have mentioned is that it is not necessarily patentable versus generic drugs. We oftentimes have a lot of biological drugs, specialty medicines that are off patent, and the

price increases continue there because there are no effective competitors.

Senator JOHNSON. Yes. So again, I am a private-sector guy. Competition solves an awful lot of problems, and we just do not have the competition, and certainly not in the PBM markets.

So again, I really, really do appreciate all your testimony here. This is very interesting. I wish it was a little bit clearer than mud. Maybe I missed some stuff and maybe you clarified this entire issue. But again, I will point out again the marketplace, the third-party payer system, those are at odds in terms of transparency, and that is what we really need to move toward.

So thank you, Mr. Chairman.

The CHAIRMAN. I thank my colleague.

Ms. Feldman, my apologies. I think I did not look down at the name tags earlier. We are glad you are here.

Everybody, take one crack at what you would say to the fact that there is nearly a 2,000-percent markup, a markup that hits seniors, hits Part D, hits taxpayers, and ought to be a symbol—and I can just tell you, I am going to go out and have all these town hall meetings, and I am going to hold that up.

Because that is the real world today of people getting clobbered. I have to hear all the lingo about, you know, rebates and exotic fees and all the rest. It is about a markup of 2,000 percent—2,000 percent—that hits seniors and hits taxpayers, and it ought to be something that we use as kind of a theme to get this thing fixed.

Ms. Feldman, right down the line. Everybody gets one idea to put into this, and we are going to have to build a coalition. Senator Johnson was not here when we talked about it. Senator Crapo and I said we are going to take the best ideas from both sides. Staffs are going to work on it over these 2 weeks, and we are just going to keep our foot to the pedal, because I think this is a good hearing.

I did not hear a bad question in the house, to tell you the truth, from my colleagues; I thought your answers were thoughtful. So we are going to dig in here.

Ms. Feldman, start us off. Your one answer to this challenge.

Ms. FELDMAN. Perverse incentives happen when interests are not aligned. The PBMs' interests are not aligned with the patient, so make sure the duties are clear about what they have to do.

The CHAIRMAN. Okay.

Dr. Van Nuys?

Dr. VAN NUYS. I am going to go back to that Federal benchmark of prices across different transaction points in the supply chain. Like we have NADAC, make those public in other places in the supply chain, so we can tell whether that 2,000-percent markup is happening in the spread, or is it happening in the specialty pharmacy.

The CHAIRMAN. Making it public?

Dr. VAN NUYS. Yes.

The CHAIRMAN. The information in the supply chain.

Dr. VAN NUYS. Yes, exactly.

The CHAIRMAN. Okay, good.

Dr. Burns?

Dr. BURNS. Yes. I would fix Part D, two things in Part D. One is, the prices that are paid ought to be pegged to net prices, not

list prices. Secondly, health plans need to have more skin in the game, more fiscal responsibility in the catastrophic phase.

The CHAIRMAN. Okay.

Mr. Levitt?

Mr. LEVITT. More transparency for the PBMs, more transparency for the rebate aggregators, on both the spread pricing on the drug side, and the rebate side as well.

The CHAIRMAN. Okay.

Dr. Gibbs?

Dr. GIBBS. I agree with Dr. Van Nuys once again. The price should be made public and everyone should be able to see it at any time.

The CHAIRMAN. Okay. Here is what we are going to do. We are going to—and by the way, it is a practice of the committee to hold the record open for, it will be 5 days, I believe, and Senators can—is that the correct number of days?

The HEARING CLERK. A business week, yes.

The CHAIRMAN. A business week. We will hold the record open for members to offer their questions. Those of you who want to submit additional information, please feel free to do so. This has been a good hearing. I want us to look back and say that today was the day that we started to get this fixed. I will welcome your ideas and suggestions. The stakes are high, and I thank you for participating.

And with that, the Finance Committee is adjourned.

[Whereupon, at 12:35 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF LAWTON ROBERT BURNS, PH.D., MBA, JAMES JOO-JIN KIM PROFESSOR, PROFESSOR OF HEALTH CARE MANAGEMENT, WHARTON SCHOOL, UNIVERSITY OF PENNSYLVANIA

INTRODUCTION

Good morning, Chairman Wyden, Ranking Member Crapo, and members of the committee. Thank you for inviting me to address the role of PBMs in the prescription drug supply chain. My name is Robert Burns, and I am a management and strategy professor specializing in health care at the University of Pennsylvania's Wharton School. My research and teaching examine how the entire U.S. health-care ecosystem operates; I have taught an Introductory Course on this material for nearly 4 decades at three business schools. I have also recently written a textbook on the topic.[1] Another part of my research agenda examines how the institutional and retail supply chains work in the health-care ecosystem; I have examined these supply chains since the mid-1990s and written two books on them.[2, 3]

To paraphrase Mark Antony in Shakespeare's *Julius Caesar,*[4] I come here today not to praise PBMs but to *bury* some concerns about them. My testimony covers three topics. Part I explains the operations of intermediaries (*i.e.,* "middlemen") in health-care supply chains and demystify their role. Part II explains why pharmacy benefit managers (PBMs) are not the drivers of the rising prices of brand drugs, as many allege. Part III explains the growing trend of vertical integration in the retail pharmaceutical supply chain and explores its possible impacts.

My conclusions and opinions are based on my own research, teaching, and firsthand experience with the health-care ecosystem since my doctoral training in late 1970s. They do not necessarily represent the views of the Wharton School.

PART I: DARK TERRITORY: LIFTING THE VEIL ON PBMS[5]

"Dark Territory" describes a section of railroad track not controlled by any signals. There are safety concerns due to the absence of train detection. There is a lessened ability to detect misalignment in track switches, broken rails, or runaway rail cars. It is dark and mysterious.

Health care's version of dark territory consists of intermediaries that connect buyers and sellers. Often, these intermediaries are widely mistrusted and vilified. They seem out of control, lack transparency and Federal regulation, act in ways that reportedly threaten patient safety, make a lot of money without making anything, and are viewed with suspicion. During the 1990s, health maintenance organizations (HMOs) constituted the dark territory. The criticisms of the HMOs back then pale in comparison with the invective leveled over the past 2 decades at two other inter-

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[1] Lawton Robert Burns. *The U.S. Healthcare Ecosystem* (New York: McGraw-Hill, 2021).
[2] Lawton Robert Burns. *The Health Care Value Chain* (San Francisco, CA: Jossey-Bass, 2002).
[3] Lawton Robert Burns. *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs* (Palgrave Macmillan, 2022).
[4] Act III, Scene 2. Just to be clear, we are *not* talking here about Mark Anthony, J Lo's third husband. Their last names are spelled differently. My students always get them confused.
[5] This section draws on Chapter 14 of *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs* (Palgrave Macmillan, 2022). It also draws on an article I recently wrote in *The Hill,* "What History Tells Us About Your Prescription Costs and the New 'Bad Boys' of Health Care" (March 22, 2023).

mediaries: group purchasing organizations (GPOs) and pharmacy benefit managers (PBMs). Like the late comedian Rodney Dangerfield, "they get no respect." Worse yet, they serve as the "whipping boys" of health care who take the rap for others.[6]

Last year, I published a 650-page volume that takes readers through this dark territory.[7] Here, I focus my remarks on the PBMs. The allegations against PBMs include: monopoly power, anticompetitive behavior, collusion with manufacturers, exclusive contracts, financial ties with suppliers that mitigate search for the best products at the lowest cost, reduced provider discretion and patient access to needed medicines, conflicts of interest, preoccupation with growing revenues, excessive fees and profits, kickbacks, secret rebates, lack of full disclosure, harms to patient quality, and higher consumer costs. Most of these allegations can usually be found in just a single newspaper story, book chapter, or industry report. Needless to say, the authors of such stories rarely "go deep" into any of these allegations.

I approach these issues through the lens of "critical thinking." I teach my undergraduate courses at Wharton using the Socratic Method: I show students an argument that someone has proposed, and then get them to first ask the question, "Is What I Just Heard Really True?" I then spend the course training students to evaluate such proposed arguments using published research evidence (both pro and con) to thereby answer the question.

My book evaluates the claims advanced by GPO critics against several bodies of evidence. These include (1) the historical PBM chronicle, (2) the agency role that PBMs play on behalf of insurers, (3) the documented tradeoffs that PBMs make regarding access, cost, and quality while serving their insurer clients, (4) the growing concentration in U.S. health care, and (5) the existential threat of supplier consolidation. I conclude that PBMs are nowhere near the villains their critics have painted them to be. They perhaps deserve a bit more thanks for the roles they perform. One should remember that the Kaiser Permanente health plans of today that policymakers laud as solutions to population health and the triple aim were the whipping boys in earlier decades.[8]

SOME HISTORY LESSONS

PBM critics rarely bother to examine their history. The narrative has (until now) never been pulled together from archival and eyewitness sources, which requires a lot of homework. As former President Harry Truman said, "the only thing new in the world is the history you don't know." My recent book devotes two chapters and 115 pages to this chronicle. The lessons from this narrative do not support the allegations and conclusions of the critics.

Like GPOs, PBMs Have Historically Served the Interests of Local Providers and Health Plans

The early PBMs began as local cooperatives providing medical and pharmaceutical services to community members through prepaid groups on a capitated basis. They were less health-care insurance and more health-care assurance providers. They were typically organized around HMOs that provided both medical and pharmacy benefits to cover the total health-care needs of their enrollees under an affordable budget. The early PBMs were thus tied to health insurers, just like they are today.

Today, following the decline of HMOs, PBMs serve insurers and providers of health services but neither supply these services nor charge for them. They are at least one or more degrees of separation from where health-care costs and quality are rendered. Efforts by critics to lay the responsibility for rising health-care costs or harms to patient quality at the feet of the PBMs are misguided.

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[6] "Whipping Boys" is not a derogatory term. It refers to the use of stand-ins who were punished for the wrongdoings of the princes that were heir to the throne of the Tudor and Stuart kings of England. It was bad optics to whip the heirs, so childhood friends who were educated alongside them served as the substitutes. A synonym for whipping boy is scapegoat.

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

[8] For a positive view of Kaiser today, *see:* Donald Berwick, Thomas Nolan, and John Whittington. "The Triple Aim: Care, Health, and Cost," *Health Affairs* 27(3) (2008): 759–769. Less than 100 years ago, however, Kaiser and other prepaid health plans were viewed as "dangerous deviations from accepted forms of practice." *See* Patricia Spain Ward. "United States versus American Medical Association et al.: The Medical Antitrust Case of 1938–1943," *American Studies* 30(2) (1989): 123–153.

PBM Leverage Over Product Suppliers

PBMs sought to amass purchasing volume to negotiate lower prices from product manufacturers. HMO–PBMs combined the prescription orders of scores (and then hundreds) of physicians on their medical staffs. Both routed these orders through a centralized negotiating hub to contract as "one" with manufacturers. The game has always been one of "leverage" over suppliers to exchange higher buyer volume for lower unit price. This game became more important for survival and customer service with intensification of input cost pressures and/or reimbursement pressures. When squeezed downstream, PBMs sought to squeeze drug manufacturers upstream.

PBMs Subject to Considerable Federal Oversight

Both GPO and PBM intermediaries have been subjected to considerable scrutiny by the U.S. Congress (House and Senate hearings), the Congressional Budget Office, and various Federal Agencies such as the Federal Trade Commission (FTC) and the Office of The Inspector General (OIG). Such scrutiny led to the development of "codes of conduct" for both intermediaries during 2004 to 2005. None of this scrutiny has since resulted in any subsequent change in legislation or regulatory oversight of either intermediary. This latter point suggests that the codes of conduct may have served their purpose, as some research suggests.

PBMs Have Utilized Many of the Same Contracting Tools for Decades

Certain PBM (and GPO) practices have irritated their critics in the new millennium. For PBMs, they include drug formularies, contract administration fees (CAFs) paid by manufacturers, discounts and rebates from manufacturers, narrow pharmacy networks, and spread pricing.

What critics fail to realize is that most of these contracting tools have long been in place without causing an uproar. That is likely because these tools served the economic interests of their sponsoring organizations downstream (health plans), who developed them to deal with competitive and reimbursement pressures. Just like many contracts between buyers and sellers in the private sector, PBM contracts are never publicly disclosed in order to encourage price discounting by manufacturers (and inhibit any collusion among them).

PBM Business Models Have Changed Over Time

Finally, the historical narrative demonstrates that the business models and revenue sources of these intermediaries have changed over time. PBMs are now heavily focused on the dispensing of specialty drugs, as are other players in the health-care ecosystem. Yet, PBM critics continue to attack them regarding strategies heavily pursued in the past, particularly manufacturer rebates and pharmacy network management. Although still a sizeable portion of their revenues, such strategies and revenue sources are on the wane.

PBMS' AGENCY ROLE IN SERVING HEALTH PLANS

PBMs seek to exert leverage over suppliers, not over their health plan sponsors. Their actions are thus consistent with being "agents." Surveys of health plans confirm this agency role via high satisfaction levels and a concordance in their goals and interests. As further evidence of this agency role:

- Suppliers have been historically skeptical of intermediaries like PBMs;
- Suppliers have sought to render them ineffective;
- Suppliers do not contract with PBMs when they do not have to (due to lack of competition);
- The relationships between suppliers and these intermediaries are characterized as "adversarial"; and
- Suppliers raise prices unilaterally "because they can," which the PBM intermediaries seek to counteract.
- PBMs believe that supplier competition is always in their interest.

TRADEOFFS: THE NAME OF THE GAME

Economics and the entire health-care ecosystem are all about tradeoffs.[9] For example, when one examines the different health plans that employers offer workers, those plans that offer a wider choice of providers (more open-network models such

[9] Lawton Robert Burns. *The U.S. Healthcare Ecosystem* (New York: McGraw-Hill, 2021): Chapter 2.

as preferred provider organizations, or PPOs) come with higher premiums—that is, PPOs trade off wider access for higher cost.

The same tradeoffs factor into the strategies employed by PBMs. PBMs (in partnership with health plans) have developed formulary tiers that allow plan participants to access the drug(s) they prefer at the cost they can afford. PBMs do not dictate the choice to their plan enrollees.

Product quality is, nevertheless, evident in the decisions made by health plan pharmacy and therapeutics committees. Such committees are heavily comprised of clinicians (physicians, nurses, pharmacists) who focus primarily on product quality, not on product cost. In other words, these committee mechanisms represent local-level decisions by clinicians on the types of products they want. PBMs are not in the business of telling doctors what they can or cannot order or prescribe. To the extent the product choice set is limited, it usually reflects committee (peer) assessments of what are comparable, therapeutically equivalent products with no evidence base to differentiate them.

Another area where strategic tradeoffs are evident is national versus local. The GPOs began as local cooperatives and developed contracts for local membership. The proximity and small membership size made it fairly easy to decide upon products and manufacturers to contract with. As they grew, however, the regional and (then) national GPOs faced increasing difficulty in developing contracts that all of their members wanted. The GPOs therefore embarked on several strategies that allowed members to customize contracts to suit local needs and clinician preferences, including regional GPO affiliates, assistance with custom contracting, contracting tiers, etc. The goal was to *balance* the economic leverage of centralized buying with access to desired products at the local level. PBMs have engaged in similar tradeoffs. They, along with their health plan sponsors, have developed national drug formularies than can be tailored or disregarded by health plans at the local level.

CONSOLIDATION

PBMs have come under fire for being concentrated sectors in which a small number of intermediaries manage the vast bulk of sales. This observation is correct. But then critics extrapolate to conclude that these huge oligopolies raise costs, harm their own members, and engage in anti-competitive practices that harm the public's welfare.

The evidence base refutes all of these charges. First, PBMs help their health plan clients by negotiating lower input prices and serve as their agents. Second, there has been no Federal antitrust enforcement activity brought against these parties since the early 2000s. There has also been a vastly reduced number of lawsuits filed against them since they adopted codes of conduct in the mid-2000s. Third, the entire health-care ecosystem and nearly all the intermediaries in the supply chain have grown more concentrated. For some reason, however, critics do not usually complain about the oligopolies among pharmacies, pharmaceutical wholesalers, and specialty distributors. If one really wants to start pointing fingers at the biggest culprits in consolidation and rising cost, one does not have to look very far: large hospital systems ("Big Med").[10, 11]

EXISTENTIAL THREAT OF SUPPLIER CONSOLIDATION, CONCENTRATION, AND PRICING

The greatest existential threat to intermediaries such as PBMs is consolidation and/or concentration among the manufacturers upstream with whom they contract. The immediate impact is (1) a reduction in the number of suppliers available for customers to contract with, and (2) the reduction in the competitive rivalry among these suppliers.

Research suggests that pharmaceutical mergers and acquisitions (M&A) are sometimes motivated by the desire to limit competition. Researchers have found that a company is 5–7 percent less likely to complete the drug development project in its acquisition's pipeline if those drugs would compete with the acquirer's existing product line (*i.e.,* "killer acquisition").[12] Other research shows that M&A can result in

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[10] David Dranove and Lawton R. Burns. *Big Med: Megaproviders and the High Cost of Health Care in America* (Chicago, IL: University of Chicago Press, 2021).

[11] Lawton Robert Burns and Mark V. Pauly. "Big Med's Spread," *Milbank Quarterly* (Spring 2023, forthcoming).

[12] Colleen Cunningham, Florian Ederer, and Song Ma. "Killer Acquisitions," *Journal of Political Economy* 129(3) (2021): 649–702.

reduced R&D spending and patenting for several years;[13] conversely, higher competition spurs R&D spending by firms.[14, 15]

The threat of supplier concentration particularly resides in the availability of specialty pharmaceuticals, many of which are off patent. There are higher entry barriers in the biologics space due to (among other reasons) the complexity of the science, uncertainty regarding the regulatory process for biosimilars, and the guidelines for "interchangeability." The result is fewer competitors and little generic threat to these newer biological products. Biologics as a percentage of drug spending doubled between 2006 and 2016, from 13 percent to 27 percent. The wholesale acquisition cost of biologics is a multiple of the cost of small molecules. The approval of biologic license applications (BLAs) for new biological products has recently overtaken the approval of new molecular entities (NMEs) for traditional drugs. The threat facing payers is containing the cost of these drugs. At the same time, the distribution of specialty pharmaceuticals has become a major revenue driver for the PBMs and others.

Moreover, specialty drugs are more buffered from the effects of drug formularies and tiers. Formulary position is driven by competition within the therapeutic area. Such competition is greater in some areas (*e.g.,* metabolic, cardiovascular, central nervous system, gastrointestinal) than in others (oncology, infectious disease, immunology, and respiratory). In the former areas, there is less clinical differentiation among drug classes and more variation in tiering; in the latter areas, there is more clinical differentiation among drug classes and much less dispersion of formulary drugs across price tiers. This reflects the considerable unmet clinical need and variation in patient response to specialty (*e.g.,* oncologic) drugs, making it harder to restrict and/or channel physician choice among products. Finally, drugs that treat widely prevalent conditions (*e.g.,* diabetes) and thus incur high aggregate spending are more likely to be targeted by formulary tiers than are specialty drugs that incur lower aggregate spending which are more likely to attract payer strategies such as step therapy.

SUMMARY

GPOs and PBMs occupy parallel roles in the institutional and retail channels of the health-care value chain. There are multiple similarities in their historical origin, product selection bodies, role in the value chain, role as agents for downstream buyers, business model, operating guidelines, transparency, rebates earned, cost management efforts, tradeoffs managed, and directional influence in the supply chain. These similarities are counter-balanced by their differences in channel served (institutional versus retail), products contracted for, customer served (hospital versus health plan), founding period, owner/sponsor, number of firms, and industry financials.

Finally, they are both intermediaries. They do not buy, sell, or price products conveyed through the supply chain. They are also not providers of health-care services. Their impact on the cost and quality of care rendered to patients is thus removed from the parties who play the major roles here. The remarkable finding here is that these intermediaries may nevertheless serve the public's welfare by controlling the rise in health-care costs.

PART II: THE BROUHAHA OVER REBATES AND THE GROSS-TO-NET PRICE DISPARITY [16]

Over the past few years, observers have noted not only the rise in drug list prices but also the growing disparity between gross and net prices for pharmaceutical

[13] Government Accountability Office. "Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals," GAO–18–40 (Washington, DC: GAO, November 2017).

[14] Richard Thakor and Andrew Lo. "Competition and R&D Financing: Evidence from the Biopharmaceutical Industry," *Journal of Financial and Quantitative* Analysis (2021).

[15] However, the threat is not always due to supplier mergers. M&A activity among large pharmaceutical manufacturers has not resulted in a more concentrated sector. In 2006, the top 10 firms accounted for 46 percent of total sales; 10 years later they accounted for only 41 percent of sales. Instead, in recent years, the threat has sometimes come from generic drugs where either market demand is too small to support more than one firm and/or all other suppliers have withdrawn for various reasons. The result is a monopoly and egregious pricing behavior. Two prominent examples are Turing Pharmaceuticals and its drug Daraprim, and Mylan Pharmaceuticals and its EpiPen—firms which continually hiked their prices because they could.

[16] This section draws on Chapter 9 of *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs* (Palgrave Macmillan, 2022).

products. As a percent of drug price growth, rebates accounted for only 6–9 percent during 2011–2012 but then accounted for 57–77 percent during 2013–2015.[17] The disparity has continued. More recent data published by IQVIA show that between 2015–2018 branded drug invoice price grew between 5.5 percent and 11.2 percent, while branded drug net price grew between 0.3 percent and 2.9 percent; between 2018–2021, branded drug invoice price grew between 4.3 percent and 6.6 percent, while net price either fell or grew only modestly (−2.9 percent to +1.7 percent).[18] The latter data indicate that net brand prices are growing less than the annual average growth in the consumer price index, and that manufacturer rebates are partly responsible. Some health economists argue that rebates roughly constitute the difference between list price and net price.[19]

Indeed, a recent report by a small, provider-owned PBM (Navitus Health Solutions) shows that per-member-per-month (PMPM) drug spending for its plan sponsor clients grew only 1.5 percent during 2021. This (low) growth rate was driven by higher utilization (9.1 percent for specialty drugs, 1.3 percent for nonspecialty drugs) and not by unit cost (−4.8 percent for specialty drugs, −2.2 percent for nonspecialty drugs).[20] Another recent report by Milliman estimates that manufacturer rebates reduced total per-capita health-care costs by 6 percent ($397) in 2022.[21]

Some observers allege that the rise in list prices is partly caused by the higher rebates (and other payments made by manufacturers to PBMs), which are represented by the gap between gross and net price. In their view, the facts that (1) higher rebates and other fees account for a higher percentage of the drug's list price increase and (2) the rebate size increases with list price are evidence of causation. The *theory* behind this presumed causality is that the PBMs benefit from higher rebates, and that this may encourage manufacturers to hike their list prices which leads to a win-win situation: the PBM earns more rebates, and the higher rebates earn the manufacturer a more favorable position on the formulary where they can achieve higher sales volume. These observers nevertheless admit that the lack of granular data on PBM rebates and drug prices (due to confidentiality clauses) renders this causal assertion uncertain. As the great "philosopher" Yogi Berra once said, "In theory, theory and practice are the same. In practice, they are not."

The flaw in this causal logic is shown by several pieces of evidence. Drug manufacturers raise prices several times a year, whereas PBMs negotiate contracts and rebates every 2 to 3 years, with the rebates remaining constant during the duration of each contract. Moreover, drug manufacturers raise prices in anticipation of losing patent protection (and thus market share), in the event of filing patent lawsuits against competitors (potentially gaining share), in anticipation of a generic product entering the market (losing market share), in anticipation of new competitors entering the market (and thus losing market share), or in the event that an existing competitor pulls their product from the market (gaining market share). In general, drug manufacturers raise prices because they can—*e.g.,* when they enjoy more of a monopoly position in their therapeutic category, when they have superior marketing, when their product is a physician preference item (PPI), and when their product has brand preference among patients. Most health economists acknowledge that drug manufacturers control list price.

Multiple factors have contributed to the growing spread between gross and net drug prices (known as the gross-to-net disparity). *First* is the growing consolidation of the PBM sector. PBM consolidation was legitimated by the Federal Trade Commission's (FTC) sign-off on Express Scripts' (ESI) acquisition of WellPoint's Next Rx

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[17] Burns. *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs,* 2022: Figure 9.9.

[18] IQVIA Institute. *The Use of Medicines in the U.S. 2022*. Available online at: *https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2022/iqvia-institute-the-use-of-medicines-in-the-us-2022.pdf.* Accessed on July 12, 2022.

[19] Gerard Anderson. Remarks to "Understanding the Role of Rebates in Presciption Drug Pricing," conference sponsored by Alliance for Health Policy (December 28, 2018). Available online at: *https://www.allhealthpolicy.org/11282018-publicbriefing-transcript/*. Accesssed on July 12, 2022.

[20] Adam Fein. "Drug Channels News Roundup," Drug Channels (June 2022). Available online at: *https://www.drugchannels.net/2022/06/drug-channels-news-roundup-june-2022.html.* Accessed on July 12, 2022.

[21] Mike Gaal, Paul Houchens, Dave Liner et al. 2022 Milliman Medical Index. Available online at: *https://www.milliman.com/-/media/milliman/pdfs/2022-articles/2022-milliman-medical-index.ashx.* Accessed on July 12, 2022.

in-house PBM in 2009, and the market valuation placed on Next Rx's business.[22] This consolidation accelerated in the 2012–2015 period, led by ESI's acquisition of Medco (2012), Catamaran's acquisition of ReStat and TPG's acquisition of EnvisionRx (both in 2013), and then Optum's acquisition of Catamaran (2015).[23] By 2017, the top three PBMs commanded 71 percent of the market (measured in scrips): CVS (25 percent), ESI (24 percent), and Optum (22 percent). The top 7 PBMs controlled 95 percent of the market. This market concentration of buyers allows PBMs and health insurers to extract large discounts in price from manufacturers in exchange for a drug's position on the formulary. This is a major driver of drug rebates (discounts on list price) paid to the PBMs.

Second, complementing the growing *concentration* on the buyer side (PBM market), there can be growing *competition* on the supplier side in the form of competing pharmaceutical products. This is also referred to as "crowded therapeutic categories." Such product competition gives PBMs and health insurers leverage over manufacturers by virtue of playing one manufacturer off another and threatening to move market share to the manufacturer who offers better terms (including higher rebates).

Third, beginning around 2012, but picking up around 2014, PBMs began to utilize the strategy of "formulary exclusion" whereby manufacturers are threatened with product removal from the PBM's national formulary.[24] CVS/Caremark removed 34 brand-name drugs from its standard national formulary in January 2012, and added another 17 drugs to the exclusion list in 2013; ESI followed CVS' example in 2014. Both PBMs have added more drugs to the list over time. Optum, Prime Therapeutics, Aetna, and Cigna embraced drug exclusions by 2016.

Such a strategy works in the presence of therapeutically comparable brand-name drugs. In 2016, more than 50 percent of the commercial market was covered by plans with formulary exclusions. Note that exclusions block access to specific products on a PBM's recommended national formulary; they are, thus, suggestions rather than mandates. ERISA Plan Sponsors and health insurers can ignore the PBM's national formulary, but then face reduced rebates and/or higher plan costs. They, thus, tradeoff higher access to drugs for higher costs incurred—much in the way that formularies financially reward patients for selecting generic and lower-tier drugs with lower costs, while allowing access to additional drugs on higher tiers but requiring patients to face higher costs via higher copays or coinsurance. Nevertheless, the prospect of exclusion leads manufacturers to offer larger rebates. A precipitating event here was the introduction of AbbVie's hepatitis C drug Viekira Pak to compete with Gilead's Sovaldi and Harvoni. The number of products on the formulary exclusion lists for two PBMs (CVS and ESI) has grown steadily since 2012.[25]

Fourth, statutory rebates are another large driver of gross-to-net discounts. The Patient Protection and Affordable Care Act (PPACA 2010) increased the mandatory rebates that pharmaceutical manufacturers must pay under the Medicaid program. For single-source (non-generic) drugs, the Unit Rebate Amount (URA) increased from 15.1 percent of a product's average manufacturer price (AMP) to 23.1 percent of AMP. It also required manufacturers to provide rebates in the Medicare Part D coverage gap. The Bipartisan Budget Act, signed into law in February 2018, increased these discounts. Rebates and other channel discounts to PBMs and pharmacies constitute "direct and indirect remuneration" (DIR) payments made to Part D Plan Sponsors. These payments were stable from 2010–2012 but began to accelerate beginning in 2013. DIRs help to create a gap between list and net prices.

Fifth, the pharmaceutical industry experienced steep patent cliffs in 2012 and 2015, and much higher level of patent expiries in the period 2013–2019 compared to earlier levels (*e.g.,* 2010).[26] Attending these patent expiries was a wave of new generic drugs entering the market. The advent of biosimilars in the biotechnology market constituted a parallel development, but on a smaller scale. Research docu-

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[22] Andrew Ross Sorkin and Michael J. de la Merced. "Drug Benefit Unit in $4.7 Billion Deal" (April 13, 2009). Available online at: *https://www.nytimes.com/2009/04/14/business/14deal.html.* Accessed on February 3, 2020.

[23] Burns. *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs,* 2022: Figure 9.10.

[24] Burns. *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs,* 2022: Figure 9.11.

[25] Drug Channels. The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Exhibit 85: 127.

[26] Burns. *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs,* 2022: Figure 9.12.

ments that drug prices decrease markedly after patent expiration.[27] In 2017, the generic dispensing rate—the percentage of drug prescriptions dispensed with a generic drug instead of a branded drug—was 90 percent. The rise in generics and generic dispensing rates occasioned a slowdown in the price growth of branded drugs.

Sixth, the same increase in rebates has been observed in Medicare Part D. Between 2006 and 2020, Part D drug rebates as a percentage of total drug costs rose from 8.6 percent to 27.0 percent.[28] This is relevant since PBMs, which administer the drug benefit, retain less than 1 percent of these rebates and thus do not benefit. Instead, analysts point out that the growing Part D rebates are tied to competition among manufacturers within a given drug class to get on the formulary.[29] Research by Milliman shows that, among drugs with rebates covered under Part D, rebates as a percentage of gross drug costs reached 39 percent in the presence of direct brand competition. Rebates reached 34 percent when there were 3+ competitors including a direct generic substitute, 27 percent when there were 1–2 competitors with a direct generic substitute, and only 23 percent in the absence of direct brand competition or a generic substitute.[30]

Seventh, the growth in the gross-to-net difference observed over time has been driven *not* by commercial rebates but instead by Medicare Part D rebates and 340B discounts.[31] According to Adam Fein, the gross-to-net difference in the price of branded drugs reflects a declining share in commercial rebates (22 percent of difference in 2021, down from 27 percent in 2017), a rising share in Part D rebates (23 percent of difference in 2021, up from 19 percent in 2017), and a sharply rising share in 340B discounts (20 percent in 2021, up from 10 percent in 2019).

Considering the Arguments of GPO Critics: Critical Thinking Exercise

PBM critics counter by asserting that PBMs are not the only drug channel parties with an incentive for higher prices under Medicare Part D. Since 99 percent+ of the manufacturer rebates flow to the health plans, there may be an incentive for the *health plan sponsors* to favor higher list prices. The prescription drug plans (PDPs) which administer the Part D benefit earn a portion of their profits from DIR payments. Manufacturer rebates comprise the vast majority (92 percent) of DIR payments, which are paid to plans to get favorable placement on their formularies.[32] Critics have expressed concern that this remuneration structure may lead health plans to favor higher-priced brand drugs (which come with rebates) on their formularies over lower-cost generics (which do not come with rebates).

As evidence, researchers examined 57 unique drug formularies across all 750 stand-alone PDPs in 2016, focusing on 935 drugs that were "multi-source" (brand and generic both available).[33] They found that 12.8 percent of multi-source drugs did not have generics covered in any formulary; they also found that 72 percent of formularies placed at least one branded product in a lower cost-sharing tier than the generic. When they examined 222 multi-source drugs covered in all formularies that had both brand and generic products covered in at least one formulary, they found that brand products were placed in a lower cost-sharing tier than the generic for only 5 percent of these drugs. If there is a problem, the low percentages suggest it is limited in scope. Additional evidence from other researchers confirms this.[34] A recent analysis of Medicare Part D plans with matched pairs of brand and generic drugs found that branded drugs are rarely covered when generics are available.

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[27] Gerard Vondeling, Qi Cao, Maarten Postma et al. "The Impact of Patent Expiry on Drug Prices: A Systematic Literature Review," *Applied Health Economics and Health Policy* 16 (2018): 653–660.

[28] *The 2022 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds.* June 2022. Table IV.B8.

[29] Jack Hoadley. Remarks to "Understanding the Role of Rebates in Prescription Drug Pricing," Conference sponsored by Alliance for Health Policy (December 28, 2018). Available online at: *https://www.allhealthpolicy.org/11282018-publicbriefing-transcript/*. Accessed on July 12, 2022.

[30] Nicholas Johnson, Charles Mill, and Matthew Kidgen. *Prescription Drug Rebates and Part D Drug Costs.* Milliman Research Report (July 16,2018).

[31] Burns. *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs,* 2022: Chapter 11.

[32] William Feldman, Benjamin Rome, Veronique Raimond et al. "Estimating Rebates and Other Discounts Received by Medicare Part D," *JAMA Health Forum* 2(6) (2021): e210626.

[33] Mariana Socal, Ge Bai, and Gerard Anderson. "Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics Are Available," *JAMA Internal Medicine* 179(6) (2019): 832–833.

[34] Stacie Dusetzina, Juliette Cubanski, Leonce Nshuti et al. "Medicare Part D Plans Rarely Cover Brand-Name Drugs When Generics Are Available," *Health Affairs* 39(8) (2020): 1326–1333.

Most of the time (84 percent), only generics were covered; some plans might cover both brand and generic products (15 percent). In the few instances where branded drugs had preferential formulary placement, beneficiary and Medicare prices were generally low for both products.[35]

Eighth, there is correlational evidence of an association between rebates and list prices, and an association between increases in rebates and increases in list prices. However, the evidence here is not consistent, and can oftentimes suggest no relationship at all.[36] Moreover, the researchers who report these findings are somewhat circumspect in their conclusions, arguing that to the degree that PBMs retain rebates (rather then pass them along to health plans) "a higher list price *might* generate more revenue for PBMs" [italics added].[37] Some of my researcher friends similarly hedge their bets, stating that rebates are *"probably at least partially* responsible for the faster increase in list prices than in the amounts received by drug manufacturers (net prices)" [italics added].[38] They are also quite clear in stating that rebates have moderated the growth in drug prices.[39]

Ninth, and finally, there is growing research evidence that a main driver in the list prices of brand drugs is not PBM rebates but rather Federal reimbursement policies. Economists suggest that Medicare Part D dynamics encourage growth in list prices and thus in rebates. These dynamics include Part D benefit design and beneficiary cost sharing. The Federal Government is at greatest financial risk for high drug spending in Part D by virtue of shouldering 80 percent of costs in the catastrophic coverage phase, thereby encouraging higher list prices. Via this mechanism, Part D cost-sharing and beneficiary out-of-pocket costs are tied to list price.[40]

In a similar vein, the Congressional Budget Office (CBO) recently concluded that Medicaid's statutory rebates provide incentives to manufacturers to negotiate higher prices with commercial insurers as well as employ higher market-wide launch prices. The CBO's causal argument is as follows: more people covered by public insurance (such as Medicaid) leads to more third-party (public) coverage of drug spending which, in turn, means more patients less exposed to high drug prices and more willing to buy high-priced drugs—all of which alleviates pressure on manufacturers to restrain their price hikes.[41] The cause is not PBM rebates, but rather moral hazard resulting from public insurance coverage. This last point suggests that—to paraphrase the old comic strip *Pogo*—we have met the enemy and the enemy is us. Rising prices and out-of-pocket of costs may have been unwittingly induced by Federal payment policy.[42]

All of these factors contribute to gross-to-net discounts. These discounts accelerated from 2014 through 2019.[43] The majority of these gross-to-net discounts were not realized by PBMs and other drug channel participants such as wholesalers and pharmacies, but rather were realized by public and private payers (62 percent). Re-

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[35] I am not sure which side is right and which is wrong. Maybe I have missed something. My colleagues are welcome to point out the error in my ways. As Jalen Hurts, the quarterback of the Philadelphia Eagles said after losing this year's Super Bowl, "You either win or you learn." Wise words to live by.

[36] *Visante. No Correlation Between Increasing Drug Prices and Manufacturer Rebates in Major Drug Categories* (2017). Available online at: *https://www.pcmanet.org/wp-content/uploads/2017/04/Visante-Study-on-Prices-vs.-Rebates-By-Category-FINAL.pdf.* Accessed on March 24, 2023.

[37] Ge Bai, Aditi Sen, and Gerard Anderson. "Pharmacy Benefit Managers, Brand Name Drug Prices, and Patient Cost Sharing," *Annals of Internal Medicine* 168(6) (2018): 436–437. A similar admission regarding the circumstantial evidence for causality is stated by Christine Buttorff, Yifan Xu, and Geoffrey Joyce. "Variation in Generic Dispensing Rates in Medicare Part D," *American Journal of Managed Care* 26(11) (2020): e355–361.

[38] Ge Bai, Aditi Sen, and Gerard Anderson. "Pharmacy Benefit Managers, Brand-Name Drug Prices, and Patient Cost-Sharing," *Annals of Internal Medicine* 168(6) (2018): 436–437.

[39] Erin Trish. *Drug Rebates in Medicare Part D* (Los Angeles: University of Southern California, Leonard D. Schaeffer Center for Health Policy and Economics, July 27, 2021).

[40] Erin Trish. *Drug Rebates in Medicare Part D* (Los Angeles: University of Southern California, Leonard D. Schaeffer Center for Health Policy and Economics, July 27, 2021).

[41] Congressional Budget Office. *Prescription Drugs: Spending, Use, and Prices* (Washington, DC: CBO, January 2022).

[42] Available online at: *https://library.osu.edu/site/40stories/2020/01/05/we-have-met-the-enemy/*. Accessed on March 24, 2023.

[43] Burns. *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs,* 2022: Figure 9.13.

searchers estimate that pharmacies capture the bulk (15 percent) of the remainder, with PBMs (5 percent) and wholesalers (2 percent) capturing much less.[44, 45]

This means that ERISA Plan Sponsors and the health insurers they contract with realized large discounts off of drug list prices, which accounts for the majority of the growing gross-to-net disparity. This is reflected in data for both small and large employers that capture the rebates flowing back to the ERISA Plan Sponsors in 2021.[46] The data indicate that a growing percentage of both smaller and larger employers are receiving 100 percent of the rebates negotiated by their PBMs. Among larger employers, the 100 percent pass-through is by far the most common rebate arrangement; a majority of smaller employers also received 100 percent pass-throughs, but nearly one-quarter receive a percentage share of rebates.

The question is, what did ERISA Plan Sponsors and health insurers do with the rebates (savings)? The rebates can be used in a number of ways, according to insurance executives.[47] First, they can be used to offset the health-care costs generated by employees (or plan members) and thereby reduce their insurance premiums; this approach benefits everyone. Second, they can be used to fund employer wellness programs, which also benefits all members. Third, they can be used to finance patient engagement programs which extend enhanced benefits to those choosing more cost-effective plans or those more compliant with their medications. Alternatively, the rebates can be used to lower patient copays for members using specific drugs or reduce the prices paid at point-of-sale; this benefits specific members.

PBMI survey data suggest that the vast majority of employers (68 percent) use the rebates to offset the overall plan costs to the employer, especially their own spending on drugs.[48] By contrast, a smaller percentage of employers (11 percent) use the discounts to reduce the premiums of their employees (11 percent), a strategy that benefits all workers. A small percentage of employers (15 percent) split the savings with employees, or reduce employee out-of-pocket costs at the point-of-sale (4 percent). This means that employers use the discounts generated by their employees with more severe illnesses that require expensive drugs (which earn higher rebates) to cover their overall health expenditures rather than benefit the employees who generate the rebates. The irony, according to industry analysts, is that the employees' actual out-of-pocket costs are set by their insurer and ERISA Plan Sponsor. It is not the PBMs, but rather the Plan Sponsors and health insurers who elect not to share the rebates directly with employees.[49]

Over time, employers' drug benefit designs have shifted out-of-pocket spending from flat co-payments to deductibles and coinsurance arrangements. By 2019, more than half of all consumer out-of-pocket spending on prescription drugs was for coinsurance or deductibles, both of which are tied to list price.[50] Evidence shows the decline in cost sharing using co-payments, the rise in cost sharing using coinsurance when employer plans include high deductibles, by drug tier, and the dollar amount of cost sharing by drug tier for both co-payment and coinsurance. Moreover, over time, the percentage of ERISA Sponsor Plans with pharmacy benefit deductibles has risen. These deductibles can be separate from or combined with the medical deductible.[51]

A recent survey of large employers by the National Business Group on Health suggests some change in employer sentiment here. In 2019, 18 percent of employers reported having a point-of-sale rebate program in place; 2 percent said they were implementing a program in 2020, and another 40 percent were considering such a

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[44] Neeraj Sood, Tiffany Shih, Karen Van Nuys et al. *The Flow of Money Through the Pharmaceutical Distribution System* (Los Angeles: University of Southern California, Leonard D. Schaeffer Center for Health Policy and Economics, 2017).

[45] Burns. T*he Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs,* 2022: Figure 9.15.

[46] Burns. *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs,* 2022: Figure 9.16.

[47] Linda Etemad. Presentation to Understanding the Role of Rebates in Prescription Drug Pricing Conference. Sponsored by Alliance for Health Policy (December 28, 2018).

[48] Pharmacy Benefit Management Institute. *2017 Trends in Drug Benefit Design* (Plano TX: PBMI, 2017).

[49] Drug Channels. *Employers are Getting More Rebates Than Ever—But Sharing Little With Their Employees* (January 18, 2018). Available online at: *https://www.drugchannels.net/2018/01/employers-are-getting-more-rebates-than.html.* Accessed on February 1, 2020.

[50] IQVIA. "Patient Affordability Part One" (May 18, 2018). Available online at: *https://www.iqvia.com/locations/united-states/library/case-studies/patient-affordability-part-one.* Accessed August 4, 2020.

[51] Burns, 2022: Figures 9.17, 9.18, 9.19, and 9.20.

program for 2012–2022.[52] Such programs pass the rebates directly to the employee at point of purchase. Such point-of-sale programs are most appropriate when the employee is filling a prescription during the deductible phase of coverage or when paying a coinsurance. As industry analysts make clear, this decision about point-of-sale programs is at the discretion of ERISA Plan Sponsors and the health insurers they contract with. These two parties choose the overall prescription drug benefit that is offered to plan participants, which can include: which drugs are covered, the different levels of cost sharing, the number of pharmacies available to participants, and the incentives for using certain network pharmacies.

These choices reflect the tradeoffs that ERISA Plan Sponsors and health insurers make between access, quality, and cost. These two parties then contract with PBMs to *administer* their prescription drug plans and *implement* the choices made by Plan Sponsors.

PART III: VERTICAL INTEGRATION ALONG THE RETAIL PHARMACEUTICAL SUPPLY CHAIN[53]

Adam Fein at Drug Channels has continued to update researchers and policymakers on the growing consolidation of diverse players operating in the retail pharmaceutical supply chain. The latest version from Adam's 2023 report is reproduced below (with his permission).

Exhibit 234: Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2023

We do not know whether the vertical chains in the Figure above are pro-or anti-competitive. There are no data on the costs, prices, or other performance metrics resulting from these combinations. Researchers acknowledge that "it is well known in antitrust economics that assessing policies in industries with important vertical relationships is challenging. . . . Even in the presence of reliable data, how vertical relationships affect consumer welfare is generally theoretically ambiguous, and under various models of supplier behavior, stronger vertical relationships can greatly improve consumer welfare or greatly harm it."[54]

Some observers look at this chart and quickly conclude that the emergence of such behemoth, bureaucratic intermediaries may not be good for the public. Even a seasoned analyst such as Adam Fein suggests, "These organizations are poised to exert

[52] Drug Channels. *Employers Slowly Warm to Point-of-Sale Rebates—But Most Move Faster for Insulin (rerun)* (September 19, 2019). Available online at: *https://www.drugchannels.net/2019/09/employers-slowly-warm-to-point-of-sale.html.* Accessed on February 1, 2020.

[53] The section draws on Chapter 13 of *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs* (Palgrave Macmillan, 2022).

[54] Zarek Brot-Goldberg, Catherine Che, and Benjamin Handel. "Pharmacy Benefit Managers and Vertical Relationships in Drug Supply: State of Current Research," NBER Working Paper Series (April 2022).

greater control over patient access, sites of care/dispensing, and pricing."[55] At the same time, Fein argues that whether they do or can exercise such control is pure speculation. Other researchers go further, concluding that competing value chains such as those depicted above might serve as the new basis of competition in an ecosystem that is quickly consolidating.[56] This sounds like a great topic for critical thinking.

THE KEY ISSUE IN VERTICAL INTEGRATION: MAKE VERSUS BUY

The type of combinations depicted in the Figure above are known as "vertical integration." Management researchers often argue that the central decision in corporate strategy concerns "make versus buy": *i.e.,* make it in house or buy it in the marketplace. The choices are also known as "insource versus outsource." There are advantages to each approach such as: use the company's managerial hierarchy versus market forces to coordinate the two parties' behaviors, seek the advantages of collaboration versus the benefits of specialization, diversify versus focus, etc. With regard to pharmaceutical benefits, the two approaches are known as "carve-in" versus "carve-out."[57] There is no clearly defined calculus regarding which option to take in the make-versus-buy decision. One has to calculate the costs and benefits of each option—and be satisfied with the tradeoffs. In the absence of data on costs and prices, no one that I know of has made these calculations for the vertically integrated firms depicted here.

It is important to note that, historically, the players in the retail pharmaceutical supply chain have taken *both* approaches. For example, the PBM sector began using a carve-in approach when staff model HMOs served as their own pharmacy benefit managers working under a capitated budget constraint.[58] The objective was to provide comprehensive coverage of both inpatient and outpatient services, including prescription drugs, at an affordable cost ("assurance" rather than insurance). Standalone PBMs that originally developed as staff-model HMOs waxed and waned in popularity. Later PBMs evolved a different set of benefits and services that attracted both employers and health plans as clients; while some PBMs could be carved in, many were carved out of the health plan. United's acquisition of Pacificare in 2005 marked the beginning of the current trend to the carved-in approach (a return to the roots). United's move was motivated by its desire to acquire Pacificare's health plan operations; the PBM came with the deal. By virtue of acquiring Pacificare's 3.3 million enrollees, United increased its enrollment stature (25.7 million lives) relative to its larger competitor Wellpoint (27.7 million lives), diversified geographically into the West (where Pacificare was located), gained traction in the Medicare risk market, and helped it to prepare for the coming Medicare drug benefit. The deal was also part of the M&A frenzy among health plans in the 2005–2006 era.[59] Thus, the sector has experimented with both approaches over time, oftentimes based on historical circumstances, opportunities, or rationales specific to that point in time—but not necessarily to get into the PBM business.

ADVERSARIAL RELATIONSHIPS

The historical lesson here is that the relationships between PBMs and health plans can vary. It is also important to note that the relationships between PBMs and their health plan clients are not always cordial and productive but could instead be unwieldy and rather adversarial. They can both wind and unwind.

Anthem-Express Scripts Litigation

In 2009, Express Scripts entered a 10-year contract with Anthem to provide exclusive pharmacy benefits. In 2016, Anthem filed a lawsuit arguing that its contract with Express Scripts guaranteed it competitive prices for prescription drugs. Anthem or a third-party consultant it retained would conduct a market analysis every 3 years to determine how competitive the PBM's pricing was; if the pricing was not competitive, then Anthem could renegotiate pricing terms with its PBM. In 2011–2012, Anthem commenced the first round of these renegotiations, which lasted for

[55] Drug Channels. *The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* (Philadelphia, PA: Drug Channels Institute): p. 366.

[56] David Dranove and Lawton R. Burns. *Big Med: Megaproviders and the High Cost of Health Care in America* (University of Chicago Press, 2021): Chapter 10.

[57] This is covered in Chapter 9 of *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs* (Palgrave Macmillan, 2022).

[58] This is covered in Chapter 10 of *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs* (Palgrave Macmillan, 2022).

[59] The historical M&A trend among PBMs is depicted in Chapter 11 of *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs* (Palgrave Macmillan, 2022).

nearly 1 year and strained the relationship between the two parties, before they reached an agreement. However, Anthem concluded it was overcharged $3 billion a year for several years. Anthem began a second round of renegotiations in 2014 by demanding $15 billion in price concessions from its PBM, and then notified it of breach of contract. Express Scripts countered that the insurer was responsible to produce a market analysis of drug prices that would serve as the basis of negotiations. It also stated that it earned well below than $3 billion annually from the PBM agreement and thus could not meet Anthem's demand.

In 2017, Anthem announced it would not new its contract with Express Scripts. This meant a loss of 20 percent of the PBM's revenue. In early 2018, a U.S. District Court Judge dismissed Anthem's suit, stating that its contract did not explicitly state that its PBM would ensure competitive pricing; Express Scripts' only obligation was to negotiate based on data the insurer provided.

Downstream Effects of the Litigation

The litigation had several downstream effects—for both insurers and PBMs. First, Anthem had to replace its big-three PBM. In October 2017, Anthem announced its plan to launch its own in-house PBM, IngenioRx, in collaboration with CVS Health; the latter would provide Anthem with claims processing, point-of-sale engagement, and prescription fulfillment services. In 2019, Anthem launched IngenioRx, which reportedly accounted for one-fifth of Anthem's revenue, and served as the insurer's PBM vehicle to target self-insured employers.

Second, Express Scripts faced the loss of its largest health plan client (Anthem) and questions about its future as a stand-alone PBM in an era of consolidation. In April 2017, Express Scripts reported in its quarterly earnings announcement that it did not expect Anthem to renew its contract; indeed, in January 2019, Anthem terminated the contract a year earlier than scheduled. Express Scripts was soon courted by another insurer, Cigna. Cigna was rebounding from its failed horizontal merger with Anthem: on February 8, 2017, the District Court for the District of Columbia sided with the Department of Justice in blocking the horizontal merger of Cigna and Anthem. In March of 2018, Cigna announced its plan to acquire Express Scripts for $67 billion and pursue a vertical merger instead. The deal closed in early December.

The February 2017 District Court ruling also blocked the proposed merger of Aetna and Humana. Within months of the decision, Aetna likewise pursued a vertical merger with CVS Health. CVS Health executives presented the merger to investors as a strategy to develop health hubs for Aetna enrollees at CVS drugstores.

HISTORICAL RATIONALES FOR VERTICAL INTEGRATION

The combinations of (1) Cigna with Express Scripts and (2) Aetna with CVS Health meant that all three major PBMs now had health plan partners. UnitedHealth had previously formed Optum in 2011 by combining its existing pharmacy benefit and care delivery services within the company. Its PBM operations stemmed from its 2005 acquisition of PacifiCare, a health plan which had a pharmacy benefit manager.

Indeed, there have been many rationales for such vertical integration offered over the past decade. These rationales reflect the period's *Zeitgeist* (spirit of the times): care coordination, manage the continuum of care, disease management and chronic disease management, use big data and data analytics to (a) stratify enrollees by their risk level and then (b) identify and intervene for those at high risk. Providers have offered similar rationales for the vertical integration mergers they have undertaken.

Vertical integration has also been partly motivated by the growth in spending on specialty drugs. Such spending is split between the pharmacy benefit and the medical benefit. Patients taking specialty medications tend to have more expensive conditions that health plans need to manage. Health plans have argued that spending under both benefits is large and roughly equal in level, thus requiring close management of both. While there is some overlap, specialty drug spend for different disease categories tends to dominate one benefit over the other (*e.g.,* multiple sclerosis on the pharmaceutical benefit side, oncology on the medical benefit side).

The vertical integration strategies were also partly motivated by Department of Justice's move to block Aetna's and Cigna's prior horizontal merger efforts (with Humana and Anthem, respectively). The latter observation suggests that, at least

initially, one underlying rationale for vertical integration was simply growth, not necessarily the specific merger partner.

CURRENT RATIONALES FOR VERTICAL INTEGRATION

Adam Fein (at Drug Channels) and Eric Percher (at Nephron Research) have done perhaps the best job of articulating the current vertical integration movement in the pharmaceutical supply chain. As noted above, Fein suggests that the issue may be control over the drug channel: "vertically-integrated payers/PBMs/providers are poised to restructure U.S. drug channels by exerting greater control over patient access, sites of care/dispensing, and pricing. If they can effectively coordinate their sprawling business operations, they will pose a substantial threat of disruption to the existing commercial strategies of pharma companies."[60] Such control could result from (1) channeling of enrollees to the specialty pharmacies and providers inside these vertical firms, (2) rewarding providers for formulary compliance, and (3) greater management and utilization control over provider-administered drugs and the buy-and-bill practices of in-house physicians.[61]

In his 2022 Report,[62] Fein summarized some additional specific goals of vertical integration that are mentioned by Percher:[63]

- Because health-care services (*e.g.,* pharmacy) are not subject to the same risk-based capital requirements or profitability regulations as insurers, integration can allow them to retain a greater share of revenues.
- Patients who are on expensive specialty medications have high overall medical spending which can benefit from the combined pharmacy and medical benefit.
- Vertical integration enables insurers to tap into the growing market for specialty pharmaceuticals and perhaps control downstream pharmacy assets.

CHALLENGES TO VERTICAL INTEGRATION

In his 2022 and 2023 reports, Fein is also careful to point out the challenges facing the strategy of vertical integrating insurers with PBMs and pharmacies.

- There is no guarantee that an insurer which owns its own PBM and pharmacy operations is assured that prescribing physicians are aware of any pharmacy network restrictions and can direct their drug dispensing.
- Employers may be skeptical about whether the savings from combining the pharmaceutical and medical benefit will accrue to them. This may slow down their adoption of such plans. Not all health plan sponsors seem to be beating a path to such integrated offerings. According to Drug Channels, 77 percent of small employers (< 1,000 workers) contracted with a combined health plan/PBM in 2021. By contrast, only 53 percent of mid-sized employers (1,000 − 5,000 workers) and only 33 percent of large employers (> 5,000 workers) did so; the latter two categories were more likely to carve out the PBM.[64]

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[60] Adam Fein. "Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?", Drug Channels (December 12, 2019).

[61] Here is what Adam Fein has to say. With regard to *buy-and-bill utilization management:* ownership of clinics enables much greater control over provider-administered drugs—including opportunities to tighten utilization management, negotiate greater rebates from manufacturers, and drive greater biosimilar adoption. For example, *Optum's MedExpress clinics currently offer infusion therapy in select Florida and Indiana locations for people with UnitedHealthcare or Humana insurance . . .* commercial health plans try to move infusions to lower-cost sites of care. This is typically achieved with utilization management strategies that guide patients to lower-cost and/or better-performing sites of care. But employed physicians and in-house clinics make site-of-care management much easier. With regard to *buy-and-bill channel management.* A physician office or clinic that is owned by a vertically integrated organization can be required to obtain provider-administered specialty pharmaceuticals from the company's own specialty pharmacy. This practice is called white bagging. It has displaced buy-and-bill for a significant share of provider-administered drugs in commercial health plans. By owning the infusion site, the insurer bypasses the challenge of getting hospitals to accept white bagging. Adam Fein. "Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?", Drug Channels (December 12, 2019).

[62] Drug Channels Institute. *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers.* Section 12.3.

[63] Eric Percher. *Optum Launches "Emisar" Contracting Entity; Navitus Aligns with Ascent via Prime* (Nephron Research, July 26, 2021). Eric Percher. *A Closer Look: Cigna/ESI Makes Waves with Ascent Contracting and Econdisc Sourcing GPOs* (Nephron Research, January 23, 2020).

[64] Drug Channels Institute. *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers.* Exhibit 80.

- Hospitals have been entering the specialty pharmaceutical business and acquiring oncologist practices. The market for physician-administered drugs is thus shifting from physician offices to hospital outpatient departments. Alternate sites of care such as home infusion account for a portion of the medical benefit spend as well as Medicare Part B spend. Hospitals may enjoy a competitive advantage over integrated insurers in this fragmented market.
- Some prior insurer/PBM/pharmacy/provider joint ventures (*e.g.,* those involving Humana, Prime Therapeutics, Centene) and prior insurer-PBM acquisitions (UnitedHealth and DPS) have unwound.[65] Humana has retrenched to focus on its core Medicare business. In 2021, it began sourcing formulary rebates for its commercial health plans via Cigna's Ascent Health Services business; in 2022, it announced it would divest its majority interest in Kindred at Home and Personal Care Divisions. Prime Therapeutics sold its 49 percent stake in the AllianceRx Walgreens Prime pharmacy; it also outsourced significant portions of its PBM operations to Cigna's Evernorth, including retail pharmacy network contracting, formulary rebates, and mail and specialty pharmacy dispensing. Centene announced plans to outsource PBM operations to Express Scripts and has already sold other businesses (*e.g.,* Magellan Rx PBM, Rare specialty pharmacy). These vertical integration formations are thus quite fluid.

The overall goal of vertical integration may be the magic word, "synergy". Like Helen of Troy, synergy may be the strategy that launched a thousand mergers.[66] Synergy results when the whole is greater than the sum of the parts (*i.e.,* 1 + 1 = 3). There are two types of synergies: cost synergies and revenue synergies. Following Fein and Percher, revenue synergies seem to be front of mind in combining the component parts depicted in the Figure above,. All of this is speculative and theoretical at the moment. We have yet to see whether these combinations can figure out how to coordinate the various parts they acquire. Success will largely hinge on getting physicians and patients to follow directives and "do the right thing": *e.g.,* use in-house pharmacies and providers (stay in network) when they are part of different organizations. Success may be challenged by having to rely on those outside, noncontracted organizations to attract needed volume. As a result, each vertical integration combination may need business from other similar combinations, who are their competitors.

CONSEQUENCES OF VERTICAL INTEGRATION

Vertical integration may have important, positive consequences for competition. According to analysts, one outcome of this vertical integration will be more aggressive price competition among health plans and PBMs.[67] This could come about by the merging parties' bundling of medical and pharmacy benefits, which would entail a diminution of carve-out contracts between employers and PBMs for just the pharmacy benefit. This would put pressure on the margins of the freestanding PBMs, because vertically integrated insurers would discount their in-house PBM's services to win the combined business. Any stand-alone PBM contracts would need to lower prices to remain competitive.

Such integration might also reduce heterogeneity in health plans' approaches to strategic alignment with PBMs (which used to vary along an outsourcing-insourcing continuum). Greater homogeneity in strategic alignment across dyads of health plans and PBMs would increase their competitive rivalry since downstream buyers discern fewer distinctive features of one vertical integration combination.

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[65] This section is taken from Drug Channels. *The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* (Philadelphia, PA: Drug Channels Institute): pp. 367–368.

[66] In his play, *The Tragical History of the Life and Death of Doctor Faustus,* the 16th-century English playwright Christopher Marlowe refers to Helen of Troy as "the face that launched a thousand ships." Helen was the queen of Sparta and the wife of the king, Menelaus. When Paris, son of the king of Troy, abducts Helen, Menelaus enlists the help of his older brother Agamemnon, King of Athens, to launch the Greek fleet (the 1,000 ships) to attack Troy. This is the start of the Trojan Wat as depicted in Homer's *The Iliad.* I have to explain all of this to my Penn students who (somehow, somewhere) neither read the book nor took a course on Greek history. They do not know what face launched a thousand ships, let alone who Menelaeus and Agamemnon were. When, in disbelief, I push further to ask them what they know about the Trojan War, I continue to get blank faces. Out of a class of 55 students one year, only one raised his hand, answering in a questioning voice, "Brad Pitt?". Our educational system is in trouble.

[67] Drug Channels Institute. *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers.*

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

Finally, growing vertical integration between health plans and PBMs will likely reduce the transparency of freestanding PBMs' financial results.[68] We have already confronted the opacity issue in trying to assess the performance of vertical integration efforts by hospitals to develop physician and health plan divisions.[69]

VERTICAL INTEGRATION: RIDE INTO THE DANGER ZONE?

Vertical integration has become a popular strategy in the health-care ecosystem. Many of the recent vertical integration efforts depicted in the Figure above include providers *(e.g.,* physicians, ambulatory surgery centers or ASCs, retail clinics) as well as insurers, pharmacies, and PBMs. A prominent illustration is UnitedHealth Group which includes the insurer UnitedHealth, its in-house PBM (OptumRx), and its Optum Health division, which employs or contracts with roughly 70,000 physicians and owns a chain of ASCs and urgent care centers. Another is CVS Health, which encompasses Aetna, CVS pharmacies, and their retail clinics. Such provider markets are typically more fragmented than the core pharmacy and PBM businesses, offer another possible revenue stream, and can involve the key prescriber.

The health-care sector is in the midst of its second or third iteration of vertical integration involving hospitals, physicians, insurers, and alternate care sites. The historical evidence among this different set of players has already been published, weighed in the balance, and found wanting.[70] It is not a pretty picture. Most of the vertical combinations fall into one of three categories—physicians with insurers, hospitals with insurers, physicians with hospitals. They have all suffered from disappointing financial performance and, sometimes, huge losses. There are an estimated 50 different reasons why combinations of providers with insurers do not work; worse yet, it may only take one of those reasons to sink the deal.[71]

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[68] Growing vertical integration between health plans and PBMs will likely reduce the transparency of freestanding PBMs' financial results. Consider UnitedHealth Group, which had revenues of $226.2 billion in 2018. For 2018, revenues at its OptumRx subsidiary were $69.5 billion. Interpreting the OptumRx figure is challenging, because: (1) it includes a combination of prescription revenues from its own mail/specialty pharmacies plus external retail network pharmacies, (2) it is reported net of rebates, (3) it *excludes* the value of members' out-of-pocket payments from revenues from retail network dispensed prescriptions, but *includes* the value of these member payments from prescriptions dispensed by its in-house pharmacies, and (4) it includes revenues of $39.4 billion (57 percent) from services provided to other subsidiaries, *e.g.,* UnitedHealthcare. Drug Channels Institute. *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers.*

United's 10–K statement from 2021 includes a depiction of the conglomerate's total revenues. The data indicate huge growth between 2018 and 2021 in the revenues of OptumRx (from $69.5 billion to $91.3 billion) and Optum Health (from $24.1 billion to $54.0 billion); they appear to be the growth drivers in UnitedHealth's total revenues (from $226.2 billion to $287.6 billion). United's biggest revenue source (60 percent) is the company's Medical and Retirement insurance segment. OptumRx may become increasingly more or less dependent on enrollees outside the parent company. It is difficult to determine the sources of United's profits coming from internal versus external sources given the conglomerate structure and the mix of customers.

[69] Jeff Goldsmith, Lawton R. Burns, Aditi Sen, and Trevor Goldsmith. *Integrated Delivery Networks: In Search of Benefits and Market Effects* (Washington, DC: National Academy of Social Insurance, 2015).

[70] David Dranove and Lawton R. Burns. *Big Med: Megaproviders and the High Cost of Healthcare in America* (Chicago, IL: University of Chicago Press, 2021). Jeff Goldsmith, Lawton R. Burns, Aditi Sen, and Trevor Goldsmith. *Integrated Delivery Networks: In Search of Benefits and Market Effects* (Washington, DC: National Academy of Social Insurance, 2015). Lawton R. Burns, David Asch, and Ralph Muller. "Vertical Integration of Physicians and Hospitals: Three Decades of Futility?", in Mark V. Pauly (ed.), *Seemed Like a Good Idea: Alchemy versus Evidence-Based Approaches to Healthcare Management Innovation* (Cambridge, UK: Cambridge University Press, 2022). Lawton R. Burns and Darrell P. Thorpe. "Why Provider-Sponsored Health Plans Don't Work." *Healthcare Financial Management: 2001 Resource Guide:* 12–16. 2001.

[71] Lawton R. Burns and Darrell P. Thorpe. "Why Provider-Sponsored Health Plans Don't Work." *Healthcare Financial Management: 2001 Resource Guide:* 12–16. 2001.

How should one evaluate vertical integration between firms in adjacent stages in the health-care value chain? According to strategy researchers, vertical integration (insourcing) makes more sense than using the market (outsourcing) when the following *general* conditions hold:

- There are few firms in the adjacent stage.
- There is need to make transaction-specific investment in an upstream/downstream firm.
- The integration ensures access to needed inputs.
- There is a need for coordination between the firms in the adjacent stages.
- The adjacent stages are similar in their optimal scale.
- The two stages are strategically similar.
- There is high certainty in market demand.
- There is low risk in the reliability of the trading partner.
- There is low need to continually upgrade capabilities.

Moreover, the following *specific* conditions must also be met if the vertical integration is to confer competitive advantage over rivals:

- The integration achieves coordination and collaboration not open to other firms.
- The integration improves the joint performance of value chain activities under one roof.
- The integration leverages resources and capabilities across the combined firm.
- Ownership is needed to capture all of this value.
- Culture clashes between the two firms can be avoided.
- Executives can get the two firms to work together.

The bar is pretty high. Many firms may be challenged to clear it. It is unclear whether executives consider the general market and specific firm conditions needed to make vertical integration succeed. Vertical integration is a specific type of corporate diversification. The evidence base for the performance of diversified firms is not much better than that for vertically integrated firms. Related diversification outperforms unrelated diversification; but, focus may outperform related diversification. The key question is how big is the overlap between the value chains of the firms that are integrating; the secondary question is whether the overlap occurs in the most important stages of their value chains. This requires a comparison of the health plan's value chain and the PBM's value chain.[72] Another key issue is that such an analysis needs to be conducted for each pair of components in the vertical chain. A final issue which most strategists fail to consider is this: given the popularity of vertical integration and the large number of firms adopting this strategy, just where is the competitive advantage?

CONCLUSION REGARDING VERTICAL INTEGRATION

In sum, vertical integration is not a guaranteed success. When pursued by hospitals and physicians, there has been a lot of red ink and unwinding of the combinations. This is all documented evidence. At the same time, hospitals have utilized vertical integration with physicians to increase the prices they charge insurers in local markets; this serves to increase their costs and total spending. This, too, is well documented. Regulators need to closely monitor what effects the combinations depicted in the Figure above exert on pricing and costs. At this point, we simply do not know.

QUESTIONS SUBMITTED FOR THE RECORD TO LAWTON ROBERT BURNS, PH.D., MBA

QUESTIONS SUBMITTED BY HON. MIKE CRAPO

PBM-OWNED GROUP PURCHASING ORGANIZATIONS/REBATE AGGREGATORS

Question. Recent years have seen the emergence of a number of PBM-owned or affiliated group purchasing organizations (GPOs), often known as rebate aggregators, through which certain PBMs have reportedly outsourced some of their functions, including with respect to manufacturer negotiations.

How do these organizations differ from traditional GPOs, what are their implications for the broader prescription drug supply chain (and for patients), and what ad-

[72] Compare Figures 11.14 and 13.5 in *The Healthcare Value Chain: Demystifying the Roles of GPOs and PBMs.*

ditional information should policymakers seek to collect and/or monitor with respect to these entities?

Answer. The major PBMs have indeed set up their own GPOs. The PBM-GPOs act like the group purchasing organizations found in the institutional channel of the supply chain. They aggregate the drug purchases for *many* health plans and their PBMs, extracting greater savings from manufacturers and pharmacies based on a larger-volume-for-lower-price discount. The larger PBM members in the PBM-GPO get some additional price concessions due to the additional volume, while the smaller PBM members in the PBM-GPO get more substantial price concessions by virtue of pooling their drug buying with the larger PBMs. Because they are usually based outside of the U.S., the PBM-GPOs only operate in the commercial business.

The PBMs that own and operate these rebate aggregators prefer to call them "Contracting Entities" rather than GPOs. Nevertheless, their contracts are structured so as to allow these aggregators to leverage the already-existing GPO safe harbor. This serves two functions, according to Eric Percher. First, it enables rebate aggregator to charge GPO administrative fees of up to 300bp, thereby creating a potential new or substitutive fee for PBM members (substitutive for admin fees with the added bonus that profits may be transferred to lower-cost tax jurisdictions). Second, it ensures that should legislative or administrative action undercut the pharmaceutical rebate/discount safe harbor, the PBM owners will continue to have access to a mechanism to collect and share administrative fees with PBM-GPO aggregator members via the separate and distinct GPO safe harbor. What the Senate might investigate is how large are the revenues shifted to lower cost tax jurisdictions.

TRANSPARENCY

Question. As you noted during the March 30th hearing, transparency measures can produce both benefits and risks, depending on their design and context.

In designing appropriate transparency provisions in the context of the prescription drug supply chain, what steps could Congress take to improve stakeholder and patient line-of-sight into practices and pricing dynamics while minimizing the risk of unintended consequences?

Answer. It is not clear that patients want/need a clear line of sight into PBM practices. Research already shows that patients do not customarily use the price and quality information on the *providers* they utilize, even when such data are made transparent. It is also unclear that patients use such information in choosing their *health plans.* Since patient understanding of PBMs is likely a quantum degree lower than their understanding of their providers and their health plans, it is not clear there is much to be gained here in terms of patient shopping behavior.

The major customers of the PBMs are (1) the health plans that PBMs serve and (2) the employers whom the health plans serve. At this time, there is nothing to prevent either PBM customer (health plan or employer) from demanding more transparency and data visibility/reporting from their agent PBMs. It is not entirely clear why the plans and employers have not demanded greater access to such information. And this is after they spend a boatload of money on benefits consultants, contract consultants, and attorneys. Are the health plans and employers really that helpless? To be sure, the PBMs have gotten really big and may be good at moving fees around; and the plans and employers may have trouble seeing their own data as well as they would like. But should the Federal Government step in here? This seems like an area of private-sector contracting, not public-sector regulation.

QUESTIONS SUBMITTED BY HON. JOHN CORNYN

Question. As part of your written testimony at the hearing, you note that PBMs are the focus of many of the allegations in the industry—including, monopoly power, anticompetitive behavior, and reduced access to medication, to name a few. You also note how the business model of this industry has changed over time.

Do you think more transparency in the PBM system—such as how rebates are used, what portion is passed onto the consumer, is an effective solution to understand the industry better?

Answer. The issue of what to do with rebates entails some interesting tradeoffs. At present, the rebates flow to the health plans and their ERISA plan sponsors, who utilize them in ways to spread the benefits across *all* of their enrollees/employees.

The rebates do not flow to those sicker members who are using the expensive drugs that generate the high rebates that flow to the plans. This means that the sicker enrollees/employees are subsidizing the healthier enrollees/employees; this is true for both commercial and Part D enrollees. The conundrum is that the former group vastly outweighs the latter group in sheer numbers—so more people actually benefit. Some employers have taken steps to move toward "point-of-service" rebates in order to help the latter, sicker enrollees. The problem is that this weakens the competitive position of their employees and their health plans, since their premiums are likely to rise.

In general, transparency has not worked in the U.S. health-care system to date. A recent report issued by the Congressional Budget Office confirms this. So does a boatload of academic research.

Question. Your written testimony indicates that many people are still focused on the older practices of PBMs, such as manufacturer rebates, whereas PBMs are more focused on specialty drugs now. Can you elaborate on this comment?

Does this mean that the solutions and actions Congress may be looked at should be focused differently?

How do PBMs make a profit off specialty drugs, and does this fit into the overall pharmaceutical supply chain?

Answer. A crucial, new part of PBM profits derives from the dispensing of specialty pharmaceuticals using their in-house pharmacies, as well as non-rebate fees from pharmaceutical manufacturers for a range of services (listed below). Conversely, PBMs now derive a smaller portion of their profits from rebate contracting with manufacturers and network management of retail pharmacies. Congressional efforts to target manufacturer rebates is, thus, misplaced and out of date.

How has this come about? Specialty pharmaceuticals now drive the rising cost of drugs: they have few (if any) competitors, very high launch prices, and very high list prices. Without any effective competitors, the PBMs have very little bargaining power.

Congress should be looking at the launch/list prices of new specialty drugs, including orphan drugs. That is where the money is being spent. That is where consumers face high out-of-pocket costs at the pharmacy (regardless of whether that pharmacy is owned by a PBM or some other party). There is a lot of competition in the specialty *pharmacy* space, but not much in specialty *pharmaceutical manufacturing.* Academic Medical Centers who administer these expensive drugs are starting their own specialty pharmacies.

Everyone makes money from the dispensing of specialty drugs. The PBMs and others who operate specialty pharmacies are taking business away from retail pharmacies. That is one reason the latter complain so much about the PBMs: they are losing market share in the growing market of dispensing these expensive drugs. According to Adam Fein of Drug Channels, the gross margin of a specialty pharmacy consists of a dispensing spread (reimbursement − acquisition cost) + fees from manufacturers for a range of services provided. (However, there can also be many hidden sources of profits such as 340B, copay maximizers, and off-invoice discounts). These services can encompass disease management, outcomes research, compliance and adherence services, side-effect management services, and managing patient service hub programs.

Health plans develop small, preferred networks of specialty pharmacies, partly because they help to increase patient adherence to their medications, but also because they obtain lower prices in a volume-for-price tradeoff. Specialty drugs can account for at least 50 percent of a health plan's net pharmacy benefit spending. That represents an enormous rise from just 23 percent in 2013. Likewise, drug manufacturers may limit the network of pharmacies that dispense their specialty drugs. We do not know much about this side of the PBM's business. Most companies do not report prescription revenues from specialty drugs.

QUESTION SUBMITTED BY HON. TIM SCOTT

Question. I have seen a lot of information regarding the gross-to-net bubble, the difference between a drug's list price and net price, which can be quite sizeable when there are rebates paid by the manufacturer. Reporting from many sources, including KPMG, Drug Channels, and others, share that discounts from manufacturers are often higher than 50 percent in Part D. Yet, patients who purchase those

medicines do not share in those rebates. The PBM business model today has evolved to a point where they are now often owned by or own an insurer, a large pharmacy chain, or both.

How do you think PBMs and related industry vertical integration and consolidation impacts the prices that patients pay directly and how might that impact the incentive to lower costs at the pharmacy counter?

Answer. The prices that patients pay at the pharmacy counter are driven largely by what their health plans have (or have not) negotiated with the manufacturers. In the commercial space, a lot of patients pay high out-of-pocket costs because they have high-deductible health plans (HDHPs) and they are still in the deductible phase of their coverage that year. That means they are on the hook for all of a drug's cost, and that cost (unfortunately) happens to be the manufacturer's list price. This is driven by the employer; the PBM has nothing to do with it.

On the Medicare Part D side, the health plans may not be aggressively negotiating prices for really expensive specialty drugs for the following reason. Part D beneficiaries pay the higher prices, they quickly move through the various coverage phases in Part D, and then reach the catastrophic coverage phase where the Federal Government covers 80 percent of the cost of the drug, while the health plan's share drops. This seems like a cost-shifting game, which Medicare Part D planners inadvertently allowed back in 2006.

Medicaid beneficiaries do not pay much out of pocket for drugs. They are, therefore, not as disadvantaged as the other two sets of beneficiaries above.

PREPARED STATEMENT OF HON. MIKE CRAPO,
A U.S. SENATOR FROM IDAHO

I have long championed efforts to improve prescription drug access and affordability for Americans, and I welcome the opportunity to engage in this vitally important bipartisan hearing.

Whether at the pharmacy counter, the doctor's office, or the hospital, some of the most lifesaving medications remain out of reach for far too many working families and seniors, especially in the face of persistent inflation. Congress took a critical step toward addressing these challenges nearly 20 years ago, when we voted to enact Medicare's prescription drug benefit, or Part D, leveraging market-based competition to create and protect high-quality coverage options for seniors.

In many ways, Medicare Part D reflects an unprecedented success story, coming in massively under budget, with low and stable monthly premiums—and with a generic drug dispensing rate of roughly 90 percent. Part D's resilient, market-oriented structure continues to ensure low-cost drug access for most seniors, even as many other medical costs have continued to skyrocket. Stakeholders across the supply chain deserve credit for these figures and trends.

That said, much has changed in the past 2 decades, and we have an obligation both to build on the aspects of Part D that work well and to address access and affordability gaps where we find them. In weighing and developing policy solutions, my priority is always the patient. We need to identify avenues for lowering out-of-pocket costs, increasing competition, and promoting access to lifesaving innovation—and we need to do so in a fiscally responsible manner.

Given the tremendous common ground and shared goals around this issue, I am confident we can fulfill these objectives and deliver real results for seniors. A few major points regularly raised by Idahoans—transparency, incentives, and out-of-pocket costs—are of key importance as we hear today's testimony.

As anyone who has looked at a flow chart or diagram of the drug supply chain can attest, the only clear thing about it is how unclear and opaque it really is. We need an all-of-the-above approach to transparency that empowers consumers, plans, providers, and pharmacies to make informed, cost-effective, and clinically appropriate decisions—as well as to practice meaningful oversight. Policymakers also need more line of sight into the black box of drug pricing relationships and transactions, especially as we look to pursue productive reforms in the future.

We also need to assess the various incentives that operate within the medication supply chain. Ideally, we should have frameworks, both within Part D and in other markets, that encourage low prices through meaningful competition. Unfortunately,

in too many cases, certain dynamics seem to drive list prices up, even as net prices, reflective of rebates and discounts, decline.

The gap between list and net price has grown dramatically in recent years, keeping premiums stable but exposing some consumers to astronomical out-of-pocket costs at the pharmacy counter, particularly for uninsured patients or families relying on high-deductible health plans.

Misaligned incentives have also constrained biosimilar uptake in Part D, driving manufacturers to launch products at multiple different price points, with PBMs sometimes preferencing the option with the higher sticker price. The incentive structures at play here clearly warrant a hard look.

Americans face an out-of-pocket cost of less than $20 for 92 percent of prescriptions filled. For the remainder, however, costs can run much higher, particularly for seniors enrolled in Part D. I look forward to discussing targeted solutions to bridge this gap without fueling premium hikes for older Americans.

With these priorities in mind, thank you to our witnesses for being here today. I look forward to your testimonies.

Thank you, Mr. Chairman.

PREPARED STATEMENT OF ROBIN FELDMAN, ARTHUR J. GOLDBERG DISTINGUISHED PROFESSOR OF LAW, ALBERT ABRAMSON '54 DISTINGUISHED PROFESSOR OF LAW CHAIR, AND DIRECTOR OF THE CENTER FOR INNOVATION, UNIVERSITY OF CALIFORNIA LAW

Thank you, Mr. Chairman and esteemed members of the committee. I am honored to be here today to address an issue that is burdening patients, taxpayers, and those trying to help them.

The supply chain for medicine is riddled with perverse incentives, and marked by sky-rocketing prices. we see persistently rising prices on the medications people depend on, day after day, to treat widespread problems such as diabetes, high blood pressure, high cholesterol, and opioid addiction.[1] Key aspects of the problem can be traced to the industry that lies at the center of drug pricing—pharmacy benefit managers, or PBMs.[2]

Historically, PBMs operated as claims processors, just handling the paperwork.[3] But 15 years ago, when Medicare coverage expanded to include prescription drugs, PBMs offered to help health plans negotiate with drug companies for better prices.

But instead of prices coming down, prices of many drugs dramatically increased. For example, the prices of 65 common medicines have almost tripled, just during

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[1] *See* Centers for Medicare and Medicaid Services, Drug Spending Information Products Fact Sheet (2018), *https://www.cms.gov/newsroom/fact-sheets/drug-spending-information-products-fact-sheet* (listing the 10 drugs with highest annual price increases from 2012 to 2016 covered by Medicare); California Office of Statewide Health Planning and Development, Prescription Drug Wholesale Acquisition Cost (WAC) Increases (2019) (detailing wholesale price increases of more than 16 percent for hundreds of drugs between 2017 and Q2 of 2019); Feldman, Devil, *supra* note 1, at 2.

[2] For additional information on pharmacy benefit managers, *see* Robin Feldman, "Drugs, Money, and Secret Handshakes: The Unstoppable Growth of Prescription Drug Prices" (2019) (discussing the role of PBMs in the pharmaceutical market); Robin Feldman, "Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills," 57 *Harv. J. on Leg.* 303 (2020) (describing the incentive structures that lead PBMs to contribute to rising drug prices); Robin Feldman, "The Devil in the Tiers," 8 *J.L. and Biosci.* 1 (2021) (analyzing the role PBMs play in distorting the organization of drug formularies); Robin Feldman, "Why prescription drug prices have skyrocketed," *Washington Post* (November 26, 2018), *https://www.washingtonpost.com/outlook/2018/11/26/why-prescription-drug-prices-have-skyrocketed/* (discussing the role PBMs play in the pharmaceutical market). For a discussion of potential solutions, see Feldman, Devil, at 31–41 (suggesting that drugs should be located on formulary tiers based on list, rather than net, price to remove the incentive for anticompetitive formulary manipulation); Feldman, Secret Handshakes, at 95–102 (describing the significance of transparency and potential State and Federal level responses).

[3] Feldman, *Washington Post, supra* note 1.

those 15 years.[4] There are many contributing factors, but PBMs have been in the middle of it.

So how did this happen? How did PBMs—which were supposed to help negotiate lower prices—end up helping to inflate drug prices instead? Rather than act as honest brokers for the health plans, PBMs have acted in their own self-interest. And as it turns out, their own interests are not aligned with low prices.

Quite simply, higher prices put more dollars into a PBM's pockets. When the starting price of a drug rises, and the PBM negotiates a rebate, the PBM appears successful. It's like a store that raises the price of a coat before putting it on sale. The markdown looks like a great bargain; but it's not. In addition, the PBM often keeps a percentage of the rebate, so it gets to pocket more.

All of this might not be so bad if no one actually paid that high list price. But people do. Many consumers have what are called high-deductible plans, in which they pay that high list price out of their pockets until they reach a certain threshold;[5] other plans require that patients pay a percentage of the high list price for what is known as co-insurance.[6] And many Americans don't have coverage for prescription drugs, even if they have health insurance.

I mentioned raising the price of a coat before you put it on sale. It gets worse. Imagine if the price jump is higher than the sale discount. That's what's happening with medicine. Medicine prices are rising faster than rebates. Between 2010 and 2017 in Medicare, prices for particular drugs *after* rebate still rose 313 percent on average.[7] We are buying the same coat, but it is costing us more and more. And a significant portion of that price increase is going to PBMs.

A PBM may be brokering deals for a health plan, but it is a strange relationship. PBMs refuse to tell the health plans—their own clients—the details of the deals they are making. Neither health plans, nor the government, nor the market has any disclosure.[8] Given their monopoly over pricing information, and the fact that just three PBMs control most of the market,[9] PBMs are setting the terms of almost every arrangement. It is not a free or fair market.

And despite the fact that PBMs should be serving as honest brokers for the health plans, PBMs also ask drug companies for side payments—again, payments that rise when the price of the drug rises. And they vigorously deny having a fiduciary or any other type of duty to act in the best interests of the health plan and its patients.

So, what so PBMs do to protect their income stream of rebates and side payments? PBMs stand at the center. As well as negotiating prices, PBMs help decide if patients will be reimbursed and how much they will be reimbursed. So, when dealing with drug companies, PBMs can offer to exclude a drug company's competitor or make it harder for patients to get the competitor's medicine.[10] As a result,

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[4] Stephen W. Schondelmeyer and Leigh Purvis, AARP Public Policy Institute, "Trends in retail prices of brand name prescription drugs widely used by older Americans, 2006 to 2020," 1–2 (2021).

[5] For an example of a plan requiring that the patient pay 100 percent of the costs of drugs up to a certain limit, *see* the Anthem insurance plan described at First Am. Consolidated Class Action Compl., at para. 13, In re Express Scripts/Anthem ERISA Litigation, 2018 U.S. Dist. LEXIS 3081 (S.D.N.Y. 2016) (No. 16–3399).

[6] *See* Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy, 408–09 (2017).

[7] Feldman, Devil, *supra* note 1, at 19, 21–22.

[8] PBMs refuse to disclose net prices, the precise size of rebates, or the details of the rebate terms, asserting that the information is a trade secret. Even auditors and regulators are not given full access. For an explanation of why prices and price terms negotiated between PBMs and drug companies do not constitute trade secrets, *see* Robin Feldman and Charles Tait Graves, "Naked Price and Pharmaceutical Trade Secret Overreach," 22 *Yale J.L. and Tech* 61 (2020).

[9] Neeraj Sood, Dana P. Goldman, and Karen Van Nuys, "Follow the money to understand how drug profits flow," STAT (December 15, 2017), *https://www.statnews.com/2017/12/15/prescription-drug-profits-pbm/* ("The top three pharmacy benefit managers, which negotiate drug prices on behalf of insurers and self-insured employers, dominate 85 percent of their market."). *See also* Neeraj Sood, Transcript of Understanding Competition in Prescription Drug Markets: Entry and Supply Chain, Dynamics Workshop (November 8, 2017), *https://www.ftc.gov/system/files/documents/videos/understanding-competition-prescription-drug-markets-panel-2/ftc_understanding_competition_in_prescription_drug_markets_-_transcript_segment_3.pdf.*

[10] *See generally* Robin Feldman, "Drugs, Money, and Secret Handshakes: The Unstoppable Growth of Prescription Drug Prices" (2019). For press reports and case allegations describing formulary exclusion as a result of rebate deals, *see, e.g.,* Charles Ornstein and Katie Thomas, "Take the Generic, Patients Are Told. Until They Are Not," *New York Times* (August 6, 2017)

less-expensive medicines are disadvantaged, and patients are channeled into higher-priced drugs.

Although the pharmaceutical supply chain is complex, the overview of these aspects of the problem can be summarized fairly simply: PBMs are able to exploit their role at the center to extract dollars and channel the system towards higher-priced drugs. Patients and taxpayers must pick up the bill.

QUESTIONS SUBMITTED FOR THE RECORD TO ROBIN FELDMAN

QUESTIONS SUBMITTED BY HON. RON WYDEN

Question. What specific data and information should PBMs share with their health plan clients in order to mitigate possible conflicts of interest?

Answer. For transparency aimed at reducing conflicts of interest, PBMs should reveal to their health plan clients the terms of any payment agreements with drug companies, along with the payment flows resulting from those agreements. This can help make the markets more fair, efficient, and transparent.

For the basic drug supply agreements, transparency should include the terms of the agreements along with both the gross and net prices that result. These should be described at the level of the individual drug and dose, rather than in the aggregate. The information should include whether the payment terms are based on conditions such as filling a quantity of drugs or limiting competing drugs.

Transparency also should include terms and payment flows related to any agreements PBMs have with drug companies, whether those are administrative fees, data management fees, or other payments. This follows the notion that if I'm negotiating on behalf of the health plan and its patients, I shouldn't be receiving payments from the other side. At the very least, the health plan should know what those payments are.

Question. Please describe price protection clauses. What incentives do these clauses create for PBMs and manufacturers?

Answer. I am aware of two types of price protection clauses. First, there is a recent innovation in PBM contracting with health plans that side-steps the issue of rebates paid by drug companies to PBMs and what the PBMs are doing with the rebate moneys. Known as "price protection," this approach completely obscures payments from drug companies to the PBM. If a large plan with some level of market clout asks for access to contract terms and claims information, a PBM can offer, as an alternative, that the overall prices won't rise more than a certain amount. The PBM is essentially saying to the health plan, "Why engage in examining all that grubby detail when what you care about is the bottom line?" Unfortunately, these price protection agreements simply obscure the agreements that block cheaper entrants from gaining a foothold in the market, entrants that could ultimately bring prices down.

Second, some rebate agreements between drug companies and PBMs include a clause ensuring a form of price protection or most-favored-nation status for the drug company. These clauses ensure that patients won't be given better access to the drug company's competitors in any way, presumably even if the competitor offers a lower price. These clauses encourage PBMs and manufacturers to maintain higher prices, at the expense of patients and payers.

(describing health plans forcing patients to pay more for the generic version of a drug or declining to reimburse for the generic at all, *https://www.nytimes.com/2017/08/06/health/prescription-drugs-brand-name-generic.html?mtrref=undefined [https://perma.cc/U4JU-4P3X]; see also Complaint, Regeneron Pharmaceuticals Inc. v. Amgen Inc.,* No. 1:22–cv–00697 (D.Del 2022) (alleging bundled rebates for cholesterol medication induced health plans to exclude competitor medication from formularies in order to obtain rebates) case number 1:22–cv–00697, in the U.S. District Court for the District of Delaware Complaint, *Shire U.S., Inc. v. Allergan, Inc.,* No. 17–7716 (D.N.J. 2017) (alleging bundled rebates for the eye medication Restasis deterred health plan formularies from including competitors); Complaint, *Pfizer, Inc. v. Johnson & Johnson and Janssen Biotech, Inc.,* 2018 U.S. Dist. LEXIS 31690 (E.D. Pa. 2018) (No. 17–4180) (bundled rebates for the rheumatoid arthritis drug Remicade resulted in hospitals and health plan formularies essentially excluding the lower-priced biosimilar).

QUESTIONS SUBMITTED BY HON. THOMAS R. CARPER

Question. Last year, Congress passed and President Biden signed into law the Inflation Reduction Act—which capped insulin prices for Medicare beneficiaries at $35 per month. Thanks to President Biden's leadership, drug manufacturers like Eli Lilly have followed suit and have voluntarily capped the price of insulin at $35 per month in the commercial market as well.

What are your thoughts on expanding the insulin price cap to other classes of drugs—for example, drugs that are older, highly rebated, and/or treat chronic conditions? What are the key things that Congress should think about when considering this type of policy? What are the trade-offs and how can we prevent costs from ballooning in other parts of our health-care system when designing such a policy?

Answer. Any relief to struggling patients is welcome relief. But copay caps alone have a hidden trade-off. Patients have no reason to choose a cost-effective drug over the expensive brand-name drug. Thus, it buys customer loyalty by shielding them from out-of-pocket costs. The plan, however, pays the lion's share of the price. If patients stay with the pricier product when less-expensive alternatives enter the market, that increases costs to the plan as a whole, which could flow through to higher premiums for all patients.

Question. Thanks to the testimony of our witnesses and questions from my colleagues, we heard a good amount of discussion about the perverse incentives that exist in the market due to how PBMs make their money. To summarize, a significant source of revenue for PBMs are rebates and administrative fees that are often based on a drug's list price. This creates bizarre and perverse incentives that have been found to lead to increased drug list prices and higher-priced drugs on formulary lists so that PBMs can bring in more revenue. That's bad for patients and its bad for taxpayers. Dr. Gibbs in his testimony talked about the transparent, flat-fee pricing model that Capital Rx has put in place.

What can we as policymakers learn from Capital Rx's pricing model and what proposals would you recommend we pursue to align pricing incentives in the various parts of the drug supply chain?

Answer. I am not familiar with Capital Rx, so I cannot comment on its model. Certainly, a transparent model that eliminates the perverse incentives would be a great improvement. Of course, as I noted in response to a question for the record from Chairman Wyden, a PBM pricing model based on a simple fee would not, in itself, eliminate the perverse incentives. Some of the price-protection agreements in place—in which PBMs guarantee that the overall price for a health plan will not rise more than a certain amount—may obscure agreements between the PBM and drug companies that block cheaper entrants from gaining a foothold in the market and ultimately bringing prices down. In that case, the price-protection approach simply encourages the plan not to ask too many questions, but leaves many of the problematic elements in place.

QUESTIONS SUBMITTED BY HON. ELIZABETH WARREN

Question. There is evidence that manufacturers may engage in rebate-based negotiating strategies with PBMs to block competitors and secure preferential formulary placement. These strategies may be used in tandem and jointly result in distorted formulary designs that may favor higher-cost and less effective products.

Please describe bundled rebates and rebate traps.

Answer. The PBM industry has evolved in a manner that puts upward pressure on prices. The name of the game is volume. The more volume a drug company has with a particular PBM, and the greater the drug company's market share, the better the potential deal that the drug company can offer as an inducement to disfavor rival drugs.

In simplified form, imagine a major drug company that sells 1 million doses of a medication to a plan's patients.[1] The company tells the PBM, "we will give you a rebate of $1 per dose if you agree to disfavor our new competitor." That deal is worth a million dollars in rebates. A new entrant, selling a small number of doses,

[1] For an expanded version of this hypothetical using beer bottles as an analogy and citations to allegations in various drug industry cases, *see* Robin Feldman, "Drugs, Money and Secret Handshakes," 21–31 (Cambridge 2019).

could never offer enough off the price of the drug to compensate for the million-dollar rebate offered by the major player. When a drug company has a portfolio of drugs to bundle together in a rebate offer, the opportunities for drug companies increase.

Bundled rebates take different forms. A drug company could offer the PBM an especially high rebate if the PBM's client accumulates a certain volume of multiple different drugs the company makes. In that case, a competitor that sells only one drug could never offer a comparable volume and thus could never offer a similarly high rebate. Or if a drug company is selling two drugs—one that is well-protected by patents against competition and one that is vulnerable to competition—the drug company could offer a break on the price of the well-protected drug (because the company doesn't fear competition) in exchange for a preferred formulary placement for the drug facing competition.

Real world examples abound. A suit against Allergan alleged that the company used bundled rebates to preserve its market share for the dry-eye medication Restasis. According to a Medicare plan administrator quoted in the complaint, given the company's scheme, a competitor could give the new drug away for free, and the numbers still wouldn't work—meaning that the new drug still wouldn't get reasonable formulary access and consumers still wouldn't end up switching to the new drug. That is a striking comment, and it captures the raw power of bundled rebates.[2]

Question. How might these practices influence formularies?

Answer. With volume and bundled rebates, more expensive drugs receive preferred positions on formularies. And research suggests that generic drugs are increasingly losing out on formulary placement. Between 2010 and 2017, the percentage of generics on the most-preferred tier dropped from 73 percent to 28 percent.[3]

Question. What effect might they have on patient drug costs?

Answer. When patients are channeled into higher-priced drugs, their costs rise. For example, any co-insurance payments that are based on a percentage of the drug's costs will be higher.

Considering only costs paid by patients and the Federal low-income subsidy program, improper tiering conservatively resulted in $4.17 billion in wasted cost in 2017 alone.[4]

Question. What effect might they have on overall drug spending?

Answer. These perverse incentives have caused dramatic increases in spending on medicine throughout the health-care system. As one doctor pointed out, it is "Alice-in-Wonderland-time in the drug world."[5] And it's our money going down the rabbit hole.

PREPARED STATEMENT OF MATTHEW GIBBS, PHARM.D., PRESIDENT, CAPITAL RX INC.

My name is Matthew Aaron Gibbs, and I am a doctor of pharmacy, also known as a Pharm.D. I have been in the pharmacy benefit management ("PBM") and managed care industry for over 20 years serving in various roles, including managing clinical strategy, sales leadership, negotiating contracts with pharmaceutical manufacturers, mail service and specialty home delivery operations, and most recently serving as a member of the executive team at Capital Rx, where I am the current president of the company. I have been at Capital Rx for nearly 3 years, and before joining Capital Rx, I served as president of another mid-market PBM for 4 years.

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[2] Compl., at 6–7, *Shire U.S. Inc. v. Allergan, Inc.,* No. 17–7716 (D.N.J. 2017) (stating that Allergan's product portfolio, which includes several popular glaucoma drugs, provides the company with the "financial wherewithal to give . . . rebates that far exceed anything that Shire could offer on [its own drug] Xiidra"); *cf. Shire U.S. Inc. v. Allergan, Inc.,* 375 F. Supp. 3d 538 (D.N.J. 2019) (granting motion to dismiss complaint because alleged relevant product market was defined so narrowly as to exclude entities that could have purchased Shire's drug, and because Shire did not allege that it couldn't itself offer bundled rebates or that bundled drugs generating Allergan's bundled rebate included any drug over which Allergan had monopoly power).

[3] *See* Robin Feldman, "The Devil in the Tiers," *Oxford J.L. and Biosci.* 1 (2021).

[4] *See* Robin Feldman, "The Devil in the Tiers," *Oxford J.L. and Biosci.* 1 (2021).

[5] Charles Ornstein and Katie Thomas, "Take the Generic, Patients Are Told. Until They Are Not," *New York Times* (August 6, 2017), *https://www.nytimes.com/2017/08/06/health/prescription-drugs-brand-name-generic.html.*

I have also managed two of the Nation's largest pharmacy consulting groups advising Fortune 100 companies on their procurement strategies for selecting PBM partners. Additionally, I have pharmacy expertise in all the relevant lines of business: Medicare, Medicaid, commercial insured plans, ACA/exchange, and self-funded employers of all types.

I am honored and humbled to address this committee regarding growing concerns around prescription drug pricing in the United States.

We must first take a step back to truly understand the problem and think through solutions. Since PBMs emerged in the 1990s they have played a critical role in the pharmacy and overall health care supply chain. PBMs were at the forefront of technology, connecting all pharmacies in the U.S. via a single and uniform communication logic known as The National Council for Prescription Drug Programs (NCPDP). This logic allows pharmacies, regardless of owner or chain name, to communicate safety edits, drug-to-drug interactions, disease-to-drug interactions, and patient payment information related to out-of-pocket costs. This happens within milliseconds and is arguably the most efficient transaction in all of health care. Through the early 2000s PBMs gained in market share, but the business model was still simpler than today-they generally collected a fair and equitable per-claim transaction fee that was disclosed and understood by the payer. As PBMs grew in scale and brand drug inflation increased, they began to negotiate directly with pharmaceutical manufacturers on rebates for preferred placement on the PBMs' formularies. While this approach likely saved payers significant dollars initially, the dollars related to rebates became the lifeblood of every PBM. Additionally, PBMs created different definitions around what is considered a "rebate." There were new terms such as administrative fees, market basket fees, data aggregation fees, etc. With this development came a web of complex layers of rebate payment terms and definitions, which created an opaque matrix of financial terms that became impossible for any employer or government entity to truly understand or track.

These rebate payments, or as I like to say, "pharmaceutical revenue," were not enough for the PBMs in terms of what they needed to optimize revenue. The market shifted in an interesting and arguably suspicious direction by choosing consolidation over innovation. It is no secret to anyone on the committee that (1) around 70 percent to 80 percent of the PBM market share is controlled by three major organizations; (2) each of these has either been purchased by an insurance carrier or has purchased an insurance carrier themselves; and (3) the major PBMs also own dispensing assets for mail service and Specialty home delivery, and in certain circumstances a retail pharmacy chain. This "all-in-one" option has narrowed the marketplace and forced even more consolidation and fewer options for payers. I'll stop there and leave the issue in the capable hands of the Federal Trade Commission, which is presently reviewing these concerns.

Last and certainly not least is the fact that nearly all payers utilize what I can only characterize as a "less than ideal" pricing benchmark as the standard for all drug pricing in the United States. This pricing benchmark, known as Average Wholesale Price (AWP), was the primary source of a class action lawsuit that required one of the major publishers of AWP to stop production of the benchmark no later than September 2011. AWP is not related to the retail acquisition cost of a pharmaceutical product. There was hope in the market at the time that a new industry benchmark would emerge. Unfortunately, most PBMs migrated to another publishing index available on the market, and AWP survived.

However, in response to many State Medicaid plans, the Centers for Medicare and Medicaid Services (CMS) did something great and started the process of creating and establishing the National Average Drug Acquisition Cost (NADAC) index. This new benchmark was initially published in draft form in 2012. It is based on voluntary survey data from retail pharmacies that report their invoiced acquisition costs at the drug level to CMS. This is performed as frequently as weekly and is available on a free public website. It should be noted that AWP data, by comparison, is a subscription-based service, and anyone wishing to review and audit AWP may have to purchase a license to examine their own drug cost benchmark data.

Founded in 2017, Capital Rx set out to change the way drugs are priced and patients are cared for to create enduring social change. We are over 1 million members strong across payers, including employers, union trusts, municipalities, school districts, commercial health plans, Medicare, and managed Medicaid clients. As a proud member of our executive team, I can confidently say Capital Rx has both financially and clinically aligned interests with its clients. In fact, Capital Rx is the only full-service PBM serving all lines of business and one of the relatively few

health-care companies that have earned B Corp™ certification, to my knowledge. This is the ultimate testament to aligning the company's interests with the patient and committing to "being a force for good" for society.

Our pricing model abandons the traditional AWP model and utilizes NADAC as the primary pricing benchmark. We have a Single-Ledger model that aligns our "books"—the drug manufacturer and pharmacy side of the house always aligns with the accounting on the client side of the house. We do not retain rebates or "spread" from any pharmacy or manufacturer contract. We are paid a fair administrative fee which is disclosed in our client contracts and appears as a line item on every client invoice. In full transparency, we also receive disclosed fees for additional clinical services that we may provide to a client as well, but the point is that there's no gray area. Everyone can (1) see the price of the drug; and (2) clients don't have to question if all "other" revenue is passed through to them or they paid a fair price.

The best way to describe what we do is to give a real-life example to which everyone can relate. If you have a headache and go to a pharmacy to pick up an over-the-counter option to get some relief, you'll see quickly that your options—Tylenol, Advil, Aleve, the generic options—have a price on the shelf, and you know what you are going to pay when you go to the register. However, if you walk to the back of the store to pick up a prescription, you're spinning a roulette wheel and hoping for the best based on what you know about your benefits; or, if you're uninsured or underinsured, what you've read about the price online. You cannot see or know what you will have to pay for that medication. That's because of AWP and the aforementioned contract complexity. It doesn't have to be like that. Today's pricing framework does not empower the pharmacist to explain why a drug costs one amount one month and then costs something different the next month. We have all been conditioned that "this is how it is and has to be." It's simply not true.

In my opinion, the traditional PBMs have trained everyone to believe that drug pricing is unstable, but they are utilizing complex algorithms to minimize their contractual reimbursements to pharmacies while at the same time not sharing the "savings" from this reimbursement reduction with the patient or the payer. This spread pricing game must stop. And while Medicare specifically prohibits this practice, most commercial and some managed Medicaid contracts still allow it to continue. One solution is to use NADAC as a publicly available benchmark price as the source of truth for drug costs. Is it perfect? No. Is it fundamentally better than the AWP industry standard? Absolutely. Are there ways to make it even better? Again, absolutely.

My simple message is this: every drug should have a price that is available for all to see and creates equity, thereby improving access for all Americans. It should be reported by all pharmacies, including retail, mail, and specialty home delivery, so patients and payers have day-to-day transparency on drug costs.

I'll leave you with a final message. I have worked my entire career to drive transparency into the pharmacy supply chain. We are at a pivotal moment in history where we can finally change what is broken and bring rational drug-level pricing to the American people. The fix is simple because the mechanisms are in place to allow both sides of the transaction—anywhere in the U.S.—to see the price of a drug.

Thank you, Chairman Wyden, Ranking Member Crapo, and this committee, for your time on this crucial issue.

QUESTIONS SUBMITTED FOR THE RECORD TO MATTHEW GIBBS, PHARM.D.

QUESTIONS SUBMITTED BY HON. RON WYDEN

Question. What specific data and information should PBMs share with their health plan clients in order to mitigate possible conflicts of interest?

Answer. Capital Rx believes that the Consolidated Appropriations Act (CAA) made great strides in increasing transparency in the PBM market by mandating certain information be shared with plan sponsors and ultimately the Centers for Medicare and Medicaid Services (CMS) and Department of Labor (DOL) as well. In so doing, prescription drug data collection (RxDC) allows CMS and other regulatory agencies to identify potential sources of administrative inefficiencies. As such, CAA promotes mitigating potential conflicts of interest in the market. Further, Capital

Rx anticipates that CAA will allow plan sponsors to begin making better-informed, and more cost-effective purchasing decisions.

Our organization posits expanding RxDC reporting elements will further drive market alignment. We believe that true transparency in the form of mandated disclosure of the following data elements will allow lawmakers and regulators to meaningfully analyze the state of the current PBM market:

- PBM profit per prescription dispensed by PBM-owned assets at mail order, specialty home delivery, and retail chain pharmacies.
- PBM retained rebates and other revenue received from manufacturers either directly, or through affiliated Group Purchasing Organizations (GPOs), and rebate aggregation partners.
- Revenue retained by brokerage firms as part of the procurement process for plan sponsors. Currently, part of section 202 of CAA however, we recommend that section 202 be expanded to include PBMs.

As an extension of the above point, we believe that better plan oversight is paramount in mitigating conflicts of interest. We also encourage the adoption of more robust health plan procurement standards to ensure financial alignment and mitigate conflicts of interest.

Question. Please detail the strengths and weaknesses of the National Average Drug Acquisition Cost (NADAC) benchmark. How could NADAC be enhanced?

Answer. Below please find an assessment of the strengths and weaknesses of NADAC, as experienced through Capital Rx's use of NADAC for our full book of business. Most proposed enhancements, also noted below, focus on increasing participation in the CMS survey model.

STRENGTHS OF NADAC

Capital Rx's position is to remain conflict-free in setting pricing benchmarks to protect our model's integrity and provide a fully aligned arrangement to plan sponsors. First published in draft form in 2012, NADAC has proven to be an effective pricing benchmark for fee-for-service Medicaid plans. Moreover, NADAC is the closest national drug pricing benchmark that calculates the true average acquisition cost for retail pharmacies to purchase a medication. Provided at the NDC–11 level, all drugs reported to CMS under NADAC have an established retail price. Capital Rx chose NADAC because it is the market's least conflicted option available today.

In contrast, Average Wholesale Price (AWP) is derived from a calculation of Wholesale Acquisition Cost (WAC) and is not generally related to the actual "cost" of a medication across the supply chain. According to a study Capital Rx developed in partnership with 3 Axis Advisors in 2020, NADAC prices for generic drugs deflated by 44 percent, while the AWP price index inflated by 1 percent. This study analyzed price fluctuations from 2015 to 2020 for the top 1,200 generic drugs in our 2019 book of business.

By using NADAC, Capital Rx's Single-Ledger model:

- Eliminates easily manipulated annual guarantees based on average AWP discounts and Maximum Allowable Cost (MAC) lists.
- Establishes a single, accurate price for nearly all NDCs, pegged to acquisition costs.
- Eliminates price variability across employer contracts.
- Eliminates price volatility for patients at the point of sale.
- Provides fair reimbursement to pharmacies.
- Empowers patients to understand drug prices and make informed health-care decisions.
- Allows Capital Rx to focus on improving plan performance and patient outcomes.

WEAKNESSES OF NADAC

NADAC is published through a CMS-administered survey, and acquisition cost is voluntarily self-reported by some pharmacies. Independent pharmacies and smaller chains most often respond to NADAC surveys. As such, larger pharmacies and chains typically prefer not to share certain information and rarely, if ever, fill out NADAC surveys.

Furthermore, NADAC represents an estimated "blended average" of actual drug costs, not a precise measure at the chain level. As such, a handful of drugs do not have an assigned NADAC price (usually <1 percent of a typical client's utilization).

In such cases, PBMs like Capital Rx, who primarily use NADAC, must rely upon AWP for the subset of drugs without a NADAC price.

ENHANCEMENTS TO THE NADAC SURVEY

Given the weaknesses noted above, there are several areas where NADAC could be improved. We suggest the following:

- Mandate all retail pharmacies who participate in Medicare/Medicaid programs to respond to the NADAC survey when requested by CMS.[1]
- Mandatory reporting by all mail service pharmacies to create a separate NADAC-mail index average.
- Mandatory reporting by all specialty home delivery pharmacies to create a separate NADAC-specialty drug index average.
- Inclusion of "off invoice" discounts as part of the net cost invoice submission for NADAC reporting across all dispensing channels.

QUESTIONS SUBMITTED BY HON. JOHN CORNYN

Question. Can you share some details about the way your current PBM is structured, and how you think this can be implemented in the market more broadly? Are these solutions scalable?

Answer. The following paragraphs describe the main differentiators of Capital Rx's business model. To preface our description, it is important for the committee to understand that as a health-care technology company, our success and the scalability of our model is partly dependent upon our next-generation technical solution, JUDI. Through an investment of over $100 million in our platform, JUDI delivers unequaled scale at the highest standard of operational efficiency currently available in the industry. To put this in perspective, JUDI can process all the prescription claim transactions in the U.S. each year, with no change to our existing architecture or infrastructure. In comparison, legacy PBMs continue to utilize platforms which are inefficient and inflexible.

JUDI, coupled with our Single-Ledger model, aligns the financial interest of the PBM with its clients. We have been able to scale our business and allocate our resources to critical aspects of the supply chain—thereby lowering costs for plan sponsors and patients while advancing best-in-class clinical outcomes and driving high patient and plan sponsor satisfaction.

Capital Rx's position is that competitors can adopt modern technology and reinforce financial alignment to streamline manual processes and reduce overall operational costs, thereby passing said savings through to plan sponsors and their patients.

CAPITAL RX IS FINANCIALLY ALIGNED WITH PLAN SPONSORS AND PATIENTS

Beyond our commitment to passing through 100 percent of all received rebate revenue, Capital Rx takes the mystery out of prescription drug pricing. The result is a fairer, fully aligned system with the ability to deliver untapped value from the supply chain by ensuring everyone knows exactly what they are getting and what it costs:

- We remain agnostic and allow patients to fill prescriptions at any pharmacy in good standing. This allows Capital Rx to serve as a truly objective strategic partner to our clients. Free from this conflict of interest, we focus on the things that matter—providing exemplary service, reducing costs, and improving the health and well-being of our patients.
- Capital Rx operates using a Single-Ledger model and passes 100 percent of manufacturer revenue to our clients. We do not believe drug pricing is proprietary, and all patients should be able to freely access and receive the lowest prescription price available. Because we do not look to retain any rebates, or other manufacturer-derived revenue, we are free from any conflict and are able to apply formulary management strategies that drive the most cost-effective, clinically appropriate therapies to manage the patients' health.

[1] This type of requirement is similar to Medicaid requirements imposed on pharmaceutical manufacturers that participate in the Medicaid program and are required to participate in the 340B program.

- We do not inflate or manipulate drug prices at retail, mail, and specialty fulfillment. The current prescription pricing system looks like drug prices change every hour, of every day, in every pharmacy. This artificial pricing volatility is fiction, and unfortunately creates a system of winners and losers in the U.S. health-care system. Our Single-Ledger model ensures every patient receives the same low price for each drug.

As such, we remain agile and unconflicted to support a framework that focuses on cost-reduction strategies supported by advanced data and analytics, improving patient outcomes and service excellence.

CAPITAL RX IS DRIVEN BY OUR MISSION

Capital Rx's mission is to change the way prescriptions are priced and patients are cared for to create enduring social change. Each individual of our company—from our CEO to our employees caring for patients each and every day—is invested in this mission. By transforming the conventional relationship between plan sponsors and PBMs, we are leading the path toward reducing prescription drug costs with greater efficiency and simplicity.

CAPITAL RX IS COMMITTED TO CLIENT SATISFACTION

As a core aspect of our client services model, we prioritize speed and efficiency. We provide front-line clinical expertise, and each account executive is a registered pharmacist. We find this model improves efficiency, strengthens relationships, and yields a superior, clinically focused experience. Our client services culture emphasizes cross-functional collaboration, ensuring clear lines of communication that prevent delays and avoidable errors.

From our state-of-the-art technology to our experienced and innovative staff, Capital Rx's comprehensive suite of PBM services delivers a new paradigm of service excellence, operational efficiency, cost savings, and the highest standards of clinical care. Our approach to client service is a key reason we have earned an unprecedented Net Promoter Score (NPS) of 96, a measure of client satisfaction.

CAPITAL RX HAS RECEIVED INDUSTRY-LEADING PATIENT SATISFACTION RATINGS

Capital Rx treats pharmacy benefits as an investment, encouraging a holistic view of health care that focuses on achieving the highest level of patient care. Capital Rx's Customer Care Center employs representatives with distinct subject matter expertise who work to understand each client's clinical requirements and recognize, appreciate, and respect pharmacy, provider, and patient concerns.

In 2022, Capital Rx was presented with a Bronze Stevie® Award in the Customer Service Department of the Year—Healthcare, Pharmaceuticals, and Related Industries category at the 16th Annual Stevie Awards for Sales and Customer Service. The Stevie Awards for Sales and Customer Service are the world's top honors for customer service.

Our approach to patient care is why we have earned a current overall satisfaction rating of 99 percent on post-call customer satisfaction surveys.

CAPITAL RX USES NEXT-GENERATION TECHNOLOGY TO DRIVE EFFICIENCIES AND IMPROVE THE PATIENT EXPERIENCE

JUDI unifies all pharmacy operations within one ecosystem. Through the use of a fully serverless architecture, JUDI allows for unprecedented scalability, instant rightsizing, and the unique capability to handle clients of any size. In fact, one instance of JUDI can process 3.6 billion claims per year. Our cloud-based architecture provides limitless scale for Capital Rx to efficiently handle all the prescription transactions in the U.S., at a fractional cost.

JUDI underlies our success in the industry—and enables a level of efficiency never thought possible in health-care management. For example, while it takes other PBMs 30–45 hours to implement a plan design change, JUDI is able to make plan design changes in under 5 minutes.

CAPITAL RX IS AGNOSTIC TO DRUG DISPENSING

Since our only source of revenue is a flat administrative fee and fully disclosed ancillary administrative fees, we have no financial interest in where a prescription is filled. We believe a PBM should focus on the administration of the pharmacy program, not the fulfillment of prescriptions.

This approach allows Capital Rx to focus on meeting our clients' unique needs, benefit designs, and pricing arrangements as they relate to the administration and adjudication of claims.

Question. You specifically call out spread pricing as a practice that should be prohibited, but are there other practices that you would like to expand on that you think are detrimental to the currently pharmaceutical supply chain structure?

Answer. Other than combating spread pricing practices, we believe the following common industry practices create opacity in the current supply chain:

- Alignment with the Plan Sponsor: PBMs have an incredible responsibility as the administrators of pharmacy benefit plans. Among the hundreds of tasks required to run a prescription benefit plan, a PBM develops client specific formularies (access to specific drugs), conducts clinical review (patient safety), and authorization (approval of high-cost medication). Unfortunately, there is an inherent conflict of interest when a PBM utilizes a spread-pricing model. Under a spread-pricing model, the more expensive the drug, the more money a PBM makes. Furthermore, the higher the price of a medication rises (inflation), spread pricing yields greater revenue. Why else would traditional PBMs (that use spread pricing) prefer high rebate yield drugs on formularies, maintain abnormally high approval rates on costly medication, and rarely intervene when a patient is not responding to an expensive medication.

  Quite simply, if a PBM does not make money on drugs (spread pricing), the PBM is no longer conflicted and can consider lower-priced medications, focus on patient outcomes, and adjust treatment plans without financial consideration. To fix this problem a PBM (including the parent organization and all affiliates) should not be allowed to make money on drug spend. If a company wants to make money on drug spend, the company should be a manufacturer, wholesaler, or pharmacy. However, if a company wants to administrate a pharmacy benefit plan on behalf of an employer or a government entity, it should be prohibited from making money on drug spend (spread pricing).

- Data Sharing: As consolidation has been the primary growth driver in the PBM marketplace, there have also been major restrictions placed on payer data. For payers who utilize different medical and PBM administrators there are often obstacles created by vertically integrated organizations and several large regional health plans, that restrict or financially penalize the sharing of critical plan/patient data. The data is utilized for payers who have integrated deductibles or use a High Deductible Health Plan (HDHP) option for their employees/members. Not having access to this plan/patient data forces payers to continue using a limited number of PBM and health plan providers. Payer data should be exchanged among all PBMs and health plans in a unified format and at no cost to the end payer. Capital Rx built JUDI with an open API architecture, which enables payers to efficiently access and securely share data without any restrictions.

QUESTIONS SUBMITTED BY HON. TIM SCOTT

Question. I have seen a lot of information regarding the gross-to-net bubble, the difference between a drug's list price and net price, which can be quite sizeable when there are rebates paid by the manufacturer. Reporting from many sources, including KPMG, Drug Channels, and others, share that discounts from manufacturers are often higher than 50 percent in Part D. Yet, patients who purchase those medicines do not share in those rebates. The PBM business model today has evolved to a point where they are now often owned by or own an insurer, a large pharmacy chain, or both.

Can you discuss some of the innovative PBM models that are springing up to address some of the pain points of the legacy market using free market principals?

Answer. First, Capital Rx would posit that the current PBM market does not adhere to free market principles. Artificial drug pricing—one set of prices for pharmacy reimbursement and another set of prices for each plan sponsor is flawed and allows PBMs to manipulate the price of each prescription. In most other markets, clear prices for goods and services are freely exchanged, which encourages competition and allows consumers to make informed decisions. As such, Capital Rx's Single-Ledger model solves two fundamental problems with the pharmaceutical supply

chain and the traditional PBM model by leveraging a single drug price for plan sponsors, the PBM, and pharmacies.

Second, it is clear that the PBM industry, in general, needs to focus on modernizing the way in which basic tasks are performed. Most infrastructure utilized by PBMs is 20–30 years old. Literally hundreds of human capital-intensive tasks associated with administering pharmacy benefits are performed using human capital-intensive, manual processes.

Moreover, our recently developed Enterprise Pharmacy Platform, JUDI, helps our clients—including those focused on Medicare and Medicaid populations—understand what's happening with their pharmacy programs in real time. The level of transparency and visibility allows health plans, for example, to better project costs. Ultimately, innovation through technological enhancements will need to happen to decrease costs for plan sponsors and patients in the United States.

Third, we would argue that traditional PBMs which own mail and specialty home delivery assets deploy specific channel steerage campaigns and pricing strategies to maximize their earnings while at the same time limiting patient choice and potentially increasing cost.

Question. Where in the process can PBMs provide additional meaningful data and transparency to understand how manufacturer rebates are calculated and impact the cost of drugs for patients in addition to utilization management requirements which may interfere with patients receiving the optimal treatment selected in consultation with their physicians?

Answer. Conventional PBMs enforce weak utilization management criteria for a subset of high-cost drugs and thus have recorded higher prior authorization approval ratings. We would encourage the committee to analyze whether negotiated utilization management criteria drives higher rebate yield or whether a pure low net cost, access-based rebate approach with more stringent utilization management criteria would decrease costs for plan sponsors and patients.

Capital Rx does not make money from the dispensing of high-cost drugs and, as such, our clinical teams freely make prior authorization (PA) decisions unbiased by the financial implications for Capital Rx. To date, we have witnessed PA approval rates well below industry averages, and we believe this has significantly decreased drug spend for plan sponsors while ensuring that patients are receiving clinically appropriate medications. While Capital Rx's approval rates for these expensive medications is lower than the traditional market leading PBMs, our member satisfaction remains at 99 percent, given the fact we utilize pharmacists in every review and consult for critical medications which require a PA. Having clinician to clinician consultants on these critical medications is not the industry norm and is often the source of patient and client frustration regarding medication access. Capital Rx's clinical team guides each PA through a white-glove process and engages the prescriber with viable alternatives or appropriate first line therapies which are often more affordable for the member and less costly for the payer.

Capital Rx would also recommend that the Finance Committee review the latest submissions tied to the Consolidated Appropriations Act (CAA) section 204 and review the "spread" margin being retained by PBMs as well as any pharmaceutical manufacturer revenue retained by a PBM from its clients.

PREPARED STATEMENT OF JONATHAN E. LEVITT, CO-FOUNDING PARTNER, FRIER LEVITT ATTORNEYS AT LAW

Chairman Wyden, Ranking Member Crapo, and members of the Senate Committee on Finance, thank you for inviting me to testify today regarding the role of pharmacy benefit managers in the drug supply chain and their impact on taxpayers, patients, and other stakeholders.

My name is Jonathan Levitt. I'm not an economist or an academic. I am a trial lawyer in the trenches within the drug space, and founder of a healthcare and life sciences law firm called Frier Levitt. We represent stakeholders in the drug supply chain, including manufacturers, distributors, associations of providers, like community oncologists, but, most relevant to this hearing, we serve independent specialty pharmacies and retail pharmacies. I've been studying pharmacy benefit managers for over 20 years.

We thank the U.S. Senate Committee on Finance for holding this important hearing.

Testimony Summary:

The actions of the largest six pharmacy benefit managers (PBMs)—that is six PBMs that control 96 percent of the Nation's prescription drug market—have adversely impacted all stakeholders in the drug supply chain, including patients, pharmacy providers, plan sponsors, and taxpayers. Interested individuals and entities looking to faithfully serve governmental programs such as Medicare and Medicaid (and private plans) are at the mercy of PBMs and their vertically integrated healthcare conglomerates.

The Centers for Medicare and Medicaid Services (CMS) have outsourced the drug benefit to private PBMs, who have proven unable to responsibly wield that massive industry power. Governmental programs are only recently awakening to PBMs financial manipulation.

PBM-imposed direct and indirect remuneration (DIR) fees force our sickest beneficiaries to pay artificially inflated copay and coinsurance. Specialty pharmacies, often accredited in specialty disease states to improve patient outcomes, face lower reimbursement rates and higher DIR fees. PBMs force manufacturers to raise their list price, in exchange for formulary placement. Drug manufacturers and distributors fear retaliation by vertically integrated PBMs that own our country's largest chain and specialty pharmacies and are manufacturers' largest customers, the largest purchasers of the manufacturers' drugs. The result is that PBM-owned pharmacies have a materially lower acquisition cost on the "buy side" and better reimbursement rates on the "sell side" when paid by their sister PBMs.

Even PBMs theoretically competing with one another cut each other special deals. Independent pharmacies are then forced to pay higher acquisition costs while PBMs simultaneously reduce reimbursement rates and then acquire the independent pharmacies causing further consolidation.

Public scrutiny of PBMs is in its infancy while the PBMs' tactics have been developed over several years. Previously left entirely unchecked, PBMs have designed a system where most disputes are "resolved" in complete secrecy, cloaked behind gag clauses, confidentiality agreements, and private arbitrations. In other instances, PBMs avoid such disputes altogether through actual or threatened retaliation.

PBMs' tactics are driving independent pharmacies out of business, creating pharmacy "deserts," especially in rural areas; fueling list drug prices higher for all Americans; and delaying and denying treatment for the sickest Americans, those with cancer and other serious diseases. These are only a few of PBMs' adverse impacts.

Today, I implore the committee to end this era of the large PBM stranglehold on the nation's healthcare system.

Detailed Testimony:

Pharmacy benefit managers or PBMs claim to lower the price of drugs for consumers, taxpayers, large employer groups, and governmental programs. But these claims are not supported by unbiased empirical evidence and do not hold up when scrutinized. In fact, such scrutiny is aggressively and effectively suppressed by PBMs. Medicare's Part D Program is estimated to cost $119 billion in 2023. While CMS has sought to form a public-private partnership between the Medicare Part D program and Part D Plan Sponsors, CMS and such Part D Plan Sponsors have outsourced the Medicare Part D Program to privately owned largely unchecked PBMs who have amassed sister companies that profit from every angle of the Medicare Program. PBMs utilize oppressive tactics, such as direct and indirect remuneration—or DIR fees—to retroactively reduce pharmacy providers' reimbursement rates, often times, below actual acquisition costs for such drugs meaning that every time the provider dispenses the drug, they take a loss. We know only through litigation that CMS has not evaluated the methodology PBMs use to judge patient medication adherence, which is the largest segment that determines the pharmacy's oppressive DIR fee rate. Victims of PBMs' conduct include the United States Government; Tricare and our military; specialty pharmacies; retail pharmacies; oncology groups that dispense drugs to cancer patients; and most importantly, numerous Americans: the consumer, the taxpayer, and most importantly, the patient.

PBMs are directly—not theoretically—responsible for the increased list price of drugs. I testify today with the hopes of reframing the narrative. Drug manufacturers save lives. Of course, drug manufacturers are in the business to make money

and have responsibility in setting drug prices. However, the gap between drug list prices and actual net prices are due to PBMs' specific actions. PBMs, through their secret sister companies, siphon a huge percentage of the list price of drugs as profits to CVS Health, Cigna and UnitedHealth, all of whom own little known companies called "rebate aggregators." Often you won't find PBMs' rebate aggregators in the United States. This is true for Cigna and UnitedHealth; Cigna owns Express Scripts, one of the big three PBMs, and also owns Ascent Health Services—its rebate aggregator, which is located in Switzerland. UnitedHealth owns a PBM called OptumRx and also a rebate aggregator called Emisar Pharma Services, located in Ireland. CVS Health owns a PBM called CVS Caremark, and a rebate aggregator called Zinc.

Consider the case of a manufacturer of oncology drugs that wants to get their life-saving cancer therapy into the hands of oncologists and the oncologists' patients. How does the manufacturer accomplish that? The manufacturer must pay tribute to the PBM-owned rebate aggregator to get the drug placed onto a list of drugs that the PBM makes available to government programs, large employer groups, and of course to patients. This list is called a drug formulary.

On the topic of drug rebates, a staggering percentage of our nation's drug spend is retained by these vertically integrated companies. Manufacturers pay rebates and believe, wrongly, that the full rebate is passed along to the plan sponsor. Manufacturers fear auditing PBM-owned rebate aggregators. After all, PBM-owned chains and specialty pharmacies are the largest buyers of the manufacturer's drugs. PBMs decide which drugs get on formulary, which drugs will have "higher tier copay" or "step therapy" or prior authorization and whether pharmacies will profit or lose money when dispensing drugs. These processes are an artifice and merely a PBM tool to extract rebates. PBMs wield this power to gain unfair advantages for each of their vertically integrated companies. PBMs frequently make decisions about which drugs will be on a specific formulary not based upon the efficacy of the drug, but based upon how much of a rebate can be negotiated and retained by the PBM.

The 340B program has come under substantial public scrutiny. But few realize that PBMs have drained the system of a huge percentage of benefit intended for patients and communities in need. Congress never intended the 340B program to benefit large for-profit corporations that provide little, if any, direct patient care for vulnerable populations. Furthermore, PBMs siphon money from the 340B drug program by improperly assessing DIR fees imposed on 340B prescriptions filled by independent pharmacy providers, by exacting huge fees from covered entities. PBM-owned pharmacies act as contract pharmacies, by imposing huge percentage-based administrative fees when PBM-owned third party administrators reconcile 340B claims on behalf of covered entities, and by paying pharmacies substantially less for 340B claims for no reason other than to retain profits which is money intended for the underserved.

Rebate aggregators invite manufacturers to attend meetings to discuss rebates, and manufacturers must bring their checkbooks. But when rebates lead to higher "list price of drugs," it's the patient, big employer groups, and Federal and State governments that ultimately pay the bill. In case you are wondering, all rebates are not fully passed through to the plans.

Rebate aggregators tell manufacturers the following. The first thing you must know is that you are going to pay a non-negotiable administrative fee and data fee that equals 5 percent. To put that in perspective, the United States total spend on retail drugs was $420 billion before rebates, with $301 billion dollars spent on specialty drugs. That 5 percent combined administrative and data fee is likely close to $20 billion. I want to emphasize how substantial in scope that 5 percent administrative fee is, in the context of the specialty drug marketplace. That PBM fee and income does not even include the portion of the drug rebate *not* passed along to plan sponsors. Consequently, manufacturers must constantly increase the list price of drugs to maintain the same margin.

The 5-percent administrative and data fee must also be analyzed in the context of patient care. Specialty pharmacies are critical providers that serve our Nation's sickest patients. They do so on margins that are often less than 5 percent. In other words, PBM rebate aggregators make far more money than our Nation's providers who actually do the clinical work to serve our sickest patients. That is perverse. Incredibly, CVS Health's "Caremark Specialty Pharmacy" controls nearly 30 percent of all specialty drugs dispensed in the United States. Express Scripts and UnitedHealth's specialty pharmacies control another 23 percent and 14 percent respectively. That is not because of PBM-owned specialty pharmacies' clinical superi-

ority, or patient choice. It's because of vertical integration and anticompetitive behavior.

I mentioned that I am a trial attorney and as a trial attorney, I get to take depositions where PBM executives and insurance company executives testify under oath. The transcripts of the testimony are sealed by PBMs. I know answers to many questions you want to explore today from the litigations and arbitrations I've handled, that are all subject to confidentiality agreements. I get to ask questions like, "What do you do with the $12.6 billion in DIR fees you collect from pharmacies? Do you send any of the $12.6 billion annual DIR fee revenue to CMS? Do you use any of that $12.6 billion to enhance the care of Medicare beneficiaries? You say that DIR fees are based on the pharmacies' performance—how do you measure adherence to specialty drugs like oncology drugs?" The answers to these questions are often staggering.

Today, I am asking the committee to consider whether it is healthy for PBMs to mandate highly confidential arbitrations. To impose strict confidentiality requirements under the threat of a lawsuit for a breach. And to prohibit class actions. These are the tools used by PBMs to keep this information from the American people. PBMs operate in the dark; they hate the light of transparency.

When making their mandatory filings with the Securities and Exchange Commission (SEC), these companies do not disclose the profits or revenues generated by their rebate aggregator subsidiaries or through spread pricing. The SEC needs to compel better insurance company revenue reporting. These insurance companies should break out their revenue and profitability on rebates and spread pricing for drugs.

The pharmacies from whom PBMs extract $12.6 billion annually in DIR fees are trying to stay in business, but they are also victims. PBMs will say that DIR fees lower Medicare beneficiaries' premiums. For beneficiaries that do not use their drug benefit, who are not on any prescription medications, a lower premium is indeed better. But most beneficiaries use the drug benefit, and 75% of Medicare beneficiaries worry about copay, coinsurance, and deductible. Low premiums are outweighed by higher copay. Many Americans have dreadful diseases like cancer, multiple sclerosis, and hepatitis and these Medicare beneficiaries use their drug benefit and pay copays. Consumers, as they are experiencing financial stress, are unaware that they are paying a copay based on a false list price of the drug. Consumers do not know that after they paid their copay, the PBM later recouped $12.6 billion in DIR fees. How much would the copay of Medicare beneficiaries have been reduced if there were no DIR fees?

More than 50 percent of DIR fees are paid by specialty pharmacies. PBMs say they recoup DIR fees based on the specialty pharmacies' performance. But PBMs do not publicly reveal their methodology. I have deposed PBM executives and once we learn the details in discovery it becomes clear PBMs measure performance dreadfully, and likely intentionally, wrong. Retail and specialty pharmacies are victims of PBM methodology that pays DIR fees based on these incorrect practices.

If PBMs continue to be left unchecked, the post-DIR fee world gets worse, not better. In May 2022 CMS released a Final Rule reinterpreting the term "Negotiated Prices." The real impact of the Final Rule essentially eliminates the profitability that Part D Plans and PBMs enjoyed arising from pharmacy DIR fees. To make up for that lost DIR profit, Part D Plans and PBMs have already started to amend contracts to remove DIR fees and reimburse pharmacies at drastically lower rates to retain their prior profitability. Some 2024 reimbursement rates have become public. In 2024 Express Scripts will reimburse brand medications at a standard benchmark of 26.3 percent off average wholesale price or AWP-26.3%. Our research shows that virtually no pharmacies, other than PBM-owned pharmacies, can acquire brand drugs at costs at or lower than Express Scripts' new rate. If Express Scripts can get away with paying only AWP-26.3%, often more than 3 percent less than the previous year's rates, other PBMs will follow. The result of reimbursement below drug acquisition costs will put independent pharmacies, and particularly pharmacies dispensing predominantly brand drugs (such as specialty pharmacies) out of business. These issues must be addressed before these dire predictions become reality.

I have attached a comprehensive expose that my firm prepared on PBM abuses as well as supplemental input for the Senate Committee on Finance. Thank you for listening to me, and to the needs of the American people. I am happy to answer any questions you may have.

SUBMISSION TO THE U.S. SENATE COMMITTEE ON FINANCE

How Pharmacy Benefit Managers Adversely Impact Patients, Taxpayers, and Other Medicare Stakeholders

Contributors: Jonathan Levitt, A.J. Barbarito, Steven Bennet, Harini Bupathi, Christopher Caltavuturo, Jesse Dresser, Adam Farkas, Dae Lee, Conor McCabe, Todd Mizeski, and Lucas Morgan

March 30, 2023

I. Executive Summary

Pharmacy Benefit Managers (PBMs) use their marketplace dominance to profit at the expense of nearly every other Medicare and Medicaid stakeholder, including Medicare beneficiaries, taxpayers, pharmacies, manufacturers, and distributors. Frier Levitt has advocated for reasonable oversight of highly vertically integrated healthcare conglomerates. When a single corporate entity combines an insurance company, PBM, chain pharmacy, specialty pharmacy, rebate aggregator, and healthcare providers under one giant corporate umbrella, it wields immense power that cannot be responsibly managed. PBMs are becoming more adept at extracting and siphoning profits from all other stakeholders. Frier Levitt hopes to provide the United States Senate Committee on Finance with more information on PBMs' impact on Medicare and Medicaid stakeholders.

Based on the information detailed below, Frier Levitt recommends that the Senate Committee on Finance take steps to:

(1) Rectify unreasonable reimbursement terms that PBMs pay to retail and specialty pharmacies and investigate discriminatory pricing in favor of PBM affiliated pharmacies. The Committee should comprehensively study PBMs' contract terms and reimbursement rates that PBMs unilaterally impose on providers. The Committee should also develop standards for reasonable contracting terms and reimbursement rates and instruct the Centers for Medicare and Medicaid Services (CMS) to establish enforcement measures where existing regulations are sufficient and implement new rules where existing regulations are insufficient. Today, we are calling for the Committee to consider whether the reimbursement rates PBMs pay to specialty pharmacies should take into account that PDPs are paid more to manage sicker beneficiaries, resulting in a reimbursement to specialty pharmacies that recognizes their important role.

(2) Bring PBMs into compliance with applicable laws including Medicare's Any Willing Provider Law. PBMs have ignored key laws such as Medicare's Any Willing Provider Law, having taken the written position in confidential sealed briefs that the laws do not apply to PBMs, or to narrowly interpreted such laws to the detriment of pharmacy providers. CMS should provide clarity on existing Medicare reimbursement rate guidance[1] and Congress should take steps to amend laws to correct for PBM abuses.

(3) Reduce the negative impact of vertical integration in the healthcare marketplace. The government should investigate the impact of consolidation, regulate these conglomerates, and enforce the law to offset the negative impact of these organizations.

II. The Big Picture: Understanding the Impact of PBMs on Medicare and Medicaid Stakeholders

A. The Pharmacy Benefits Landscape

The current system of coverage and reimbursement for drug products within the United States is complex and opaque. The profit PBMs earn on spread pricing when they pay pharmacy providers and the amount of profit PBMs earn on rebates demanded from manufacturers remains unknown. The costs, extent of coverage, reimbursement rates, out-of-pocket amounts and applicable rights may vary substantially depending on the payor, the state, the type of drug, the method of administration, the site of service and the site of care. To sift through this morass, we begin by understanding the relevant stakeholders, as well as their respective roles in benefits design and the provision of care.

[1] *E.g.,* Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50.3.

- **Plan Sponsors:** Plan sponsors are the ultimate financial guarantors and decision makers when it comes to creating a health care benefits plan. Plan sponsors include a variety of public programs, such as Medicare, Medicaid, and TRICARE programs, as well as private entities, including employers, union groups, and retirement funds. Plan sponsors, in turn, contract with several other entities for the purposes of administering the plan. In the context of Medicare Part D, the Federal government (through CMS) is arguably the plan sponsor, as it contracts with and provides subsidies to private Part D Plan Sponsors, known as Prescription Drug Plans (PDPs) to offer prescription drug plans. CMS outsources the management of Medicare to private PDPs, who retain PBMs to manage the drug benefit. In addition, when patients exceed the catastrophic coverage threshold, CMS provides reinsurance coverage to these plans. In the context of Medicaid programs, the state Medicaid agencies are generally considered the plan sponsors, as they contract with Medicaid managed care organizations or PBMs directly to administer pharmacy benefit plans and provide direct and indirect financial subsidies and funding for such programs. In the private marketplace, large employer groups are also plan sponsors.
- **Health Insurance Companies:** Health insurance companies create and operate healthcare plans, managing healthcare claims submitted by providers for care provided to patients who are employees, beneficiaries and/or members of the plan, or their dependents. Health insurance companies are private companies, and can operate in several ways, including as a licensed health insurer, a managed care organization (MCO), or a health maintenance organization (HMO). In the context of Medicare Part D, health insurance companies are Part D Plan Sponsors (PDPs), which are state-licensed insurance companies that offer Medicare Part D prescription drug plans to Medicare beneficiaries, and who have entered into a contract with CMS to provide prescription drug coverage to Medicare beneficiaries. In the context of Medicaid, health insurance companies are private state-licensed insurance companies and MCOs who have contracted with state Medicaid agencies to provide healthcare services to Medicaid beneficiaries.
- **Pharmacy Benefit Managers (PBMs):** PBMs are third-party administrators of prescription drug programs covered by a plan sponsor. The PBM is primarily responsible for processing and paying prescription drug claims submitted by participating providers on behalf of covered patients. PBMs also provide bundled services related to the administration of pharmaceutical benefits, including formulary design, formulary management, negotiation of branded drug rebates, and controlling network access of participating pharmacies. Although plan sponsors may occasionally engage PBMs directly, in many cases, health insurance companies procure PBMs' services on behalf of plan sponsors. This is also true for Medicare Part D and Medicaid, where the responsibility of contracting with PBMs falls on the Part D Plan Sponsor and/or Medicaid MCO.
- **Rebate Aggregators:** Also known as rebate group purchasing organizations (GPOs), rebate aggregators negotiate and collect rebates from manufacturers on behalf of their members, who include one or more PBMs. While rebate aggregators may pass some portion of the rebates collected to their members, rebate aggregators may also retain a portion of the rebate, which is not always readily known.
- **Pharmacy Providers:** On the frontline of providing care, pharmacy providers include retail, specialty, health-system and mail-order pharmacies, and dispensing physician practices. Pharmacy providers contract with PBMs to dispense medications to plan members and participate in PBM networks.
- **Prescribers:** Prescribers include licensed healthcare professionals, such as doctors and nurse practitioners, who are authorized to prescribe medication to patients. Prescribers work with pharmacy providers to ensure that patients receive the medication they need.
- **Patients:** Patients include beneficiaries of government-sponsored health care programs, as well as the employees (and dependents) of employers sponsoring health plans. They are also uninsured or underinsured individuals who are left to find a way to cover drug costs themselves. In the context of Medicare Part D, eligible patients (*i.e.,* individuals who are 65 years of age or older, individuals with certain disabilities, etc.) select a Part D Plan and pay premiums to receive prescription drug coverage. In the context of Medicaid programs, patients who are Medicaid-eligible (*i.e.,* low-income individuals and families, individuals with disabilities, etc.) select and enroll in Medicaid managed care plans

administered by MCOs or enroll directly in a fee-for-service program administered by the State Medicaid agency.

- **Manufacturers:** Manufacturers include both brand manufacturers, who develop and produce innovative prescription drugs and biologics, or generic manufacturers, who produce medications that are equivalent to brand-name medications in terms of active ingredients, dosage, strength, quality, and intended use. Manufacturers negotiate drug prices with PBMs and are forced to pay PBMs administrative fees, data fees and rebates in order to get their drugs on formularies and promote their drugs to prescribers and patients.
- **Wholesalers:** Wholesalers are companies that purchase prescription drugs in bulk from pharmaceutical manufacturers and distribute them to pharmacies, hospitals, and other healthcare providers.

Each of these stakeholders plays a different and unique role in the drug delivery process. Historically, each stakeholder has operated separate but interconnected entities, working together to provide different aspects of patient care. However, as discussed below, horizontal and vertical integration has eroded many of the checks and balances, particularly in the Medicare Part D context, and has allowed a small cadre of multibillion dollar companies to control all the levers of decision-making around drug benefits, reimbursement rates, provider access and plan benefits design. Unfortunately, because of conflicts of interest, patients, manufacturers and plan sponsors have been harmed as PBM corporate profits have soared at the expense of healthy competition.

B. Vertical Integration Stifles Competition and Limits Patient Choice

PBMs traditionally have played a critical role in the administration of prescription drug programs. However, over the past ten years, the PBM marketplace has transformed considerably. Changes include both horizontal and vertical integration among health insurance companies, PBMs, chain pharmacies, specialty pharmacies, rebate aggregators, long-term care pharmacies and more recently healthcare providers. As a result, a smaller number of large companies wield nearly limitless power and influence over the prescription drug market.

Within the PBM marketplace, over 80% of the covered lives are controlled by only three PBMs.[2] As a result, of this increasing concentration (the same PBMs made up 75% of the market concentration just three years prior[3]), a pharmacy's access to these three PBM networks is critical.[4] Being out of network with just one PBM (which in some regions, could make up more than 85% of the market), and being unable to bill that PBM for drug claims, would render it financially unviable for any pharmacy provider to operate, period. The lack of competition in the marketplace stems, in large part, from a series of mergers, integrations and consolidations. These consolidations and integrations are undoubtedly a factor in many abusive PBM practices, ranging from seeking to exclude independent pharmacy providers, retaliation against providers who challenge PBM abuse, to "under water" reimbursement rates that force pharmacy providers to lose money on each fill, to PBM diversion of patients from independent pharmacy providers to the PBMs' wholly-owned or affiliated pharmacies. This becomes possible due to the increased market power of the top PBMs resulting from the consolidation.

The breadth of PBM power did not occur suddenly. It initiated through a series of vertical consolidations in which certain PBMs acquired large specialty pharmacies, while others acquired insurance companies. In 2007, the shareholders of Caremark Rx, one of the nation's largest PBMs at the time, approved a $26.5 billion takeover of CVS Pharmacy, which effectively created the first vertically integrated retail pharmacy and PBM.[5] Vertical integration of the industry continued in 2011, as Blue Cross Blue Shield of North Carolina, one of Medco's largest customers, began shift-

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[2] *See https://www.hirc.com/PBM-market-landscape-and-imperatives; https://www.managedhealthcareexecutive.com/view/beyond-the-big-three-pbms.*

[3] *See https://www.latimes.com/business/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html.*

[4] Of note, CVS Caremark's specialty now maintains a market share of more than 30% in terms of in specialty drug revenue among specialty pharmacies. Thus, this consolidation at the PBM level has had a direct and proximate impact on CVS Caremark's ability to capture specialty pharmacy prescriptions. *See, https://www.beckershospitalreview.com/pharmacy/top-15-specialty-pharmacies-by-revenue-2.html.*

[5] Evelyn M. Rusli, Caremark Approves CVS Merger, *Forbes* (March 16, 2007, 4:59 PM), *http://www.forbes.com/2007/03/16/caremark-approves-update-markets-equity-cx_er_0316markets29.html.*

ing its PBM business away from Medco to Prime Therapeutics,[6] a PBM that is wholly owned by a group of thirteen Blue Cross plans across the country. In 2012, UnitedHealthcare (United), the nation's largest insurance company, began migrating the administration of its plans from Medco Health Solutions to OptumRx, United's wholly-owned PBM.[7]

Consolidation of the PBM and payer space has not been limited to vertical integration. In 2011, two of the nation's then-largest PBMs—Medco Health Solutions, Inc. and Express Scripts, Inc.—announced a $29 billion merger. After a contentious regulatory approval process, the Federal Trade Commission ultimately approved the merger in 2012.[8] Thereafter, the industry continued consolidation both horizontally and vertically. In 2013, a regional PBM—SXC Corporation—agreed to buy another regional PBM—Catalyst, Inc.—for $4.4 billion to form a national PBM, known as Catamaran Corp.[9] In July 2015, Catamaran was acquired by United, OptumRx's parent company, for $12.8 billion. The two PBMs are now integrating operations and operate under one name, OptumRx. In 2015, Rite Aid acquired the PBM EnvisionRx for approximately $2 billion.[10]

Unfortunately, in the last five years, the trend of consolidation and integration has increased exponentially. In November 2018, CVS Health completed a controversial $69 billion acquisition of Aetna, a managed health care company specializing in selling traditional and consumer-directed health insurance along with related services including dental, vision, and disability plans. Not to be outdone, in December 2018, health insurer Cigna acquired Express Scripts for $54 billion.[11] Since then, Cigna and Express Scripts have continued to expand in creative ways. In December 2019. Express Scripts and Prime Therapeutics announced a three-year collaboration, whereby Express Scripts took over the contracting and administration of the pharmacy benefits for Prime Therapeutics' members.[12] As a result, Express Scripts now manages the prescription benefits for more than 100 million Americans.[13]

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[6] Jon Kamp, Medco Faces Loss of Blue Cross Customer, *Wall St. J.* (August 3, 2011, 6:04 PM), *http://www.wsj.com/articles/SB10001424053111903454504576486653127464070.*

[7] Anna Wilde Mathews, UnitedHealth's Answer to Express Scripts-Medco Merger?, *Wall St. J.* (July 21, 2011, 8:34 AM), *http://blogs.wsj.com/deals/2011/07/21/unitedhealths-answer-to-express-scripts-medco-merger/*.

[8] Reed Abelson and Natasha Singer, F.T.C. Approves Merger of 2 of the Biggest Pharmacy Benefit Managers, *N.Y. Times* (April 2, 2012), *http://www.nytimes.com/2012/04/03/business/ftc-approves-merger-of-express-scripts-and-medco.html.*

[9] Michael J. De La Merced, SXC Health Solutions to Buy Catalyst Health for $4.4 Billion, *N.Y. Times* (April 18, 2012, as updated 3:07 PM), *http://dealbook.nytimes.com/2012/04/18/sxc-health-solutions-to-buy-catalyst-for-4-4-billion/*.

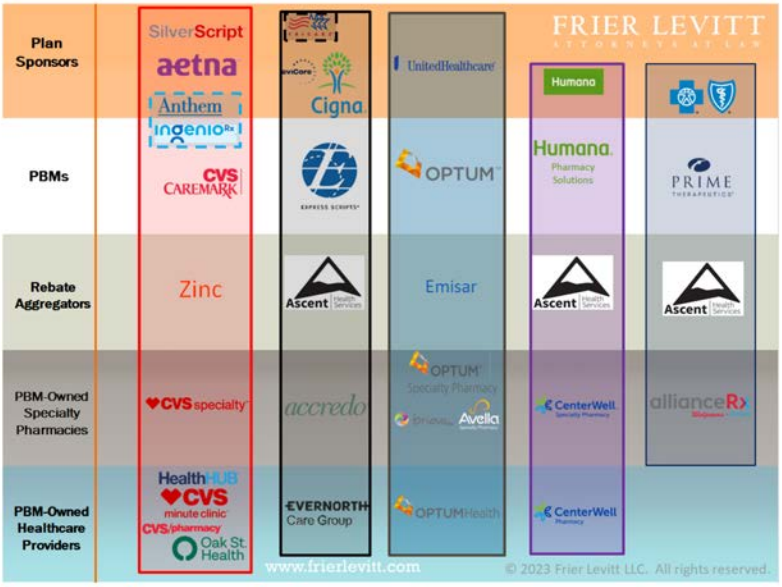
[10] Rite Aid Completes Acquisition of Leading Independent Pharmacy Benefit Manager EnvisionRx, *Bus. Wire* (June 24, 2015), *http://www.businesswire.com/news/home/20150624005906/en/Rite-Aid-Completes-Acquisition-Leading-Independent-Pharmacy.*

[11] Bruce Japsen, Cigna-Express Scripts Merger's A Done Deal, *Forbes,* December 19, 2018, *https://www.forbes.com/sites/brucejapsen/2018/12/19/cigna-express-scripts-merger-a-done-deal-by-thursday/#261d98a55688).*

[12] *See https://medcitynews.com/2019/12/express-scripts-strikes-partnership-with-prime-therapeutics/*.

[13] *See https://www.primetherapeutics.com/en/news/pressreleases/2019/release-prime-express-scripts-collaboration.html.*

Figure 1. Vertical Integration of PBMs and Health care Conglomerates



PBMs are extending vertical integration in new and unique ways. First, as plan sponsors have become savvier with respect to the rebates received by PBMs, several large PBMs created an additional layer between themselves and manufacturers to effectively "delegate" the collection of manufacturer rebates to "rebate aggregators."[14] Sometimes referred to as rebate GPOs, these mysterious entities include Ascent Health Services, a Switzerland-based GPO that Express Scripts launched in 2019, Zinc, a contracting entity launched by CVS Health in the summer of 2020, and Emisar Pharma Services, an Ireland-based entity recently rolled out by OptumRx.[15] Even some of the major PBMs (*i.e.,* the "Big Three" PBMs) sometimes find themselves contracting with other PBMs' rebate aggregators for the collection of manufacturer rebates (for example, in the case of OptumRx contracting with Express Scripts for purposes of rebate aggregation for public employee plans).[16] Worse yet, several such entities have claimed that they are not subject to the federal GPO Safe Harbor,[17] leading to a lack of transparency, as well as few limits on the levels of profitability of these companies.

Likewise, just as PBMs have moved up the chain of the drug supply chain, they have also sought to integrate downward, and are increasingly acquiring prescriber businesses, such as physicians' practices, and expanding into primary care. For several years, UnitedHealth Group's healthcare services division, Optum, has been quietly buying up physician practices, and according to recent estimates, Optum's physician network—comprising more than 70,000 physicians—is reported to make

[14] *See* Office of Broward County Auditor, "Audit of Pharmacy Benefit Management Services Agreement," 2017, accessible online: *https://www.broward.org/Auditor/Reports/Documents/2017_1212%20Agenda%20Review%20of%20Pharmacy%20Benefit%20Management%20Services%20by%20StoneBridge/2017_1212%20Exh1_OptumRx.pdf.*

[15] *See,* Alia Paavola, "CVS Health reportedly launching a GPO called Zinc," *Becker's Hospital Review,* June 30, 2020. Accessible at: *https://www.beckershospitalreview.com/pharmacy/cvs-health-reportedly-launching-a-gpo-called-zinc.html; https://www.drugchannels.net/2021/08/drug-channels-news-roundup-august-2021.html.*

[16] *See* Office of Broward County Auditor, "Audit of Pharmacy Benefit Management Services Agreement," 2017, accessible online: *https://www.broward.org/Auditor/Reports/Documents/2017_1212%20Agenda%20Review%20of%20Pharmacy%20Benefit%20Management%20Services%20by%20StoneBridge/2017_1212%20Exh1_OptumRx.pdf.*

[17] 42 CFR § 1001.952(j).

up over 5% of all U.S. physicians.[18] Similarly, CVS Health—already known for its operation of in-store Minute Clinics, as well as its $8 billion acquisition of Signify Health [19]—recently acquired Oak Street Health, an operator of nearly 170 medical centers—for $10.6 billion.[20] Possibly based on fear of giving up territory, Evernorth, the health services arm of Cigna, invested $2.5 billion in Walgreens-backed VillageMD's acquisition of medical practice, Summit Health, for almost $9 billion,[21] highlighting the veritable "arms race" for primary care providers integrated within PBM businesses.[22] In each instance of creative consolidation or integration, medical providers that do not sell out are weakened through reduced rates, pharmacies are harmed by reduced reimbursement rates and network shut outs, consumers are harmed through increased copays.[23]

Finally, each of the big three PBMs has equally sought to find other areas of vertical integration to give themselves greater control of the marketplace and drug supply chain. PBMs and their affiliated companies use their influence over the marketplace to ensure their own specialty pharmacies get access to many Exclusive or Limited Distribution Drugs (EDDs/LDDs). EDDs/LDDs are sold by drug manufactures to a single or limited number of specialty pharmacies. Those pharmacies able to buy these EDDs/LDDs gain immediate benefits by way of exclusive or near exclusive access to patients that require these unique medications. PBMs assert their influence even on more commonly accessible medications. For drugs distributed through a broader supply chain, PBMs can demand lower price from manufacturers and distributors and then distributors are forced to charge independent pharmacies more for the same drugs sold to PBM-owned pharmacies.

Further, in a bid to corner the explosive 340B market, CVS Health acquired the software provider and third-party administrator, Wellpartner, in 2018, giving it direct insight and control into millions of 340B reconciliations between covered entities and contract pharmacies, even when CVS is not involved as a pharmacy or PBM.[24] This has enabled CVS Health to dominate the 340B contract pharmacy and third-party administrator (TPA) marketplace, to the point where State Attorney Generals have begun to initiate enforcement actions against the conglomerate over antitrust and anticompetition violations.[25] Today, we are calling on the government and manufactures to investigate just how much of 340B revenue is siphoned by PBMs and their wholly owned TPAs.

Likewise, in 2017, Express Scripts acquired eviCore Healthcare, a utilization management and "medical benefits manager," providing Express Scripts visibility and access to millions of drug claims billed and reimbursed under the medical benefit (as opposed to the pharmacy benefit).[26] Medical providers must take note. Lastly and perhaps most concerningly is United HealthGroup's acquisition of Change Healthcare for $13 billion, which was completed last year, despite a direct (albeit, unsuccessful) legal challenge by the Department of Justice.[27] The Department of Justice had good reason to block this transaction, as Change Healthcare operates a "healthcare claims clearinghouse," receiving, processing and transmitting claims data from many different pharmacy providers and PBMs, and United's ownership of the platform would give the company insight into virtually every pharmacy claim processed in the country.[28]

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[18] *See https://www.medpagetoday.com/special-reports/exclusives/100531; https://www.beckerspayer.com/payer/meet-americas-largest-employer-of-physicians-unitedhealth-group.html.*

[19] *See https://www.healthcaredive.com/news/cvs-signify-amazon-unitedhealth-acquisition-home-health/631200/#:~:text=Dive%20Brief%3A,for%20the%20home%20healthcare%20company.*

[20] *See https://www.costar.com/article/790165595/cvs-races-rivals-in-expanding-primary-care-centers-with-106-billion-oak-street-health-deal.*

[21] *See https://www.healthcaredive.com/news/cigna-evernorth-villagemd-investment-walgreens-summit-value-based-care/636116/.*

[22] *See https://www.healthcaredive.com/news/cigna-merger-acquisition-strategy-insurers/635709/.*

[23] *Ibid.*

[24] *See https://www.blueandco.com/cvs-health-has-acquired-340b-software-provider-wellpartner-inc/.*

[25] *See https://ag.ny.gov/press-release/2022/attorney-general-james-sues-cvs-harming-new-york-safety-net-hospitals-and-clinics.*

[26] *See https://www.prnewswire.com/news-releases/express-scripts-closes-acquisition-of-evicore-companies-unite-to-improve-healthcare-for-100-million-americans-300572207.html.*

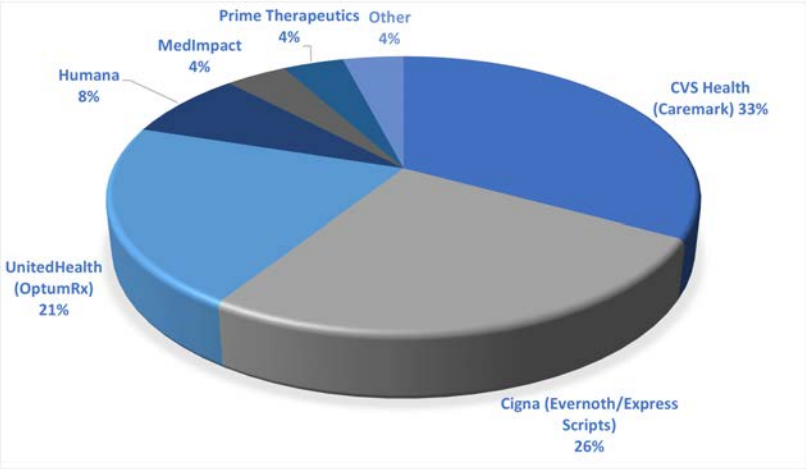
[27] *See https://www.forbes.com/sites/brucejapsen/2022/10/03/unitedhealth-closes-optums-13-billion-change-healthcare-deal/?sh=593f7ee7ccc9.*

[28] *See https://www.justice.gov/opa/pr/justice-department-sues-block-unitedhealth-group-s-acquisition-change-healthcare; https://www.fiercehealthcare.com/payers/doj-appeal-unitedhealth-change-healthcare-merger-challenge.*

This rapid evolution of the PBM and health insurance industry shows how a limited number of corporations wield an outsized level of power in the prescription drug coverage marketplace. Fewer payers harms patients, especially those requiring specialty medications. Powerful payers, when integrated with PBMs, chain pharmacies and PBM-owned specialty pharmacies, present unique challenges to drug wholesalers and manufacturers. These integrated companies have greater abilities to control the nature and direction of patients' care, drug formularies, including what type of care/drugs patients receive, from whom they receive it, and in what setting they are treated.

Fewer payers means that a provider is not able to survive without network access to each PBM. Exclusion from one PBM with a market share of 35% means that the provider loses out on a major portion of the patient population.

Figure 2. Market Share by PBM in U.S. Prescription Benefits Market in 2021[29]



As illustrated in the figure above, consolidation has created merged entities that have oppressive power over many stakeholders in the supply chain. This creates a virtual chokehold note only on independent pharmacy providers, but on pharmacy services administrative organizations (PSAOs), plan sponsors, manufacturers, distributors and patients alike. Market dominance has allowed PBMs to get away with abusive practices. Challenges are met with retaliation, actual, threatened or perceived.

Whether it is outsized manufacturer rebates PBMs demand from manufacturers or direct and indirect remuneration (DIR) fees extracted from pharmacies, PBM practices fuel drug prices. Whether it is unreasonable barriers to entry such as requiring specialty pharmacies to have multiple "accreditations", network exclusions or mandatory "white bagging"[30] forcing patients to receive inferior service at higher costs. Whether it is employing insidious copay maximizer programs[31] or deceptive pricing

[29] Exhibit 87 in The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute. Available at *http://drugchannelsinstitute.com/products/industry-reports/*.

[30] White bagging is a practice involving healthcare providers (such as doctors, clinics, and hospitals) and pharmacies, whereby a patient's medication to be used in a procedure is sent directly by the pharmacy to the provider at which the patient is receiving care. Many payers, primarily large national insurers, have recently begun to mandate white bagging by requiring that in-office administered medications be purchased and dispensed through the payers' pharmacies, as opposed to being sourced and provided by the administering provider. Healthcare providers are then expected to receive and administer this medication filled and dispensed by the payer-owned pharmacy.

[31] Copay maximizers are programs instituted to ensure that the maximum value of a manufacturer's copay coupon is realized by the PBM, even if normal plan design would yield a lower copay amount. Copay maximizer programs often intentionally "increase" the patient's out-of-pocket costs to reflect the maximum availability of support offered by a manufacturer copay cou-

and reimbursement techniques. Or worse yet, whether it is essentially practicing medicine, through "fail first" step therapy, prior authorization requirements, or formulary exclusions, many of which favor not the least expensive medication, but the most profitable one for the PBM. Through vertical integration, PBMs have become both the "arsonists and firefighters" of drug prices.[32] Each tactic is made possible by the PBMs' sheer levels of dominance at all levels of the health care continuum. This consolidation has hurt medical care, made independent pharmacy unprofitable, while fueling both drug prices and costs to patients and plan sponsors alike.

C. Who Chooses PBMs?

This level of horizontal consolidation, combined with vertical integration, leaves little choice for patients, pharmacy providers and plan sponsors in trying to escape PBM abuses. Because of vertical integration, no patient, no plan sponsor, and no pharmacy provider can choose a PBM.

As noted above, PBMs are typically contracted directly with plan sponsors, or through health insurance companies. But PBMs have structured the system to their benefit through consolidation. For example, PDPs often give no bid contracts to their wholly-owned PBM subsidiaries, *i.e.,* SilverScript/Aetna selects Caremark at its PBM; Cigna selects Express Scripts as its PBM; and UnitedHealthcare selects OptumRx as its PBM. Why is this practice a cause for concern? When these relationships are structured in a vertically integrated manner with affiliated entities participating in every aspect of the process, it diminishes accountability. For example, PBMs can hide rebates and manipulate the drug expense/medical loss ratio. This consolidation also has an impact on the quality of patient care. Consider a scenario where a patient has received subpar care or been compelled to pay higher prices as a result of a PBM's actions. What meaningful choice does that patient have in selecting another PBM? If the patient receives prescription drug coverage through their job, it is the patient's employer (or more likely, the employer's benefits broker) who selects the PBM. The patient's only option at that point would be to look for another job. Patients' ability to meaningfully select a new PBM does not improve if they are a Medicare Part D beneficiary. Patients select among Part D Plan Sponsors, not PBMs. When Part D Plan Sponsors are owned directly by PBMs, patients are locked into a particular PBM. Moreover, the number of standalone Part D Plans has steadily decreased since 2006, and geographic market share concentration often result in no real choice for patients to switch PBMs.[33]

This concept is even more pronounced in the context of Medicaid managed care. For example, in Bronx County, New York, eight of the thirteen Medicaid MCO plans utilized Caremark as the processing PBM, nearly guaranteeing that a Medicaid-eligible patient will have benefits processed by Caremark, regardless of the insurance plan selected.[34]

D. Ripe Conditions for PBM Profiteering

As a result of this control over the marketplace, PBMs have created truly ripe conditions to profit at the expense of patients, plan sponsors, manufacturers, taxpayers and other pharmacy providers. For example, PBMs have used this leverage and vertical integration to pay their own pharmacies more money than the PBM pays independent pharmacy providers, allowing PBMs to squeeze out competition.[35] At the same time, PBMs continually charge plan sponsors more than what they are paying pharmacy providers through a tactic known as "spread pricing." Dozens of states have filed suit against numerous PBMs over spread pricing in state Medicaid programs.[36] In addition to increasing profits by spread pricing, PBMs actively re-

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pon program. This aims to ensure that the full value of the manufacturer's copay savings program is extracted for the benefit of the plan.

[32] *See https://www.healio.com/news/rheumatology/20220214/vertical-integration-secures-pbms-as-arsonists-and-firefighters-of-drug-prices.*

[33] See *https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-medicare-prescription-drug-plans-in-2022/; https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovgenin.*

[34] *See https://www.health.ny.gov/health*_care/managed_*care/plans/mcp_dir*_by_*cnty.htm.*

[35] 3 Axis Advisors, Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis, 1, 3–4, January 30, 2020.

[36] *See,* 3 Axis Advisors, Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis, 1, 3–4, January 30, 2020; 46 Brooklyn, New Pricing Analysis Reveals Where PBMs and Pharmacies Make Their Money, April 21, 2019, *https://www.46brooklyn.com/research/2019/4/21/new-pricing-data-reveals-where-pbms-and-pharmacies-make-their-money* (observing that despite lower payouts to pharmacies and a deflating

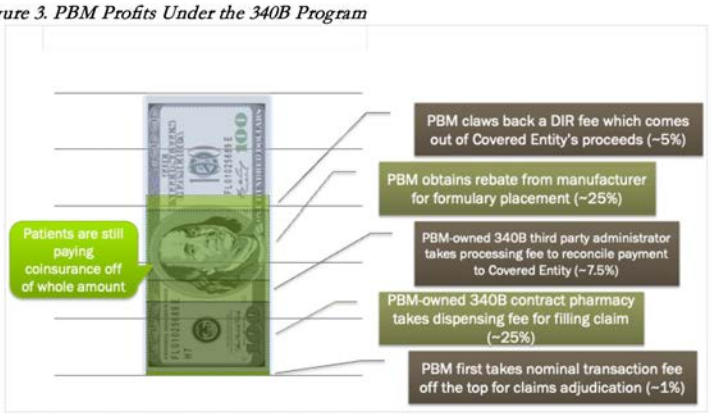
Continued

duce coverage of potentially lower cost products in favor of highly reimbursable products.[37] In particularly egregious examples of this, PBMs have taken to deceptively including prescription discount card programs into their benefit, literally deceiving Medicare Part D patients into believing that their low-cost generic medications are being covered, when in reality, they have been processed through a prescription discount card. Thus, rather than simply cover a lower cost generic where the patient could pay little to no copay, the PBM excludes coverage for the generic altogether in favor of a highly-rebated brand, forcing the patient to unknowingly pay the entire amount of the generic medication.[38]

The level of PBM profiteering only expands when considering other lines of business operated by PBMs. For example, in the context of 340B, in addition to fees taken by contract pharmacies owned and operated by PBMs, third-party administrators, such as CVS-owned Wellpartner, assess additional fees on every 340B eligible claim, which are "percentage[s] of margin," and can be as high as 15% of the cost of the drug, destroying the intended purpose of 340B.[39]

This all begs the question: just how much do PBMs siphon off? Between spread pricing and pharmacy direct and indirect remuneration (DIR) fees,[40] rebates and transaction fees, 340B third party administrative fees, for every dollar spend towards a prescription medication, it can be estimated that PBMs (or their affiliates) retain more than $0.50. This is illustrated in Figure 3.

Figure 3. PBM Profits Under the 340B Program



Thus, vertical integration and horizontal consolidation has harmed patients, plan sponsors, manufacturers, taxpayers and providers, alike.

III. Top Barriers Erected by PBMs

Alongside consolidation, PBMs and their affiliated entities leverage their increasing influence over the marketplace to force manufacturers to increase the list price of drugs, increase PBM profits, reduce patient drug coverage, and decrease the viabil-

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generic market, Ohio's generic drug unit costs increased 1.8% in SFY 2017 and, of the total state spending on generic drugs, 31.4% went to PBMs via spread pricing); *https://www.paauditor.gov/Media/Default/Reports/RPT_PBMs_FINAL.pdf.*

[37] Federal Trade Commission, Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products at 1 (June 16, 2022).

[38] *See, United States ex rel. Ellsworth Associates, LLP v. CVS. Health Corp., et al.,* 2:19–cv–02553, Dkt 18 (2022); *https://www.fiercehealthcare.com/payers/whistleblower-suit-cvs-prevented-part-d-members-accessing-generics.*

[39] *See, RxStrategies, Inc. v. CVS Pharmacy, Inc. and Wellpartner, LLC,* 8:18–cv–01087, Dkt 1 (2018); *https://news.bloomberglaw.com/health-law-and-business/cvs-facing-twin-lawsuits-over-conduct-in-drug-market.*

[40] "DIR" stands for "Direct and Indirect Remuneration," and describes any kind of remuneration Part D Plan Sponsors (PDPs) or their Pharmacy Benefit Managers (PBMs) may receive from any source that offsets the PDP's costs. "DIR" is a colloquial term generally used by the pharmacy industry that has been adopted by most stakeholders, and even legislators, to describe a particular kind of DIR that CMS typically refers to as "pharmacy price concessions." *https://www.frierlevitt.com/articles/what-are-dir-fees-and-clawbacks/.*

ity of independent pharmacy competitors. Below is a discussion of the top barriers erected by PBMs.[41]

With respect to specialty medications, which make up an ever-increasing segment of the drug spend, the Department of Health and Human Services Assistant Secretary for Planning and Evaluation, Office of Science & Data Policy released a report[42] on "Trends in Prescription Drug Spending, 2016–2021" in September 2022 detailing the impact of specialty medications. The report identified that the U.S. health care system spent $421 billion for drugs filled in an outpatient setting, including standalone pharmacies and mail order prescriptions. The report specified, "[d]rug spending is heavily driven by a relatively small number of high-cost products." Following the 80/20 rule, 80% of prescriptions that Americans fill are for less costly generic drugs, yet the 20% brand name prescriptions represent 80% of the cost of drugs dispensed. The report also highlighted that "the top 10% of drugs by price make up fewer than 1% of all prescriptions." Expensive specialty drugs represent about more than 50% of drug spend.[43] In short, a relative few expensive specialty drugs drive a significant portion of the drug spend in the United States.

A. PBMs Set Unreasonably Low Specialty Drug Reimbursement Hurting Independent Competition In Violation of the Law

PBMs know the unique considerations surrounding specialty medications, and routinely pay an unreasonably low reimbursement for specialty medications dispensed by independent pharmacy providers. The impact of this unreasonable reimbursement is acutely targeted to only a few—yet critical—specialty pharmacies. According to PBMs' own analyses, less than 1% of pharmacies dispense more than 25% of their claims as specialty medications.[44] The most insidious PBM tactic to effectuate unreasonable reimbursement is DIR Fees. PBMs assess DIR Fees only after the pharmacy is it will be paid a *higher* price by PBM. Specialty pharmacies[45] pay more than one-half of the total DIR Fees that PBMs collect from pharmacy providers.[46] Incredibly, even CMS found that pharmacy DIR fees "grew more than 107,400 percent between 2010 and 2020."[47] Medicare Payment Advisory Commission (MedPAC), an independent congressional agency established to advise Congress on issues affecting the Medicare program, estimated that in 2021 pharmacy DIR Fees totaled $12.6 billion, or 6% of gross Medicare Part D spending.[48] Making matters worse, specialty pharmacies have incredibly small profit margins as a proportion of revenue after the cost of acquiring expensive specialty medications. The single digit gross profit margins after the cost of drug acquisition are easily eclipsed by the percentage-based DIR fees now prevalent in the Medicare Part D marketplace. Currently, specialty pharmacies regularly experience DIR Fees in excess of 10% with the true range of up to 31% of ingredient cost. The DIR Fees PBMs charge to specialty pharmacies has increased at exponential rates. The below chart plots out the exponential increase in DIR Fees experienced by a single provider in a PBM network from 2016 through 2022.

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[41] Redactions are made in the remainder of this submission because of PBM requirements that certain contract documents, disputes, and facts learned in arbitration are required to remain confidential.

[42] The Department of Health and Human Services Assistant Secretary for Planning and Evaluation, Office of Science and Data Policy, Trends in Prescription Drug Spending, 2016–2021 (September 2022). Available at *https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf.*

[43] *https://www.drugchannelsinstitute.com/files/Fein-Long-Asembia-03May2022.pdf.*

[44] *See, e.g.,* CVS Health/Caremark, Performance Network Program, Specialty Strategy 2017/2018.

[45] There are only 1,123 ACHC accredited pharmacies offering specialty services in the United States. *See https://www.achc.org/find-a-provider/.*

[46] *Id.*

[47] 87 FR 1842, 1910.

[48] Medicare Payment Policy Report to Congress, Medicare Payment Advisory Commission, March 2023. *https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_SEC.pdf.*

Figure 4. DIR Fees as a Percentage of Ingredient Cost Experienced by a Single Provider from 2016-2022:

New York Cancer and Blood Specialists, LLC v Caremark, LLC et al., AAA Case No. 01–21–0016–4612, Expert Report of Laura E. Coe (December 30, 2022). DIR Fees of this magnitude simply cannot be justified and lead directly to unreasonable reimbursement rates notwithstanding the clear law, regulation, and guidance that terms and conditions must be reasonable and relevant.

B. Federal Law, Regulation and Guidance Requires that Medicare Part D Terms and Conditions be "Reasonable and Relevant"—DIR Fees and Unreasonably Low Reimbursement Terms Violate the Law

The law creates obligations on PBMs and plan sponsors to not only offer standard terms and conditions that allow participation in Medicare Part D network, but also require those terms and conditions to be both reasonable and relevant, with reimbursement that is not unreasonably low. Congress enacted the federal "Any Willing Provider" law (AWPL) as part of the Social Security Act applicable to Medicare Part D. 42 U.S.C. § 1395w–104(b)(1)(A) states that "[a] prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan." CMS has enacted additional regulations and guidance documents to enforce the AWPL. In doing so, CMS enacted regulations to ensure the "terms and conditions for participation" in Medicare Part D networks are "reasonable and relevant," so that providers, themselves, are not only willing to participate, but able to do so under objectively reasonable terms. DIR fees violate that standard because they are not "reasonable" and are also not "relevant." Congress permits agencies like CMS to clarify statutes by enacting regulations that expand upon—but cannot be inconsistent with—federal statutes. CMS codified the meaning of the AWPL in guidance documents contained in the Code of Federal Regulations (CFR). CMS codified the AWPL to require that Part D plan sponsors must agree to have "a standard contract with **reasonable and relevant terms and conditions of participation** whereby any willing pharmacy may access the standard contract and participate as a network pharmacy." 42 C.F.R. § 423.505(b)(18) (emphasis added). To further clarify the aforementioned statutes and regulations applicable to the Medicare Program, CMS has issued guidance in the form of the Medicare Prescription Drug Benefit Manual (the "Med D Manual"). CMS is cognizant that one of, if not the most important term and condition for a provider to effectively participate in the Part D network, is the reimbursement rate. To ensure that Plan Sponsors offer a "standard contract with reasonable and relevant terms and conditions of participation" CMS has explicitly stated that:

> **Offering pharmacies unreasonably low reimbursement rates for certain "specialty" drugs** may not be used to subvert the convenient access standards. In other words, **Part D sponsors must offer reasonable and relevant reimbursement terms** for *all* Part D drugs as required by [the Medicare AWPL].[49]

[49] Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50.3.

Unreasonable reimbursement impacts not only specialty pharmacies, but also patients. CMS has found that DIR Fees negatively impact patients because these fees are "not reflected in lower drug prices at the point-of-sale and are instead used to reduce plan liability," and "beneficiaries who utilize drugs end up paying a larger share of the actual cost of a drug."[50] More broadly, though, is that unreasonably low reimbursement rates results in significant pharmacy consolidation, exacerbating the impact of broader consolidation in the healthcare marketplace. Unreasonable low reimbursement rates increase PBM acquisition of independent pharmacy providers because the same entities that set unreasonable low reimbursement rates (health insurance companies and their PBMs) are the entities profiting from DIR and then purchasing independent pharmacy providers. After the PBM purchases the independent pharmacy provider, the pharmacy will likely receive a higher reimbursement. This is because of preferential reimbursement agreements between PBMs and their wholly owned pharmacies.

To illustrate this consolidation in real-world terms, consider the changes in the largest specialty providers from 2015 to 2022. In 2015, the total specialty drug spend equaled $98.3 billion. Fifty-six percent of the specialty drug spend was channeled through specialty pharmacies owned by the same parent company as Caremark, ESI, OptumRx and Humana. By 2021 those figures ballooned to total $191.6 billion with $127.1 billion, or 66.5% of the specialty market captured by specialty pharmacies owned by the same parent company as Caremark, ESI, OptumRx and Humana. Perhaps even more telling is a comparison between the specialty pharmacy market share in 2015 to 2021, below. In short, the largest independent specialty pharmacies in 2015 have been acquired by PBMs.

Figure 5. Pharmacy Revenue and Market Share from Specialty Pharmacies in 2015:

Pharmacy Revenues and Market Share from Specialty Pharmaceuticals, by Company, 2015

Pharmacy Name	Parent Organization	Estimated 2015 Dispensing Revenues from Specialty Drugs ($ billions)	Share of Revenues
CVS Caremark Specialty Pharmacy/ CVS drugstores [1]	CVS Health	$29.6	30%
Accredo	Express Scripts	$17.2	18%
Walgreens Specialty Pharmacy/ Walgreens drugstores [2]	Walgreens Boots Alliance	$9.8	10%
BriovaRx [3]	UnitedHealth Group (OptumRx)	$6.5	7%
Diplomat Pharmacy [4]	n/a	$3.4	3%
Prime Therapeutics Specialty Pharmacy	Prime Therapeutics	$2.5	3%
Humana Specialty Pharmacy	Humana	$1.7	2%
Avella Specialty Pharmacy	n/a	$1.1	1%
Cigna Specialty Pharmacy	Cigna	$0.9	1%
BioPlus Specialty Pharmacy Services	n/a	$0.8	1%

[50] 87 FR 1842, 1911.

Pharmacy Revenues and Market Share from Specialty Pharmaceuticals, by Company, 2015—Continued

Pharmacy Name	Parent Organization	Estimated 2015 Dispensing Revenues from Specialty Drugs ($ billions)	Share of Revenues
All other retail, mail, and specialty pharmacies	n/a	$24.9	25%
Total		**$98.3**	**100%**

Includes revenues from retail, specialty, and mail pharmacies. Excludes revenues from network pharmacies of PBM-owned specialty pharmacies and infusion services covered by medical benefit. Totals may not sum due to rounding.

[1] Includes CVS/Caremark Specialty Pharmacy and CVS/retail drugstores. Includes Aetna specialty pharmacy volume. Includes pro forma full-year estimated revenues from Omnicare's specialty pharmacy (Adanvced Care Scripts). Excludes estimated infusion services covered by medical benefit and specialty revenues from Target pharmacies.

[2] North American revenues only.

[3] Includes pro forma full-year estimated specialty dispensing revenues from Catamaran.

[4] Includes pro forma full-year revenues from BioRx and Burman's Specialty Pharmacy.

Source: Pembroke Consulting research and estimates. This table appears as Exhibit 41 in: Fein, Adam J., The 2016 Ecomomic Report on Retail, Mail, and Specialty Pharmacies, Drug Channels Institute, January 2016. Available at *http://drugchannelsinstitute.com/products/industry_report/pharmacy/*.

By 2021, Avella Specialty Pharmacy and Diplomat Pharmacy, two of the largest at the time, were both bought by OptumRx's owner United Healthcare in 2018[51] and 2019[52] respectively. Further, Prime Therapeutics and Walgreens entered a joint venture to form AllianceRx,[53] and later Prime Therapeutics entered a joint venture with Express Scripts[54] whereby Prime Therapeutics utilizes Express Scripts' PBM services as a significant portion of Prime Therapeutics' claims adjudication.

Figure 6. Pharmacy Revenue and Market Share from Specialty Pharmacies in 2021:

Prescription Revenues and Market Share from Specialty Pharmaceuticals, By Company, 2021

Pharmacy Name	Parent Organization	Estimated 2021 U.S. Prescription Revenues from Specialty Drugs ($ billions)	Share of Prescription Revenues from Specialty Drugs
CVS Specialty[1]	CVS Health	$52.9	28%
Accredo/Freedom Fertility	Cigna (Evernorth/ Express Scripts)	$43.5	23%
Optum Specialty Pharmacy[2]	UnitedHealth Group (OptumRx)	$25.8	14%
AllianceRx Walgreens Prime/ Walgreens stores	Walgreens Boots Alliance[3]	$19.2	10%
Humana Specialty Pharmacy	Humana	$4.9	3%
Acaria Health[4]	Centene (Envolve Health)	$4.7	2%

[51] UnitedHealthcare, Inc., (2018), Form 10–Q. U.S. Securities and Exchange Commission. *https://www.unitedhealthgroup.com/content/dam/UHG/PDF/investors/2018/UNH-Q3-2018-Release.pdf.*

[52] UnitedHealthcare, Inc. (December 9, 2019), Diplomat, OptumRx Combining to Advance Access to Specialty Pharmacy Care and Infusion Services, Improve Health Outcomes. *https://www.unitedhealthgroup.com/newsroom/2019/2019-12-9-optumrx-diplomat-combination.html.*

[53] *See https://www.alliancerxwp.com/contents/press-releases/alliancerx-walgreens-prime-begin.html.*

[54] *See https://medcitynews.com/2019/12/express-scripts-strikes-partnership-with-prime-therapeutics/.*

Prescription Revenues and Market Share from Specialty Pharmaceuticals, By Company, 2021—Continued

Pharmacy Name	Parent Organization	Estimated 2021 U.S. Prescription Revenues from Specialty Drugs ($ billions)	Share of Prescription Revenues from Specialty Drugs
Kroger Specialty Pharmacy/ Kroger stores	Kroger	$4.0	2%
CarePathRx [5]	n/a	$2.0	1%
Specialty Pharmacy Solutions [6]	McKesson	$1.8	1%
AHF Pharmacy	AIDS Healthcare Foundation	$1.7	1%
US Bioservices	AmerisourceBergen	$1.6	1%
SenderraRx	n/a	$1.3	1%
Walmart Specialty Pharmacy/ Walmart stores	Walmart	$1.1	1%
Elixir Specialty/Rite Aid stores	Rite Aid	$0.8	0%
Amber Pharmacy/Hy-Vee stores	Hy-Vee	$0.6	0%
All other retail, mail, long-term care, and specialty pharmacies	n/a	$25.7	13%
Total		**$191.6**	**100%**

Source: *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers,* Drug Channels Institute, 2022, Exhibit 48. Includes revenues from retail, specialty, and mail pharmacies. Includes specialty revenues from retail locations, where relevant. Excludes revenues from network pharmacies of PBM-owned specialty pharmacies and infusion services covered by medical benefit. Totals may not sum due to rounding.

[1] Includes CVS Caremark Specialty pharmacies and CVS retail pharmacies.

[2] Formerly known as BriovaRx.

[3] On December 31, 2021, Walgreens purchased Prime Therapeutics' 45% ownership interest in AllianceRx Walgreens Prime, so this business has no PBM ownership in 2022. Effective June 2022, the company will be known as AllianceRx Walgreens Pharmacy.

[4] Includes Drug Channels Institute estimated revenues from AcariaHealth, Exactus Pharmacy Solutions, Foundation Care, and PANTHERx Rare Pharmacy.

[5] Includes Drug Channels Institute estimated revenues from BioPlus Specialty Pharmacy, ExactCare Pharmacy, and the management services organization of Chartwell Pennsylvania.

[6] Includes Biologics by McKesson and the Patient Assistance Pharmacy (formerly known as Care Advantage).

Already in 2023, there have been additional consolidations. For example, in February, CarepathRx sold its specialty pharmacy, BioPlus, to Elevance [55] (previously known as Anthem), a plan sponsor that utilizes CVS Health's PBM, Caremark. Independent reports by 3 Axis Advisors found that PBMs are overpricing medications when dispensed at PBM affiliated pharmacies, illustrating one way in which consolidation increases costs.[56]

C. The Post-DIR Fee World Does Not Improve Pharmacy Reimbursement

In May 2022 CMS released a Final Rule reinterpreting the term "Negotiated Prices."[57] Effective January 1, 2024, CMS removed an exception where contingent pharmacy payment adjustments that "cannot reasonably be determined at the point-of-sale" (aka DIR fees) were not included in the Negotiated Price upon which PDPs submit bids. The real impact of the Final Rule essentially eliminates the profitability that Part D Plans and PBMs enjoyed arising from pharmacy DIR fees, be-

[55] *See https://www.elevancehealth.com/newsroom/elevance-health-announces-closing-of-bioplus-acquisition.*

[56] Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis, annuary 30, 2020. *https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/5e384f26fc490b221da7ced1/1580748598035/FL+Master+Final+Download.pdf.*

[57] *See https://www.frierlevitt.com/articles/pharmacy-alert-cms-proposes-rule-that-may-end-dir-fees-but-whether-pharmacies-will-benefit-is-questionable-comments-on-new-rule-due-by-march-7-2022/.*

cause when DIR fees can be excluded from the Negotiated Price, nearly all DIR fee revenue goes right to Part D Plan profits. To make up for that lost DIR profit, Part D Plans and PBMs have already started to amend contracts to reimburse pharmacies at drastically lower rates to keep their past profitability.[58] Some 2024 reimbursement rates have become public. In 2024 Express Scripts (ESI) will reimburse brand medications at AWP-26.3%. Our research shows that virtually no pharmacies, other than PBM-owned pharmacies or 340B Covered Entities are able to acquire brand drugs at rates at or lower than ESI's new rate.[59] If ESI can get away with AWP-26.30%, often more than 3% lower than the previous year's rates, more than other PBMs are sure to follow. The result of reimbursement below drug wholesale costs will put pharmacies, and particularly pharmacies dispensing predominantly brand drugs such as specialty pharmacies out of business.

D. Even as PBMs Reimburse Specialty Pharmacy Less, Affiliated Plan Sponsors are Paid More For the Sicker Beneficiaries Specialty Pharmacies Serve

In the capitated Medicare Part D space, explained below, Medicare Plan Sponsors are paid more per member per month for sicker patients, such as when a Medicare beneficiary has cancer. Medicare Part D Plan Sponsors are paid better for managing patients receiving specialty medications.

Medicare Part D is funded using federal monies drawn from the government's Supplementary Medical Insurance trust fund. The Supplementary Medical Insurance trust fund's chief revenue sources are contributions from the federal general fund (74%), beneficiary premium payments (15%), and state contributions (11%). The monthly premium paid by enrollees is set to cover 25.5% of the cost of standard prescription drug coverage, with the Medicare program subsidizing the remining 74.5% based on bids submitting by PDPs.[60]

Medicare Part D is a capitated model, meaning that CMS will make a capitated, or fixed, per member per month, payment to the PDP to cover the prescription drug benefits for each of the PDP's beneficiaries. PDPs base their capitated payments to PDPs based on bids submitted to CMS on an annual basis and through a process referred to as "risk adjustment." In other words, the amount CMS pays a PDP to manage the prescription drug benefits for Part D beneficiaries is not always uniform. Rather, CMS' per member per month capitated payments to PDPs reflect anticipated costs of providing care to beneficiaries under the PDP. Risk adjustment is thus an important process to ensuring adequate payments to PDPs.[61] Without it, PDPs may be incentivized to attract healthier patient pools, and discourage sicker (costlier) patients from enrolling.

Through the "risk adjustment" process, CMS adjusts the per member per month payments to PDPs to account for cost differences associated with various diseases and demographic factors. PDPs are paid based on average rates, adjusted, for specific ailments and population base.[62] In other words, the *sicker* a PDPs beneficiary base is, the *higher* CMS' pays PDP per member per month. Today, we are calling for the Government to consider whether the reimbursement rates PBM pay to specialty pharmacies should take into account that PDPs are paid more to manage these sicker beneficiaries, resulting in a reimbursement to specialty pharmacies that recognizes their important role.

E. PBMs Argue Federal AWPL and Other Laws are not Applicable to PBMs

Medicare's AWPL guides all Medicare stakeholders. The importance of the AWPL to curb PBM abuses, which impacts all stakeholders, cannot be overstated. But when independent pharmacy providers or other stakeholders attempt to leverage the AWPL to gain access to restricted networks, challenge DIR fees, or obtain reasonable reimbursement rates, PBMs craft legal arguments designed to limit the AWPL. These arguments include: (1) the AWPL does not apply to PBMs and only applies to separate entities, (*i.e.,* insurance companies and Part D Plan Sponsors);

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[58] *See https://www.frierlevitt.com/articles/a-new-world-order-of-drastically-lower-pharmacy-reimbursement-series-part-1-lower-net-pharmacy-reimbursement-following-cms-final-rule-on-dir-fees/.*

[59] *See https://www.frierlevitt.com/articles/a-new-world-order-of-drastically-lower-pharmacy-reimbursement-part-2-the-threatened-future-of-independent-pharmacies/.*

[60] *See https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/.*

[61] *See https://www.americanactionforum.org/research/primer-medicare-risk-adjustment/.*

[62] *See generally* Medicare Managed Care Manual, Chapter 7—Risk Adjustment.

(2) even if the AWPL does apply to PBMs, the AWPL does not contain an expressed private right of action, cannot be enforced by private parties, and only CMS can enforce the AWPL; and (3) even if the AWPL applies to PBMs and could be enforced by private parties, the scope of the AWPL is narrow and only requires the PBM and Part D Plan Sponsors to provide sufficient access for patients (which, in theory, could be satisfied solely through the PBMs' wholly-owned pharmacies without independent providers). These arguments have consistently been successful for PBMs in public venues (court proceedings) and private venues (arbitration). Examples can be found in the Eighth Circuit.[63] Emboldened by the lack of expressed private right of action in the AWPL, PBMs rely heavily on these arguments and consistently discriminate against independent pharmacy providers.

The PBMs' arguments are crafty but ignore governing federal law. The regulatory "Flow Down" provisions of the AWPL unequivocally require Medicare Part D Plan Sponsors to incorporate the AWPL into the contractual agreements with "first tier"[64] and "downstream"[65] entities. Congress enacted the AWPL to govern the administration of Medicare Part D benefits. CMS requires that Part D sponsors (*e.g.,* Aetna, Blue Cross Blue Shield, Centene, Humana, SilverScript, and United Healthcare), the "First Tier" entities (*e.g.,* PBMs like Caremark, Express Scripts, Humana, OptumRx, and Prime Therapeutics) and other "downstream" entities (*e.g.,* pharmacy providers), to incorporate *all Part D Rules* (including the AWPL), into *all* contracts. In fact, Congress could not have more clearly articulated the requirement that "each and every contract must specify that first, downstream, and related entities must comply with all applicable federal laws, regulations, and CMS guidance."[66] PBMs cannot seriously dispute that, as a "first tier entity" like a PBM must comply with the AWPL. This conclusion is in accord with other publicly disclosed arbitrations against PBMs, including *Senderra v. Caremark, LLC, et al.,*[67] and *Mission Wellness v. Caremark, LLC, et al.*[68] Tellingly, in briefing this issue, after year of litigation, Caremark was all but forced to *admit* that the AWPL governs Caremark's contract with pharmacy providers as part of an ultimately unsuccessful effort to vacate an arbitrator's award.[69]

PBMs posit that the Medicare Part D Prescription Drug Benefits Manual, Chapter 5, Section 50.5.3, comes under the title of "Convenient Access to LTC Pharmacies." PBMs argue that this *only* means there needs to be a pharmacy within a certain geographic range of patients. To PBMs, the AWPL is only designed to ensure network "access" even if that means patients only have access to PBM-owned pharmacies, ignoring the clear regulations and CMS guidance. By virtue of vertical consolidation there are few areas where a PBM-owned chain or specialty pharmacy does not have a physical location. CVS Pharmacy alone has over 9,600 locations. Further, if mail order services are considered, CVS Specialty Pharmacy already processes approximately 29% of all specialty drug claims. If geographic access alone is the only metric to trigger Medicare's AWPL, then Medicare's AWPL would only apply to an incredibly rural area like Craig, Alaska (population less than 2,000 people), serviced by Whale Tail Pharmacy, where the next closest pharmacy is 2,000 miles away. Thus, PBMs take the position that if there is a PBM-owned pharmacy

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[63] *See, e.g., United/Xcel-RX, LLC v. Express Scripts, Inc.,* No. 4:19–CV–00221–SRC, 2019 WL 5536806, at *4–5 (E.D. Mo. October 25, 2019) (dismissing plaintiff pharmacy's breach of contract claim because the AWPL did not confer a private right of action to private parties or entities); *see also Heartland Med., LLC v. Express Scripts, Inc.,* No. 4:17–CV–02873 JAR, 2018 WL 6831164, at *2 (E.D. Mo. December 27, 2018) (dismissing plaintiff's complaint entirely because AWPL does not have a private right of action). The reason this is prominent in the Eighth Circuit is a venue provision in Express Scripts' PBM-pharmacy contract mandating all disputes be resolved exclusively by litigation in the Eastern District of Missouri.

[64] First tier entity is defined as "any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D." 42 CFR § 423.501.

[65] Downstream entity is defined as "any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services." *Id.*

[66] 42 CFR § 423.505(i)(3)(iii).

[67] The Final Order explaining in Footnote 1 that "the arbitrator has already determined that the AWPL applies to Caremark as a first-tier downstream entity."

[68] The Final Award concluding that Caremark breached the "Compliance with Laws" provision by violating the AWPL.

[69] *Caremark LLC v. AIDS Healthcare Foundation,* 2022 WL 4267791 (D. Ariz. Sept. 15, 2022) (Wherein Caremark's Post-Hearing Brief wherein Respondents admit the Any Willing Provider Law governs Caremark's standardized contract with pharmacies).

across the street from an independent pharmacy, that independent pharmacy can seek no refuge in the AWPL.

CMS is clear that the AWPL is not to be read this narrow. CMS guidance states that "[o]ffering pharmacies unreasonably low reimbursement rates for certain 'specialty' drugs may not be used to subvert the convenient access standards. In other words, Part D Plan Sponsors must offer reasonable and relevant reimbursement terms for all Part D drugs as required by [the Medicare AWPL]."[70] We ask that the Senate direct CMS to reenforce this clear guidance that reimbursement terms must be reasonable and relevant and investigate instances where PBMs are forcing competitors out of the market simply to maintain their own profit margins.

F. Unconscionable PBM Contracts Restrain Pharmacy Providers Which Further Stifles Healthy Competition

Unconscionable PBM contract provisions impose unreasonable restraints on providers who attempt to vindicate their contractual rights. However, both arbitrators and courts have agreed that provisions of Caremark and OptumRx contract are unconscionable.[71] Generally, a contract or provision must be procedurally and substantively unconscionable before a court or arbitrator will decline to enforce it. Procedural unconscionability occurs when there is a defect in the bargaining process where one party lacks bargaining power or competitive advantage to negotiate the contract.[72] Additional factors include who drafted the contract, whether the terms were explained to the weaker party, and whether negotiations were possible.[73] Substantive unconscionability occurs when the terms of the contract areoverly harsh or one-sided, which can result from procedural unconscionability (*i.e.,* lack of bargaining power).[74]

In one of the few public results against CVS Caremark, the Arbitrator in *Aids Healthcare Foundation v. Caremark* ("AHF") determined that the terms and conditions of Caremark's DIR fee program could not be enforced because they were unconscionable due to Caremark's considerable bargaining power, lack of alternative options, and unilaterally imposed contractual terms.[75] Similarly, the California Court of Appeals held that provisions of Optum's contract are unconscionable, noting the lack of bargaining power for pharmacies, Optum's ability to unilaterally impose new contract terms at will, and that Optum can and has denied pharmacies the same remedies that Optum has reserved for itself.[76]

These unconscionable terms are unilaterally imposed upon providers all with the purpose of preventing PBMs practices from being challenged. The lack of bargaining power, PBM's ability to unilaterally impose new contract terms at will, and the fact that PBMs deny pharmacy providers the same remedies that they reserve for themselves is a shocking standard that is pervasive throughout the industry.

1. PBMs Impose Contract Revisions and Updates Unilaterally Without Negotiations or Even Signatures by Contracting Providers

Pharmacies are not able to negotiate PBM contract terms and conditions. PBMs regularly issue and unilaterally impose contract updates and addenda to their Provider Manuals, which are a core contract document that govern the relationship between the PBM and pharmacy provider. See Trial Testimony of Stephanie Harris, *Infinity Pharmacy, LLC et al. v. CVS Caremark, LLC et al.,* AAA Case No. 01–02–0001–1835 T44:18 to 46:16 (August 3, 2022). Pharmacy providers typically learn that the terms of their contract have been altered once a new document is received electronically, via facsimile, or sometimes through mail. Most often, and contrary to the basic tenets of contract law, a signature is often not required for these contract addenda to take effect. Caremark's network enrollment forms typically advise that "[y]ou will be enrolled as a Provider [. . .] under the terms detailed in the attached Network

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[70] Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50.3.

[71] *See Caremark, LLC, et al. v. AIDS Healthcare Found.,* 2022 WL 4267791 (D. Ariz., September 15, 2022) (public confirmation of Arbitration award in favor of AHF that found terms of Caremark's contract were unconscionable); *See also Platt, LLC v. OptumRx, Inc.,* 2023 WL 2507259 at *4 (Cal. Ct. App. March 15, 2023).

[72] *See Clark v. Renaissance West, L.L.C.,* 232 Ariz. 510, ¶ 8 (2013); *Cicle v. Chase Bank USA,* 583 F.3d 549, 554 (8th Cir. 2009); *Armendariz v. Found. Health Psychare Servs., Inc.,* 6 P. 3d 669, 690 (Cal. Sup. Ct. 2000).

[73] *Longnecker v. American Exp. Co.,* 23 F. Supp.3d 1099, 1109 (D. Ariz. 2014); Cicle, 583 F.3d at 554 (8th Cir. 2009); Armendariz, 6 P.3d at 767 (2000).

[74] *Id.*

[75] AHF Award, p. 57 ¶¶ 4–5.

[76] *See Platt, LLC v. OptumRx, Inc.,* 2023 WL 2507259 at *4 (Cal. Ct. App. March 15, 2023).

Enrollment Forms unless you notify CVS Caremark in writing (via facsimile) [. . .] that you do not want to enroll." See *Infinity Pharmacy, LLC et al. v. CVS Caremark, LLC et al.,* AAA Case No. 01–02–0001–1835 Exhibit J–8, August 17, 2020 Communication.

PBMs also regularly issue Network Enrollment Forms ("NEFs"), which are considered part of the contract between the parties but do not require providers to sign them. These NEFs contain terms for reimbursement and are typically presented to providers without any opportunity to negotiate Unfortunately, if a provider opts out of a particular network, that provider is typically unable to re-enter that network until the next year as illustrated in the figure below:

See Infinity Pharmacy, LLC, Exhibit J–8, August 17, 2020 Communication.

Further, providers are required by PBMs to opt-out before they know which plans will be participating in which network making it impossible for providers to "model out" reimbursement because it doesn't know which claims will process through which networks. However, providers cannot simply opt out of a network because physicians will simply cease sending prescriptions to a pharmacy provider unless it is member of every major PBM due to administrative costs. See *Tri Pharmacy Corp. D/b/a Hartley Pharmacy v. Caremark, L.L.C. et al.,* AAA Case No. 01–22–0005–2609, Verified Statement of Claims, ¶ 51. Thus, choosing not to participate in a particular network has dire consequences for an independent pharmacy provider.

2. PBMs Impose Unreasonable Dispute Resolution Procedures

PBMs impose unreasonable dispute resolution procedures and limitations in an attempt to curtail pharmacy providers from filing claims against them. For example, Caremark requires that disputes be filed "within six (6) months from the date of the final audit findings; (b) for termination related disputes, within six (6) months from the date of the notification of termination; and (c) for all other disputes, within six (6) months from the date on which the facts giving rise to the dispute first arose." See 2022 Caremark Provider Manual, § 15.09.07. Further, OptumRx requires that such notice "shall be provided [. . .] within one year of the facts giving rise to the Dispute." See 2023 OptumRx Provider Manual, p. 128. Thus, a pharmacy provider's claim will be barred entirely if it is asserted outside of this contractually imposed period. PBMs also impose a short statute of limitations between dispute notice and filing of an arbitration demand. Caremark requires that "any demand for arbitration must be filed within six (6) months from the date of the issuance of the Dispute Notice." See 2022 Caremark Provider Manual, § 15.09.07.

3. PBMs Impose Unilateral Escrow Requirements on Independent Pharmacies wishing to Initiate Arbitration or Litigation

Additional barrier to dispute resolution, PBMs impose unilateral escrow requirements for providers seeking to initiate arbitration or litigation. Providers are required to escrow money in an amount contemplated to cover the estimated amount in controversy, including attorneys' fees. But smaller stakeholders often cannot escrow large sums of money prior to filing for arbitration and are often dissuaded from filing suit on this reason alone, or in conjunction with the reasons detailed below.

4. PBM Contracts with Providers Contain Fee Shifting Clauses Which Serves as an Additional Barrier for Providers to Initiate Litigation.

PBM contracts shift fees and costs of the arbitration to the unsuccessful party. See 2022 Caremark Provider Manual, § 15.09.02; see also 2023 OptumRx Provider Manual, p. 130. However, because PBMs unilaterally draft and impose their contracts, the "deck" is stacked in their favor. As a result, many providers are unwilling to take such considerable risk to challenge a PBM's unreasonable conduct, have to escrow money, pay their attorneys' fees and arbitration costs, and potentially have to pay for the PBM's fees and costs as well.

5. As a Further Deterrent to Provider Litigation, PBMs Often Require a Panel of Three Arbitrators Which Increases Costs Exponentially

As a further deterrent, PBMs often require a panel of three arbitrators which increases costs exponentially. Under the Commercial Rules of Arbitration for the American Arbitration Association, unless the parties can agree otherwise, "three arbitrators shall hear and determine the case" where the amount in dispute exceeds $3,000,000. Commercial Arbitration Rules, L–2(a). Perhaps recognizing that the cost is more prohibitive for providers than it is for PBMs, PBMs simply refuse to consent to cases being heard by a single arbitrator, opting for a panel of three instead. See

Tennessee Oncology, PLLC v. Caremark, L.L.C., et al., AAA Case No. 01–20–0001–7548; *New York Cancer and Blood Specialists v. Caremark, L.L.C., et al.,* AAA Case No. 01–21–0016–4612. Coupled with fee shifting clauses, providers are heavily dissuaded from pursuing their rights against PBMs because of these exorbitant costs. See Also 2023 OptumRx Provider Manual, § L, p. 128.

6. PBMs Require Waiver of Class Action, Multiple Party Arbitrations, and Consolidated Actions, Preventing Providers and the Public from Identifying Widespread Abuses

As a significant bar to litigation and arbitration, PBMs prevent providers from engaging in disputes as part of a class, mass, or consolidated action. This further prevents providers and the public from identifying widespread PBM abuses.[77] The limitation on class, mass, and consolidated actions also prevents pooling of resources to challenge PBM abuses that otherwise go unchallenged because it is not cost effective to do so. Further, restrictive confidentiality provisions prevent providers from talking about PBM abuses and determining whether they could be experiencing the same or similar legal issues, and disclosing those issues publicly.

7. Due to Confidentiality, PBM Contracts are Shrouded in Secrecy and Prevent Their Abusive Tactics from Becoming Public

PBM contracts with providers are highly confidential, and they take great steps to prohibit providers from discussing any information obtained during the course of the PBM relationship with any other parties outside that relationship, including patients, physicians, plan sponsors, and even the general public.[78] Thus, providers are prohibited from communicating with each other, plans, patients, and even government entities absent a lawful reason to do so, such as a lawful government request or subpoena. As a result, many of the PBM's abusive tactics simply never become public because of strict confidentiality requirements.

G. DIR Performance Measurements Are Incorrect and not Reasonable or Relevant, and Therefore Violate the Federal Any Willing Provider Law

Each major PBM has a Medicare Part D Performance Network ostensibly designed to measure pharmacies' performance in certain categories, most often focused on patient adherence to medication (See, *e.g.,* Caremark 2021 Medicare Part D Program Overview; Express Scripts Performance Network Protocol; Humana Rx Quality Program; OptumRx UHC M&R Specialty Network Amendment). If a pharmacy does not meet performance goals, the pharmacy is penalized with higher DIR fees, thus greatly reducing reimbursement for Part D drugs, and enriching Plans and PBMs.[79]

PBMs employ secretive, often unreasonable, and simply incorrect metrics that are not relevant to pharmacies' clinical goals—especially as the metrics are applied to specialty pharmacies and physician dispensing practices. Specialty pharmacies often do not dispense the retail drugs that PBMs measure. Aside from medication adherence, these programs often include metrics focused on other metrics that are not reasonable or relevant to some or all pharmacies.[80] Some of the most egregious examples include PBMs focusing on adherence metrics for typical "maintenance" medications—that is, medications that patients are expected to take regularly and with few, if any, interruptions, typically including drugs treating high cholesterol, high blood pressure, and diabetes. Caremark 2021 Medicare Part D Program Overview. Most specialty pharmacies do not dispense these drugs, instead focusing on specialty disease states.[81] For some, this means that they are subjected to alternative adherence metrics that are equally inapplicable to their business, like Generic Dispense Rate (GDR). OptumRx 2022 M&R Network Amendment To The Medicare Part D Addendum To The Pharmacy Network Agreement. For others, it means they are assigned mysterious and un-auditable average scores from other pharmacies in the network that actually dispense these products, or a default score. Caremark 2021

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[77] *See* 2023 OptumRx Provider Manual, p. 129. *See* 2022 Caremark Provider Manual, § 15.09.03. *See* 2022 Express Scripts Provider Manual, p. 127 ¶ 2.

[78] *See* 2022 Caremark Provider Manual, § 14.03–14.04. *See* 2022 Express Scripts Provider Manual, p. 123, Confidentiality; *See* 2023 OptumRx Provider Manual, p. 130, § M; *See* 2022 Caremark Provider Manual, § 14; *See* 2022 Prime Therapeutics Provider Manual, p. 34.

[79] *See* 87 FR 89 at 27850.

[80] 42 CFR 423.505(b)(18) requires Part D Plans to offer "reasonable and relevant terms and conditions" in all contracts for participation in their Part D networks.

[81] Frier Levitt, LLC, Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers, 26, February 2022, *https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf.*

Medicare Part D Program Overview, Express Scripts Performance Network Protocol. Ultimately, these metrics are not reasonable or relevant to specialty pharmacies and dispensing practices and serve merely as a means to extract DIR fees from pharmacies without a benefit to patients and, indeed, often increasing patient coinsurance.[82]

1. PBMs Use Incorrect Methods to Calculate Specialty Pharmacy Medication Possession Ratio

Medication Possession Ratio ("MPR") is a method some PBMs use to calculate a Medicare beneficiary's adherence to a specialty drug, and examines whether a patient had her prescribed medication in her possession during the entire period during which she was directed by her prescriber to take that medication. However, MPR is a poor measure for assessing patient adherence specialty drugs, especially because the PBM will incorrectly treat specialty drugs as though they are "maintenance" medications, expecting the patient to remain on the therapy indefinitely. Deposition of David Hutchins, *New York Cancer & Blood Specialists v. Caremark, LLC et al.,* AAA case 01–21–0016–4612, T201:17–203:9.

MPR is problematic in specialty settings like oncology "because adverse events experienced by oncology medications often call for a temporary discontinuation of therapy until the patient's status returns to an acceptable level."[83] Even though a patient has fully complied with the physician's order, PBMs will not account for holds in therapy, disease progression, referrals to palliative care, or even death in their MPR calculation. *Tennessee Oncology v. Caremark,* Transcript of Final Hearing, Volume 1, T179:4–22. This measurement is wholly unfair to specialty pharmacies and dispensing practices.

2. Some PBMs Incorrectly Use Mean Imputation to Score Specialty Pharmacies in DIR Fee Programs because the Specialty Pharmacies have no Relevant Experience in the Categories that the PBMs Measure

Because PBMs designed DIR fee programs for retail pharmacies, PBMs have had difficulty rationally applying adherence metrics to specialty pharmacies. Another method employed by PBMs to extract DIR fees from specialty pharmacies and dispensing practices is the use of "Mean Imputation," in which the average score of all pharmacies in a network are "imputed" to a pharmacy that has no volume for a particular metric. 2022 CVS Caremark Trimester 1 Report for NCPDP 3360271 at 15. In other words, specialty pharmacies that do not dispense retail drugs are nonetheless assigned a score as though they had an average performance in the network, meaning that the pharmacy can never achieve the highest score in the network and therefore be assigned the lowest possible DIR fees, despite the PBM's assurance that the pharmacy will not be "disadvantaged" in this process. *Ibid.* The PBM believes this is appropriate because, in their words, specialty pharmacies "self-niche . . . [o]r limit their own dispensing[.]" Deposition of Steven McCall, *New York Cancer & Blood Specialists v. Caremark, LLC et al.,* AAA case 01–21–0016–4612, 2T122:4–12.

PBMs minimize the importance of specialty dispensing and penalize these providers for their focus on these vulnerable populations. This is especially egregious where a dispensing oncology practice is legally prohibited from dispensing any drugs except for those pursuant to an oncological protocol, as is the case in New York.[84] Thus, even where a dispensing practice is legally prohibited from dispensing retail drugs, PBMs paradoxically insist that they should dispense those drugs, and penalize oncology practices for not doing so. 2022 CVS Caremark Trimester 1 Report for NCPDP 3360271 (demonstrating the mean imputed assessment of non-specialty DIR fees against a New York dispensing practice where that practice was legally prohibited from dispensing those drugs). Thus, applying the AWPL regulation at 42 CFR 423.505(b)(18), mean imputation is not reasonable or relevant to specialty providers, and is simply another means by which PBMs assess DIR fees.

3. Formulary Compliance

PBMs also assess DIR fees based on formulary compliance. 2022 CVS Caremark Trimester 1 Report for NCPDP 3360271. This metric is measured by taking all the

[82] 87 FR 89 at 27834.

[83] Hassett and Willyard, The DIR Labyrinth: How Conflicting Adherence Rules Hamper MID Clinics, *Oncolytics Today* at 2, Spring 2021.

[84] N.Y. Educ. Law § 1A6807 ("no prescriber who is not the owner of a pharmacy or who is not in the employ of such owner, may dispense more than a 72 hour supply of drugs, except for: . . . the dispensing of drugs pursuant to an oncological or AIDS protocol.").

claims that were submitted by the pharmacy during the measured time period, then dividing that number by the formulary medications that were filled in the period, without accounting for whether the medication was prescribed for patient health reasons or subject to prior authorization by the PBM. Deposition of Steven McCall, *New York Cancer & Blood Specialists v. Caremark, LLC et al.,* AAA case 01–21–0016–4612 T310:9–311:12. This practice harms all pharmacies because pharmacies are often not permitted to dispense a different drug than prescribed by a physician. Moreover, this metric is particularly burdensome for oncology practices. Such practices often use genetic testing to identify the oral oncolytic that will provide the greatest chance of survival.[85] These tests may indicate a drug that is not on formulary, but is nevertheless the clinically appropriate drug for the patient. Regardless, PBMs will penalize this "off formulary" prescription when the provider dispenses the drug.

4. PBMs Maintain a Lack of Transparency that Prevents Providers from Verifying Accuracy in Performance Networks, and Requires Providers to Resort to Arbitration/Litigation Discovery to Properly Audit DIR Programs

As they assess DIR fees against pharmacy providers, PBMs lack transparency, prevent pharmacies from performing any PBM audit absent arbitration or litigation. Pharmacies have brought claims in arbitration against Caremark over DIR fees multiple times, with some of these cases being made public.[86] Each time pharmacies are forced to confirm awards against Caremark, as shown above, Caremark has assiduously attempted to hide the results from the public, despite the high bar for sealing these matters.[87] In the *Mission Wellness* case, the now public Award revealed Caremark refused to produce calculations related to its assessment of DIR fees, such that the arbitrator applied an adverse inference to Caremark for the lack of transparency.[88] Other PBMs are no different, with PBMs refusing to provide such information on a regular basis. *Biologics, Inc. v. OptumRx, Inc.,* AAA Case 01–20–0007–3159, Order on Claimant's Motion to Compel Documents (granting the pharmacy's request for the underlying surveys supporting OptumRx's NPS scores for the pharmacy). A lack of transparency makes it impossible for pharmacies to truly understand the manner in which they are assessed DIR fees, and serves only to advantage the PBMs, who are in a better position to afford the expense of litigation.

H. Patient Steering to PBM-Owned Pharmacy

Patient-steering is a practice where PBMs utilize their position and control over (1) plan development and (2) the "network" of pharmacy providers to direct patients away from non-affiliated providers to affiliated providers. PBMs use various methods of steering with the ultimate goal of directing patients to the PBM affiliated pharmacy.[89] Examples of patient steering include incentives to plan sponsors and/or patients for using affiliated pharmacy operations including lower copays. *Id.* Pharmacies learn of patient steering in different ways but often will find that in adjudicating a claim, the PBM requires the prescription to be transferred to a PBM owned pharmacy operation. *Id.* There are valid concerns with patient steering including (1) eliminating fair competition thus promoting further consolidation and (2) interference with patient choice of provider. *Id.*

I. PBMs Utilize Unfair Audit Practices and Policies Against Network Providers to Increase Profits and Create Narrow Networks

PBMs have employed several unfair audit practices and policies to levy significant and unnecessary chargebacks against pharmacies on prescription drug claims. As a result of such aggressive auditing practices and associated chargebacks, often in violation of State Pharmacy Fair Audit Laws, pharmacies are often subjected to further network action (*i.e.,* termination) or are forced to close down.

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[85] National Cancer Institute, *https://www.cancer.gov/about-cancer/treatment/types/biomarker-testing-cancer-treatment.*

[86] *See Senderra Rx Partners LLC v. CVS Health Corporation, et al.,* 2:19–cv–05816–SPL; *Mission Wellness Pharmacy LLC v. Caremark LLC,* No. CV–22–00967–PHX–GMS, 2022 WL 2488817 (D. Ariz. June 16, 2022); *Caremark LLC v. AIDS Healthcare Found.,* No. CV–21–01913–PHX–DJH, 2022 WL 4267791 (D. Ariz. September 15, 2022).

[87] *Ibid.*

[88] *Mission Wellness v. Caremark, LLC et al,* AAA case 01–19–0000–3552, Final Award at 6.

[89] *See, e.g.,* Frier Levitt, LLC, Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers, 40–47, February 2022, *https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf.*

1. Unreasonable Audit Fees Cause Significant Financial Harm to Providers

In addition to seeking a full chargeback of the claims identified as discrepant during an audit, PBMs will also assess audit fees, claiming that they need to cover the cost of an audit. As a result, not only are pharmacies required to remit the full reimbursement of the claim back to the PBM, they are often also required to pay an additional fee up to 20% of the total audit amount, causing their total chargeback to be exponentially higher. It is even more concerning that in some instances, PBMs are essentially "double-dipping" to cover the cost of an audit through audit fees from pharmacies despite already being compensated from their Plan Sponsor clients for the cost of conducting audits.

2. PBMs Seek Additional Network Sanctions Without Procedural Due Process

Often, even before audit results are issued and before the pharmacy has an opportunity to defend against audit results, PBMs will place pharmacies on payment suspension. Pharmacies that are placed on payment suspension even before they receive any audit results are faced with an impossible position because they do not know the amount at issue in the audit and have not been given an opportunity to resolve the basis of suspension. *OptumRx Pharmacy Provider Manual 2023 Second Edition Version 2.1.* PBMs will even go so far as to prevent pharmacies from adjudicating claims, which means that pharmacies cannot service their patients, causing an interruption and harm to patient care. *Elixir Solutions Pharmacy Manual 2022.* Similarly, PBMs will take unilateral decisions to terminate pharmacies over audit results that are minor and do not otherwise justify termination and even before pharmacies have an opportunity to appeal or dispute the results. PBMs have guised terminations to be justifiable based on audit results even though the results might be inaccurate and importantly, do not amount to a pharmacy's network termination that in turn impacts patient care.

3. Unreasonable Limitations on Third-Party Copay Processors and Bulk Purchases Create Challenges for Pharmacies

PBMs also place onerous contractual limitations on pharmacies despite there being no similar prohibition under relevant State and Federal rules and regulations. For example, PBMs limit the way pharmacies may collect copayment from their patients. Similarly, PBMs will also limit the window of purchase information to consider when conducting invoice reconciliation audits, and by doing so, PBMs ignore standard pharmacy practices under which a pharmacy makes continuous, if not bulk, purchases based on anticipated patient need. This limitation directly conflicts with many PBMs' requirement that pharmacies need to maintain "adequate inventory" of prescription drugs and supplies. *OptumRx Pharmacy Provider Manual 2023 Second Edition Version 2.1.* Though pharmacies must maintain sufficient quantities of drugs, they are faced with chargebacks when PBMs do not consider their purchases information during an audit. A violation of these unreasonable contract terms results in significant chargebacks and often network termination.

4. PBMs Unreasonably Terminate Pharmacies Despite Having Sufficient Documentation to Resolve Audit Discrepancies

During audits, PBMs will identify certain documentation they will accept to resolve a discrepancy. However, even though pharmacies closely adhere to these documentation guidelines when appealing an audit and obtaining the required documentation, PBMs often still deny their appeal efforts. For example, a pharmacy may get an attestation from the patient to confirm a prescription, but if the PBM cannot later get in touch with the same patient to validate the attestation, the pharmacy will still be subject to a full chargeback of the claim and potential network termination. As a result, PBMs will subject pharmacies to chargeback and potential termination for the failure to produce medical records, despite the unreasonable requirement that pharmacies maintain this information.

IV. PBM Retaliation and Silencing Opposition: The Medicare Part D Program Protects Providers with Anti-retaliation regulation, but PBMs still Retaliate Against Providers Who Bring Meritorious Claims

PBM and Payor consolidation has resulted in a marketplace in which network participation with all PBMs is necessary to remain in operation. Consequently, network termination is the worst fear of many providers. When discussing litigation or arbitration against PBMs, providers prudently express concern over potential retaliatory action by a PBMs for asserting statutory and contractual rights. These concerns are not always misplaced. Even though the law is clear, PBMs often take the position

that the law does not apply. However, a review of anti-retaliation laws shows the prohibition on retaliation is clear.

The Social Security Act and related regulations expressly prohibit retaliation by a prescription drug plan sponsor or Part D sponsor's agent, the PBM, against a provider for exercising a right of action. *Public Health and Welfare Act, Requirements for and contracts with PDP Sponsors,* 42 U.S.C. § 1395w–112(b)(4)(F)(ii); 42 CFR § 423.520. Medicare statutes and regulations also require that a contract between a provider and a Part D plan sponsor, or agents thereof, incorporate anti-retaliation provisions. *Public Health Welfare Act, Medicare Program, Contract Provisions,* 42 CFR § 423.505(b)(19) (incorporating 42 CFR § 423.520). In a scenario where the PBM has "inadvertently omitted" the anti-retaliation language from the provider agreement, a court will likely read the language into the contract because of these statutory obligations. Thus, pharmacies should be protected against retaliatory conduct, such as network termination or sudden audits.

Providers are also afforded additional anti-retaliation protections under ERISA. In addition to the protections that the Social Security Act provides regarding Federal healthcare programs, ERISA prohibits retaliatory action arising out of commercial plans. As such, PBMs are expressly prohibited from engaging in retaliatory action against pharmacies for exercising their contractual rights. *Employee Retirement Income Security Program, Interference with Protected Rights,* 29 U.S.C. § 1140 (stating that "it shall be unlawful for any person to discharge, fine, suspend, expel, discipline or discriminate against a participant or beneficiary for exercising any to which he is entitled . . ."). In addition to the foregoing, providers are also be protected under State law directly associated with retaliatory action by PBMs.[90] Thus, providers are entitled to anti-retaliation protections in both federal and commercial healthcare programs.

Unfortunately, pharmacy providers face a real threat of retaliation by PBMs for any challenge to the PBM's DIR Program. Retaliation in this manner is prohibited in the Medicare Part D Program. 42 CFR § 423.505(b)(19) (incorporating 42 CFR § 423.520(g) ("Anti-retaliation. Consistent with applicable Federal or State law, a Part D sponsor may not retaliate against an individual, pharmacy, or provider for exercising a right of action under paragraph (g)(1) of this section."). Heedless of the law, PBMs have retaliated against pharmacies in direct contravention of the law.

In the arbitration *Caremark, LLC and CaremarkPCS, LLC v. Senderra Rx Partners, LLC,* AAA Case No.: 01–20–0007–3182, a PBM retaliated against a specialty pharmacy specifically for bringing challenges to its DIR Program by attempting to terminate the pharmacy entirely from its networks. In their Final Award, the Panel found the PBM had, in fact, retaliated against the pharmacy in violation of federal law by attempting to terminate the pharmacy because the pharmacy sent a dispute notice to the PBM challenging its DIR Program. *Caremark, LLC and CaremarkPCS, LLC v. Senderra Rx Partners, LLC,* AAA Case No.: 01–20–0007–3182. Final Award, at 17. The Panel entered a permanent injunction against the PBM based upon this illegal retaliation. *Ibid.* Unfortunately, due to the lack of transparency in the PBMs' secretive contracts with pharmacies, it is unknown whether this or other PBMs' retaliatory actions will be brought to light.

Other pharmacies have been similarly retaliated against. In another arbitration, a specialty pharmacy had to bring an emergency action to prevent its termination from a PBM's network, again because the pharmacy had challenged the DIR Program. *AON Pharmacy, LLC v. Caremark et al.,* AAA Case No. 01–22–0003–8522. That retaliation was resolved when the PBM withdrew its termination during oral argument, but only after the pharmacy expended tremendous resources in bringing the emergency claim. *AON Pharmacy, LLC v. Caremark et al.,* AAA Case No. 01–22–0003–8522, Order Approving Respondents' Withdrawal of Termination Notice. Yet other Specialty Pharmacies have been threatened with termination for bringing similar claims. Caremark letters to Onco360, BioPlus. Retaliation is a real and continuing problem, and PBMs can hide these retaliative acts behind the cloak of confidentiality.

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[90] For example, in Massachusetts, PBMs are prohibited from refusing to contract with a provider if the provider has advocated on behalf of past, current or prospective patients against the PBM. *See* Mass. Gen. Laws Ann. ch. 176O, § 4. Moreover, such retaliatory action would likely be deemed an unfair trade practice and subject to an action under Massachusetts law. Mass. Gen. Laws Ann. ch. 176D, § 3.

V. PBM Conduct Conflicts With Plan Sponsor Interests By Imposing Spread Pricing to Increase Plan Sponsor Cots and Using Rebate Aggregators to Avoid Obligations to Pass Through Drug Manufacturer Rebates

A. Spread Pricing/Differential Pricing

PBMs retain the margin between what they charge plan sponsors such as Medicare or Medicaid, and what they reimburse dispensing pharmacies for the same prescription claim—a process referred to as "spread pricing." When PBMs retain these margins, or "spreads," the costs to plan sponsors are artificially inflated above the actual cost of each prescription claim. Plan sponsors are often unaware that their PBM Agreements allow PBMs to retain spread—effectively handing the PBM a "blank check." For example, buried in Exhibit D of Express Scripts, Inc.'s ("ESI") contract with County of Ventura for the Ventura County Health Care Plan, it states:

> PBM agreements generally provide that a client pay ESI an ingredient cost, plus dispensing fee, for drug claims at a unform rate. *If the rate paid by a client exceeds the rate contracted with a particular pharmacy, ESI will realize a positive margin on the applicable claim.*[91]

In the Medicare and Medicaid contexts, taxpayers/patients bear the costs of these artificially inflated prices. By way of example, on August 16, 2018, the Auditor of the State of Ohio issued an audit report on the State Medicaid Managed Care Pharmacy Services wherein the audit report revealed staggering "spread" findings.[92] From April 1, 2017 through March 31, 2018, the Auditor's analysis determined that CVS Caremark (*"Caremark"*) and OptumRx, Inc. (*"Optum"*), the PBMs contracted with Ohio Medicaid's managed care organizations, retained, on average, $5.71 as spread across all claims.[93] With respect to generic drugs, which made up eighty-six point one percent (86.1%) of all claims, the average spread was $6.14 per claim.[94] In total, Caremark and Optum retained nearly $225 million in spread in only one plan year.[95] Caremark and Optum paid pharmacists nearly $225 million less than what they charged taxpayers through Ohio's Medicaid program.

Spread pricing is not unique to Ohio Medicaid's program. 3 Axis Advisors, LLC ("3 Axis"), a research and analytics firm focused on understanding the prescription drug supply chain and prescription drug cost drivers, has "found strong evidence of spread pricing in Medicaid programs in New York, Illinois, and Michigan," and noted that state government work in Kentucky, Georgia, Virginia, and Maryland "has definitively quantified spread in their state's Medicaid programs as well.[96] Likewise, in their analysis of Florida Medicaid prescription drug claims, 3 Axis

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[91] Express Scripts, Inc. and County of Ventura, Pharmacy Benefit Management Agreement, Exhibit D, 39, available at *https://nationalprescriptioncoveragecoalition.com/wp-content/uploads/2017/07/WebPage-1.pdf.*

[92] Yost, David, Ohio's Medicaid Managed Care Pharmacy Services Auditor of State Report (August 16, 2018), 1, available at *https://ohioauditor.gov/auditsearch/Reports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.*

[93] *Id.*

[94] *Id.*

[95] *Id.*

[96] 3 Axis Advisors, LLC, Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis, (January 30, 2020), 1, available at *https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/5e384f26fc490b221da7ced1/1580748598035/FL+Master+Final+Download.pdf* (citing 3 Axis Advisors, LLC, Analysis of PBM spread pricing in New York Medicaid managed care (January 17, 2019), available at *https://www.3axisadvisors.com/projects/2019/1/17/analysis-of-pbm-spread-pricing-in-new-york-medicaid-managed-care;* 3 Axis Advisors, LLC, Illinois Medicaid Managed Care Pharmacy Analysis (March 13, 2019), available at *https://www.3axisadvisors.com/projects/2019/3/12/illinois-medicaid-managed-care-pharmacy-analysis;* 3 Axis Advisors, LLC, Analysis of PBM Spread Pricing in Michigan Medicaid Managed Care (April 28, 2019), available at *https://www.3axisadvisors.com/projects/2019/4/28/analysis-of-pbm-spread-pricing-in-michigan-medicaid-managed-care;* Langreth, R., Drug Middlemen Took $123.5 Million in Hidden Fees, State Claims (February 21, 2019), available at *https://bloomberg.com/news/articles/2019-02-21/drug-middlemen-took-123-5-million-in-hidden-fees-state-claims;* Langreth, R., Drug Middlemen Face State Probes Over Complex Pricing System (April 9, 2019), available at *https://www.bloomberg.com/news/articles/2019-04-09/drug-middlemen-face-state-probes-over-complex-pricing-system;* Kimsey, K., Report on Managed Care Pharmacy Benefit Manager (PBM) Transparency Report (October 1, 2019), available at *https://rga.lis.virginia.gov/Published/2019/RD593/PDF?fbclid=IwAR3uI8LVdO0xrVrtV65HFi02cYWEjfo8S4jjo5BEdLq9TdxJ79WYopPTIP8.*

found that in 2017 and 2018, Caremark retained $8.27 per claim—generating just over $10 million in 2018 alone.

3 Axis's analysis of Florida Medicaid also exposes the concept of differential pricing. Differential pricing occurs when PBMs charge or reimburse different rates for filling the same drug at different pharmacies, almost always with the intent of advantaging the PBM-owned or affiliated pharmacy.[97]

To illustrate, one of Florida's top MCOs, Sunshine/Centene (managed in part by Caremark), reported a weighted average unit cost of aripiprazole of $11.18 when filled at CVS pharmacies.[98] However, when the same aripiprazole was filled at competing pharmacies, the weighted average unit cost reported ranged from $0.53 across independent pharmacies.[99] In the aggregate, Sunshine/Centene priced generics to create $3.1 million in Margin over NADAC[100] in 2018—of which $2.9 million (94%) was reported at a CVS pharmacy.[101] Although Florida determined the cost of dispensing a prescription claim is $10.24 in the Medicaid fee-for-service context,[102] Florida pharmacies participating in Medicaid managed care that are not affiliated with PBMs received a weighted average of $1.97 per claim as payment for servicing Florida's Medicaid patients.[103]

Differential pricing is a product of vertical integration in the prescription drug supply chain. When differential pricing results in independent pharmacies receiving razor-thin payments—as discovered in Florida—it is ultimately Medicaid patients and independent pharmacies that face the most risk. Disadvantaged patients are put at risk when independent pharmacies are forced to close because of minimal or negative margins received from PBMs. When local pharmacies are forced to close, particularly in low-income and rural areas, patient access to medication and medication adherence rates suffer. Consequently, the likelihood of disease state complications and hospital visits rises—resulting in disproportionate financial risk to state and/or federal governments and worse healthcare outcomes for Medicare and Medicaid patients.[104]

B. Rebates/Rebate Aggregators

Aside from pricing schemes designed to boost PBM profits at the expense of patients, taxpayers, independent pharmacies, and plan sponsors, possibly the most significant area of PBM profit arises in the context of manufacturer rebate manipulation. Similar to spread pricing provisions, PBMs impose misleading or opaque language in the PBM Agreements to allow themselves or an affiliated rebate aggregator to withhold rebate dollars from plan sponsors. PBMs routinely purport to provide their clients with one hundred percent (100%), but these "pass-through" contract provisions are designed to deceive plan sponsors. For example, in its contract with Orange County, Optum agreed to provide the Orange County the greater of "100% pass-through of actual Total Rebates"[105] or the minimum guarantees.[106] By limiting the Orange County's entitlement to rebates Optum actually receives, the agreement fails to address portions of rebate dollars retained by Optum's subcontracted or affiliated rebate aggregators.

Each of the three major PBMs, Caremark, Optum, and ESI, have vertically integrated rebate aggregators tasked with administering their rebate programs,[107] mak-

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[97] *See Id.,* at 61.
[98] *See Id.,* at 65.
[99] *See Id.,* at 66.
[100] It is the total reported MCO claim payment less the claim's National Average Drug Acquisition Cost.
[101] *See Id.,* at 74.
[102] *See Id.,* at 2.
[103] *See Id.,* at 142.
[104] *See Id.,* at 78 (citing Lee, David, Lack of Pharmacy Access Sends Some Patients Back to the Hospital (August 1, 2016).
[105] *Id.,* at 24. ("Total Rebates will include all compensation or remuneration Contractor receives from pharmaceutical manufacturers (branded and generic), attributable to the purchase or utilization of covered drugs (including Specialty Drugs) by an eligible member").
[106] OptumRx, Inc. and the County of Orange, Pharmacy Benefit Management and Claims Administration Program, (January 1, 2021), at 31, available at: *http://cams.ocgov.com/Web_Publisher_SAM/Agenda01_26_2021_files/images/O00220-001235A.PDF.*
[107] *See* Stargard, Andreas, et al, FTC Report on "PBM Rebate Walls" Reveals Impact on Drug Spending, *Patient Care and Competition* (June 28, 2021), available at *https://www.frierlevitt.com/articles/ftc-report-on-pbm-rebate-walls-reveals-impact-on-drug-spending-patient-care-and-competition/* (providing that Ascent Health Services, LLC is affiliated with ESI; Emisar Pharma Services, LLC and the Coalition for Advanced Pharmacy Services, Inc. are affiliated with OptumRx, Inc., and that Zinc Health Services, LLC is affiliated with CVS Caremark.).

ing it difficult to grasp the full extent of rebate dollars collected by PBMs and rebate aggregators. PBMs and their subsidiary rebate aggregators carefully guard this revenue to prevent clients from identifying the payment arrangement. These major PBMs have vertically integrated rebate aggregators including Ascent Health Services (owned by Cigna/ESI), Emisar Pharma Services and Coalition for Advanced Pharmacy Services (owned by UnitedHealth Group/Optum), and Zinc Health Services (owned by CVS Health/Caremark). These rebate aggregators also provide services to other PBMs. For example, Humana and Prime use Ascent Health Services for rebate aggregation. Also, it is worth noting that Ascent Health Services is based out of Switzerland and Emisar Pharma Services is headquartered in Ireland.

In 2017, Broward County, Florida, released an Audit Report detailing the rebate scheme perpetuated by Optum.[108] Optum utilized a complex web of subcontracts that included Optum's arrangement with its wholly owned rebate aggregator and additional contract with ESI. Optum maximized the rebates it retained at the expense of the Broward County and the taxpayers, all while representing that it paid Broward County all rebate funds it received.[109]

Rebate aggregators are also prevalent in Medicare Part D space. Frier Levitt represented a Medicare Part D Sponsor in its rebate dispute against a PBM owned by a publicly traded company. Frier Levitt uncovered that the PBM, unbeknownst to the Part D Sponsor, delegated its rebate functions to a rebate aggregator, who in turn, subcontracted with a major PBM.[110] We recovered $6.25M in rebates for one (1) calendar year for the Part D Sponsor. It is also worth noting that the PBM provided rebate-related data to the Part D Sponsor to submit the annual DIR reports to the CMS. However, in the DIR reports, the PBM did not specify whether the rebates that were not passed to the Part D Sponsor included rebates retained by the rebate aggregators. In fact, the Medicare Part D DIR Reporting Guidance fails to require PBMs to report rebates retained by rebate aggregators.[111] PBMs drive up the total drug spending of plan sponsors including Medicare and Medicaid through spread pricing on reimbursement for prescription drugs and manufacturer rebates, and by utilizing PBM-owned or affiliated rebate aggregators.

VI. PBMs Have Systematically Warped the Benefit and Intent of the 340B Drug Program for Their Own Financial Gain By Redirecting a Significant Portion of 340B Revenue Intended for Healthcare Providers

Congress implemented and designed the federal 340B Drug Pricing Program ("340B Program" or "340B") in 1992 through the Veteran's Health Care Act (P.L. 102–585) to assist certain healthcare providers—referred to as "Covered Entities"—that serve poor, uninsured or otherwise vulnerable populations by permitting them to purchase prescription drugs at lower costs from manufacturers.[112] Specifically, pursuant to the 340B Program, drug manufacturers are required to charge Covered Entities no more than a significantly discounted "ceiling price" on certain outpatient prescription, in exchange for the manufacturer's drug products being covered by Medicaid and Medicare Part B.[113]

Under 340B, Covered Entities can acquire drugs from manufacturers at extreme discounts from what is normally available. In turn, Covered Entities are (in theory) able to "pass on" those savings to their patients through lower costs for medications, or, as contemplated by 340B itself, Covered Entities can seek reimbursement for 340B drugs in the normal course and use those greater profit margins to subsidize other unfunded areas of their operations. It is fundamental to the 340B Program that Covered Entities are credited for their ability to "provide direct clinical care

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[108] Melton, Robert, Audit of Pharmacy Benefit management Services Agreement, Report No. 18–13 (December 7, 2017), available at *https://www.broward.org/Auditor/Reports/Documents/2017_1212%20Agenda%20Review%20of%20Pharmacy%20Benefit%20Management%20Services%20by%20StoneBridge/2017_1212%20Exh1_OptumRx.pdf.*

[109] *See Id.*

[110] *See* Caltavuturo, Christopher, et al., Frier Levitt Successfully Obtains a $6.25 Million Settlement on Behalf of its Plan Sponsor Client Against a Pharmacy Benefit Manager (December 23, 2020), 14–20 available at *https://www.frierlevitt.com/articles/service/pharmacylaw/recent-successes/frier-levitt-successfully-obtains-a-6-25-million-settlement-on-behalf-of-its-plan-sponsor-client-against-a-pharmacy-benefits-manager/*.

[111] *See* Centers for Medicare and Medicaid Services, Final Medicare Part D DIR Reporting Guidance for 2021, March 30, 2022, available at *https://www.cms.gov/files/document/final2021dirreportingreqsmemo508v3.pdf.*

[112] *See* Veterans Health Care Act of 1992, Pub. L. No. 102–585, § 602 (codified as amended at 42 U.S.C. § 256b); *see also* Overview of the 340B Drug Discount Program, *https://crsreports.congress.gov/product/pdf/IF/IF12232* (October 14, 2022).

[113] 42 U.S.C. § 256b(a)(1),(4).

to large numbers of uninsured Americans" regardless of the patient's ability to pay.[114] As articulated by Congress itself, the 340B Program's purpose is "to enable covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[115]

Since its implementation in 1992, the 340B Program has grown exponentially. Approximately 14% of all pharmaceutical sales in the United States, or $93.6 billion, are accounted for under 340B.[116] 340B has grown five times faster than the overall drug market,[117] with 340B expenditures quadrupling since 2014.[118] In terms of magnitude, it is the second largest federal drug program, behind only Medicare Part D. By 2026, 340B is expected to exceed the size of both Medicaid and Medicare.[119]

Industry experts have opined that "[t]he enormous growth in 340B contract pharmacy arrangements seems to boil down to a *single* factor: *outsized profit margins.*"[120] Leveraging their role as the middle-men of the prescription drug industry, and substantial vertical integration amongst plan sponsors and pharmacies, PBMs have systematically, and increasingly, warped the benefit of intent of the 340B Program for their own financial gain. These abusive and problematic PBM practices are well documented, and negatively affect both patients and providers alike.[121] Astoundingly, through these practices, **vertically integrated health care conglomerates that own or are affiliated with PBMs retain upwards of 63.5% of the total 340B cost to payors and their patient beneficiaries.**[122] In effect, PBMs have diverted the 340B discounts and "outsized profit margins"—intended to benefit the nation's most vulnerable and the providers that serve them—into the coffers of Fortune 500 companies. Put simply, PBMs have mutated the 340B Program, a well-intentioned community benefit, into a virtual ATM cash machine for themselves, at the expense of Covered Entities, community contract pharmacies, and the patients they serve.

A. While Managing the 340B Drug Program, PBM-Owned Pharmacies Syphon Benefits Away from Covered Entities

Because certain Covered Entities, such as small community health centers, may not have in-house pharmacies, HRSA issued sub-regulatory guidance in 1996 permitting Covered Entities to "contract" with outside pharmacies (referred to as "Contract Pharmacies").[123] Initially, HRSA restricted Covered Entities to contracting with only a single Contract Pharmacy.[124] In 2010, however, HRSA dramatically shifted the 340B Contract Pharmacy landscape by permitting Covered Entities to maintain an unlimited number of Contract Pharmacy relationships.[125] In the wake of this HRSA guidance, for-profit pharmacies, especially those owned or affiliated with PBMs, seized on the opportunity to capitalize on substantial 340B drug discounts. In fact, Contract Pharmacies owned by or affiliated with PBMs can retain upwards of twenty-five percent (25%) of the total 340B cost as their dispensing fee.[126]

Notably, the Contract Pharmacies participating in 340B are primarily not independent pharmacies. Rather, the vast majority of Contract Pharmacy arrangements are between Covered Entities and large for-profit pharmacies that are owned by or

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[114] *See* H.R. Rep. No. 102–384, pt. 2, at 12 (September 22, 1992).

[115] *Id.; see also* HRSA, Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,551 (August 23, 1996) (wherein the Health Resources and Services Administration ("HRSA"), the federal agency charged with administering the 340B Program, opines that 340B is designed so that CEs would "pass all or significant part of the discount to their patients.")

[116] Rory Martin, IQVIA, 340B Program Continues to Grow While Contract Pharmacy Restrictions Take Effect, at 2.

[117] *Id.*

[118] Adam Fein, Drug Channels, Exclusive: The 340B Program Soared to $38 Billion in 2020—Up 27% vs 2019, *https://www.drugchannels.net/2021/06/exclusive-340b-program-soared-to-38.html.*

[119] Berkeley Research Group, LLC, 340B Program at a Glance, *https://media.thinkbrg.com/wp-content/uploads/2021/12/09062840/340B_Forecast-Report-Infographic_2021.pdf.*

[120] Berkeley Research Group, LLC, For-Profit Pharmacy Participation in the 340B Program, *https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf* (emphasis added).

[121] *See AstraZeneca Pharmaceuticals LP v. U.S. Dept. Health and Human Services,* No. 22–1676 (United States Court of Appeals, Third Circuit), ECF. #36, Brief of Community Oncology Alliance, Inc. as Amicus Curiae.

[122] *See infra,* Section II.D., Figure 3.

[123] *See* 61 F.R. at 43549.

[124] *Id.* at 43,551.

[125] *See* 75 F.R. 10272–01 (March 5, 2010).

[126] *See infra,* Section II.D., Figure 3.

affiliated with the largest PBMs.[127] Indeed, CVS Health, Walgreens, Cigna, UnitedHealth Group and Walmart—now control 73% of all Contract Pharmacy relationships.[128] Each of these entities also operate or are affiliated with a PBM. The three largest PBMs (Caremark, ESI and OptumRx), controlling 80% of the total prescription drug market, account for 39% of all Contract Pharmacy relationships through their owned or affiliated Contract Pharmacies.[129] In 2021, Walgreens and CVS held the greatest 340B Contract Pharmacy market share with Walgreens controlling 31% of all retail Contract Pharmacies (up from 28% in 2020) and CVS controlling 19% of all retail Contract Pharmacies (up from 20% in 2020).[130] More than 80% of Walgreens retail pharmacy locations and two-thirds of CVS locations are Contract Pharmacies.[131] Also noteworthy, in 2022, the three largest PBMs—Caremark, ESI and OptumRx—collectively owned 500 mail order, specialty, and infusion Contract Pharmacies.[132] These 500 PBM-affiliated mail, specialty, and infusion pharmacies account for only 1.5% of all 340B Contract Pharmacy *locations,* but total a stunning 21% of the total 340B Contract Pharmacy *relationships* with Covered Entities.[133] And PBM-affiliated pharmacy's control over these channels continues to rapidly increase. As of 2020, there were 16,293 Contract Pharmacy arrangements between Covered Entities and vertically integrated specialty pharmacies, representing a 1,006% growth from 2016.[134]

Based on this market dominance, Contract Pharmacies affiliated with Walgreens, Caremark, ESI and OptumRx are conservatively estimated to retain upwards of $2.58 billion in 340B discounts in 2022 alone.[135] This is no small matter. If these corporations retain these discounts as profit, which is likely considering the Covered Entity supplies 340B drugs to the Contract Pharmacy at essentially no cost to the Contract Pharmacy, it would equate to between 6.4% to 17.4% of their adjusted operating profit.[136] Further, in 2021, Walgreens Contract Pharmacies retained $994 million of 340B drug discounts, ESI Contract Pharmacies retained $561 million and OptumRx Contract Pharmacies retained $281 million.[137] Further evidencing the material impact the 340B Program is to the bottom lines of PBMs—who are notably *not* the intended beneficiaries of the Program—PBMs and their affiliated Contract Pharmacies have indicated that reductions to their 340B Contract Pharmacy footprint would significantly and materially affect overall profitability. For example, the annual reports of CVS Health and Walgreens Boots Alliance confirm that 340B profits are material to their business operations and warn that restrictive Contract Pharmacy policies enacted by drug manufacturers, which have been the subject of

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[127] Karen Mulligan, Ph.D., University of Southern California, The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments (October 14, 2021) at 4, *https://healthpolicy.usc.edu/wp-content/uploads/2021/10/The_340B_Drug_Pricing_Program.pdf* (noting that "[l]arge retail pharmacy chains—Walgreens, CVS, Walmart, and Rite Aid—are disproportionately represented among contract pharmacies"); *see also* GAO 2018, at 21–22; (noting 75% of CP arrangements are held by "chain pharmacies").

[128] Adam Fein and Doug Long, The Specialty Pharmacy Industry Update and Outlook, May 3, 2022, *https://drugch.nl/asembia22; see also* 2018 GAO Rep., at 20–21 (noting approximately 75% of 340B Contract Pharmacies are chain pharmacies, notwithstanding that chain pharmacies represent scarcely half of all pharmacies nationwide).

[129] *Id.*

[130] Nephron, Decade-Long 34B Tailwind Gives Way to Significant Pharmacy Headwind in 1Q 2022, at 9–10; *see also* Karen Mulligan, Ph.D., University of Southern California, The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments (October 14, 2021) at 4, *https://healthpolicy.usc.edu/wp-content/uploads/2021/10/The_340B_Drug_Pricing_Program.pdf.*

[131] Adam Fein, Drug Channels, Exclusive: 340B Continues Its Unbridled Takeover of Pharmacies and PBMs, *https://www.drugchannels.net/2021/06/exclusive-340b-continues-its-unbridled.html.*

[132] *Id.*

[133] *Id.*

[134] Berkeley Research Group, LLC, For-Profit Pharmacy Participation in the 340B Program, *https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf* (emphasis added); Adam Fein, Drug Channels, PBM-Owned Specialty Pharmacies Expand Their Role In—and Profits From—the 340B Program, *https://www.drugchannels.net/2020/07/pbm-owned-specialty-pharmacies-expand.html;* Nephron, Decade-Long 34B Tailwind Gives Way to Significant Pharmacy Headwind in 1Q 2022, at 10 (noting that CVS controls the largest share of specialty Contract Pharmacies, with 30.1% of the market).

[135] *Id.*

[136] *Id.*

[137] Nephron, at 8–12.

recent litigation,[138] will negatively impact their bottom lines.[139] Clearly, with the huge increase in Contract Pharmacies, 340B has mutated away from the original intention of Congress, to serve communities and patients in need, to increasing profits for large corporations.

B. PBM-Owned 340B Third Party Administrators Wrongful Conduct

The process of determining whether a particular claim is 340B eligible is complex, and responsibility for compliance lies with the Covered Entity.[140] Covered Entities hire third-party administrators ("TPAs") to retroactively determine 340B eligibility and rely on them to ensure 340B compliance.[141] TPAs generally provide claims processing and management services and retroactively determine which claims are 340B eligible. Covered Entities also utilize the services of TPAs to appropriately calculate and reconcile the payments between themselves and Contract Pharmacies. TPAs are typically for-profit businesses and charge Covered Entities a fee for TPA services. For all such services, TPAs charge Covered Entities a fee, which is generally assessed on a per claim basis as a percentage of the amounts paid by the patient and their insurance. Some TPAs charge an estimated 7.5% of the total payment per claim for their reconciliation services. Notably, the largest TPAs are also vertically integrated with the largest PBMs: CVS Health owns the TPA Wellpartner.[142] Cigna owns the TPA Verity Solutions.[143] Walgreens owns the TPAs 340B Complete and Shields Health Solutions.[144]

Consistent with their virtual stranglehold on the Contract Pharmacy market, and motive to divert every 340B discount to themselves, TPAs vertically integrated with PBMs require Covered Entities to contract with and use their own Contract Pharmacies. For example, beginning in 2018, CVS Health required Covered Entities seeking to enter into a 340B Contract Pharmacy arrangement with CVS to also utilize CVS Health's wholly owned TPA, Wellpartner, for 340B claim reconciliation.[145] Covered Entities were presented with a choice: either use the PBM's TPA or not contract with CVS' vast network of Contract Pharmacies. CVS's Wellpartner now serves as the *exclusive* TPA for any CVS Contract Pharmacy arrangement—accounting for 19% of all retail Contract Pharmacies and 30.1% of all specialty Contract Pharmacies.[146] Compounding this situation, Wellpartner charges Covered Entities a percentage of each claim they reconcile.

C. PBMs Divert Funds Away from the Intended Beneficiaries of the 340B Program

Through their business practices described herein, and below, PBMs make every effort to divert as much of the substantial savings offered by the 340B Program away from their intended beneficiaries—the Covered Entities and their patients—to them-

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[138] *See Sanofi Aventis, U.S. LLC v. United States Department of Health and Human Services., et al.,* No. 21–3167, 21–3379 (United States Court of Appeals, Third Circuit); *Eli Lilly and Company v. Norris Cochran et al.,* No. 1:21–00081 (United States District Court, Southern District of Indiana).

[139] *See e.g.,* CVS Health Corporation, Form 10–K FY 2021, p. 22–23 ("[a] reduction in 'Covered Entities' participation in contract pharmacy arrangements, as a result of the pending enforcement actions or otherwise, a reduction in the use of [CVS/Caremark's] administrative services by Covered Entities, or a reduction in drug manufacturers' participation in the program could materially and adversely affect [CVS/Caremark]"; WBA, Form 10–K FY 2021, p. 22 ("[c]hanges in pharmaceutical manufacturers' pricing or distribution policies and practices as well as applicable government regulations, including, for example, in connection with the federal 340B drug pricing program, could also significantly reduce [WBA's] profitability."); *see also* Nephron, at 9 ("Walgreens is by far the most exposed to 340B, given long dominance in contract pharmacy, TPA, and tech services to covered entities").

[140] Covered Entities are responsible for the compliance of their Contract Pharmacy(ies) and must comply with Section 340B of the Public Health Service Act, 42 U.S.C. § 256b and relevant HRSA guidance.

[141] OIG Report, Contract Pharmacy Arrangements in the 340B Program (February 4, 2014), at 5, *https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.*

[142] BRG, For-Profit Pharmacy Participation in 340B Program, at 4 (October 2020), *https://bit.ly/36X0eUG; see also* AIR340B, The Impact and Growth in 340B Contract Pharmacy Arrangements—Six Years Later, at 8, *https://340breform.org/wp-content/uploads/2021/04/AIR340B_340B-Contract-Pharmacies.pdf.*

[143] *Id.*

[144] *Id.*

[145] *See RxStrategies, Inc. v. CVS Pharmacy, Inc.,* 390 F. Supp.3d 1341, 1347 (M.D.Fl. 2019) ("CVS now requires any covered entity that wants to fill 340B Program prescriptions at a CVS pharmacy to use Wellpartner as its program administrator. If the covered entity does not want to use Wellpartner as its 340B program administrator, it cannot utilize CVS as a contract pharmacy for the 340B program.").

[146] Nephron, at 10.

selves and their affiliates. Two particular PBM abusive practices that are most concerning are: (1) PBMs collect substantial sums of DIR fees (described above) on 340B claims—which diverts 340B funds away from Covered Entities, community Contract Pharmacies, and the patients they serve, and into the pockets of the PBMs; and (2) PBMs pay pharmacies below market pricing on 340B claims, further diverting 340B savings away from providers and into the PBM (and their affiliate's) pockets.

1. PBMs Collect Significant DIR Fees on 340B Claims

PBMs force Contract Pharmacies to pay DIR fees on 340B claims, long after the PBM has adjudicated the claim and effected payment to the pharmacy. As described above, these DIR fees can be substantial percentages (for example 5%) of the overall reimbursement received by the pharmacy. By assessing DIR fees on 340B claims, PBMs are reducing the reimbursement amounts to pharmacies and pocketing these funds for themselves. In other words, the 340B savings intended to compensate providers for serving indigent populations, and to promote these providers to continue providing these essential services, are systematically siphoned away by PBMs through the assessment of DIR fees on 340B eligible claims. Making matters worse, the largest TPAs (such as Wellpartner) do not account for DIR fees assessed by their affiliated PBMs, which causes the TPAs to artificially inflate the total reimbursements received by the Covered Entity and/or Contract Pharmacy. Again, the TPA's fee is generally based on a percentage of the total dollar amount of the claim. Thus, an inflated claim amount (*i.e.,* a claim that fails to account for DIR fees, reducing the total reimbursement) results in an inflated fee to the TPA. Thus, DIR fees on 340B claim enrich not only PBMs, but also their TPA affiliates.

2. PBMs Pay Less for Medications Dispensed to 340B Patients

Not only do PBMs take a percentage DIR fee off the top of many 340B claims, PBMs reimburse providers at significantly reduced rates on 340B claims. This flies in the face of the intention of the 340B Program—which specifically contemplates Covered Entities and their Contract Pharmacies obtaining a profit margin on 340B drugs as a means of funding charity care operations, that Congress has deemed essential. In other words, PBMs have unilaterally decided that *PBMs* should also share in the 340B Program's savings—even though PBMs do not provide any patient care and are not the intended beneficiaries of the Program.

Recently, several PBMs have sought to make the identification of 340B claims mandatory by 340B providers specially so that they can pay pharmacies less on these claims. ESI, for example, issued notice in February 2021 that Contract Pharmacies must retrospectively identify 340B claims.[147] Thereafter, PBMs (like ESI) began to impose significantly lower reimbursement rates for 340B claims, essentially usurping the savings that should have flowed to Covered Entities, even when a PBM owned or affiliated pharmacy may not have been the CP.[148] It must be noted that while the PBMs are paying the pharmacy a significantly discounted rate, many PBMs are still charging the plan sponsor as if the claim were not 340B-eligible. The "spread" between the higher amounts the PBM charges the plan sponsor and the lower amounts the PBM reimburses the pharmacy for 340B claims, is retained by the PBM. This "spread" is intended for the Covered Entity, the Contract Pharmacy, and their patients; not the PBM. In effect, PBMs are singling out 340B drugs for reduced reimbursement, "which essentially transfers the benefit of the program from safety net providers to for-profit payers."[149] PBMs have thus ensured that they profit from 340B in as many ways as possible.

VII. Recommendations to the U.S. Senate Committee on Finance

Based on the foregoing, we recommend that the Committee take action to address the outsized and deleterious impact of PBMs on patients, plan sponsors, manufacturers, distributors, taxpayers and pharmacy providers. The vertical integration among PBMs has led to reduced competition, limited drug access, a lack of transparency, and higher costs for patients and plan sponsors. At the same time, PBMs have severely harmed the ability of unaffiliated pharmacy providers to continue to

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[147] Rhiannon Klein, cv340b, Express Scripts Issues 340B Claims Identification Requirements, (March 11, 2021), *https://www.cv340b.org/express-scripts-issues-340b-claims-identification-requirements/*.

[148] Adam Fein, Drug Channels, How Hospitals and PBM Profit—and Patients Lose—From 340B Contract Pharmacies (July 23, 2022), *https://www.drugchannels.net/2020/07/how-hospitals-and-pbms-profitand.html.*

[149] Legacy Health Endowment, PBMs and the 340B Program, at 1, *https://340breport.com/wp-content/uploads/2021/06/PBMs-and-340B-White-Paper-June-29-2021.pdf.*

operate, putting a significant burden on pharmacy providers and their ability to provide essential care to patients.

To that end, we recommend the Committee address the following issues:

1. **Inadequate Reimbursement to Pharmacy Providers by PBMs to Maintain a Robust Network of Quality Providers**
   Through a variety of tactics, including DIR fees, generic and brand effective rate reconciliation, and outright below water reimbursement rates, PBMs seriously threaten the viability of a robust network of pharmacy providers outside of their affiliated providers. We call upon the Committee to investigate reimbursement rates to pharmacy providers (both those owned by PBMs and those that are unaffiliated), including a comprehensive study of reimbursement rates, network access and network adequacy. We further call upon the Committee to take action to set appropriate standards for establishing reimbursement rates to pharmacy providers. These standards must take into account actual available acquisition costs in the marketplace (including the differences based on pharmacy provider type), as well as reasonable dispensing fees taking into account the actual costs to dispense different types of medications. Such standards may either create a floor, or, alternatively, establish an appropriate formula for determining appropriate reimbursement rates, based on the aforementioned standards. Finally, the Committee must act to create an enforcement procedure to address instances where PBMs have not offered such appropriate reimbursement terms, as well as a dispute resolution framework in order for pharmacy providers and PBMs to effectively resolve such matters between themselves.
2. **Bring PBMs Within the Bounds of the Law**
   PBMs routinely and consistently maintain that they are not bound by a host of laws aimed at regulating conduct within the drug supply channel. Most notably, PBMs have asserted (successfully in some instances) that they are not bound by the federal any willing provider law, and thus, do not take such compliance obligations in mind when establishing pharmacy networks within the Medicare Part D program. Thus, we urge the Committee to clarify existing guidance regarding the applicability of such laws to PBMs, and, where necessary, amend relevant federal laws to apply to more clearly PBMs.
3. **Reduce the Negative Impact of Vertical Integration and Rebate GPOs**
   Through secretive offshore companies, PBMs have been able to circumvent the oversight and regulation intended by recent legislative and regulatory efforts aimed at adding transparency to rebates received on behalf of plan sponsors. Simply put, PBMs are still *not* passing through rebates received on behalf of their plan sponsor clients. We call upon the Committee to investigate the negative impact of PBM-owned Rebate GPOs on patients, plan sponsors and the federal government. We further call upon the Committee to take action to regulate PBMs' vertical integration, to reduce the negative consequences of such vertical integration, including the abusive power PBMs hold over formularies, and on wholesalers through unchecked buying power. Finally, we call on the Committee to recommend enforcement actions regarding PBMs' vertical integration, to protect patients, plan sponsors, pharmacy providers and taxpayers, alike.

The time for action is now. Pharmacy providers face existential threats due to PBM consolidation and integration. Thus, we implore the Committee to take action to protect patients, plan sponsors, taxpayers, and pharmacy providers, alike.

Exhibit

Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers.

Prepared by Frier Levitt, LLC

Commissioned by the Community Oncology Alliance

February 2022

1 Executive Summary

There is growing awareness of the problems and pitfalls with Pharmacy Benefit Managers (PBMs) in the United States health care system. Contracted by plan sponsors (including government programs, self-insured employers and insurance companies) to negotiate on their behalf with pharmaceutical companies, these "middlemen" corporations have quietly become an unavoidable part of our nation's health care system.

Today, fewer than five PBMs control more than 80% of drug benefits for over 260 million Americans, which includes the power to negotiate drug costs, what drugs will be included on plan formularies, and how those drugs are dispensed. Oftentimes, patients are required to receive drugs through PBM-owned or affiliated specialty and mail-order pharmacies and suffer serious, sometimes dangerous, and even deadly, impact of their abuses as a result of medication delays and denials.

However, while the role PBMs play in the U.S. health care system is complex and under scrutiny by both federal and state policymakers and the public, it is increasingly becoming clear that PBMs make up an oligopoly of rich, vertically integrated conglomerates that routinely prey on health care practices, providers, and their patients. PBMs have done this by overwhelmingly abusing their responsibility to protect Americans from this country's drug pricing crisis, instead exploiting the opacity throughout the nation's drug supply chain to enrich themselves.

Unfortunately, their impact is only becoming more pronounced, especially in the world of cancer care. More and more cancer medications are coming out in oral formulations, resulting in a shift away from the medical benefit and into the pharmacy benefit. And because cancer medications are among the most expensive out there, they are very attractive to PBMs because they yield higher rebates, higher "DIR fees," and other pricing gimmicks that yield substantial profits.

Through vertical integration and sheer market power, PBMs have also been able to creep into other areas of our health care system, such as injectable biosimilars and intravenous chemotherapies. Not only can PBMs leverage these products for steep originator drug rebates (thereby stifling the biosimilar industry for their own gain), but PBMs have also begun to institute policies such as mandatory "white bagging" to take the in-office administration out of the hands of patients' oncologists.

The purpose of this exposé is to reveal and explain PBMs' advantage and leverage by providing transparency where now there is total darkness, and by delving into the many ways that PBMs have abused their power. This report comprehensively explores and documents the myriad of PBM abuses, and their impact on patient care—focusing especially on cancer care. It explores how the recent levels of consolidation among PBMs and health insurers is adversely impacting cancer care, fueling drug costs, all while allowing for massive profits for PBMs and health insurance companies. Examining the most pervasive and abusive PBM tactics, each section highlights the adverse impact of PBMs on patients, health care payers (including Medicare, Medicaid, employers, and taxpayers), and providers, while also detailing potential solutions.

Each day that goes by, physicians, practices, and most importantly, patients become increasingly powerless because of horizonal PBM consolidation and vertical integration with insurers. The result is a system designed for patients to receive inferior treatment, while paying more out-of-pocket for their medications.

The time for sitting back and hoping for PBMs to become good faith actors is over. It is time for action to stop PBM abuses once and for all, and this exposé provides a road map for tackling them one dirty PBM trick at a time.

2 Introduction

In the eyes of many Americans, the problem with drug pricing is caused by unscrupulous pharmaceutical manufacturers who have increased drug prices over the last two decades with reckless abandon. This has been exemplified by a handful of highly visible bad actors, such as "pharma-bro" Martin Shkreli or Nostrum Pharmaceuticals founder Nirmal Muyle, who rightfully captured the public's attention, but wrongfully over-simplified the causes of our nation's drug pricing issues.

Far more dangerous and insidious actors have quietly grown to dominate the nation's pharmaceutical industry and drive high drug prices through the secretive pharmacy benefit manager (PBM) industry. Ironically, in the country's attempt to rein in ruthless operators like Shkreli and Muyle, we ended up inadvertently creating the PBM problem that now plagues us. Expanding the role of PBMs, first from simple processors of pharmacy claims to middlemen more actively managing the

prescription benefit initially made some sense. Clients—employers, unions, state governments, and other payers of medical care—did not have the expertise to manage complex drug benefits. Thus, they could hire a PBM to administer their prescription benefit, which would include simplifying and streamlining a complicated drug supply chain, designing formularies to exclude wasteful drugs, using their size and leverage to negotiate better discounts from pharmaceutical manufacturers, and managing pharmacy networks to create better outcomes for patients.

However, as this exposé on PBM business tactics, dirty tricks, and their negative impacts will detail, what seemed like a good idea "on paper" has not come to fruition. Instead, the nation's largest PBMs have capitalized on the complexity of the drug supply chain and used the secrecy in which they operate to hide the true cost of drugs. And rather than eliminate the costly arbitrage within the supply chain, PBMs co-opted and embraced it, exacerbating the very problems of high drug prices that they were originally hired to control. They saw the financial windfall that would come through vertical integration and bought or set up their own mail-order and specialty pharmacies, steering patients away from independent community pharmacies and medical practices to their wholly-owned or affiliated pharmacy facilities where they could retain the inflated prices (and profits) they themselves were responsible for creating.

The perverse result is that PBMs have abandoned their most sacrosanct function of protecting their clients from high cost or low benefit drugs, instead letting higher priced drugs "buy" their way onto their clients' formularies via rebates that the PBMs mostly retain. They then set up affiliated rebate aggregator entities to further obfuscate the flow of pharmaceutical manufacturer dollars, retaining a larger portion of their clients' rebates, and leaving patients on high deductible plans exposed to drugs with exploitative list prices. **The result is that patients pay more for their drugs off of artificially inflated list prices and the PBM clients have higher prescription drug costs.**

The PBM's purpose in the drug supply chain was to "police" the system. Had the largest PBMs not been lured in by the immense profit potential borne out of the complete opacity of drug costs, a PBM's greatest asset would have been trust—trust from payers *and* providers that they were tirelessly working to protect the American public from high drug prices. However, this unfortunately did not come to pass. **Instead, the PBM's greatest advantage has become the almost total opacity of the U.S. drug supply chain and a lack of understanding among employers, unions, state governments, and American taxpayers of how most PBMs have chosen to abuse it.**

The purpose of this exposé is to reveal and explain the PBM advantage by providing transparency where now there is total darkness and delving into the many ways that PBMs have abused their power to become "crooked cops." Throughout this exposé, we comprehensively explore and document the myriad of PBM abuses, and their impact on patient care—focusing especially on cancer care. **Finally, we explore how the recent levels of consolidation among PBMs and health insurers is adversely impacting cancer care, fueling drug costs, while allowing for massive profits for PBM and health insurance companies.** We have thoroughly examined and detailed the most pervasive and abusive PBM tactics, in each section highlighting their adverse impact on patients, health care payers (including Medicare, Medicaid, employers and taxpayers), and providers.

With the ultimate goal of this exposé being transparency, Frier Levitt went beyond the law, partnering with 3Axis Advisors LLC to create infographics derived from their analysis of millions of prescription claims across multiples states. The goal of these infographics is to help crystallize and simplify the very complex topics we will discuss throughout this exposé. Lastly, because PBMs have been known to hold themselves out as being "above the law,"[1] we have provided the applicable law and legal principles governing each topic, and detailed the PBMs' thin legal footing as it comes to these abusive practices. Finally, we have laid out potential, workable solutions to these issues, which may be legislative, regulatory, or legal in nature.

We intend for this report to serve as an authoritative source and reference guide for federal and state policymakers, regulators, and employers seeking greater understanding of PBM behavior, as well as frameworks for reshaping the industry for the better. While not all PBMs engage in these types of practices, or the degree with which they engage in these practices may vary from plan to plan, program to pro-

[1] *See, CZ Servs. v. Express Scripts Holding,* Case No. 3:18–cv–04217–JD, Dkt. No. 301–3.

gram, state to state, and so on, we believe that a thorough exposure of the blind spots, latitude for abuse, and backwards incentives is essential for any coherent understanding of the inherent flaws within the drug supply chain.

This exposé was commissioned by the Community Oncology Alliance (COA). The findings reflect the independent research of the authors, Frier Levitt, LLC, and does not endorse any product or organization. If this exposé is reproduced, we ask that it be reproduced in its entirety, as pieces taken out of context can be misleading.

3 Background

3.1 The Stakeholders

Any examination of the PBM industry must necessarily begin with an overview of the relevant stakeholders. These include five major categories of industry participants: (1) plan sponsors, (2) health insurers, (3) patients, (4) manufacturers, (5) providers, and (6) PBMs. Understanding who the major stakeholders are, and their relationship with one another, is paramount.

At the top of the hierarchy are plan sponsors. These include governmental health benefits programs (such as Medicare, Medicaid and TRICARE), employer-sponsored health plans, Taft-Hartley and union welfare plans, and private health insurance companies. These entities sponsor a health benefits plan for their members, beneficiaries or employees, and provide coverage for pharmacy expenses and drug costs (in addition to traditional medical expenses). In the Medicare Part D context, the Centers for Medicare & Medicaid Services (CMS) contracts with private insurance companies that submit bids to become Part D plan sponsors, and CMS in turn subsidizes certain costs associated with the operation of the plans.[2] Likewise, in the Medicaid space, the majority of states operate a managed care model with respect to pharmacy benefits, contracting with Medicaid Managed Care Organizations (MCOs), who in turn, contract with PBMs to administer the pharmacy benefit.[3] Finally, in the private sector, employers either directly or through an insurance company contract with PBMs to administer pharmacy benefits. These employer-sponsored plans may either be fully-insured (meaning the employer hires an insurance company and pays all or part of the premiums on behalf of its employees) or self-insured (meaning the employer bears all of the financial risk with the costs of care).[4] In any case, these plan sponsors bear the ultimate costs of care, and suffer when PBM abuses cause prices to rise or waste to occur. Plan sponsors may or may not hire a health insurance company to help offset the risks associated with the cost of care, and pay premiums on behalf of their beneficiaries. These health insurance companies may in turn be the entity that directly contracts with the PBM for pharmacy care. However, as noted below, the lines have become increasingly blurred between health insurers and PBMs; thus, the key distinction between plan sponsors and health insurers is that the plan sponsors are typically the ultimate financial guarantors of the costs of the health care for their beneficiaries, including not only drug costs but also major medical expenses.

At the other end of the continuum are the patients. Patients include beneficiaries of government sponsored health care programs, as well as the employees (and dependents) of employers sponsoring health plans. They are also uninsured or underinsured individuals who are left to find a way to cover drug costs themselves. In oncology, they are cancer patients needing care from a complex and disjointed health care system. As a group, they not only bear a disproportionate share of the out-of-pocket costs associated with PBM abuses, but also suffer from the inferior care caused by certain PBMs' tactics of putting profits over patients. These include delays and denials as a result of PBMs' unnecessary obstacles to care.

On the front line of care are the providers. These include retail, specialty and mail-order pharmacies, and in oncology, community oncology practices. In addition to providing direct medical care, community oncology practices provide in-office and outpatient pharmacy services, which can take two basic forms (depending on applicable state law): dispensing physician practices (*i.e.,* in-office dispensing under a plenary medical license), or oncologist-owned pharmacies (*i.e.,* the oncology practice owns

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[2] *http://medpac.gov/docs/default-source/reports/jun19_medpac_reporttocongress_sec.pdf.*

[3] *https://www.kff.org/medicaid/issue-brief/management-and-delivery-of-the-medicaid-pharmacy-benefit/.*

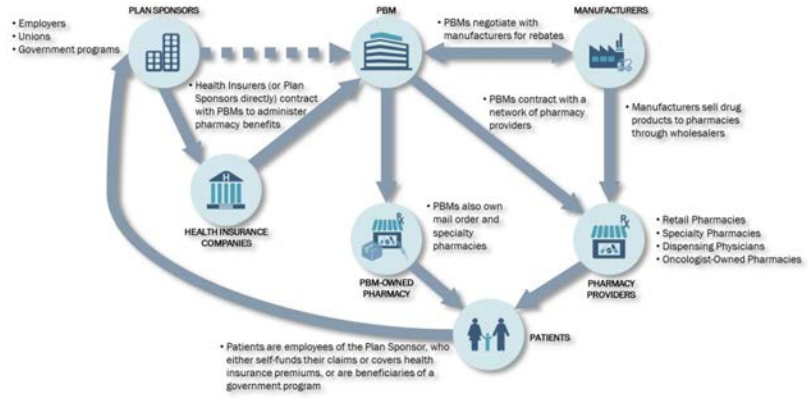
[4] *https://www.shrm.org/hr-today/news/hr-magazine/pages/0909wellsc.aspx.*

and operates a licensed retail pharmacy within the clinic).[5] These providers contract with PBMs to dispense medication to plan members, and participate in PBM networks. In so doing, they are tasked with providing appropriate care to their patients, while remaining bound to the PBMs who set reimbursement rates and other terms for participation.

While not directly involved in the provision of care, manufacturers are equally part of the continuum and impacted by PBM actions. These include drug and biologic manufacturers, including both brand and generic companies. Manufacturers have had a particular important role in the biosimilar market, becoming captive to PBMs' rebate traps, and stifling the biosimilar market before it even has a chance to take hold.

The final piece of the puzzle is the PBM. PBMs are third-party administrators of prescription drug programs covered by a plan sponsor. The PBM is primarily responsible for processing and paying prescription drug claims submitted by participating providers on behalf of covered beneficiaries. However, a PBM's role is not limited to processing and paying prescription drug claims. Rather, PBMs also provide bundled services related to the administration of pharmaceutical benefits, including formulary design, formulary management, negotiation of branded drug rebates, and controlling network access of participating pharmacies. Perhaps most importantly, PBMs often also own and operate their affiliated retail, mail-order and/or specialty pharmacies, and in so doing, directly compete with independent providers participating in PBM networks. They are not just the gatekeepers, but also competitors operating in the same marketplace. This blatant conflict of interest has serious consequences. Finally, as the result of consolidation and vertical integration within the marketplace, virtually all of the major PBMs have merged with, acquired or become acquired by health insurers, greatly blurring the lines between insurer and PBM. As a result, health insurers and PBMs are often referred to jointly as "payers."

Figure 1. The Pharmacy Benefits Landscape



The Figure 1, above, visually demonstrates the different stakeholders, and their relationship with one another.

3.2 Consolidation of PBMs and Health Insurers, and the Resulting Influence on Recent PBM Actions

PBMs traditionally have played a critical role in the administration of prescription drug programs. However, over the past ten years, the PBM marketplace has transformed considerably. Changes include both horizontal and vertical integration among health insurance companies, PBMs, chain pharmacies, specialty pharmacies, and long-term care pharmacies. As a result, a smaller number of large companies now wield nearly limitless power and influence over the prescription drug market.

[5] *See,* Mark Munger et al., Emerging Paradigms: Physician Dispensing, Presentation to the National Association of Boards of Pharmacy (May 20, 2014), available at *https://www.nabp.net/system/rich/rich_files/rich_files/000/000/338/original/munger-202.pdf.*

Within the PBM marketplace, over 80% of the covered lives in the United States are controlled by only five PBMs.[6] As a result of this concentration, a pharmacy's access to these five PBM networks is critical. Being out of network with just one PBM (which in some regions, could make up more than 85% of the market), and being unable to obtain reimbursement for claims dispensed to those patients, could make it financially unviable for any community oncology practice to provide dispensing services at all. The lack of competition in the marketplace stems, in large part, from a series of mergers, integrations, and consolidations. These consolidations and integrations are undoubtedly a factor in many abusive PBM practices, ranging from seeking to exclude independent providers, to reimbursement rates that force providers to lose money by filling prescriptions, to outright diversion of patients to the PBMs' wholly-owned or affiliated pharmacies. The consolidation increases the market power of the top PBMs, which makes this possible.

The breadth of PBM power did not arise overnight. It began with a series of vertical consolidations in which some PBMs acquired pharmacies and other PBMs acquired insurance companies. In 2007, the shareholders of Caremark Rx, one of the nation's largest PBMs at the time, approved a $26.5 billion takeover of CVS Pharmacy, which effectively created the first vertically integrated retail pharmacy and PBM.[7] Vertical integration of the industry continued in 2011, as Blue Cross Blue Shield of North Carolina, one of Medco's largest customers, began shifting its PBM business away from Medco to Prime Therapeutics,[8] a PBM that is wholly owned by a group of thirteen Blue Cross plans across the country. In 2012, UnitedHealthcare (United), the nation's largest insurance company, began migrating the administration of its plans from Medco Health Solutions to OptumRx, United's wholly-owned PBM.[9]

Consolidation of the PBM and payer space has not been limited to vertical integration. In 2011, two of the nation's then-largest PBMs—Medco Health Solutions, Inc. and Express Scripts, Inc.—announced a $29 billion merger. After a contentious regulatory approval process, the Federal Trade Commission ultimately approved the merger in 2012.[10]

Thereafter, the industry continued consolidation both horizontally and vertically. In 2013, a regional PBM—SXC Corporation—agreed to buy another regional PBM—Catalyst, Inc.—for $4.4 billion to form a national PBM, known as Catamaran Corp.[11] In July 2015, Catamaran was acquired by United, OptumRx's parent company, for $12.8 billion. The two PBMs are now integrating operations and operate under one name, OptumRx. In 2015, Rite Aid acquired the PBM EnvisionRx for approximately $2 billion.[12] Later that year, Walgreens announced its intention to acquire Rite Aid and EnvisionRx for $9.4 billion.[13] Also in 2015, Aetna, the nation's third largest insurer, announced its intention to acquire Humana, the nation's fourth largest insurer, as well as Humana's wholly-owned PBM, Humana Pharmacy Solutions, for $37 billion.[14] Finally, in 2015, Anthem announced its agreement to

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[6] *See, https://www.latimes.com/business/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html.*

[7] Evelyn M. Rusli, Caremark Approves CVS Merger, *Forbes* (March 16, 2007, 4:59 PM), *http://www.forbes.com/2007/03/16/caremark-approves-update-markets-equity-cx_er_0316 markets29.html.*

[8] Jon Kamp, Medco Faces Loss of Blue Cross Customer, *The Wall Street Journal* (August 3, 2011, 6:04 PM), *http://www.wsj.com/articles/SB10001424053111903454504576486653127 464070.*

[9] Anna Wilde Mathews, UnitedHealth's Answer to Express Scripts-Medco Merger?, *The Wall Street Journal* (July 21, 2011, 8:34 AM), *http://blogs.wsj.com/deals/2011/07/21/unitedhealths-answer-to-express-scripts-medco-merger/.*

[10] Reed Abelson and Natasha Singer, F.T.C. Approves Merger of 2 of the Biggest Pharmacy Benefit Managers, *New York Times* (April 2, 2012), *http://www.nytimes.com/2012/04/03/business/ftc-approves-merger-of-express-scripts-and-medco.html.*

[11] Michael J. De La Merced, SXC Health Solutions to Buy Catalyst Health for $4.4 Billion, *New York Times* (April 18, 2012, as updated 3:07 PM), *http://dealbook.nytimes.com/2012/04/18/sxc-health-solutions-to-buy-catalyst-for-4-4-billion/.*

[12] Rite Aid Completes Acquisition of Leading Independent Pharmacy Benefit Manager EnvisionRx, *Business Wire* (June 24, 2015, 10:23 AM), *http://www.businesswire.com/news/home/20150624005906/en/Rite-Aid-Completes-Acquisition-Leading-Independent-Pharmacy.*

[13] Dana Mattioli, Michael Siconolfi, and Dana Cimilluca, Walgreens, Rite Aid Unite to Create Drugstore Giant, *The Wall Street Journal* (October 27, 2015, 9:01 PM), *http://www.wsj.com/articles/walgreens-boots-alliance-nears-deal-to-buy-rite-aid-1445964090.*

[14] Aetna to Acquire Humana for $37 Billion, Combined Entity to Drive Consumer-Focused, High-Value Health Care, *Business Wire* (July 3, 2015, 2:08 AM), *http://www.businesswire.com/news/home/20150702005935/en/Aetna-Acquire-Humana-37-Billion-Combined-Entity#.VZYpMe TD9OI.*

buy Cigna (including its PBM arm) for $48 billion, which would result in, yet again, fewer players in the space.[15] However, on July 21, 2016, the Justice Department filed lawsuits to block both the Aetna-Humana and Anthem-Cigna mergers, asserting that the mergers would quash competition, leading to higher prices and reduced benefits.[16]

Figure 2. PBM Mergers and Consolidations in Last Ten Years

Unfortunately, the last five years has only seen this trend of consolidation and integration expand at an exponential rate. In November 2018, CVS Health completed a controversial $69 billion acquisition of Aetna, a managed health care company that specializes in selling traditional and consumer-directed health insurance along with related services including dental, vision, and disability plans. Not to be outdone, in December 2018, health insurer Cigna acquired Express Scripts for $54 billion.[17] Since that time, Cigna and Express Scripts have continued to expand in creative ways. In December 2019. Express Scripts and Prime Therapeutics announced a three-year collaboration agreement, whereby Express Scripts would take over the contracting and administration of the pharmacy benefits for Prime Therapeutics' members.[18] As a result of the arrangement, Express Scripts will now manage the prescription benefits for more than 100 million Americans.[19]

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[15] Michael J. De la Merced and Chad Bray, Anthem to Buy Cigna Amid Wave of Insurance Mergers, *New York Times* (July 24, 2015), *http://www.nytimes.com/2015/07/25/business/dealbook/anthem-cigna-health-insurance-deal.html.*

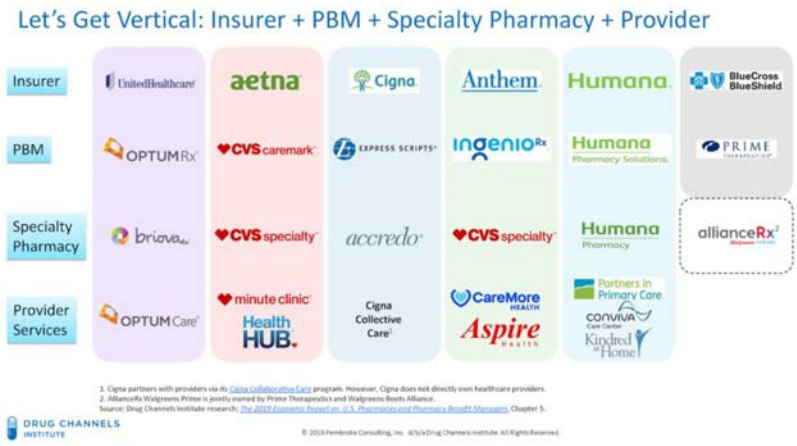
[16] Leslie Picker, U.S. Sues to Block Anthem-Cigna and Aetna-Humana Mergers, *New York Times* (July 21, 2016), *http://www.nytimes.com/2016/07/22/business/dealbook/us-sues-to-block-anthem-cigna-and-aetna-humana-mergers.html.*

[17] Bruce Japsen, Cigna-Express Scripts Merger's a Done Deal, *Forbes,* December 19, 2018, *https://www.forbes.com/sites/brucejapsen/2018/12/19/cigna-express-scripts-merger-a-done-deal-by-thursday/#261d98a55688.*

[18] *https://medcitynews.com/2019/12/express-scripts-strikes-partnership-with-prime-therapeutics/.*

[19] *https://www.primetherapeutics.com/en/news/pressreleases/2019/release-prime-express-scripts-collaboration.html.*

Figure 3. Vertical Integration of PBMs and Health care Conglomerates

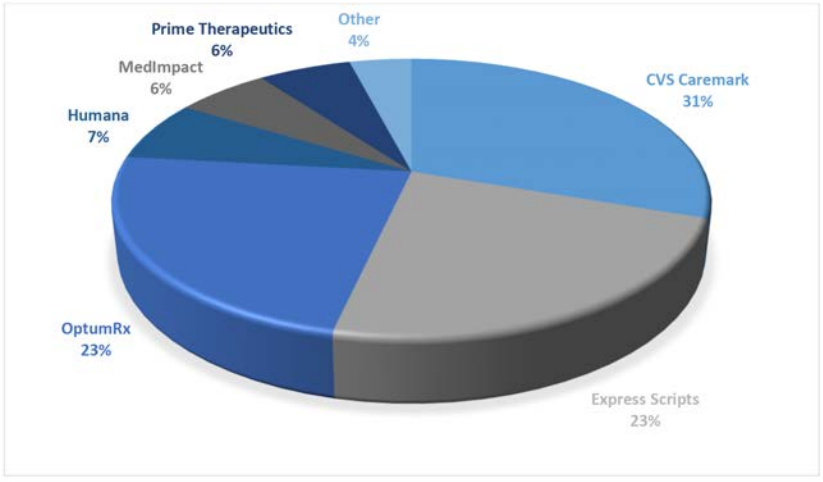


This rapid evolution of the PBM and health insurance industry shows how a limited number of corporations wield an outsized level of control and influence in the prescription drug coverage marketplace. Fewer payers spells harm to patients, especially cancer patients. These integrated companies have greater abilities to control the nature and direction of patients' care, including what type of care/drugs they receive, from whom they receive it, and in what setting they are treated. The level of PBM intrusion into the care received by patients borders on the practice of medicine by these PBMs and health insurance conglomerates.

Fewer payers also results in harm to plan sponsors, especially employers sponsoring health plans, who have fewer choices based on decreased competition. This hits small employers the hardest, who lack the overall leverage and resources to either demand competitive rebates or restructure entrenched PBM practices.

Fewer payers also exponentially increases the importance of network access for providers. Exclusion from one PBM with a market share of 35% means that the provider loses out on a major portion of the patient population.

Figure 4. Market Share by PBM in U.S. Prescription Benefits Market in 2018



As can be seen in the figure above,[20] consolidation has created merged entities that have oppressive power. This creates a virtual chokehold note only on community oncology practices and pharmacy providers, but on plan sponsors and patients alike. It is through this market dominance that PBMs are able to get away with their abuses. Whether it is outsized rebates and DIR fees fueling drug prices. Whether it is unreasonable barriers to entry, network exclusions or mandatory white bagging forcing patients to receive inferior service at higher costs. Whether it is employing insidious copay accumulator programs or deceptive pricing and reimbursement techniques. Or worse yet, whether it is essentially practicing medicine, through "fail first" step therapy, prior authorization requirements, or formulary exclusions, many of which favor not the least expensive medication, but the **most profitable one for the PBM.** Each of these tactics are made possible by the PBMs' sheer levels of dominance at all levels of the health care continuum. This consolidation has hurt medical care, while fueling both drug prices and costs to patients and plan sponsors alike.

While the Federal Trade Commission (FTC) and Department of Justice (DOJ) Antitrust Division recently embarked on a process to rewrite vertical merger guidelines, this effort is seen by many as coming "too little, too late."[21] Providers, patients and plan sponsors have long realized that the vertical integration between payer-PBM-provider would spell disaster for quality and freedom of choice.[22] Dramatic and urgent action is necessary to curtail this wide ranging abuse of power.

4 Manufacturer Rebates, Rebate Aggregators, and the "Gross-to-Net Bubble"

It is axiomatic to say that the PBM market is highly concentrated, with three companies (*i.e.,* CVS Caremark, Express Scripts, and OptumRx) covering nearly 80 percent of the market, or 180 million American lives. As a result, pharmaceutical and biosimilar manufacturers face exceedingly high stakes when negotiating for formulary placement.[23] Among the different sources of revenue, the most prolific by far is in the form of rebates from pharmaceutical manufacturers that PBMs extract in exchange for placing the manufacturer's product drug on a plan sponsor's formulary or encouraging utilization of the manufacturer's drugs.[24] Rebates are mostly used for high-cost brand-name prescription drugs where there are interchangeable products and aim to incentivize PBMs to include pharmaceutical manufacturers' drugs on plan sponsors' formularies and to obtain preferred tier placement.[25]

While drug prices are too high, ironically, the growing number and scale of rebates is the primary fuel of today's high drug prices. The truth is that PBMs have a vested interest to have drug prices remain high, and to extract rebates off of these higher prices. PBM formularies tend to favor drugs that offer higher rebates over similar drugs with lower net costs and lower rebates.[26]

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[20] Exhibit 76 in The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute. Available at *http://drugch.nl/pharmacy.*

[21] *https://www.cnbc.com/2022/01/18/ftc-doj-seek-to-rewrite-merger-guidelines.html.*

[22] *https://www.ftc.gov/system/files/attachments/798-draft-vertical-merger-guidelines/vmg11_ncpa_comment.pdf; https://www.pbgh.org/despite-claims-vertical-integration-isnt-great-for-health-care-consumers-or-purchasers/.*

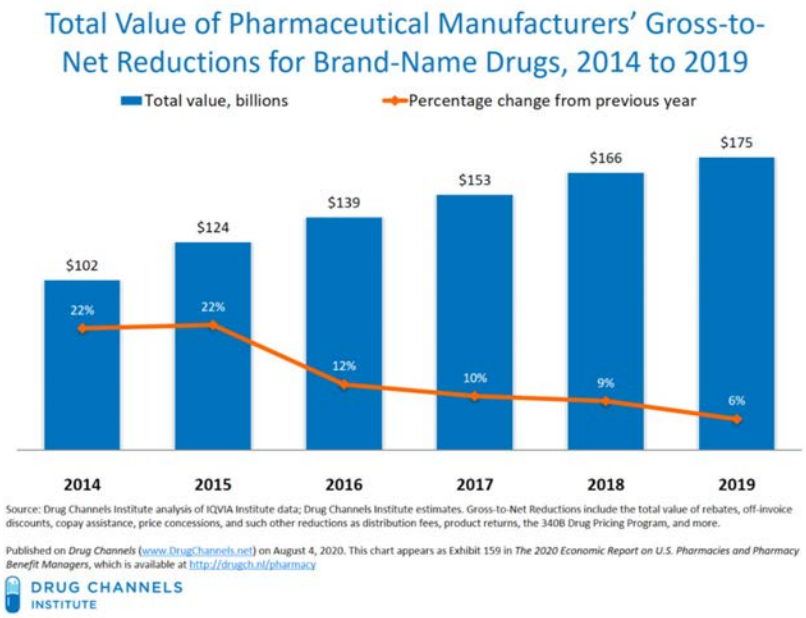
[23] *See,* Bai, G., A.P. Sen, and G.F. Anderson, "Pharmacy Benefit Managers, Brand-Name Drug Prices, and Patient Cost Sharing." *Annals of Internal Medicine,* 2018. 168(6): p. 436–437; *See also,* Applied Policy, "Concerns Regarding The Pharmacy Benefit Management Industry," 2015, accessible online: *http://www.ncpa.co/pdf/applied-policy-issue-brief.pdf.*

[24] *See,* Federal Trade Commission, "Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies," August 2005, accessible online: *https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf.*

[25] *See,* AMCP, "Maintaining the Affordability of the Prescription Drug Benefit," 2019, accessible online: *https://amcp.org/sites/default/files/2019-03/Maintaining%20the%20Affordability%20of%20the%20Prescription%20Drug%20Benefit.pdf.*

[26] *See,* Neeraj Sood, et al., "The Association Between Drug Rebates and List Prices," 2020, accessible online: *https://healthpolicy.usc.edu/wp-content/uploads/2020/02/SchaefferCenter_RebatesListPrices_WhitePaper.pdf; see also,* Ornstein, C. and K. Thomas, "Take the Generic, Patients Are Told. Until They Are Not," 2017, accessible online: *https://www.nytimes.com/2017/08/06/health/prescription-drugs-brand-name-generic.html.*

Figure 5. Gross-to-Net Bubble



Apart from increasing costs today, these destructive practices will have a long-lasting impact on the future of health care and drug innovation. Traditionally, generic drugs offer significant price relief for brand medications; however, there are an ever-growing subset of medications that are unlikely to ever have a traditional generic alternative. As a result, federal policy was enacted to create eventual competition for these brand products such as the biosimilar pathway. However, the PBMs' practice of maximizing rebates may effectively neuter the nation's biosimilar market before it even gets off the ground. Unlike traditional drug products, biologics are unique and complex molecules, and represent many of the new breakthrough treatments that have come to market over the past ten years. But with such breakthrough comes extremely high cost. As a result, biosimilars—that is, products that are "highly similar" to the reference biologic[27]—have emerged to provide alternatives and competition in the biologics space. The first biosimilar product in the United States was approved in March 2015 and marketed in September 2015.[28] The greater use of biosimilars has the potential to reduce the overall drug spending, while providing greater clinical options for providers and patients.[29] However, PBMs and biologics manufacturers have erected "rebate walls" that have severely depressed biosimilar development and widespread adoption.[30] According to former FDA Commissioner, Dr. Scott Gottlieb, Americans could have saved more than $4.5

[27] US Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER). Scientific Considerations in Demonstrating Biosimilarity to a Reference Product. Guidance for Industry. April 2015. *https://www.fda.gov/media/82647/download.* Accessed June 25, 2018.

[28] *See,* What Are Biosimilars?, available at: *https://www.biosimilarsresourcecenter.org/faq/what-are-biosimilars/.*

[29] *See,* James D. Chambers, et al., "Coverage for Biosimilars vs. Reference Products Among US Commercial Health Plans," May 19, 2020, *JAMA.* 2020;323(19):1972–1973. doi:10.1001/jama.2020.2229; *see also,* Ed Silverman, "Biosimilars got the cold shoulder from health plans when it came to preferred coverage," May 20, 2020, accessible online: *https://www.statnews.com/pharmalot/2020/05/20/biosimilars-biologics-health-coverage-drug-prices/.*

[30] *See,* Cathy Kelly, FTC Wades Into Rebate Walls And Biosimilar Access With Remicade Investigation, available at: *https://pharmaintelligence.informa.com/resources/product-content/ftc-wades-into-rebate-walls-and-biosimilar-access-with-remicade-investigation.*

billion in one year alone, if they had bought FDA-approved biosimilars.[31] While the FDA had approved 11 biosimilars through 2018, only three were then being marketed in the U.S.[32] As of January 2022, nearly 32 biosimilars have been approved, while only 29 are currently being marketed.[33] PBM rebates represent a clear and existential threat to the future of the biosimilar marketplace.[34]

As the American public and plan sponsors have become more aware of the nature and extent of rebates, they have begun demanding that all or nearly all rebates negotiated on their behalf be fully reported and passed-through. As a result, PBMs have begun to market themselves as transparent and assert that many of their customers are able to negotiate "pass-through pricing" allowing pharmaceutical manufacturer rebates and other concessions to flow directly to plan sponsors.[35] However, a dangerous new trend has grown exponentially over the last few years through which PBMs seek to "circumvent" these pass-through requirements. PBMs have increasingly "delegated" the collection of manufacturer rebates to "rebate aggregators," which are often owned by or affiliated with the PBMs, without seeking authorization from plan sponsors and without telling plan sponsors.[36] Sometimes referred to as rebate GPOs, these mysterious entities include Ascent Health Services, a Switzerland-based GPO that Express Scripts launched in 2019, Zinc, a contracting entity launched by CVS Health in the summer of 2020, and Emisar Pharma Services, an Ireland-based entity recently rolled out by OptumRx.[37] Even some of the major PBMs (*i.e.,* the "Big Three" PBMs) sometimes find themselves contracting with other PBMs' rebate aggregators for the collection of manufacturer rebates (for example, in the case of OptumRx contracting with Express Scripts for purposes of rebate aggregation for public employee plans).[38]

In both the private sector and with respect to government health care programs, the contracts regarding manufacturer rebates (*i.e.,* contracts between PBMs and rebate aggregators, as well as contracts between PBMs/rebate aggregators and pharmaceutical manufacturers) are not readily available to plan sponsors.[39] Moreover, PBMs do not provide plan sponsors access to claim-level rebate information unless demanded through the contracts entered by and between plan sponsors and PBMs.[40]

Within Medicare Part D, Part D Sponsors are required to submit direct and indirect remuneration (DIR) reports to CMS disclosing the total amount of rebates, inclusive

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[31] Yanchun Liu, MarketWatch News, "FDA chief says pharmas use rebates to block biosimilar competition," available at: *https://www.marketwatch.com/story/fda-chief-says-pharmas-use-rebates-to-block-biosimilar-competition-2018-07-19.*

[32] *See, id.*

[33] *See,* Biosimilar Approval Status, available at: *https://biosimilarsrr.com/us-biosimilar-filings/.*

[34] *https://www.forbes.com/sites/joshuacohen/2021/03/01/rebate-walls-stifle-prescription-drug-competition/?sh=4b07ed3966ae.*

[35] *See,* ERISA Advisory Council, "PBM Compensation and Fee Disclosure," 2014, available online: *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/about-us/erisa-advisory-council/ACDanzon061914.pdf.*

[36] *See,* Office of Broward County Auditor, "Audit of Pharmacy Benefit Management Services Agreement," 2017, accessible online: *https://www.broward.org/Auditor/Reports/Documents/2017_1212%20Agenda%20Review%20of%20Pharmacy%20Benefit%20Management%20Services%20by%20StoneBridge/2017_1212%20Exh1_OptumRx.pdf.*

[37] *See,* Alia Paavola, "CVS Health reportedly launching a GPO called Zinc," *Becker's Hospital Review,* June 30, 2020. Accessible at: *https://www.beckershospitalreview.com/pharmacy/cvs-health-reportedly-launching-a-gpo-called-zinc.html; https://www.drugchannels.net/2021/08/drug-channels-news-roundup-august-2021.html.*

[38] *See,* Office of Broward County Auditor, "Audit of Pharmacy Benefit Management Services Agreement," 2017, accessible online: *https://www.broward.org/Auditor/Reports/Documents/2017_1212%20Agenda%20Review%20of%20Pharmacy%20Benefit%20Management%20Services%20by%20StoneBridge/2017_1212%20Exh1_OptumRx.pdf.*

[39] *See,* Office of Broward County Auditor, "Audit of Pharmacy Benefit Management Services Agreement," 2017, accessible online: *https://www.broward.org/Auditor/Reports/Documents/2017_1212%20Agenda%20Review%20of%20Pharmacy%20Benefit%20Management%20Services%20by%20StoneBridge/2017_1212%20Exh1_OptumRx.pdf; see also,* Office of the Legislative Auditor General for the State of Utah, "A Performance Audit of PEHP's Pharmacy Benefit Manager," 2019, accessible online: *https://le.utah.gov/audit/19_13rpt.pdf; see also,* MedPAC, "Status Report on Part D. Report to Congress: Medicare Payment Policy," 2016.

[40] *See,* Office of Broward County Auditor, "Audit of Pharmacy Benefit Management Services Agreement," 2017, accessible online: *https://www.broward.org/Auditor/Reports/Documents/2017_1212%20Agenda%20Review%20of%20Pharmacy%20Benefit%20Management%20Services%20by%20StoneBridge/2017_1212%20Exh1_OptumRx.pdf; see also,* Office of the Legislative Auditor General for the State of Utah, "A Performance Audit of PEHP's Pharmacy Benefit Manager," 2019, accessible online: *https://le.utah.gov/audit/19_13rpt.pdf.*

of manufacturer rebates, retained by PBMs regardless of whether such rebates were passed to Medicare Part D plan sponsors.[41] And while PBMs and rebate aggregators are obligated to provide, *among other things,* the aggregate amount and type of rebates, discounts, or price concessions to the plan sponsors (who in turn provide the same to CMS),[42] PBMs and rebate aggregators do not have to provide claims-level information on the actual amounts received on behalf of plan sponsors.

4.1 Who Is Impacted?

The deleterious effects of rebates, and the furtive work of rebate aggregators, are felt across the health care spectrum.

4.1.1 Harm to Patients

Whether a patient has insurance or not, rebates serve to increase the overall costs of drugs and out-of-pocket expenditures for patients.[43] With one in four people in the United States having difficulty paying the cost of their prescription medications,[44] the extent of the negative impact of rebates is felt far and wide.

For uninsured patients, the rebates negotiated by a PBM or health insurance company do nothing to lower their out-of-pocket costs. Rebates promote high drug list prices. "Higher drug prices hurt uninsured patients who pay list prices . . . based on drugs' list prices."[45] And because these rebates are received and kept among secretive health care conglomerates, and not shared with providers or other groups, even discount programs like GoodRx do little to help uninsured patients receive savings on the most expensive drugs.

Even for patients with insurance, rebates ultimately increase costs to the patient for the benefit of PBMs and health insurers. At the point of sale, the inflated list prices caused by rebates "hurt . . . insured patients who pay coinsurance and deductibles based on drugs' list prices."[46] Over the past several years, the number of patients on high-deductible health plans has skyrocketed.[47] This has turned the insurance market upside down, causing the relatively small number of sick patients who pay high copays off of inflated list prices to subsize the cost of care for healthy people. In this form of "reverse insurance," the sickest patients (*e.g.,* those taking expensive cancer medications) generate a large share of manufacturer rebate payments, which in turn are used to "subsidize the premiums for healthier [patients]."[48] This is the opposite of how insurance is supposed to work.

What's worse, PBMs' preference of highly-rebated drugs not only increases patients' out-of-pocket expenses, but also creates unnecessary burdens in receiving appropriate care, even to the point of fatality.[49] PBMs have an incentive to favor high-priced drugs over drugs that are more cost-effective, because rebates are often calculated as a percentage of the manufacturer's list price. PBMs receive a larger rebate for expensive drugs than they do for ones that may provide better value at lower cost. This can also occur "when a brand drug goes generic under the Hatch-Waxman Amendments, with the first generic version being granted six months of market exclusivity," and "[i]n exchange for substantial rebates, manufacturers [are given] an exclusive extension of their brand drug, which circumvents Hatch-

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[41] *See,* Social Security Act § 1860D 15, 42 U.S.C. [1395w–115].

[42] *See,* 42 CFR § 423.514(d).

[43] *See,* Neeraj Sood, et al., "The Association Between Drug Rebates and List Prices," 2020, accessible online: *https://healthpolicy.usc.edu/wp-content/uploads/2020/02/SchaefferCenter_RebatesListPrices_WhitePaper.pdf.*

[44] *See,* Chaarushena Deb, et al., "Relentless Prescription Drug Price Increases," *JAMA,* 29 February 2020, 323(9):826–828.

[45] Neeraj Sood, et al., "The Association Between Drug Rebates and List Prices," 2020, accessible online: *https://healthpolicy.usc.edu/wp-content/uploads/2020/02/SchaefferCenter_RebatesListPrices_WhitePaper.pdf.*

[46] Neeraj Sood, et al., "The Association Between Drug Rebates and List Prices," 2020, accessible online: *https://healthpolicy.usc.edu/wp-content/uploads/2020/02/SchaefferCenter_RebatesListPrices_WhitePaper.pdf.*

[47] *https://www.kff.org/report-section/ehbs-2019-section-8-high-deductible-health-plans-with-savings-option/#:~:text=Enrollment%20in%20HDHP%2FSOs%20has,in%202019%20%5BFigure%208.5%5D.*

[48] *https://www.drugchannels.net/2017/11/will-cms-pop-gross-to-net-bubble-in.html.*

[49] *See,* Community Oncology Alliance, "Pharmacy Benefit manager Horror Stories—Part IV," April 4, 2019, accessible online: *https://communityoncology.org/pharmacy-benefit-manager-horror-stories-part-v/.*

Waxman and blocks generic competition."[50] PBMs' financial motivations often result in more expensive and less efficacious drugs being placed on the drug formulary, which in turn hurts patient care.[51]

Again, PBMs are able to do this because of the sheer levels of market consolidation and integration, which is adversely impacting cancer care and fueling drug costs all in the interests of PBM profits.

4.1.2 Harm to Plan Sponsors

While rebates are intended to lower the "net price" of drugs, thereby reducing costs to plan sponsors (including employers), there are several important ways that PBM rebates increase the costs of drugs for both plan sponsors and patients.

The first way relates to the ability of plan sponsors, especially self-funded employers, to ensure the full amount of rebates are reported and passed through to them by PBMs. As noted above, it is extremely difficult to gauge the true amount of drug manufacturer rebates collected by PBMs, and this is only made more difficult by the advent of rebate aggregators.[52] Unlike in the Medicare Part D program, PBMs typically do not legally owe self-funded employers any reporting on rebates. PBMs employ exceedingly vague and ambiguous contractual terms to recast monies received from manufacturers outside the traditional definition of rebates, which in most cases must be shared with plan sponsors. Rebate administration fees, bona fide service fees, and specialty pharmacy discounts/fees are all forms of money received by PBMs and rebate aggregators which may not be shared with (or even disclosed to) the plan sponsor.[53] These charges serve to increase the overall costs of drugs, while providing no benefit whatsoever to plan sponsors.

And while there might be greater reporting and disclosure obligations in the Medicare Part D and Medicaid programs,[54] the growth of rebate aggregators has created a way for PBMs (or their corporate affiliates) to retain rebates and not share them with plan sponsors. This causes the Part D plan sponsor to become liable to CMS to "true up" any reductions in cost caused by these rebates, despite the fact that the Part D plan sponsor never actually received any rebates. Moreover, studies have shown that PBM rebates extracted from drug manufacturers drive up the drug spending of plan sponsors including Medicare and Medicaid.[55] This is especially draining on already budget-strapped state governments. Since Medicare Part D is financed through general revenues, beneficiary premiums, and state payments for dual-eligible beneficiaries (who received drug coverage under Medicaid prior to 2006), rebates also drive up the drug spending of the participating states and in turn, taxpayers' financial obligations to support Medicare Part D and Medicaid continues to rise.[56] The total drug spend of a plan sponsor, regardless of whether it is a federal or state governmental program or a self-funded employer, will inevitably increase because PBMs are incentivized to favor expensive drugs that yield high rebates.[57] In some instances, PBMs purposely misclassify generic drugs as brand drugs to charge higher prices to plan sponsors, which ultimately generate higher re-

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[50] Rumore, Martha M., and F. Randy Vogenberg. "PBM P&T Practices: The HEAT Initiative Is Gaining Momentum." *P & T: a peer-reviewed journal for formulary management* vol. 42,5 (2017): 330–335.

[51] *See,* Community Oncology Alliance, Letter to Defense Health Agency, "The Perverse Financial Impact of Pharmacy Benefit Managers on Our Military Service Members Covered by the TRICARE Program," 2019.

[52] *See, supra,* Office of Broward County Auditor, "Audit of Pharmacy Benefit Management Services Agreement," 2017.

[53] *See,* National Prescription Coverage Coalition, "It's Time to Determine How Much Your PBM Is Depriving Your Plan of Rebates: File An 'Accounting' Procedure," available at: *https://nationalprescriptioncoveragecoalition.com/its-time-to-determine-how-much-your-pbm-is-depriving-your-plan-of-rebates-file-an-accounting-procedure/*.

[54] *See,* Social Security Act § 1860D–15, 42 U.S.C. [1395w–115].

[55] *See, e.g.,* U.S. Department of Health and Human Services, "Increases in Reimbursement for Brand-Name Drugs in Part D," 2018, accessible online: *https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf; see also,* Auditor of the State of Ohio, "Ohio's Medicaid Managed Care Pharmacy Services," August 16, 2018.

[56] *See, e.g.,* Juliette Cubanski, et al., "A Primer on Medicare: Key Facts About the Medicare Program and the People it Covers," March 20, 2015, available at: *https://www.kff.org/report-section/a-primer-on-medicare-how-is-medicare-financed-and-what-are-medicares-future-financing-challenges/*.

[57] U.S. Department of Health and Human Services, "Fraud and Abuse; 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," available at: *https://www.govinfo.gov/content/pkg/FR-2019-02-06/pdf/2019-01026.pdf/*.

bate revenue.[58] Moreover, the gross-to-net bubble (*i.e.,* the dollar difference between sales at brand-name drugs' list prices and their sales at net prices after rebates, discounts, and other reductions) has been growing at an exponential pace.[59] The upward trend in the gross-to-net bubble reached $175 billion in 2019.[60] Based on this trend and the fact that plan sponsors are not receiving full value of the rebates from PBMs, it is evident that rebates increase total drug spend of plan sponsors and only benefit PBMs.

The final and perhaps most long-term impact that rebates will have on plan sponsors is in the suppression of the biosimilar market. The greater use of less expensive biosimilars (essentially "generic" versions of biologic medications) has the potential to reduce overall drug spending. However, many health plans do not include biosimilars in their preferred tiers.[61] This is because of the "rebate trap," where PBMs prefer the higher cost, branded biologics that offer rebates, over cheaper biosimilar alternatives.[62] The result is that when biosimilars do make their way to the market, many patients do not have access to them because their PBM does not cover it.[63] These policies stifle advancements, and will, in the long term, keep plan sponsors beholden to higher cost, branded medications.

4.1.3 Harm to Providers

Finally, rebates also impact providers in several ways. First, PBMs preference of highly rebated drugs limits providers' choice of optimal drug therapy for patients.[64] Once again, this results in the PBM inserting itself in between the prescribers and their patients and violates the sanctity of the doctor-patient relationship. This is especially true with biosimilars. The greater use of biosimilars has the potential to reduce overall drug spending and provide greater clinical options for providers, including community oncology practices. However, due to rebates, many PBMs do not include biosimilars in their preferred tier, thereby prevent wide-spread adoption and cost savings.[65]

In instances where biosimilars are included on formularies, this is done so inconsistently and on a patchwork basis, tied solely to the rebates that the PBM can extract from the drug manufacturer, and not the efficacy of the product. The result is that community oncology practices often are required to stock several different versions of very expensive biosimilars based on the rules of the patient's PBM, rather than being able to prescribe and dispense the product that is best suited for their patients.[66]

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[58] Complaint, *Ohio Highway Patrol Retirement System v. Express Scripts, Inc.,* Case No. AM–20CV004504, Court of Common Pleas, Fraknlin County, Ohio.

[59] *https://www.drugchannels.net/2021/01/surprise-brand-name-drug-prices-fell.html.*

[60] *https://www.drugchannels.net/2020/08/the-gross-to-net-bubble-hit-175-billion.html.*

[61] *See,* James D. Chambers, et al., "Coverage for Biosimilars vs. Reference Products Among US Commercial Health Plans," May 19, 2020, *JAMA.* 2020;323(19):1972–1973. doi:10.1001/jama.2020.2229; *see also,* Ed Silverman, "Biosimilars got the cold shoulder from health plans when it came to preferred coverage," May 20, 2020, accessible online: *https://www.statnews.com/pharmalot/2020/05/20/biosimilars-biologics-health-coverage-drug-prices/.*

[62] *See,* FiercePharma, "Could adoption of biosimilars be slowed by 'rebate trap'? Yale experts think so", available at: *https://www.fiercepharma.com/pharma/could-adoption-biosimilars-be-slowed-by-rebate-trap-yale-experts-think-so; https://jamanetwork.com/journals/jama/article-abstract/2625049?resultClick=1.*

[63] *See,* Thomas Sullivan, "January MedPAC Recommendations: Rebates and Biosimilars," available at: *https://www.policymed.com/2019/03/january-medpac-recommendations-rebates-biosimilars.html.*

[64] *See* generally, "Pharmacy Benefit Manager Horror Stories—Part IV," April 4, 2019, accessible online: *https://communityoncology.org/pharmacy-benefit-manager-horror-stories-part-v/; see also,* James D. Chambers, et al., "Coverage for Biosimilars vs. Reference Products Among US Commercial Health Plans," May 19, 2020, *JAMA.* 2020;323(19):1972–1973. doi:10.1001/jama.2020.2229; *see also,* Ed Silverman, "Biosimilars got the cold shoulder from health plans when it came to preferred coverage," May 20, 2020, accessible online: *https://www.statnews.com/pharmalot/2020/05/20/biosimilars-biologics-health-coverage-drug-prices/.*

[65] *See,* James D. Chambers, et al., "Coverage for Biosimilars vs. Reference Products Among US Commercial Health Plans," May 19, 2020, *JAMA.* 2020;323(19):1972–1973. doi:10.1001/jama.2020.2229; *see also,* Ed Silverman, "Biosimilars got the cold shoulder from health plans when it came to preferred coverage," May 20, 2020, accessible online: *https://www.statnews.com/pharmalot/2020/05/20/biosimilars-biologics-health-coverage-drug-prices/.*

[66] *See generally,* James D. Chambers, et al., "Coverage for Biosimilars vs. Reference Products Among US Commercial Health Plans," May 19, 2020, *JAMA.* 2020;323(19):1972–1973. doi:10.1001/jama.2020.2229; *see also,* Ed Silverman, "Biosimilars got the cold shoulder from health plans when it came to preferred coverage," May 20, 2020, accessible online: *https://www.statnews.com/pharmalot/2020/05/20/biosimilars-biologics-health-coverage-drug-prices/; see also,* Sean McGown, "Five years on, biosimilars need support from all health care players,"

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Rebates further intrude on the doctor-patient relationship when combined with step therapy, prior authorization, or other utilization management protocols. "Fail first" step therapy requires a patient to first fail once or twice on a medication specified by the PBM or health insurer before being allowed to "step up" to the therapy prescribed by the physician.[67] In many cases, the medication dictated by the PBM or health insurer is not the least expensive medication, but rather, is the most profitable drug to the PBM due to rebates. The impact of step therapy, driven by rebating, is that it "takes the medical decision-making out of the hands of doctors" and puts it into the hands of the actuaries, accountants and businesspeople at the PBM, who are not choosing the drug that is most efficacious, or cheapest, or even most efficient—they are choosing the drug that is the most profitable.[68]

4.2 What Does the Law Say?

Medicare Part D plan sponsors are required to submit DIR reports to CMS disclosing the total amount of rebates, inclusive of manufacturer rebates and pharmacy rebates, retained by PBMs regardless of whether such rebates were passed to Medicare Part D plan sponsors.[69]

In the commercial market, many states have enacted laws that require transparency from PBMs and "pass through" pricing. For example, Delaware House Bill 194 enacted into law on July 17, 2019, permits the Insurance Commissioner to examine the affairs of PBMs, among other things.[70] Likewise, under New York Senate Bill S1507A enacted into State Budget for the 2019–2020 Fiscal Year on April 12, 2019, PBMs are required to fully disclose to the Department of Health and plan sponsors the sources and amounts of all income, payments, and financial benefits.[71] Similarly, Utah House Bill 272, which was enacted into law on March 30, 2020, requires PBMs to report all rebates and administrative fees to the Insurance Department including the "percentage of aggregate rebates" that PBMs retained under its agreement to provide pharmacy benefits management services to plan sponsors.[72]

However, Maine Bill 1504, enacted into law on June 24, 2019, takes these reporting requirements a step further, and provides that "[a]ll compensation remitted by or on behalf of a pharmaceutical manufacturer, developer or labeler, directly or indirectly, to a carrier, or to a pharmacy benefits manager under contract with a carrier, related to its prescription drug benefits must be: A. Remitted directly to the covered person at the point of sale to reduce the out-of-pocket cost to the covered person associated with a particular prescription drug; or B. Remitted to, and retained by, the carrier. Compensation remitted to the carrier must be applied by the carrier in its plan design and in future plan years to offset the premium for covered persons."[73]

4.3 What Can Be Done?

If high drug prices meaningfully addressed then outsized negative impact of rebates, rebate aggregators, and the resulting high gross-to-net bubble must be addressed. Luckily there are several varied options available to the affected parties:

- Legislative
    - Policymakers should enact laws that mandate PBMs and rebate aggregators to report drug manufacturer rebates procured by utilizing drugs dispensed to plan sponsors' patients in a given year. Requirements set forth under 42 CFR § 423.514(d) are not sufficient to cast the light of full transparency on PBMs (and rebate aggregators) that contract with Medicare Part D plan sponsors.[74]

March 6, 2020, accessible online: *https://www.statnews.com/2020/03/06/biosimilars-in-us-turn-five/*.

[67] *http://prescriptionprocess.com/barriers-to-access/step-therapy/*.

[68] *https://www.lilly.com/news/stories/time-to-tear-down-rebate-wall.*

[69] *See,* Social Security Act § 1860D–15, 42 U.S.C. [1395w–115].

[70] *See,* Delaware General Assembly House Bill 193, An Act to Amend Title 18 of the Delaware Code Relating to Pharmacy Benefit Managers, available at: *https://legis.delaware.gov/BillDetail?LegislationId=47636.*

[71] *See,* New York State Budget for 2019—2020 Fiscal Year incorporating New York Senate Bill S1507A, available at: *https://www.cqstatetrack.com/texis/redir?id=5c43ef1197.*

[72] *See,* House Bill 272, Pharmacy Benefits Act, available at: *https://www.cqstatetrack.com/texis/redir?id=5e3cc83dc51.*

[73] *See,* Maine Bill 1504, available at: *https://www.cqstatetrack.com/texis/redir?id=5ca593682.*

[74] *See, e.g.,* Social Security Act § 1860D–15, 42 U.S.C. [1395w–115].

- Laws should be enacted that allow plan sponsors to gain access to the drug manufacturer rebates reported by PBMs and rebate aggregators.[75]
- Laws should be enacted that entitle Medicare Part D plan sponsors and state Medicaid agencies to conduct full and complete audits of PBMs and rebate aggregators and these entities should not have any ability to limit the scope and extent of such audits.[76]
- Laws should be enacted that limit Medicare Part D plan sponsors' financial obligation to CMS in the event that PBMs and rebate aggregators retained drug manufacturer rebates that were not relayed to Medicare Part D plan sponsors.

It should be called out that some in Congress have the mistaken belief that drug manufacturers are the primary beneficiary of rebates in terms of "buying" formulary access for their drugs. Although this may be true in a limited number of cases, the reality is that PBMs use rebates to extract—some would say "extort"—drug manufacturers to pay the rebate "toll" in order for PBMs to include these drugs on formulary or to avoid being part of a "fail first" step therapy scheme. Congress has been held hostage to PBMs and their corporate affiliated health insurers by threatening to increase plan premiums if rebates are eliminated or made illegal.

- Plan Sponsor Action
  - As part of the PBM contracts, plan sponsors should: . Require PBMs to seek approval from plan sponsors prior to delegating the rebate aggregation function to rebate aggregators.
    - Require PBMs to disclose a list of rebate aggregators to plan sponsors.
    - Require PBMs to disclose an unredacted contract with the rebate aggregator.
    - Require PBMs to be pay fees to rebate aggregators for their services but such fees should not come from drug manufacturer rebates.
    - Require PBMs to agree to rebate audits conducted by plan sponsors and/or third-party auditors at plan sponsors' choosing.
    - Require PBMs to report claims-level data on rebates collected on claims paid by pan sponsors.

5 Pharmacy Direct and Indirect Remuneration Fees

As a result of a 2014 CMS rule change that went into effect in Plan Year 2016, PBMs have developed shrewd and calculated methods of financial engineering, maximizing their revenue at the expense of the patient, the Medicare Part D Program, and providers. This was accomplished through pharmacy direct and indirect remuneration fees, or "DIR fees." DIR fees are typically post point-of-sale fees ranging from 1.5% to 11% of a drug's list price assessed by PBMs upon network pharmacy providers, typically three to six months after the provider has dispensed the medication.

The concept of DIR fees arose out of Medicare Part D coverage for prescription drugs. Part D plan sponsors and Medicare Advantage plans offering drug coverage are paid by the government based on the actual cost for drug coverage. The actual cost is based on the Part D plan sponsor's "negotiated price," which is then used as the basis to determine plan, beneficiary, manufacturer (in the coverage gap), and government costs during the course of the payment year, subject to final reconciliation following the end of the coverage year.

Unfortunately, very few pharmacy price concessions have been included in the negotiated price at the point of sale. All pharmacy and other price concessions that are not included in the negotiated price must be reported to CMS as pharmacy DIR.[77] As employers and plan sponsors are demanding a greater share of the PBM rebates, and as those rebates have been threatened with regulation by state and federal law-

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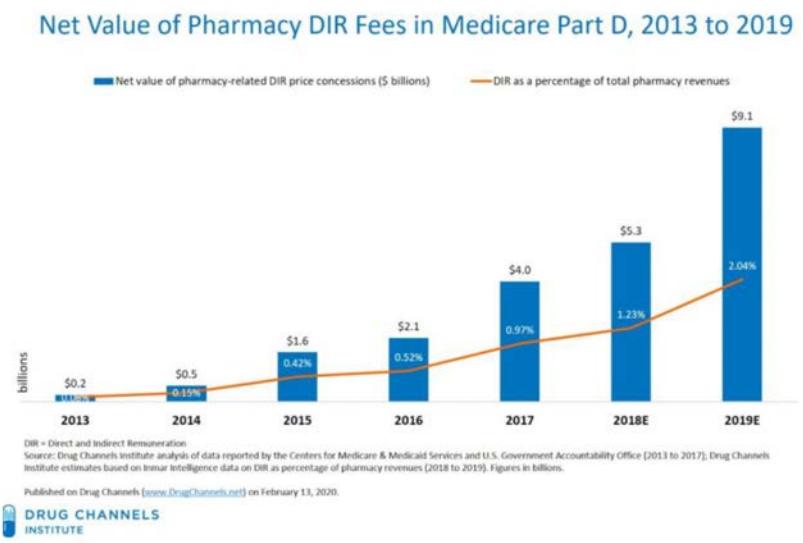
[75] *See, e.g.,* New York State Budget for 2019–2020 Fiscal Year incorporating New York Senate Bill S1507A, available at: *https://www.cqstatetrack.com/texis/redir?id=5c43ef1197; see also,* Eugene A. DePasquale, Bringing Transparency and Accountability to Drug Pricing (December 11, 2018), available at: *https://www.paauditor.gov/Media/Default/Reports/RPT_PBMs_FINAL.pdf.*

[76] *See, e.g.,* Maine Bill 1504 enacted into law on June 24, 2019, available at: *https://www.cqstatetrack.com/texis/redir?id=5c80b75c13.*

[77] Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62175 (November 30, 2018).

makers, PBMs have gone "downstream" to make up for any rebate revenue shortfalls by assessing DIR fees on pharmacy providers. In fact, DIR fees categorized as pharmacy price concessions have increased 45,000 percent between 2010 and 2017, and have hit a whopping $9.1 billion in 2019.[78]

Figure 6. Explosion of Pharmacy DIR from 2013 to Present



PBMs purport to pass a large portion of DIR fees to their plan sponsor clients, especially Part D plan sponsors—ironically, many of which are under the same corporation as the PBMs (*e.g.,* CVS Caremark, one of the nation's largest PBM, and SilverScript, the nation's largest Medicare Part D plan sponsor, are both owned by CVS Health). However, no study has been conducted to match the deductions from pharmacy remittances for "DIR" with the DIR reported to CMS. Unfortunately, CMS cannot even perform such an audit today, as it does not require plans to submit DIR collected from each pharmacy, but rather requires DIR to be reported by drug, on an NDC number basis.

Even if pharmacy DIR fees are reported accurately, Medicare risk corridors allow a Part D plan sponsor that spends less than its bid estimate of costs to keep all savings up to 5% and a portion of those savings thereafter, which, in practice, allows PBMs and Part D plan sponsors to retain the vast majority of DIR fees collected.[79] **Thus, PBMs and Part D plan sponsors financially benefit from DIR fees.**

Worse yet, DIR fees on expensive specialty drugs are typically calculated as a percentage of a drug's list price. As such, DIR fees provide another incentive for PBMs to keep drug list prices high—high list prices yield not only larger rebates, but also larger DIR fees. As such, over the past several years DIR fees have become a larger percentage of the overall revenue that PBMs and Part D plan sponsors receive. Simply put, PBMs are making their money one way or another—rebates or DIR fees from pharmacy providers.

More problematic than the growth of DIR fees is the manner in which DIR fees are assessed on providers, especially community oncology practices. These fees are charged against community oncology practices based on their performance in a num-

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[78] Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62174 (November 30, 2018); *https://www.drugchannels.net/2020/02/pharmacy-dir-fees-hit-record-9-billion.html#:~:text=February%2013%2C%202020-,Pharmacy%20DIR%20Fees%20Hit%20a%20Record%20%249%20Billion%20in%202019,reached%20%249.1%20billion%20in%202019.*

[79] Medicare Part D Prescription Drug Benefit, Congressional Research Services, Suzanne M. Kirchhoff, August 13, 2018, available at: *https://fas.org/sgp/crs/misc/R40611.pdf.*

ber of primary-care focused "quality metric" categories, which are totally unrelated and irrelevant to the cancer patients these practices treat. As a result, these community oncology practices have no meaningful ability to influence their performance scores—with no ability for upside—and such fees amount to nothing more than extortion from practices. Given the market clout of the top PBMs in terms of the percentage of prescription drugs they manage, community oncology practices simply have to pay these DIR fees to stay in network, lest they lose the ability to provide dispensing services to their patients.

These DIR fees are assessed after the point-of-sale. While they are sometimes recouped as soon as PBMs reimburse providers (*i.e.,* extracted from initial reimbursements), in most cases DIR fees are assessed months after patients receive their medications. The total amount of DIR fees assessed on providers may not be known by providers until more than a year after a drug has been dispensed, as some PBM contracts create the *potential* for a partial or total refund of DIR fees (though a total refund is practically unobtainable).

DIR fees increase patients' cost sharing responsibilities because patient out-of-pocket costs are based on an artificially inflated list drug prices at the point-of-sale; thus, in the case of Medicare patients, prematurely pushing them into the Medicare Part D "donut hole." The cost of DIR fees also shifts the burden of drug costs to the federal government as more patients are prematurely pushed into the catastrophic phase of the Medicare benefit, resulting in higher financial contribution by the Medicare program. Ultimately, DIR fees weakens the overall benefit of the Medicare insurance benefit intended to provide health care coverage for our nation's oldest and most vulnerable citizens.

Finally, DIR fees extracted from reimbursement to providers often results in drugs reimbursed below drug acquisition cost. Some speculate that this is yet another strategy by PBMs to ultimately drive pharmacy providers out of business so that the PBMs can take over the business with their retail, specialty, or mail-order pharmacies.

PBMs are able to effectively "extort" DIR fees due to their size and hegemony. As of 2018, three companies—UnitedHealth, Humana and CVS Health—covered over half of all Medicare Part D patients.[80] Pharmacy providers do not have a meaningful choice but to accept the terms being provided to them—rejecting just one Part D plan could mean losing out on being able to service nearly a quarter of their Medicare Part D patients. PBMs know the power they hold and use it to its fullest extent.

5.1 Who Is Impacted?

The expansion of DIR fees has had a substantial negative impact on both Medicare beneficiaries and the program as a whole. As confirmed in recent CMS studies, DIR fees ultimately shift financial liability from the Part D plan sponsor to the patient, then ultimately to the federal government, through Medicare's catastrophic coverage phase. The shifting of financial liability away from the Part D plan sponsor and to Medicare and the patient is even more pronounced with specialty medications, such as oral cancer medications.

5.1.1 Harm to Patients

The primary harm to patients from DIR fees is that patients' out-of-pocket costs are higher because they are based on list drug prices. Once again, PBMs have a vested financial interest to have drug list prices as high as possible as DIR fees are assessed as a percentage of the list prices for expensive specialty drugs. Medicare Part D patients find themselves paying more for their medications because they pay increased copayments and coinsurance on inflated point-of-sale list prices, which do not reflect the after-the-fact price adjustment in DIR fees that the PBM is clawing back from the pharmacy provider.

The use of DIR fees by PBMs has degraded the quality of the Medicare Part D benefit available for beneficiaries, all the while providing an additional lucrative revenue source for PBMs and affiliated Part D plan sponsors.[81] It has shifted the benefit of the Medicare Part D program from those who rely on it for drugs, to those that do not use it, in the form of lower (or zero dollar) premiums. Meanwhile, DIR has put upward pressure on drug expenditures for those that use the benefit. Stud-

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[80] *https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/.*

[81] *See, e.g. https://www.communityoncology.org/wp-content/uploads/2017/01/COA_White_Paper_on_DIR-Final.pdf; https://naspnet.org/dir-white-paper/.*

ies conducted by CMS have concluded that DIR fees increase out-of-pocket costs for Medicare patients at the point of sale.[82]

Consider for example, that Medicare Part D beneficiaries' cost sharing is based on the PBM-determined rate at the point-of-sale. DIR fees are by definition not assessed at the point of sale. Thus, the patient's copayment or coinsurance that is based on the price at the point-of-sale is artificially inflated. CMS similarly concluded that DIR fees cost patients money, noting "[w]hen pharmacy price concessions and other price concessions are not reflected in the negotiated price at the point of sale (that is, are applied instead as [Direct and Indirect Remuneration] at the end of the coverage year), beneficiary cost-sharing increases."[83]

Likewise, up until the end of the 2020 plan year when the "donut hole" existed in the Medicare Part D Program, DIR fee programs pushed patients through the coverage stages much faster. Within the donut hole, patients pay 25% of the drug cost based on the (inflated) list price at the point-of-sale. The concern that patients continue to foot the bill for increased costs is not hidden from scrutiny as a group of 21 U.S. Senators urged HHS to address DIR fees because "beneficiaries face high-cost sharing for drugs and are accelerated into the coverage gap (or "donut hole") phase of their benefit."[84]

In addition, despite PBMs' purported justifications for such programs, DIR fees have not benefitted the quality of Part D plans offered to Medicare beneficiaries. For example, SilverScript had a 4.0 Star Rating from Medicare in 2018[85] (based on 2017 data), but saw its score drop to a 3.5 Star Rating in 2019[86] despite the widespread usage of DIR fees. At the same time, as the impact of DIR fees has increased dramatically since 2016, patients have also been impacted by diminished access to care as providers facing decreased net reimbursement are forced out of business, forcing patients to receive services from pharmacies owned by or affiliated with the very PBMs and Part D plan sponsors extracting DIR fees (see, Section 6, *infra*).[87]

5.1.2 Harm to Plan Sponsors

Just as DIR fees negatively impact patients, PBM-Imposed DIR fees shift costs away from Part D plan sponsors, while increasing the costs to the Medicare program (and in turn, the taxpayer) for catastrophic coverage and subsidy payments.[88] As mentioned, when a Medicare beneficiary is pushed through the benefits tiers and reaches the "catastrophic coverage" stage, the cost of services shifts to 80% paid by Medicare, while only 15% paid by the plan sponsors.[89] The government covers these costs in part by turning to the reinsurance marketplace. From 2007 through 2018, a period similar to when CMS saw DIR fees from pharmacy price concessions increase by more than 45,000 percent, reinsurance costs of Medicare soared by 411%.[90] Part D plan sponsors and their PBMs have a financial incentive to move Medicare beneficiaries into the catastrophic phase of coverage, to the detriment of the taxpayer.

In fact, the National Community Pharmacists Association (NCPA) commissioned a report by Wakely Consulting Group, LLC to estimate the cost savings that would occur if congress prohibited retroactive reductions in payments by Part D plan sponsors in the form of DIR fees. Wakely Consulting Group, LLC found $3.4 billion in Part D payments over a nine-year period if these fees were prohibited.[91]

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[82] *https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir; see also, https://www.cms.gov/newsroom/press-releases/cms-takes-action-lower-out-pocket-medicare-part-d-prescription-drug-costs.*

[83] 83 Fed. Reg. 62152, 62176 (November 30, 2018).

[84] *https://www.cantwell.senate.gov/imo/media/doc/7-18-18%20DIR%20Azar%20Letter.pdf.*

[85] *https://q1medicare.com/PartD-2018StarRatingsPartCPartDOverall.php?state=SC&contractId=S5601&planId=018&plan=SilverScript%20Choice%20(PDP)%20-%20S5601-018&utm_source=partd&utm_medium=pdpfinder&utm_campaign=starimglink.*

[86] *https://www.silverscript.com/pdf/star-ratings.pdf.*

[87] *See, https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html* ("The largest insurers, PBMs, and specialty pharmacies have now combined into vertically-integrated organizations. . . . these companies have also been rapidly integrating with healthcare providers.")

[88] *See,* CMS, Medicare Part D—Direct and Indirect Remuneration (DIR), (January 19, 2017), *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html.*

[89] *https://archive.segalco.com/media/2521/me-5-4-2016.pdf.*

[90] *http://medpac.gov/docs/default-source/default-document-library/part_d_public_jan_2020.pdf?sfvrsn=0.*

[91] The Wakely Consulting Group, Impact of H.R. 1038/S. 413 on CMS Payments Under Part D addition to harming patients, improper MAC pricing.

Unfortunately, the harm from DIR fees goes beyond the Medicare program and American taxpayers. Like rebates, DIR fees have the effect of driving up the cost of drugs, through higher list prices. From 2013 to 2019, DIR fees rose from $229 million to an estimated $9.1 billion.[92] Most striking, however, is that DIR fees now account for more than 18% of all Medicare rebates received by Part D plans.[93] This increased reliance on DIR fees relative to drug rebates, both of which are tied to the list price of drugs, highlights the upward pressure DIR fees have placed on list prices for drugs. During this same period, drug list prices grew between 10–15% per year.[94] Meanwhile, net prices have been relatively flat throughout this time period.[95] These inflated list prices are felt by all plan sponsors—especially employers and state Medicaid programs—who do not receive any of the supposed benefits of DIR fees (such as lowered premiums).

PBMs have used their consolidation in the marketplace to use DIR fees and rebates in concert, fueling higher drug prices, while adversely impacting cancer care.

5.1.3 Harm to Providers

To say that DIR fees have had an adverse impact on providers is an understatement. DIR fees decrease pricing transparency creating uncertainty as to the true real reimbursement rates for drugs, very often driving reimbursement rates below the providers' acquisition cost of drugs (see, section 8, *infra*).

The metrics utilized by PBMs in implementing DIR fee programs are typically completely inapplicable to community oncology practices. Specifically, community oncology practices dispense primarily (and almost exclusively) specialty medications for cancer patients. As such, they have virtually no ability to influence their performance based on PBMs' "quality metric" categories measuring patient drug adherence relating to cholesterol, heart disease, and diabetes medications, which are relevant to dispensing general medications, not specialty drugs.[96]

Worse yet, adherence-based metrics are particularly problematic and in cases not only wholly inapplicable in treating cancer patients, but also may be very dangerous. Community oncologists are extremely vigilant about monitoring their patients' cancer medication regimens and may temporarily discontinue or "hold" medications until a patient's status returns to an acceptable level, especially relating to adverse drug side effects. The period during which the medication is "held," or therapy is temporarily discontinued, is wrongly and obtusely measured by the PBM as a lack of adherence in one of the few areas where the community oncology practices may be measured, ultimately causing the community oncology practices' performance to decrease, and the DIR fee assessment to subsequently increase.

Consider, for example, Imbruvica (ibrutinib), which is dispensed by many community oncology practices to treat mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL). Studies have shown that Imbruvica tends to cause hematologic effects such as neutropenia and thrombocytopenia in MCL and CLL.[97] If these adverse events occur at certain levels, the standard of care—as articulated directly by the FDA-approved package insert—is to hold the medication until the patient's lab values return to normal ranges.[98] This can happen in as many as 46% of cases, resulting in discontinuing the patient's medication for up to a month. If community oncology practices are required to continue to dispense this drug, it will result in additional (and avoidable) costs to Medicare for the discontinued fills, as well as potential harm to the patient (along with potentially increased costs to Medicare for associated medical costs).

Further, due to the high cost of specialty drugs, and in particular, oncology medications, any small change in perceived adherence rates due to the purposeful physician-directed temporary discontinuation of therapy results in unreasonably low re-

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[92] *https://www.drugchannels.net/2020/02/pharmacy-dir-fees-hit-record-9-billion.html.*

[93] *https://www.drugchannels.net/2020/02/pharmacy-dir-fees-hit-record-9-billion.html.*

[94] *https://www.aarp.org/content/dam/aarp/ppi/2019/11/brand-name-drug-prices-increase-more-than-twice-as-fast-as-inflation.doi.10.26419-2Fppi.00073.005.pdf.*

[95] *https://www.aarp.org/content/dam/aarp/ppi/2019/11/brand-name-drug-prices-increase-more-than-twice-as-fast-as-inflation.doi.10.26419-2Fppi.00073.005.pdf.*

[96] It is important to note that neither these metrics, nor the methodology in determining the performance scores are approved by CMS, and in fact, are not permitted by Medicare regulations.

[97] IMBRUVICA (ibrutinib) [package insert]. Sunnyvale, CA; Pharmacyclics LLC; Revised April, 2020.

[98] U.S. Department of Health and Human Services. Common Terminology Criteria for Adverse Events. CTEP. 2017;5:88–90. *https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_5x7.pdf.* Accessed September 24, 2020.

imbursement rates.[99] Many PBMs justify their DIR fee programs as being designed to influence providers to deliver better care to patients in their Medicare Part D networks. On that clinical basis, if community oncology practices were to be "influenced" by the PBMs' DIR fee metrics by adhering to a medication when the FDA-approved label calls for the therapy to be held, patients would suffer. As such, community oncology practices are often left without any meaningful way to impact PBMs' so-called "quality metrics" and improve their DIR fee performance.

Ultimately, community oncology practices have no way out. For them, due to the clout and market leverage of PBMs, DIR fees are simply a form of extortion that community oncology practices are forced to pay.

5.2 What Does the Law Say?

The most directly applicable legal principles relating to pharmacy DIR fees are found in the federal Any Willing Provider law. Within the federal Any Willing Provider law, CMS expressly recognized that unreasonably low reimbursement, which often result after accounting for DIR fees, violates the federal Any Willing Provider law.[100] As it relates to the methodologies being used to assess DIR fees, performance criteria, and the manner in which PBMs and Part D plan sponsors are using those programs must also be reasonable and relevant.[101] For community oncology practices, performance criteria that they are unable to influence or performance criteria that does not reasonably measure optimal cancer care can run afoul of the federal Any Willing Provider law.

In addition to explicit statutory language and CMS guidance, many of these principles are incorporated within, and apply directly to, the contract between PBMs and community oncology practices. PBM contracts include explicit obligations that the PBMs will comply with federal code, statues, rules, and CMS guidance, including but not limited to the Medicare Part D Provider Manual. These contractual obligations are not included in the contract with pharmacies by choice, but rather federal law requires these terms to be included in the contract between CMS and plan sponsors, and in contracts with their first tier entities (including PBMs, and in contracts between PBMs and pharmacy providers). This creates affirmative obligations on PBMs to comply with these laws, as well as the ability for pharmacy providers to directly challenge PBMs for breaches of contract when PBM actions do not comply with federal law.

In January 2022, CMS introduced a proposed Final Rule that would alter the way PBMs and Part D plan sponsors are required to report DIR fees.[102] In particular, CMS has proposed that PBMs and Part D plan sponsors report the lowest possible reimbursement to pharmacy providers (inclusive of all potential DIR fees) as the "negotiated price."[103] While this proposed rule (if finalized) could have the result of removing the financial incentive for PBMs and Part D plan sponsors to institute retrospective DIR fees, it does little to protect pharmacy providers against unreasonably low reimbursement rates or wholly irrelevant "quality" metrics when assessing DIR fees.

5.3 What Can Be Done?

- Legislative Solutions
  - Federal legislation should be enacted requiring that any DIR fee program (i) be tied to relevant quality programs to the specialty being measured; (ii) actually measured on an individual pharmacy level; (iii) provide equal opportunity for upside performance (*i.e.,* not just a way for PBMs to "rig" the program to always measure downside performance resulting in DIR fees extracted from the provider); and (iv) require that DIR fees be applied equally and fairly across all network pharmacies, specifically including PBM-owned or affiliated pharmacies).
  - Federal legislation should require that all pharmacy price concessions, including DIR fees, be included in the negotiated price at point-of-sale.

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[99] Notably, most cancer medications entering the market cost more than $100,000 per year of treatment.

[100] *See,* 42 U.S.C. § 1395w–104(b)(1)(A); 42 CFR § 423.505(b)(18) Medicare Prescription Drug Benefit Manual, Chapter 6, Section 50.3.

[101] 42 U.S.C. § 1395w–104(b)(1)(A); 42 CFR § 423.505(b)(18) Medicare Prescription Drug Benefit Manual, Chapter 6, Section 50.3.

[102] *https://www.cms.gov/newsroom/press-releases/cms-takes-action-lower-out-pocket-medicare-part-d-prescription-drug-costs.*

[103] *https://www.cms.gov/newsroom/fact-sheets/cy-2023-medicare-advantage-and-part-d-proposed-rule-cms-4192-p.*

- Federal legislation should give CMS greater latitude in regulating the reimbursement structure between Part D plan sponsors and pharmacy providers.

- Regulatory
  - CMS should issue regulation providing "guard rails" on what constitutes reasonable and relevant terms and conditions, and clarify that whether given terms are "reasonable" or "relevant" can be adjudicated in a private contractual dispute between Part D plan sponsors/PBMs and pharmacies.
  - CMS should initiate complaints against Part D plan sponsors and PBMs who have failed to pass on negotiated prices to patients at the point-of-sale, when DIR fees were known or knowable (*i.e.,* the PBM maintained a minimum range of DIR fees that were to be assessed against every pharmacy no matter what).
  - CMS should initiate complaints against Part D plan sponsors and PBMs who have not paid providers based on reasonable and relevant terms and conditions, including through unreasonably low reimbursements, or irrelevant performance criteria.
  - CMS should require reporting of pharmacy DIR fees by both NDC number and pharmacy National Provider Identifier (NPI) allowing for full end-to-end audits of the flow of money from pharmacies to the Medicare program. The results of these audits should be made available to the public.

6 Restrictive Networks, Credentialing Abuses, and Artificial Barriers of Entry

PBMs maintain a monopoly-like grasp on the industry, the natural result of which is the inability of patients to freely choose a provider based on his or her personal health care decisions, as opposed to the mandates of his or her PBM. As noted previously, only three PBMs process more than three-quarters of all prescription claims: CVS Health, Express Scripts, and OptumRx,[104] while five PBMs process over 80% of all prescription claims. Each of the three major PBMs share common ownership with a major insurer and in turn with a mail-order and/or specialty pharmacy. These vertical, integrated relationships allow the PBMs to control the pharmaceutical supply chain, and erect superficial barriers to entry or even outright exclude entire classes of potential pharmacy providers.

This is particularly pronounced in the context of cancer care, where the introduction of new oncology therapies over the past several years, specifically, oral treatments for cancer and related conditions, presents new challenges for patients, plan sponsors, and providers alike. Between 2017 and 2019, there have been over 24 new oral cancer medications introduced into the marketplace.[105] In 2020 alone, ten new oral oncolytics were approved by the FDA.[106] As it stands, oral oncolytics make up 25% to 35% of cancer medications in development, making it likely that over the next several years, oral therapies will encompass an indispensable component of any treatment plan for cancer patients.[107] While traditional chemotherapy infusion therapy that is "administered" is covered under a patient's "medical" benefits, oral oncolytics that are "dispensed" are being shifted to the patient's "pharmacy" benefits, managed by PBMs. Unlike chemotherapy administered in the clinic setting, the advent of oral oncolytics have given the PBMs a tremendous new opportunity to control cancer care and divert prescriptions and profits to themselves.

These new oral cancer medications can be extremely expensive, often ranging more than $10,000 per month.[108] This is what is attracting PBMs, and as a result, PBMs

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[104] *See,* CVS, Express Scripts, and the Evolution of the PBM Business Model, available at *https://www.drugchannels.net/2019/05/cvs-express-scripts-and-evolution-of.html). See also* Brief for Community Oncology Alliance, Inc. et al. as Amici C Curiae Supporting Respondents, *Rutledge v. Pharmaceutical Care Management Association,* 140 U.S. 812 (2020), 2020 WL 1372777.

[105] *https://scholarlycommons.baptisthealth.net/cgi/viewcontent.cgi?article=4573&context=se-all-publications.*

[106] *https://www.clinicaloncology.com/FDA-Watch/Article/12-20/New-Oncology-Drug-Approvals-in-2020/61464.*

[107] *See, https://www.onclive.com/view/oral-oncolytics-will-require-health-care-system-to-adapt* (citing Stokes M, Reyes C, Xia Y, Alas V, Goertz HP, Boulanger L. Impact of pharmacy channel on adherence to oral oncolytics. *BMC Health Serv Res.* 2017;17(1):414. doi:10.1186/s12913–017–2373–2).

[108] *https://www.onclive.com/view/oral-oncolytics-will-require-health-care-system-to-adapt.*

have attempted to use their market size and leverage to limit dispensing of oral oncolytics through certain specialty and/or mail-order pharmacies, most often their own or affiliated pharmacy.[109]

PBMs use several different tactics to maintain their control over where patients receive their care. The first and foremost of these is creating restricted networks, blocking access to any provider that is not affiliated with their PBM. In these instances, the PBM will contend that the network is "closed" or that there is no "network," and thus, pharmacy providers are not even given the opportunity to apply for network admission. This occurs more frequently in the commercial insurance space involving employer-sponsored plans, but can also involve Medicaid managed care programs, where the PBM will require patients to receive their cancer medication from the PBM's wholly-owned or affiliated pharmacy, and no one else. This is anticompetitive conduct—pure and simple—where patients are trapped into using one particular provider not based on the quality of care provided by that provider but based on the financial arrangements and the corporate affiliation between the pharmacy provider and the PBM and/or health insurer.

A related, but slight variation of this tactic is to restrict access to certain classes of providers (*i.e.,* retail pharmacies), while excluding wholesale other classes of providers (*i.e.,* dispensing physician practices). For example, beginning in early 2016, CVS Caremark espoused a self-serving stance that dispensing physician practices were now to be deemed "out-of-network" and no longer able to participate in Medicare Part D networks. This would have the effect of dramatically interrupting the ongoing relationship between treating oncologists and their patients. CVS Caremark later backtracked on this position and began allowing "grandfathered" dispensing physicians (*i.e.,* those that previously held a contract with the PBM) to continue in-network, but delayed the processing of any new, non-grandfathered dispensing physician practices. In another instance, in January of 2018, Prime Therapeutics (Prime)—the PBM owned by a consortium of approximately twenty-two Blue Cross Blue Shield plans—announced that it would no longer accept any new dispensing physicians into its pharmacy networks on the alleged basis of "fraud, waste, and abuse" concerns and a commitment to maintaining to compliant networks. Without providing any further details, Prime claimed that Dispensing Physicians did not adhere to Prime's Provider Manual. This trend expanded to existing in-network dispensing physicians actively servicing patients when, recently, Prime announced that it would also terminate existing, or "grandfathered" dispensing physicians from its networks. Despite having credentialed, contracted, and paid dispensing physicians as "in-network" Medicare Part D providers for over a decade, Prime seemingly unilaterally took the position that dispensing physicians are now considered "out-of-network providers" under Medicare Part D. Like wholesale network exclusion, these practices disadvantage vital providers while allowing PBM-owned or affiliated pharmacies to capture a greater share of prescription volume.

Even in instances where a PBM nominally allows a community oncology practice to apply for network participation, the PBM can still place other barriers in the way of providers being able to service their patients by imposing onerous credentialing processes. For a community oncology practice to service patients within a PBM's network, PBMs require that the provider adhere to specific and extremely onerous, credentialing requirements, including the requirement that the provider maintain certain accreditations. These conditions are made even more onerous where PBMs delay the review of credentialing applications (seemingly with the intention to avoid admitting these providers), enact credentialing applications with terms and conditions designed to keep out providers (rather than ensuring the quality of providers) or allow participation but at rates so low that reimbursement may not even cover the acquisition cost of a drug.

These obstructionist policies harm patients, degrade the quality of prescribers and benefit only PBMs that are incentivized to continue to these illegitimate practices.

Finally, even when a community oncology practice has ultimately been admitted into a PBM's network, PBMs continue to utilize other tactics to drive patients away from community oncology practices, and towards PBM-owned or affiliated pharmacies. This includes tactics such as patient slamming and claim hijacking (see, section 7, *infra*), misleading communications aimed at steering patients to PBM-owned

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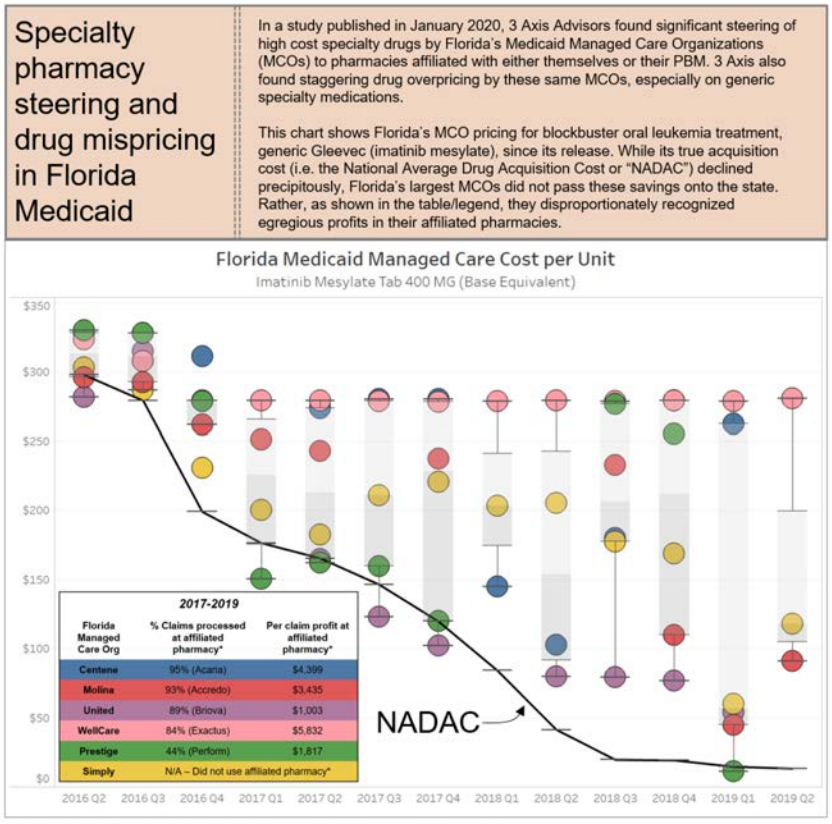
[109] *See,* Nancy J. Egerton, In-Office Dispensing of Oral Oncolytics: A Continuity of Care and Cost Mitigation Model for Cancer Patients, *Am. J. Manag. Care* Vol. 22, Supp. No. 4, S100 (2016), *https://www.ncoda.org/wp-content/uploads/bp-attachments/7218/ajmcpan032016inofficedispensingcontinuityofcarebynancyegerton.pdf.*

or affiliated pharmacies, and creating patient incentives for patients (such as lower copays, larger days' supply or free products/services) to utilize preferred PBM-owned or affiliated pharmacies. PBMs also utilize other tactics, such as abusive auditing practices (*i.e.,* requiring the production of thousands of pages of documentation to support claims billed) and terminating providers without cause or on pretextual bases (*i.e.,* that they only dispense one class of medications).

PBMs employ these tactics to maintain their oppressive market dominance. But at the same time, in a vicious cycle, these tactics are themselves the consequence of the horizontal and vertical consolidation within and between insurance and PBM markets, which has created merged entities with such oppressive power that it a virtual chokehold on community oncology practices and pharmacy providers. The result of these tactics is that patients are steered away from receiving care at their community oncology practices, and forced to receive care from PBM-owned or affiliated pharmacies. This is not only without regard to the impact on patient care and outcomes, but as the chart below demonstrates, only continues to prop up higher drug prices and charges.



* Either affiliated directly with the MCO, or affiliated with the PBM working for the MCO

6.1 Who Is Impacted?

The overall lack of industry standards and oversight in the PBM credentialing sphere has led to arbitrary denials and lengthy, costly application processes, that ultimately have a negative impact on a community oncology practice's ability to focus on patient care. Instead of allowing community oncology practices to enter into their networks, PBMs attempt to limit the dispensing of oral oncolytics through

their own specialty pharmacies, leading to poor patient compliance and adherence to life-saving treatments, causing the quality of cancer care to suffer.[110]

These tactics have had negative impact all across the spectrum, affecting patients, health care payers (including Medicare, Medicaid, employers and taxpayers), and providers.

6.1.1 Harm to Patients

These exclusionary practices—whether they be unreasonable barriers to entry or outright exclusion of certain classes of providers—result in serious harm to patients, specifically those who are seeking the services of community oncology practices that have been excluded from a PBM specialty network. For one, these exclusionary practices destroy existing patient-provider relationships. In early 2016, when CVS Caremark undertook re-interpreting longstanding CMS regulations, it did so in such a way as to effectively cut out physicians from continuing to dispense medications to their existing Medicare Part D patients.[111] PBMs have no regard for the continuity of these vital health care relationships and their impact on patients' well-being and outcomes.

This is critical, as patients are more likely to raise certain questions or concerns about their medications, when these medications are dispensed by community oncology practices. To strip patients, who are facing serious life-threatening diseases, of that important patient-provider relationship could result in serious patient harm.[112] This also has the effect of decreasing medication adherence, which would further affect patients, especially those undergoing life-saving treatments at community oncology practices.[113]

The ultimate outcome of creating restricted networks or excluding entire classes of providers, namely, that patients are essentially required to obtain medications at a PBM-owned or affiliated pharmacy. It is well-documented[114] that when the PBM-owned or affiliated pharmacy is responsible for filling the patients' prescriptions, it results in worse care. The near-monopolistic control of the network, combined with the lack of patient choice, remove any checks and balances on the quality of the care being provided.

Consider, for example, a patient battling cancer was denied life-saving medications by a PBM due to the PBM being unwilling to enter medications into its computer system.[115] In another example, a patient had been diagnosed with Philadelphia chromosome-positive + chronic myeloid leukemia and had been responding positively to "180mg" of a certain medication. However, according to the patient's PBM, the medication had to come from the PBM's mandated mail order specialty pharmacy instead of a pharmacy of their choice. Since the medication was not available in a single 180mg dosage form, the prescription clearly indicated that the patient was to receive a "100 mg tablet and an 80 mg tablet." Instead, over the course of the next several months, the PBM pharmacy dispensed either a 100 mg tablet or an 80 mg tablet, but never both. Ultimately, the patient did not respond well to the lowered dosages of the medication.[116] Finally, in a particularly disturbing example, a colorectal cancer patient was prescribed a common oral medication that had been on the market for nearly 20 years. The patient's PBM mandated that the patient

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[110] *See* American Pharmacists Association, Pharmacy credentialing—challenges and opportunities (August 21, 2017), *https://www.pharmacist.com/article/pharmacy-credentialing-challenges-and-opportunities. See also,* Egerton, *supra,* at S100.

[111] *See,* CVS Health Corp., Letter to Congressman Ed Whitfield from Senior Vice President of Government and Public Affair Melissa A. Schulman (February 19, 2016) ["CVS-Whitfield Letter"].

[112] *See,* First Coast Health Solutions, How In-Office Dispensing Can Improve Patient's Clinical Outcomes (June 30, 2019), *https://firstcoasthealthsolutions.com/2019/06/30/how-in-office-drug-dispensing-can-improve-patients-clinical-outcomes-2/.*

[113] *See,* Jacob G. Moroshek, Improving outpatient primary medication adherence with physician guided, automated dispensing (2017), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5221544/; see also* Marie T. Brown, MD and Jennifer K. Bussell, MD, Medication Adherence: WHO Cares? (April 2014), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068890/.*

[114] *See,* Georgia General Assembly, 2019–2020 Regular Session, HB 233 (available at *http://www.legis.ga.gov/Legislation/en-US/display/20192020/HB/233; https://www.theatlantic.com/health/archive/2019/04/pbms-health-care-drug-delays-prices/586711/; https://patientsrisingnow.org/how-do-pbm-business-policies-affect-patients/; https://communityoncology.org/wp-content/uploads/2018/08/COA_PBM-paperHorrorStories_VolII.pdf.*

[115] *See, https://pbmabuses.org/a-4000-co-pay-forced-this-prostate-cancer-patient-to-admit-defeat-and-not-receive-a-treatment-that-could-have-extended-his-life/.*

[116] *See,* Community Oncology Alliance, Pharmacy Benefit Manager Horror Stories—Part IV (August 1, 2018), *https://communityoncology.org/pharmacy-benefit-manager-horror-stories-part-iv-2/.*

fill the prescription at a large, well-known specialty pharmacy, and the patient's oncologist prescribed the medication to be taken in rounds with the following specific instructions: "two weeks on, one week off." The PBM mail-order pharmacy neglected to include the "one week off" instruction on the label, and as a result, the patient ended up in the intensive care unit of a hospital.[117]

Unfortunately, patients often do not have any ability or choice to switch their PBMs in order to have control over which pharmacy provider from whom they would like to receive service. PBMs who undertake these restrictive practices are typically selected by the patient's employer (or sometimes by the insurance company selected by the patient's employer). The patients are two, sometimes three steps removed from any part of the decision-making process. Since most patient get their health care coverage through their jobs, the only way a patient can exert any control over the network of pharmacy providers is to change jobs and hope that their new employer utilizes a different PBM's network. But, in a world where three PBMs account for nearly 80% of the marketplace, the odds of getting a better PBM are slim to none.

The PBMs know the level of power that they wield. And their focus is on profits, not patients. Ultimately, given the acute focus on patient care inherent in community oncology practices, patients suffer when those providers are forced out of the space.[118]

6.1.2 Harm to Plan Sponsors

In addition to patients, these exclusionary practices harm plan sponsors, such as Medicare and Medicaid, because they cause an artificial rise in the cost of specialty medication, particularly within the oncology space. Specifically, the exclusion of community oncology practices from PBM networks require more patients to utilize PBM-owned or affiliated mail-order and/or specialty pharmacies. This, in turn, leads to exponentially more waste of medication, causing increased costs to plan sponsors.[119] Mail-order pharmacies, without proper access to patient outcomes, routinely dispense 90-day supplies of medications. In several instances, patients continue to receive medications despite their repeated requests to have the mail-order pharmacy cease sending medication, often due to a change in their course of treatment. In more tragic cases, the PBM mail-order pharmacies continue to dispense medications to the patient's residence despite the patient having passed away, leading to the waste of unwanted, expensive medications.[120]

Moreover, when pharmacy care is diverted from community oncology practices to PBM-owned or affiliated pharmacies, plan sponsors lose out on tremendous value-based contracting opportunities.[121] In the Medicare space, CMS is developing new payment and delivery models designed to improve the effectiveness and efficiency of specialty care. Among those specialty models is the Oncology Care Model, which aims to provide higher quality, more highly coordinated oncology care at the same or lower cost to Medicare. The Oncology Care Model "provides an incentive to participating physician practices to comprehensively and appropriately address the complex care needs of the beneficiary population receiving chemotherapy treatment and heighten the focus on furnishing services that specifically improve the patient

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[117] *See, https://pbmabuses.org/already-fighting-for-her-life-one-mistake-at-the-hands-of-the-pbm-nearly-killed-her/.*

[118] *See,* Allison Gilchrist, The Advantage of Independent Pharmacies, *Pharmacy Times,* March 12, 2016, *https://www.pharmacytimes.com/view/the-advantage-of-indepdendent-pharmacies.*

[119] *https://cdn.ymaws.com/www.papharmacists.com/resource/resmgr/Legislative/TPA-Drug-Report-print.pdf; https://www.pharmacist.com/article/study-raises-mail-order-pharmacy-patient-adherence-dispensing-questions#:~:text=Prescriptions%20filled%20by%20mail%20order,from%20the%20Community%20Pharmacy%20Foundation; https://www.pharmacytimes.com/news/ncpa-mail-order-waste-all-too-common-documented-by-federal-officials.*

[120] *See,* Egerton, *supra,* at S100. *See also,* NCPA: Mail Order Waste All Too Common; Documented by Federal Officials, March 5, 2013, *https://www.pharmacytimes.com/news/ncpa-mail-order-waste-all-too-common-documented-by-federal-officials. See also* National Community Pharmacists Association, Waste Not, Want Not: Examples of Mail Order Pharmacy Waste, May 27, 2020, *http://www.ncpa.co/pdf/waste-not-want-not---examples-of-mail-order-pharmacy-waste.pdf.*

[121] *See,* NCPA: Mail Order Waste All Too Common; Documented by Federal Officials, March 5, 2013, *https://www.pharmacytimes.com/ajax/NCPA-Mail-Order-Waste-All-Too-Common-Documented-by-Federal-Officials. See also,* National Community Pharmacists Association, Waste Not, Want Not: Examples of Mail Order Pharmacy Waste, May 27, 2020, *http://www.ncpa.co/pdf/waste-not-want-not---examples-of-mail-order-pharmacy-waste.pdf.*

experience or health outcomes."[122] PBM exclusionary practices would thwart this initiative. Likewise, in the private sector, value-based care (VBC) innovations are on the rise, increasing the quality while lowing the overall cost to health care payer and their patients. The ability to tie benefits to providers and value to patients is critical to aligning interests in the health care space and has long been a long-term goal of health policy experts. However, this type of integration of medical and pharmacy care is against the interest of current PBM practices to implement. Absent changes to PBM regulation, the federal government will be unable to achieve some of the same cost-saving/quality improving measures as is being utilized in primarily the self-funded employer sponsor health care space.

Unfortunately, these lost opportunities are not made up for in savings garnered by PBMs, and in fact, quite the opposite has occurred. As illustrated in the figure on page 36, the exclusion of community oncology practices and other independent providers allows PBMs to pocket more through their wholly-owned or affiliated mail-order and specialty pharmacies.

In a study conducted by Ohio's Medicaid Managed Care Pharmacy Services, PBMs billed taxpayers 8.8% more for medications than what they paid pharmacies. This difference, commonly referred to as "spread" has been growing and is typically the highest on specialty medications, such as oral oncolytics.[123] Worse yet, similar data has shown that the spread between plan sponsor funded PBM revenue and pharmacy-captured reimbursement has increased over time. In short, PBMs are keeping more and more revenue from health care costs to the detriment of others in the health care space.

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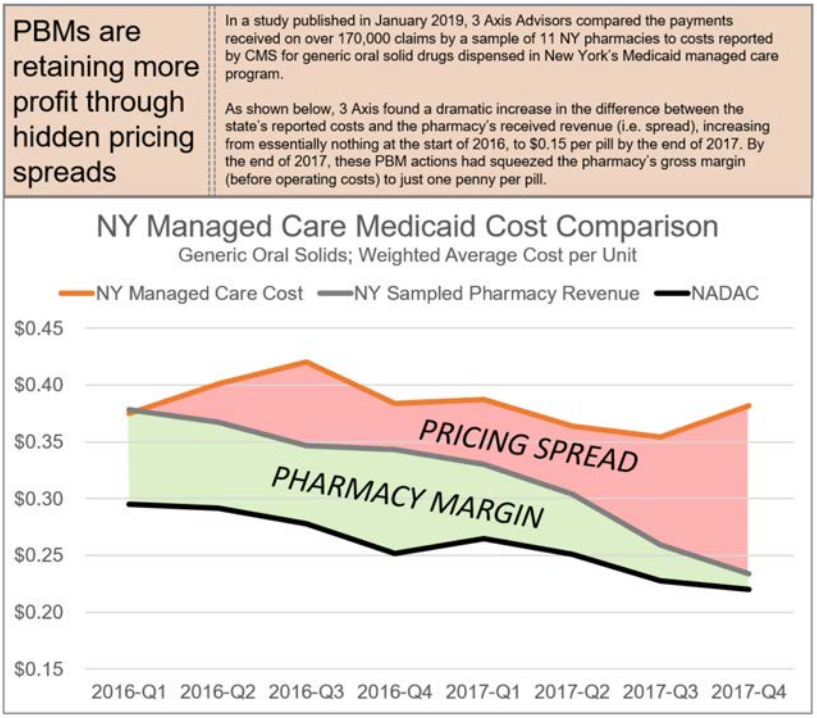
[122] *See,* Oncology Care Model (last updated May 15, 2020), *https://innovation.cms.gov/innovation-models/oncology-care. See also* Value-Based Care Leads the Way to Lower Costs and Better Quality (December 4, 2019), *https://www.ahip.org/news/articles/value-based-care-leads-the-way-to-lower-costs-and-better-quality/. See also* The Oncology Care Model 2.0 (May 28, 2019), *https://communityoncology.org/wp-content/uploads/sites/20/2019/06/COA-PTAC.pdf.*

[123] *See,* Auditor of State Report (August 16, 2018), *https://audits.ohioauditor.gov/Reports/AuditReports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf. See also,* Analysis of PBM Spread Pricing in Michigan Medicaid managed care (April 18, 2019), *https://www.3axisadvisors.com/projects/2019/4/28/analysis-of-pbm-spread-pricing-in-michigan-medicaid-managed-care* (identifying that PBMs overcharged Michigan Medicaid by at least $64 million).



Ultimately, when compared to costs of PBM exclusionary practices, the savings associated with dispensing by community oncology practices are palpable. Reports estimate that physician point-of-care dispensing could save seniors and taxpayers over $20 billion in Medicare Part D alone.[124]

6.1.3 Harm to Providers

An increasingly important component of the physician-patient relationship with oncology is the dispensing of medications to patients through the community oncology practice, at the site of care. Excluding community oncology practices from PBM networks prevents physicians from providing consistent care to their patients.[125]

When PBMs impose unreasonably high or arbitrary requirements for network admission, designed for no purpose other than to serve as an artificial barrier of entry, they place immense and undue burdens on community oncology practices seeking to service their patients. As noted above, these credentialing standards often require a provider to hold multiple forms of accreditation, such as URAC and ACHC. These specified accreditations are often not the most relevant or appropriate form of accreditation for community oncology practices, and do not constitute the most applicable form of endorsement based on the unique and specialized services provided by community oncology practices.

Between the standards set forth under the Oncology Care Model (OCM) and Quality Oncology Practice Initiative (QOPI®) Certification Program, community oncology practices also attain high standards of practices, validated by third parties, that obviate the need for separate accreditation. For example, QOPI has a certification program specifically designed for clinical oncology practices as this process "can routinely evaluate practice performance against quality measures and standards estab-

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[124] *See,* Physician Point-of-Care Dispensing Could Save Seniors and Taxpayers $20 Billion on Generic Drug Costs in Medicare (August 20, 2019), *https://aapsonline.org/physician-point-of-care-dispensing-could-save-seniors-and-taxpayers-20-billion-on-generic-drug-costs-in-medicare/*.

[125] *See,* National Evaluation of Prescriber Drug Dispensing (2014), *https://dopl.utah.gov/PrescriberDrugDispensing.pdf*.

lished by experts in the oncology field." Likewise, through the CMS-created OCM, community oncology practices have entered into payment arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients. The practices participating in OCM have committed to providing enhanced services to Medicare beneficiaries such as care coordination, navigation, and national treatment guidelines for care. The fact that CMS has involved itself in the creation of this type of model with standards that directly correlate to community oncology providers demonstrates that these two programs (OCM and QOPI) would be the best industry standards to judge a network provider. Moreover, requiring dual accreditation—including URAC accreditation in Specialty Pharmacy—apart from being redundant, also increases the risks that the provider will have multiple, sometimes contradictory compliance requirements, needing to comply with not just ACHC standards, but also URAC standards, which at times can be diverging. Finally, these accreditations can be prohibitively expensive and costly, making it impracticable for providers to undertake the steps necessary to even seek admission to the networks.

Likewise, when PBMs take steps to delay credentialing, this too harms pharmacy providers. Community oncology practices have to divert considerable amount of time and resources to respond to repeated follow ups on their credentialing applications under normal circumstances. However, when a PBM "slow rolls" an application and takes months to review and respond to inquiries, this has often led to the PBM asking the provider to provide the same documentation over, and over and over again (*i.e.,* licenses that expire and are renewed over the course of the sometimes 18-month long credentialing process). This takes time away from being able to service patients.

But perhaps the most direct way providers are harmed by these tactics is through the actual effects of network exclusion. Due to the size and market share of each PBM (see, Section 3, *supra*), a PBM termination or exclusion often spells irreparable harm for a provider seeking to participate in pharmacy networks and/or the Medicare Part D program.[126] Particularly alarming is the fact that about two-thirds of all Medicare Part D Prescription Drug Plan enrollees are concentrated in networks across just three payers: OptumRx, CVS Caremark, and Humana. Exclusion from any one of these payers could make dispensing simply not a viable option for a community oncology practice.[127]

6.2 What Does the Law Say?

Among all the barriers that PBMs put in front of providers—including onerous credentialing processes, restricting network access, steering to owned or affiliated pharmacies—the core legal principles largely tie back to rules promulgated around freedom of patient choice and network participation. Remarkably, there are several federal and state laws on the books that seek to safeguard the rights of patients to select the provider of their choice, or to protect community oncology practices from undue network termination or exclusion. In the federal statutes establishing and governing the Medicare program, Congress has included explicit "Any Willing Provider" requirements, which relate directly to network access for Medicare providers, including community oncology practices. These statutes apply to all Part D plan sponsors, as Part D plan sponsors are under the purview of CMS, pursuant to contracts between the Part D plan sponsors and CMS.

The Medicare Any Willing Provider law (42 U.S.C. § 1395w–104) explicitly requires that all Part D prescription drug plans permit "the participation of any pharmacy that meets the terms and conditions under the plan." The federal "Any Willing Provider" law further prohibits health insurers from creating exclusive provider networks—or unduly barring entry to such networks (such as through artificial barriers of entry)—to which insured patients are directed to the exclusion and detriment of non-network providers.[128] In fact, as it relates to credentialing abuses, CMS has also questioned whether mandatory accreditations should be considered "standard terms and conditions" of a network, and whether PBMs should instead explore other reasonable and relevant alternatives to ensure quality assurance and actual im-

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[126] *See,* Pharmacy Benefit Managers' Attack on Physician Dispensing and Impact on Patient Care: Case Study of CVS Caremark's Efforts to Restrict Access to Cancer Care (August 2016), *https://communityoncology.org/wp-content/uploads/2018/08/PBMs_Physician_Dispensing-WhitePaper_COA_FL.pdf.*

[127] *See,* Adam J. Fein, Medicare Part D 2016: 75% of Seniors in a Preferred Pharmacy Network (PLUS: Which Plans Won and Lost), Drug Channels (January 20, 2016), *http://www.drugchannels.net/2016/01/medicare-part-d-2016-75-of-seniors-in.html.*

[128] *See, e.g., Kentucky Association of Health Plans v. Miller,* 538 U.S. 329 (2003).

proved patient care, particularly where certain accreditation requires may be arbitrary and not directly proven to ensure quality assurance.[129]

Likewise, federal law provides protection directly for patients to have the freedom to select a provider of their choice.[130] Pursuant to 42 CFR §431.51(a), Medicaid beneficiaries may obtain services from any qualified Medicaid provider that undertakes to provide services to them. However, plan sponsors commonly use preferred networks to incentivize beneficiaries to fill claims at pharmacies of the Plan's choice (rather than the beneficiary's choice), by offering reduced co-pays at preferred pharmacies.

Several states also maintain their own versions of "Any Willing Provider" protections. For example, North Carolina's Any Willing Provider Law provides that a health benefit plan shall not "[p]rohibit or limit a resident of th[e] State . . . from selecting a pharmacy of his or her choice when the pharmacy has agreed to participate in the health benefit plan according to the terms offered by the insurer," or "[d]eny a pharmacy the opportunity to participate as a contract provider under a health benefit plan if the pharmacy agrees to provide pharmacy services that meet the terms and requirements, including terms of reimbursement, of the insurer under a health benefit plan. . . ."[131]

Similarly, Tennessee's Any Willing Provider Law provides similar limitations on the ability to exclude providers such as community oncology practices, mandating that "[n]o health insurance insurer and no managed health insurance insurer may . . . deny any licensed pharmacy or licensed pharmacist the part to participate as a participating provider in any policy, contract, or plan on the same terms and conditions are offered to any other provider of pharmacy services under the policy, contract or plan" or "[p]revent any person who is a party to or a beneficiary of any policy, contract, or plan from selecting a licensed pharmacy of the person's choice . . . provided that the pharmacy is a participating provider under the same terms and conditions of the contract, policy or plan as those offered any other provider of pharmacy services."[132]

These laws prohibit not just outright network exclusion, but also a host of other PBM practices aimed at requiring that patient use their wholly-owned or affiliated pharmacies.

At both the federal and state levels, policy recognizes the importance of provider access and, ultimately, competition via the enactment of these "Any Willing Provider" rules. Unfortunately, these laws have not been without attack by the powerful PBMs,[133] and in few instances do they provide pharmacies a private right of action to enforce and ensure they are meaningfully applied.

6.3 What Can Be Done?

- Legislative
  - Congress should enact federal legislation that provides a private right of action for community oncology practices to exercise their rights under the federal Any Willing Provider law, particularly when they are unfairly excluded from PBM networks and a private right of action will allow the enforcement of a regulation by a private party, such as a community oncology practice, allowing for litigation or the threat of litigation to incentivize compliance of the law.
  - Congress should enact state legislation that curbs credentialing abuses and provides for stronger Any Willing Provider laws and provides for a private right of action for community oncology practices to exercise.

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[129] *See, e.g.,* Caremark's Specialty Credentialing Application; *see, e.g.,* OptumRx's Specialty Designated Network Application. *See also,* Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 42 Fed. Reg. 16597 (April 16, 2018)

[130] *See,* 42 CFR §431.51(a).

[131] N.C. Gen. Stat. Ann. §58–51–37(c).

[132] Tenn. Code. Ann §56–7–2359 (a)(1)–(2).

[133] *See, CZ Services, Inc. v. Express Scripts Holding Co.,* Case No. 3:18–cv–04217 Dkt. No. 27 (order denying Plaintiff's request for temporary restraining order); *Park Irmat Drug Corp. v. Express Scripts Holding Co.,* No. 18–1628 (8th Cir. 2018).

- Regulatory
  - CMS should pursue complaints against PBMs for their construct of artificial barriers of entry and failure to adhere to the establishment of reasonable and relevant terms and conditions of participation.
  - CMS should also enact regulation to specify "reasonable" and "relevant" standards of participation to allow for defined requirements PBMs must adhere to.
  - CMS should issue regulation providing "guard rails" on what constitutes reasonable and relevant terms and conditions, and clarify that whether given terms are "reasonable" or "relevant" can be adjudicated in a private contractual dispute between Part D plan sponsors/PBMs and pharmacies.
  - State Departments of Insurance should pursue complaints against PBMs for violations of Any Willing Provider Laws, and Medicaid Free-Choice-of-Provider provisions.
- Plan Sponsor Action
  - Plan sponsors should require PBMs to seek approval from plan sponsors prior to establishing a standard and/or qualification for a provider network.
  - Plan sponsors should have the full and final authority to make any modification to a standard and/or qualification for a provider network.
  - Plan sponsors should retain the right to participate in an administrative hearing requested by a provider who has been terminated or rejected from a PBM's provider network.
  - Plan sponsors should retain the full and final authority to make accept or deny a provider's request to participate in a PBM's provider network.

7 Prescription Trolling, Patient Slamming, and Claim Hijacking

A patient's decision on where to fill his or her medication, especially a cancer medication, is of immense importance. Cancer patients require ease of treatment and as little confusion as possible, in order to have a positive outcome. Based on these principles, Section 30.2.2.3 of the Medicare Prescription Drug Benefit Manual prohibits PBMs and Part D plan sponsors from "Steering of physicians or beneficiaries to a sponsor's and/or PBM's own mail order Pharmacy." Such prohibition specifically includes steering of prescribers' patients to a specialty pharmacy owned by or affiliated with a plan sponsor/PBM and most PBM contracts require adherence to CMS Guidance and contain compliance with law provisions.

Despite the law, there are innumerable instances where the PBMs haves effectively utilized claims or fill data and sought to move the prescription away from the provider of the patient's choice and toward the PBM's wholly-owned or affiliated pharmacy. This practice, sometimes referred to as "prescription trolling," "patient slamming," or "claim hijacking," plays out fairly consistently. A typical case might involve a situation where the PBM allows the provider to submit a claim (typically a high-cost specialty medication), then reject it claiming that it required a prior authorization (PA). Then, once the provider has done all the required work to obtain the approval for the PA, it is subsequently rejected once again by the PBM, this time for the apparent reason that it "must" be filled at the PBM-owned or affiliated specialty pharmacy.

Pharmacy providers typically transmit prescription claims (and sometimes PA requests) to the patients' PBM for purposes of having it adjudicated and receiving reimbursement. Such transmissions clearly contain protected health information (PHI) and are directed solely at the PBM acting as the claims adjudicator. Instead of simply reviewing and processing this claim, in its fiduciary capacity as the PBM, the PBM improperly and unlawfully accesses the PHI, and illegally communicates the claim information to its related entity (a PBM-owned specialty pharmacy). While the PBM is processing the PA, the PBM-owned or affiliated pharmacy surreptitiously communicates to the patient, prescriber, or both, with the goal of having the prescription filled at the PBM-owned or affiliated specialty pharmacy. Community oncology practices have documented[134] some egregious instances where the PBM blatantly lied to the patient and pharmacy staff, saying the prescribing physician had

[134] *https://communityoncology.org/research-publications/studies/the-real-life-patient-impact-of-pbms-volume-i/*.

authorized the transfer, when in fact, they clearly had not. Further, with complete disregard to not only patient privacy laws, but also state Pharmacy Practice Acts, PBM-owned specialty pharmacies have brazenly filled and dispensed the medication in complete absence of having an actual, signed prescription in hand.[135]

Worrisomely, more deceitful and underhanded variations of this also exist. In some instances, PBM-owned or affiliated pharmacies have sought to mislead patients into thinking that their physician wants the prescription to be filled at the PBM-owned or affiliated pharmacy, or otherwise imbed prescription transfer documentation in the information the PBM provides to the physician in order to renew the prescription for refill (and the physician unknowingly signs to have the prescription transferred).

7.1 Who Is Impacted?

7.1.1 Harm to Patients

A direct result of prescription trolling is severe confusion and distress for cancer patients, who are caught in the middle, uncertain of when or from where they will receive their next dose of their life saving medication.[136] These concerns in the context of prescription trolling go beyond those when a PBM takes steps to create a restricted network (see, section 6, *supra*); it is far more insidious here. While patients cannot be compelled to fill their prescription from a specific dispenser, many report receiving correspondence from their PBM implying that they must use a pharmacy owned by or affiliated with the PBM. These letters often explain that the insurance company has its own "preferred" pharmacy, from which the patient may already be receiving other prescribed drugs and offer for the patient to also get their oral cancer drug from this same source. PBMs may try to entice patients to select their "preferred" pharmacy through lower patient copayments to the patient only for the patient to later realize their oral oncolytics cost more at the "preferred" pharmacy than a non-preferred provider. Many patients find this confusing and do not understand the repercussions that jeopardize the monitoring, care control, and clinical management that they receive at their community oncology pharmacy, and they mistakenly, or unintentionally, switch their drug dispenser.[137]

Many patients may require special assistance from their community oncology practice that has documented and understands their medical history, monitors for drug interactions between their medications, and is able to make appropriate dosing adjustments at the time of administration. Furthermore, a patient who is switched over to a PBM-owned or affiliated mail-order pharmacy often has his/her medication shipped from a distance (sometimes several states away), running the risk that the drug could be rendered ineffective in treating that patient's condition due to a lack of sufficient temperature control during transit.[138] In short, the harm can literally be deadly for patients with cancer, because of the disease and drugs involved—medications arriving too late or failure to timely amend dosing regimens can be the difference for life and death for these patients.

Perhaps worst of all, PBMs and their wholly-owned or affiliated specialty pharmacies have been known to employ underhanded tactics to "hijack" the prescription. In one particularly egregious instance, a PBM-affiliated specialty pharmacy contacted a community oncology practice claiming that one of the clinic's patients had requested that his lung cancer medication be transferred to the PBM-affiliated pharmacy and demanded the clinic's immediate compliance in the matter. Surprised by the news, the oncologist contacted the patient to inquire about his decision, only to discover that this was the first time the patient had heard of the matter. "Please do not transfer it anywhere else!" the patient requested. "I want to get it filled through the dispensary. I did not ask for this. I love being able to get this right away and with no hassles. I was on an oral chemo before and it was filled by a spe-

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[135] *See,* Hot Topics in Specialty Pharmacy Law: PBM Prescription Trolling, HUB Arrangements, DIR Fees Update, Opioid and Naloxone Laws, and NADAC Pricing, May 26, 2020, available at *https://www.frierlevitt.com/wp-content/uploads/2017/06/Hot-Topics-in-SPRX-Law-Final_PDF.pdf.*

[136] *See,* Pharmacist says CVS Strong-Arms Cancer-Drug Business, May 27, 2020 available at *https://www.dispatch.com/news/20180603/pharmacist-says-cvs-strong-arms-cancer-drug-business/1.*

[137] *See,* PBMs: Their Role, the Problems, and How Practices Can Work With Them, May 27, 2020, available at *https://www.ajmc.com/journals/evidence-based-oncology/2017/october-2017/pbms-their-role-the-problems-and-how-practices-can-work-with-them.*

[138] *See,* Healthcare Bullying: Some Call it Steering, We Call it Scare Tactics, May 26, 2020, available at *https://www.truthrx.org/theputtblog/healthcare-bullying-some-call-it-steering-we-call-it-scare-tactics.*

cialty pharmacy and I always was getting it late, missed a few days of medication sometimes and had numerous phone calls from them. They never seemed to know what was going on with my medication."[139] As evidenced by this true story account, patients receiving their oral drugs from a community oncology practice have access to those drugs within 24 hours of prescribing, and they can begin treatment immediately. Patients receiving their oral cancer drugs through a PBM, on the other hand, often have a much longer wait, sometimes 14 days or more. In addition to the delays, it is clear the oncology practices have access to patient records and can more closely monitor patients which empowers them to provide the most coordinated care.[140]

In the end, the PBMs' lack of transparency to the patient and the general public usurps the patient's right of choice and circumvents the prescriber's orders and independent professional judgment.

7.1.2 Harm to Plan Sponsors

The greatest harm to plan sponsors stemming from prescription trolling and claims hijacking is increased potential for waste, particularly compared to when the claim would otherwise be filled by the community oncology practice. Many times, a community oncology practice can identify certain medications that may be difficult to tolerate or patients whose conditions may require multiple dosing refinements. In these cases, in anticipation of such modifications, practices will often dispense a 15-day supply rather than a 30- or 90-day supply. PBM specialty mail order pharmacies can lack the expertise for such forethought or do not have the experience with care management to know when a smaller supply might be the wiser, more economical choice.[141]

Ultimately, mandatory diversion of patients to PBM mail order pharmacies leads to increased waste of often-expensive and unwanted medication, thereby increasing overall health care spending, at the expense of Medicare and taxpayers.[142] In a study funded by the Community Pharmacy Foundation reviewing medications being returned for disposal and destruction, it was found that prescriptions originating through mail order were far more likely to have excessive amounts of unused medication remaining (*i.e.,* 80% or more of the prescribed quantity) when compared to retail pharmacies.[143] In the cancer space, these issues of waste can be extremely costly. ln a particularly well-documented instance, a battling advanced colorectal cancer was told that his health plan would only cover his prescription for oral oncolytics if he obtained them through the PBM's mail-order pharmacy.[144] After he waited nearly 2 weeks to receive his prescription, when it finally came, it included incorrect dosing instructions, and he was told by the PBM-owned pharmacy to send back the medication (worth $20,000) so it could be destroyed.[145] Even when the medication was ordered again, it came with fewer pills than were prescribed.[146] While the PBM-owned or affiliated pharmacies continue to make errors and cause patients to endure life-threatening delays, the plan sponsors—like employers and Medicaid programs—are left footing the bill for these wasted products to the tune of tens of thousands of dollars in this one instance alone.

7.1.3 Harm to Providers

In addition to circumventing the prescriber's orders and independent professional judgment, the PBMs' tactics of prescription trolling further serves to push the bur-

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[139] *See,* The Real-Life Patient Impact of PBMs: Volume I, May 27, 2020, available at *https://communityoncology.org/research-publications/studies/the-real-life-patient-impact-of-pbms-volume-i/*.

[140] *See,* PBMs: Their Role, the Problems, and How Practices Can Work With Them, May 27, 2020, available at *https://www.ajmc.com/journals/evidence-based-oncology/2017/october-2017/pbms-their-role-the-problems-and-how-practices-can-work-with-them.*

[141] *See,* PBMs: Their Role, the Problems, and How Practices Can Work With Them, May 27, 2020, available at *https://www.ajmc.com/journals/evidence-based-oncology/2017/october-2017/pbms-their-role-the-problems-and-how-practices-can-work-with-them.*

[142] *See,* National Community Pharmacists Association, Waste Not, Want Not: Examples of Mail Order Pharmacy Waste, May 27, 2020, available at *http://www.ncpa.co/pdf/waste-not-want-not---examples-of-mail-order-pharmacy-waste.pdf.*

[143] *https://www.managedhealthcareexecutive.com/view/mail-order-pharmacy-5-things-mcos-should-consider.*

[144] *https://www.mountcarmelhealth.com/news/mail-order-pharmacy-system-delays-meds-for-some-patients.*

[145] *https://www.mountcarmelhealth.com/news/mail-order-pharmacy-system-delays-meds-for-some-patients.*

[146] *https://www.mountcarmelhealth.com/news/mail-order-pharmacy-system-delays-meds-for-some-patients.*

den of performing the initial administrative functions on to the community oncology practices, while removing any attendant benefits, as the first fill is the most expensive claim. The first fills of a prescription are typically a pharmacy's most expensive claims due to several factors, including coordination with prescriber, prior authorization efforts, researching and liaising with patient assistance programs, engaging in patient training and providing skilled nursing administration.[147] And further, at its core, through these claim rejections, the PBMs are once again depriving providers of any ongoing and expected future business relationships with patients who initially sought to fill prescriptions with their provider.[148]

Apart from just the lost revenue, at their core, these tactics create a lot more work for already burdened community oncology practices and make patient treatment much more difficult. In the course of the PBMs' efforts jockeying for control of the prescription, staff at community oncology practices spends hours on the phone with all the disconnected and disjointed stakeholders, just trying to get the prescription filled and in the patient's hands. This includes speaking with the PBM, then the insurance company, then the PBM-owned or affiliated pharmacy, then the PBM again—and this all assumes everything goes "smoothly." It is well-documented that these additional layers of unnecessary administrative complexity burden the health care system, with health care stakeholders spending about $496 billion on billing and insurance-related costs each year.[149] These additional administrative burdens have been found to have a direct negative impact on patient care.[150]

Yet PBMs remained focused on maximizing profits. As the chart below show, immense profit comes along with diverting prescriptions to PBM-owned pharmacies. Within the Florida Medicaid program, the overwhelming majority of "profits" earned from dispensing brand name drugs (including cancer medications) was retained by just three PBM-owned or affiliated pharmacies.

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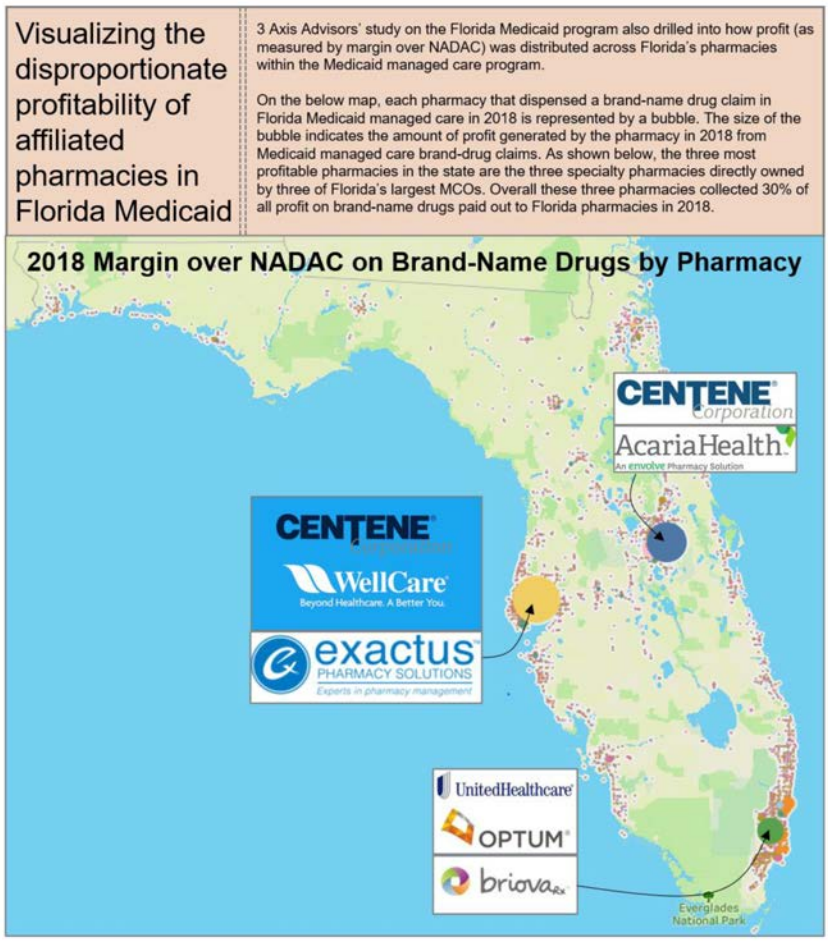
[147] *See,* Hot Topics in Specialty Pharmacy Law: PBM Prescription Trolling, HUB Arrangements, DIR Fees Update, Opioid and Naloxone Laws, and NADAC Pricing, May 26, 2020, available at *https://www.frierlevitt.com/wp-content/uploads/2017/06/Hot-Topics-in-SPRX-Law-Final_PDF.pdf.*

[148] *See,* Hot Topics in Specialty Pharmacy Law: PBM Prescription Trolling, HUB Arrangements, DIR Fees Update, Opioid and Naloxone Laws, and NADAC Pricing, May 26, 2020, available at *https://www.frierlevitt.com/wp-content/uploads/2017/06/Hot-Topics-in-SPRX-Law-Final_PDF.pdf.*

[149] *https://www.americanprogress.org/issues/healthcare/reports/2019/04/08/468302/excess-administrative-costs-burden-u-s-health-care-system/.*

[150] *https://www.acpjournals.org/doi/10.7326/m16-2697.*



The combination of restricted networks, prescription trolling, and the mandating of dispensation of specialty drugs at specific pharmacies has been a boon to the specialty pharmacy arms of the nation's largest insurers and PBMs, driving disproportionate profit to them vis-à-vis their unaffiliated pharmacy peers.

7.2 What Does the Law Say?

In addition to federal and state Any Willing Provider and Freedom of Patient Choice laws, which are certainly implicated by PBMs directing patients to their wholly-owned or affiliated pharmacies and excluding community oncology practices (see, section 6, *supra*), several other federal and state laws bear on the tactic of prescription trolling. First and foremost, this activity runs afoul of the Health Insurance Portability and Accountability Act and the regulations promulgated thereunder (HIPAA), which limit the disclosure of PHI by covered entities, including pharmacies and PBMs,[151] without patient authorization.[152] In the absence of a valid authorization, disclosures of PHI may only be made for purposes of treatment, payment, or health care operations of the covered entity.[153] As such, a PBM's access to and use of PHI to steer patients toward the PBM's wholly-owned or affiliated

[151] 45 CFR § 160.102.
[152] 45 CFR § 164.508.
[153] 45 CFR § 164.506.

pharmacy is a breach[154] of HIPAA, and compromises the privacy and security of patients' personal information. HIPAA provides, in addition to substantial civil penalties, criminal sanctions for the use of PHI in this way,[155] which demonstrates the significance of maintaining patient privacy.

In addition, these practices likely violate many states' Anti-Patient Steering Laws which prohibit PBM or insurer-owned or affiliated pharmacies from "steering" profitable prescriptions to their own affiliated PBM and insurance pharmacies. For example, Louisiana provides that a PBM shall not directly or indirectly engage in patient steering to a pharmacy in which the PBM maintains an ownership interest or control without making a written disclosure and receiving acknowledgment from the patient; and the PBM is further prohibited from retaliation or further attempts to influence the patient, or treat the patient or the patient's claim any differently if the patient chooses to use the alternate pharmacy.[156] Likewise, New Jersey makes it unlawful for a pharmacist to enter into an arrangement with a health care practitioner who is licensed to issue prescriptions, or any institution, facility, or entity that provides health care services, for the purpose of directing or diverting patients to or from a specified pharmacy or restraining in any way a patient's freedom of choice to select a pharmacy.[157] When the PBM engages in these underhanded tactics, it is not only directly steering the patient to a particular pharmacy without their knowledge or consent, but forcing the community oncology practice to go along with the scheme, by consenting to transfer the prescription.

Lastly, even beyond state laws, prescription trolling may impinge on other federal requirements, including section 2 of the Sherman Act (*i.e.,* attempted monopolization using their role and leverage as PBM gatekeeper to divert business to the PBM-owned or affiliated pharmacy), and the Employee Retirement Income Security Act of 1974 (ERISA) and its requirements that fiduciaries discharge their duties with respect to the plan solely in the interest of the participants and beneficiaries (misappropriate PHI for pecuniary gain certainly could arise to the breach of a fiduciary duty for PBMs).[158]

The overarching legal principles are potentially tempered somewhat by recent case law involving PBM appropriation of claims data. In *Trone Health Services, Inc. v. Express Scripts Holding Co.,* No. 4:18–CV–467 RLW, 2019 WL 1207866, (E.D. Mo. March 14, 2019), a retail pharmacy brought claims against Express Scripts, alleging Unfair Competition, breaches of contract, breaches of the implied covenant of good faith and fair dealing, interference with economic advantage, violation of uniform trade secrets act and fraud for the practice of "slamming," that is, collecting claims information received by the PBM at the point-of-sale from retail pharmacies submitting claims for their patients, and providing that same data to Express Scripts' wholly-owned mail order pharmacy for the purpose of soliciting the same patients to receive their prescriptions via mail order. The core of all the claims was Express Scripts' conduct of collecting and using prescription data to boost its mail-order operations. Parsing the "black letter" language of the one-sided contract of adhesion, the Judge, however, held that the conduct was not prohibited and, in fact, was expressly allowed under the terms of the agreement with the pharmacies. While the Eighth Circuit revised the standard slightly as it relates to the pharmacy provider's rights under HIPAA, the Court of Appeals ultimately upheld the lower court's decision, serving as a reminder of the unbridled power that the PBMs believe themselves to hold.[159]

7.3 What Can Be Done?

Prescription trolling and patient slamming is perhaps one of the most deceitful of the PBM tactics and requires a response at many levels to end it once and for all:

- Legislative
    - Congress should enact federal legislation which would protect patient choice of pharmacy and prohibit PBMs from requiring patients to use the

[154] 45 CFR § 164.402.
[155] 42 U.S.C. § 1320d–6.
[156] La. Stat. Ann. § 40:2870(A)(5)(a).
[157] N.J. Admin. Code § 13:39–3.10.
[158] 29 U.S.C. § 1104(a)(1).
[159] *Trone Health Services, Inc. v. Express Scripts Holding Co.,* No. 19–1774 (8th Cir. 2020).

mail order and specialty pharmacies they own, creating a conflict of interest, or exploiting private patient data for those purposes.[160]

- State lawmakers should enact anti-steering laws like Louisiana's or Georgia's, which prohibit PBMs from directly or indirectly steering patients to a pharmacy in which the PBM maintains an ownership interest or control.[161]

- Regulatory
  - The Office of Civil Rights (OCR) should pursue complaints against PBMs and PBM-owned pharmacies for misappropriation of PHI for pecuniary gain and seek fines as well as injunctive relief.
  - State Boards of Pharmacy should pursue complaints against PBMs and PBM-owned pharmacies for violations of Pharmacy Practice Acts, including anti-patient steering laws.
  - State Departments of Insurance should pursue complaints against PBMs and health insurers for violations of Any Willing Provider laws, stemming from efforts to deny patients the right to receive care at the pharmacy provider of their choice.
- Plan Sponsor Action
  - Plan sponsors should negotiate PBM contract terms to require adherence to state laws and CMS guidance.
  - Plan sponsors should demand that protections be given for physician-dispensed oncology medications.

8 Low-Ball Reimbursement

Low-ball reimbursement—when PBMs reimburse providers less than the cost of the drug—is yet another tactic taken by PBMs to effectively exclude community oncology practices, in order to retain and ensure a higher market share for the specialty drug market for their fully owned specialty pharmacies.[162] Also known as "below water" or "underwater" reimbursement, PBMs intentionally lowball the reimbursement rates offered in one-sided, take-it-or-leave-it agreements with providers. No negotiation is offered. The ultimate goal of low-ball reimbursement is to allow the PBM to have it both ways: nominally "comply" with Any Willing Provider laws by "offering" open participation in the network, but in reality, effectively excluding pharmacy providers by pushing them to reject these unsustainable reimbursement rates, thereby diverting more patients to their wholly-owned or affiliated specialty pharmacies. While guised as a cost saving measure, PBMs actually profit off the low-ball reimbursements. As complex, multifaceted health care entities, PBMs are able to recoup any losses that might be incurred at the dispensing level by charging plan sponsors more money through spread pricing (see, section 4, *supra*) or receiving rebates or other "fees" from manufacturers at the PBM level (see, section 3, *supra*).

This recently played out in the wake of the collaboration agreement between Prime Therapeutics and Express Scripts, causing low-ball, below water reimbursement for community oncology practices. On April 1, 2020, Prime Therapeutics began applying Express Scripts' lower reimbursement rates and pharmacies have been receiving abhorrently low, even negative, reimbursements. Claims specifically for lifesaving medications and limited distribution drugs are rendered below water. Notably, in June 2020, Blue Cross Blue Shield of Alabama (recognizing that these rates may not be sustainable) began increasing rates to independent pharmacies in Alabama for Blue Cross Blue Shield Alabama plans[163] (however, this plan was the exception to the rule). Many community oncology practices continue to face unsustainable, below cost reimbursement, which is only exacerbated when taking into account direct costs associated with pharmacy operations (such as salaries and benefits of

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[160] *See,* Generic Drug Pricing Transparency in Federal Health Programs, May 27, 2020 (available at *https://scpa.memberclicks.net/assets/Lauren/hr%201316%20generic%20drug%20pricing%20transparencey%20in%20federal%20health%20programs.pdf).*

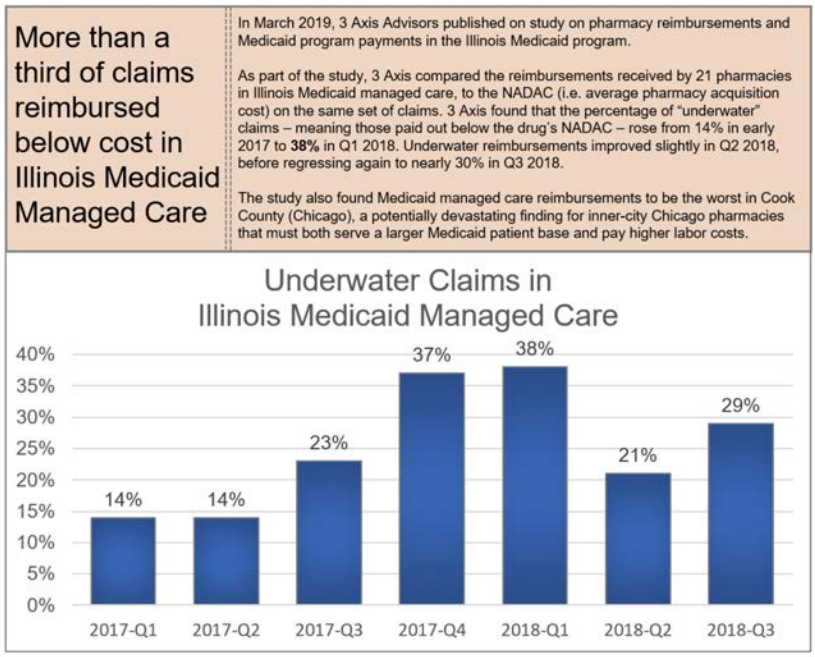
[161] La. Stat. Ann. § 40:2870(A)(5)(a); Ga. Code Ann., § 26–4–119.

[162] *See,* CVS Caremark Will No Longer Be Accepted at Walmart Pharmacies Starting in May, May 27, 2020, available at *https://www.5newsonline.com/article/news/local/outreach/back-to-school/cvs-caremark-insurance-will-no-longer-be-accepted-at-walmart-pharmacies-starting-in-may/527-ba777e55-4f39-4edc-a976-79cb990e8199.*

[163] *See,* Blue Cross increasing reimbursements for independent drug stores, June 4, 2020, available at *https://www.brc.com/2020/06/04/blue-cross-increasing-reimbursements-independent-drug-stores/.*

pharmacy staff, accreditation fees, shipping, dispensing fees, supplies and equipment, license fee, pharmacy dispensing software fees and adherence and symptom management software fee, postage, etc.), and indirect overhead (including rent, utilities and telephone charges).

With the impact that this has across the industry, a question is often asked: how are PBMs able to do this? The answer is simple: their excessive market power enables them to unilaterally dictate reimbursement rates where pharmacy providers have essentially no choice but to accept them. As noted above (see, section 3, *supra*), over 80% of the covered lives in the United States are controlled by just five PBMs.[164] In some markets, a single PBM could cover over 85% of the patients seen by a community oncology practice. As a result of this concentration, and the inability of patients to freely select their PBM (see, section 3, *supra*), being in network with each PBM network is critical.



8.1 Who Is Impacted?

Ultimately, the substantial and unreasonable reduction in reimbursements creates a provider "desert," making it impossible for them to stay in business because market share is shifted to PBMs. This turns patients into "hot potatoes" who are passed between different providers because no provider wants to fill medications at losses of hundreds of dollars, with scant guarantee of whether any of these downward prices are actually being passed on to plan sponsors.[165] As vertically integrated models enable PBMs to dominate the pharmaceutical supply chain, community oncology practices are often forced to accept reimbursement below cost because patients have no other choice but to participate in a plan that chooses to use one of

[164] *https://www.latimes.com/business/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html.*

[165] Adam Fein, Behind Diplomat Pharmacy's Plunge: A Primer on DIR Fees in Medicare Part D, Drug Channels (November 8, 2016), available at *http://www.drugchannels.net/2016/11/behind-diplomat-pharmacys-plunge-primer.html* (last visited on May 29, 2020); Eugene A. DePasquale, Bringing Transparency and Accountability to Drug Pricing (December 11, 2018), at 6, 10–16.

these PBMs to manage its pharmacy benefit.[166] Ultimately, low-ball reimbursement harms the provider of choice for the patient, which in turns harms the well-being of patients.[167]

8.1.1 Harm to Patients

As a result of low-ball reimbursements, patients are often forced to receive care only from pharmacy providers owned by or affiliated with PBMs, replete with conflicts of interest between patient care and costs of service. This has had disastrous consequences.

For one, it is well-established that provider participation in pharmacy networks will be decreased as a result of low-ball reimbursement, leaving patients with fewer choices for care.[168] This, in turn, will lead to worse overall care (see, section 6, *supra*).

Worse yet, this has the possibility of turning patients into "hot potatoes," where even contracted specialty pharmacies (including ones owned by or affiliated with PBMs) refuse to fill a patient's prescription and risk losing money. Sadly, this was the experience of many patients in the immediate wake of the Express Scripts-Prime Therapeutics collaboration. In one particular example involving a Blue Cross Blue Shield of Alabama beneficiary (whose benefits processed under Prime Therapeutics), a provider attempted to fill a prescription for one of its patients but was unable to because of the unsustainable loss the below water reimbursement would have. Consequently, the provider had to attempt to transfer the patient's prescription to at least four different specialty pharmacies (including several PBM-owned or affiliated pharmacies), in order to finally find a pharmacy that was able to fill the medication (*i.e.,* had access to the limited distribution drug), was contracted with the payer to be reimbursed for the prescription (*i.e.,* held the Blue Cross Blue Shield Alabama Oncology Specialty Network contract), and was willing to accept the reimbursement (*i.e.,* take a substantial loss on the prescription). After trying multiple pharmacies in four states, the patient was finally able to get their medication from a specialty pharmacy located several states away. The whole process took almost two weeks to fill the medication for the patient, causing the patient to run out of her life-saving medication.

These low-ball reimbursement practices have not been limited to commercial plans. As yet another example of patients being "hot potatoes" with no regard for their well-being, within the TRICARE program, which was established by statute to provide health benefits coverage to active duty and retired military service members and their dependents, community oncology practices have reported per-fill losses of $500.00 on every prescription for Imbruvica (an oral oncolytic used to treat certain lymphomas and leukemias), $525.00 on every prescription for Jafaki (a common oral oncolytic used to treat certain bone marrow disorders), and $740.00 on every prescription for Alecensa (an oral oncolytic used to treat lung cancer). Community oncology practices have reported that over eighty percent of their TRICARE claims reimburse at or below cost, while those that reimburse above cost generally have a margin of less than one percent. As a result, this has caused veterans to become "hot potatoes" passed between pharmacy providers (even by PBM-owned or affiliated pharmacies), who are unwilling to fill the medication at a loss.

8.1.2 Harm to Plan Sponsors

As noted, any so-called benefits or savings are nebulous at best. In reality, vertically-integrated PBMs are able to take a "loss" at the pharmacy level, and make up for it by overcharging the plan sponsor. The anticompetitive nature of low-ball reimbursements further allows PBMs to receive "off invoice" discounts and manufacturer payments that help offset the low and under water reimbursement rates at the pharmacy level. For example, PBM-owned or affiliated pharmacies can be willing to nominally "accept" the same reimbursement terms applicable to other pharmacy providers, but they are able to recoup those "losses" by either obtaining

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[166] *See,* Rutledge to Investigate Reimbursement Rates from CVS Caremark, February 9, 2018, available at *https://www.pharmacist.com/article/rutledge-investigate-reimbursement-rates-cvs-caremark.*

[167] *See,* National Conference of State Legislatures, Health Insurers and Access to Health Care Providers: Any Willing Providers, November 5, 2014, available at *http://www.ncsl.org/research/health/any-willing-or-authorized-providers.aspx.*

[168] *See,* Statement for the Record: The National Community Pharmacists Association, United States H. Subcomm. on Regulatory Reform, Commercial and Antitrust Law Hearing: Competition in the Pharmaceutical Supply Chain: The Proposed Merger of CVS Health and Aetna (February 27, 2018), available at *http://www.ncpa.co/pdf/judiciary-statement-on-cvs-aetna-merger.pdf.*

discounts from the manufacturer in drug purchases (which are not passed through to the plan sponsor), or simply utilizing spread pricing which is where the PBM charges the plan sponsor an amount much higher than what is paid to the provider and pocketing the profits, or the "spread," for itself (see, Section 10, *infra*). In a recent examples, patients and providers have studied Explanations of Benefits (EOBs) and identified instances where a PBM or health insurance company issued, in essence, two separate EOBs for the same claim: one to the provider and one to the patient. The EOBs transmitted to the provider showed the actual amounts being paid, while the one to the patient made it appear as though a much larger amount was being paid by the plan sponsor to the provider. In reality, PBM was simply keeping the difference. Thus, PBMs are using the plan sponsor's money to profit from driving independent pharmacy providers out of the marketplace. Ultimately, the fact that plan sponsors will not experience increased savings will lead to fewer pharmacy providers in the network, making it more difficult for plan sponsors to get fair terms in the future.[169]

8.1.3 Harm to Providers

The harm of low-ball reimbursement to community oncology practices is self-evident. Each day, more and more community pharmacy providers go out of business due to negative margins as a result of reimbursements below the acquisition and dispensing costs of the prescriptions they provide to patients.[170] Providers often times are not able to pick and choose which rates they will accept and which ones they will not. As a result, if providers challenge low-ball reimbursement at the initial contracting stage, PBMs will likely exclude the provider from the network. For community oncology practices, that means they would be unable to dispense oral chemotherapy to patients.[171] Likewise, when providers have raised concerns about unsustainable reimbursement rates after agreeing to participate, they risk being immediately and summarily terminated without cause.[172]

For practices that choose to stay and accept the low-ball reimbursement rates, they experience a reduction in the ability to provide enhanced services and coordinate patient care, as a direct result of the underwater reimbursements.[173] And when combined with the heightened credentialing standards necessary to even seek admission to these networks, providers face a veritable Catch-22 of having to choose between undertaking the high costs and extra workload of becoming accredited in order to participate in the network, only to then become unable to afford to perform the required services because of low reimbursement once admitted.[174]

8.2 What Does the Law Say?

As in the case of restrictive networks and unreasonable barriers of entry (see, section 6, *supra*), federal and state Any Willing Provider laws can offer protection against low-ball reimbursement to the extent they require PBMs to offer participation on "reasonable" and "relevant" terms and conditions. In this regard, as it relates to the federal Any Willing Provider law, CMS expressly recognized that unreasonably low reimbursement terms, which would include below water reimbursements, violate the federal Any Willing Provider law.[175] This serves as a strong rebuke to low-ball reimbursement in the Medicare Part D space.

Recognizing this as a growing problem in the private commercial insurance sector, many states have passed "Fair Price Laws." For example, the recently enacted New

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[169] *See,* The Top 15 Specialty Pharmacies of 2018: PBMs Keep Winning, May 27, 2020, available at *https://www.drugchannels.net/2019/04/the-top-15-specialty-pharmacies-of-2018.html.*

[170] *See,* Linette Lopez, *Business Insider,* What CVS is doing to mom-and-pop pharmacies in the US will make your blood boil, May 27, 2020, online Internet at *https://www.businessinsider.com/cvs-squeezing-us-mom-and-pop-pharmacies-out-of-business-2018-3. See also,* Michael Stahl, Brooklyn Daily Eagle, The price of filling a prescription: Independent pharmacies fight for survival, May 27, 2020 at 1:30pm, available at *https://brooklyneagle.com/articles/2019/05/20/the-price-of-filling-a-prescription-independent-pharmacies-fight-for-survival/.*

[171] *See,* Walmart Dispute with CVS Caremark Pharmacy Networks Highlights Low Reimbursement, May 27, 2020, available at *https://www.mpha.org/news/434664/Walmart-Dispute-with-CVS-Caremark-Pharmacy-Networks-Highlights-Low-Reimbursement.htm;* Ryan White Clinics for 340B Access, CVS Caremark to Delay Reimbursement Cuts until April 1st, May 27, 2020, available at *https://www.rwc340b.org/cvs-caremark-to-delay-reimbursement-cuts-until-april-1/.*

[172] *Wholesale Alliance, LLC v. Express Scripts, Inc.,* 366 F.Supp.3d 1069 (2019).

[173] *See,* Jason Hoffman, PharmD, RPh, In-House Specialty Pharmacies Improve Quality of Care, available at *https://www.cancertherapyadvisor.com/home/cancer-topics/supportive-care/in-house-specialty-pharmacies-improve-quality-of-care/* (last visited May 30, 2020).

[174] *See, https://www.pharmacytimes.com/publications/Directions-in-Pharmacy/2019/September2019/lessons-learned-starting-a-healthsystem-oncologyfocused-specialty-pharmacy.*

[175] *See,* Medicare Prescription Drug Benefit Manual, chapter 6, section 50.3; 42 CFR § 423.505(b)(18).

Jersey law, codified at N.J.S.A. 17b:27f–1 to –10, provide PBM pricing transparency and strengthen the rights of pharmacies to contest below-cost reimbursement. Likewise, Arkansas law prohibits PBMs from setting the price for certain generic medications below available pharmacy acquisition costs.[176]

Several unfair trade and unfair competition laws may also be implicated by a PBM's conduct of setting below water reimbursement to increase market share for its wholly-owned or affiliated specialty pharmacy. For example, under California's Unfair Competition Law (UCL), section 1702 of the California Business and Professions Code, known as the "Unfair Competition Law" or "UCL," "any person who engages, has engaged, or proposes to engage in unfair competition may be enjoined in any court of competent jurisdiction."

Finally, to the extent such PBM's low-ball reimbursement is deemed to be seeking monopolization, Section II of the Sherman Antitrust Act may be implicated as well.[177] The Sherman Act provides that it is unlawful to "monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several states, or with foreign nations."[178] And further, in the context of state-level UCL claims, conduct may also be deemed to be "unfair" under the UCL if it is "conduct that threatens an incipient violation of an antitrust law, or violates the policy or spirit of one of those laws because its effects are comparable to or the same as a violation of the law, or otherwise significantly threatens or harms competition."[179]

8.3 What Can Be Done?

Low-ball reimbursement has the potential to fundamentally and irreparably impact our health care system for years to come, and requires action at many levels:

- Legislative
  - Congress should enact federal legislation extending Medicare's Any Willing Provider requirements to the TRICARE program, requiring that terms and conditions be reasonable and relevant, and allow for private enforcement of these requirements.
  - States should enact Any Willing Provider Laws (where none currently exist) or amend existing Any Willing Provider laws to require that health insurance companies and PBMs allow all pharmacy providers (including community oncology practices) the right to participate in pharmacy networks based on "reasonable and relevant" terms and conditions, applicable to other similarly situated participating providers.
  - States should enact laws, like New Jersey's Fair Price law,[180] requiring PBM pricing transparency and prohibiting below-cost reimbursement to pharmacies.
- Regulatory
  - CMS should pursue complaints against Part D plan sponsors and contracted PBMs for unreasonably low reimbursement in violation of the federal Any Willing Provider Law and the Medicare Part D Drug Benefit Manual, seeking fines, Warning Letters, and injunctive relief.
  - CMS should issue regulation providing "guard rails" on what constitutes reasonable and relevant terms and conditions, and clarify that whether given terms are "reasonable" or "relevant" can be adjudicated in a private contractual dispute between Part D plan sponsors/PBMs and pharmacies.
  - State Departments of Insurance should pursue complaints against PBMs and health insurers for violations of Any Willing Provider laws, stemming from efforts to constructively deny providers the right to participate in pharmacy networks based on unreasonably low, below cost reimbursement rates.

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[176] Ark. Code Ann. § 17–92–507(c)(4)(C)(iii).
[177] 15 U.S.C. § 2.
[178] In re Adderall XR Antitrust Litig., 754 F.3d 128, 133 (2nd Cir. 2014) (quoting 15 U.S.C. § 2) (alteration in original).
[179] *Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co.,* 20 Cal.4th 163, 188 (Cal. 1999). *See also, Blank v. Kirwan,* 39 Cal.3d 311, 320 (Cal. 1985) (noting that California law looks to the Sherman Act for guidance); *Otter Tail Power Co. v. United States,* 410 U.S. 366, 377 (1973) (stating that the Sherman Act prohibits companies from leveraging monopoly power to "foreclose competition or gain a competitive advantage, or to destroy a competitor.")
[180] N.J.S.A. § 17b:27f–1 to –10.

9 Mandatory White Bagging for Cancer Medications

A growing—and extremely concerning—trend that has emerged is the concept of mandatory "white bagging" of oncology medications that are administered in-office by community oncology practices.

"White bagging" occurs where a physician writes and orders a particular medication for an in-office procedure, and rather than being sourced from the physician's medication inventory, a separate specialty pharmacy fills a prescription, and delivers the drug directly to the prescriber or clinic who retains the medication until the patient arrives at their office for administration.

Likewise, "brown bagging," which is less common, involves a similar concept, except that instead of causing the prescription to be delivered directly to the community oncology practice, the specialty pharmacy dispenses the medication to the patient him or herself, who then brings the medications into their physicians' offices for administration in those settings.

In seeming unison, several health insurance companies (who coincidentally have integrated PBMs and specialty pharmacies) have begun to mandate that certain intravenous (IV) medications that were previously purchased by practices and administered in-office to patients, are now requiring that they be filled by the PBM-owned or affiliated specialty pharmacy through white or brown bagging. These are medications that historically have been administered in-office by community oncology practices and billed to patients' medical benefit (as opposed to their pharmacy benefit). Because these are IV medications, they cannot be self-administered by the patient, and still need to be infused by a health care provider. In essence, these payers (which include Anthem Blue Cross of California, Blue Cross Blue Shield of Tennessee, and Cigna) have mandated that cancer patients receive their chemotherapy through white or brown bagging, to be supplied by the payers' affiliated specialty pharmacy.

Each of these scenarios present immense concerns for patients, plan sponsors and providers alike. Community oncology practices note that white or brown bagging disrupts the chain of control of expensive cancer drugs; risking improper storage and handling of toxic substances; can unnecessarily cause delays in the onset of treatment; create waste when dosages are changed to, for example, manage adverse events; and places an administrative and liability burden on both patients with cancer and their oncologists.[181]

9.1 Who Is Impacted?

9.1.1 Harm to Patients

Patients stand to suffer the greatest as a result of payer and PBM mandatory white or brown bagging policies. Unlike instances where the community oncology practice sources the medication from its own inventory, the physician has no control over the sourcing, storage, preparation, or handling of the specialty oncology medications in white or brown bagging situations, and as a result, patients are exposed to potentially serious harm. The community oncology practice cannot guarantee the integrity and legitimacy of the products being provided by the PBM-owned or affiliated pharmacy, especially as it relates to the shipment and delivery from the specialty pharmacy to the practice. "The difficulties that white bagging policies place on cancer patients are a prime example of the potential harm."[182]

When medications do not follow the typical chain of custody, the integrity and safety of the medication cannot be guaranteed. When a community oncology practice sources a medication from its wholesaler to be infused in a patient, the community oncology provider is given a Transaction Report or "T3" that details every single transaction involving that medication, going all the way up to the manufacturer that made it. This ensures proper pedigree at each stage along the way. When the practice receives the drug as a white bag from a PBM-owned specialty pharmacy, it is not provided with that information. Worse yet, it has no control or insight into how the specialty pharmacy is handling that product, or how it ensured stability and integrity during the delivery process. This provides risks for patients receiving medications of unknown integrity, where chain of custody cannot be guaranteed.

Patients also stand to be impacted by excessive delays and unnecessary burdens from white bagging when forced to receive their cancer and related treatments from

[181] *https://communityoncology.org/coa-white-brown-bagging-position-statement/.*

[182] *https://www.aha.org/white-papers/2021-03-08-health-insurer-specialty-pharmacy-policies-threaten-patient-quality-care.*

PBM-owned or affiliated pharmacies (as compared to when the community oncology practice sources products from its own inventory for in-office administration). Delays in receiving the medication past an anticipated date are commonly caused by a variety of factors, including failed delivery, incorrect medications being delivered, medications shipped to the wrong address, prior authorization issues, out of stock medications, etc. When medications are sourced from the community oncology practice, issues such as drug shortages can be identified right away, and adjustments made. Requiring that the prescription be sent to and filled by a PBM-owned or affiliated specialty pharmacy can cause confusion and the potential for missed treatment doses.

Finally, patients may be subject to higher out-of-pocket liability when prescriptions are "white bagged" for in-office administration. In addition to having to pay the copayment or coinsurance for the administration procedure, patients will also be responsible for a separate copayment from the pharmacy associated with the dispensed drug product. Required use of the PBM-owned or affiliated specialty pharmacy means that "reimbursement comes not from a patient's medical benefit but from the pharmacy benefit, and that can mean higher out-of-pocket costs for patients,"[183] as pharmacy benefit copays are typically higher than copays under the medical benefit. Moreover, because PBM-owned or affiliated pharmacies will require patients to have paid for drugs before they are shipped, this can interrupt critical treatment if patients cannot afford to pay for the therapies (a problem that is only exacerbated if the PBM-owned or affiliated pharmacy does not assist the patient in qualifying for payment assistance programs to help meet their cost-sharing obligations, which few do).[184]

Alternatively, even when everything goes "smoothly," waste can result if extenuating life circumstances cause a treatment plan to be adjusted or an appointment to be rescheduled and the pre-provided "white bagged" medication will not still be good by the time the appointment is rescheduled. This would not occur if the community oncology practice were able to simply source the medication from its own inventory at the time of the patient's visit.

9.1.2 Harm to Plan Sponsors

The greatest harm to health care payers stemming from mandatory white bagging is in the form of excess drug waste. When a physician utilizes drugs the community oncology practice has on hand in its inventory, the physician is able to quickly and efficiently address patient care real time and avoid waste. Oncology regimens are complex and often require dosing adjustments at the time of administration or therapy cancellation depending on the patient's laboratory results, scans, and other clinical considerations, such as shifts in the patient's weight.[185] When utilizing medications from the onsite inventory, physicians are able to make these changes at the time of administration without any delays or risk of waste (they can simply select a different medication or dose off the shelf). However, the same cannot be said if the medications are supplied by PBM-owned or affiliated specialty pharmacies.

Under white bagging mandates, the physician is required to write a "prescription" and send it to the PBM's wholly-owned or affiliated specialty pharmacy to be filled. Circumstances requiring dosing adjustments or therapy cancellation could occur in the time between when an "order" is written by the physician, and when the medication is received from a specialty pharmacy. Moreover, once the prescription has a patient-specific label, it cannot be returned to stock, unlike products kept within the practice's inventory for in-office administration. As a result, the entire medication would essentially go to waste, costing the plan sponsor and patient potentially thousands of dollars.

Moreover, plan sponsors face a great risk of being double billed when PBM-owned or affiliated pharmacies bill separately for the drug product, while community oncology practices bill for the procedures and supplies associated with in-office administration. When a community oncology practice submits a claim to an insurer for in-office administration of a drug to its patient, it typically submits a CPT Code for the professional services associated with the administration (*e.g.,* CPT 96413), as well as a J-Code for the medication (*e.g.,* J9271 in the case of Keytruda). CPT Code

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[183] *https://www.ajmc.com/view/white-brown-bagging-of-therapies-creates-extra-steps-for-oncology-practices.*

[184] *https://www.ajmc.com/view/white-brown-bagging-of-therapies-creates-extra-steps-for-oncology-practices.*

[185] Schwartz RN et al. NCCN Task Force Report: Specialty Pharmacy. *J NCCN Network.* 2010;8(Supp 4):S1–S12.

96413 corresponds with "Chemotherapy administration, intravenous infusion technique, up to one hour, single or initial substance." Thus, when submitting claims in this manner, the physician receives his or her fee for the professional services associated with mixing the drug and administering it to the patient but is also reimbursed for the costs of the medication, the diluents, the supplies, the tubing, as well as the associated overhead.

At the same time, when the PBM-owned or affiliated specialty pharmacy uses an NDC number to bill the patient's PBM, the pharmacy may also be billing (and receiving reimbursement) for overlapping products/services (which it is not actually providing or performing). Many PBM contracts prohibit pharmacies from dispensing medications in their unfinished form, and prohibit billing medications that require reconstitution (*e.g.,* injectable medications) as compounds (suggesting that reimbursement for the diluent and other supplies necessary for administration are included within the total payment).

In addition, many PBMs pay a "dispensing fee" on all claims in addition to the reimbursement for the drug, which is intended to cover costs that are incurred at the point of sale in excess of the ingredient cost of the drug, including the "measurement or mixing of the drug," "filling the container," physically providing the completed prescription to the patient, "delivery," "special packaging," "salaries of [workers]," "costs associated with maintaining the [ ] facility and acquiring and maintaining technology and equipment necessary to operate the [ ] facility."[186] While the wholly-owned or affiliated specialty pharmacy that is white bagging will be selecting the product, processing the claim, and causing delivery to the practice, many of these items for which the wholly-owned or affiliated specialty pharmacy will be receiving reimbursement are actually tasks that will ultimately be completed by the community oncology practice. The community oncology practice will continue to be responsible for mixing the drug, procuring the diluent and other necessary supplies, and physically administering the medication to the patient. Thus, this has the risk of the wholly-owned or affiliated specialty pharmacy being paid by the patient's PBM for the same services that are also being reimbursed by the plan sponsor to the community oncology practice (and which in fact are being performed and provided by the practice).

9.1.3 Harm to Providers

Finally, the greatest harm to community oncology practices stemming from mandated white bagging are increased, unfunded administrative burdens, along with increased legal liability which the providers have no choice but to accept. Community oncology practices are faced with increased administrative burdens as they are expected to undertake all work associated with preparing, diluting, and administering the drug, without being able to seek reimbursement for the medication itself.[187] When medications are white bagged, they typically come in the original manufacturer vials. Apart from the added burdens of storing the products and maintaining them in a separate inventory (since they are patient-specific), in order to be administered to the patient, the products must also be mixed by the practice's staff and placed into a bag to be infused intravenously. In many instances, IV chemotherapy products are combined with other drug products, as physicians often order a "cocktail" of different drugs and therapies that must be taken in concert. Community oncology practices have to perform these services, despite the fact that they are not being reimbursed for the drug itself. This burden is only exacerbated when the physician makes changes or amendments to the treatment, often after the prescription has been written, but closer in time to when the patient is receiving care. Because the prescription has already been filled and provided by the specialty pharmacy, the practice's staff must engage in extra work to remedy the problem.

In addition, and more concerningly, community oncology practices face additional liability for their part in prescribing and administering drugs received from outside pharmacies. In October 2012, 64 people died and over 700 people became sick as a result of contaminated compounded steroid injections supplied by New England Compounding Center (NECC). The medications had been ordered by physicians for in-office administration to their patients in clinics and surgery centers. However, due to unsanitary conditions at the pharmacy, several batches of the medications had become tainted with fungus, causing many patients to develop fungal meningitis and become seriously ill or die. In the wake of this, dozens of lawsuits (includ-

[186] 42 CFR § 100.

[187] *See,* Drug Table at Transmittal 10, Chapter 17 of the attached Medicare Claims Processing Manual—Payment Rules for Drugs and Biologicals; *Commun Oncol* 2005; 2:173–181.

ing multiple class actions) were filed against not only the pharmacy, but also the clinics, surgery centers and underlying physicians. Under current white bagging mandates, community oncology practices are forced to accept this additional risk and exposure, as "the primary onus for patient safety remains with providers despite [PBMs and] health plans stripping those providers of their control over the quality and handling of drug therapies."[188] With white bagging, practices no longer control the acquisition of these medications, and as drug therapies become more complex, thereby requiring additional resources and focus in storing, mixing, compounding and administering the products, they are bearing an inappropriate share of the risks.[189]

9.2 What Does the Law Say?

In April 2018, the National Association of Boards of Pharmacy issued a report entitled "White and Brown Bagging: Emerging Practices, Emerging Regulation."[190] The report concluded that while "the terms and conditions of this business model are most often set by third-party payers," issues regarding authenticity and integrity of the drug and adverse patient outcomes are left to the state boards of pharmacy to grapple with in an effort to protect the public. As such, some state boards (*e.g.,* Massachusetts)[191] have specifically prohibited these practices, under various provisions such as "re-dispensing of medication" or handling hazardous drugs.

On the state level, several state legislatures have either prohibited or allowed white and brown bagging practices. For example, Texas, Minnesota, and New York (Medicaid) have prohibited one or both of these practices. Other states like California, have laws that require health plans to demonstrate that their medical decisions are "unhindered by fiscal and administrative management."

At the same time, many states' laws may bear directly on arrangements mandating that community oncology practices write prescriptions and send them to PBM-designated specialty pharmacies. For example, many states have "Anti-Patient Steering" laws, which generally prohibit health care providers from agreeing to prescriptions to a particular pharmacy. As an example, New Jersey law provides that "[i]t shall be unlawful for a pharmacist to enter into an arrangement with a health care practitioner, or any institution, facility or entity that provides health care services, for the purposes of directing or diverting patients to or from a specified pharmacy or restraining in any way a patient's freedom of choice to select a pharmacy."[192] As another example, Georgia law likewise specifically prohibits pharmacies from presenting (and prohibits pharmacy benefits managers from paying) claims for reimbursement that were received pursuant to a referral from an affiliated PBM.[193]

9.3 What Can Be Done?

Mandatory white bagging harms both patients and plans sponsors, while increasing liability to community oncology practices, and requires a response at many levels:

- Legislative
  - States should enact laws prohibiting payer-mandated white bagging for community oncology practices and allow patients to receive their in-office oncology medications from their treating oncologist.
- Regulatory
  - State Boards of Pharmacy should adopt regulations requiring pharmacies that fill prescriptions for white bagging obtain written consent from the physician's office prior to dispensing the medication, and have policies and procedures in place that (i) track and assure security and accuracy of delivery for dispensed prescriptions until they are administered to the patient; (ii) provide for counseling to patients who are administered white bagged

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[188] *https://www.aha.org/white-papers/2021-03-08-health-insurer-specialty-pharmacy-policies-threaten-patient-quality-care.*

[189] *https://www.aha.org/white-papers/2021-03-08-health-insurer-specialty-pharmacy-policies-threaten-patient-quality-care.*

[190] National Association of Boards of Pharmacy. White and Brown Bagging Emerging Practices, Emerging Regulation. April 2018.

[191] 247 CMR 9.01(4)(5)(6). "Unless otherwise permitted by law, a licensee shall not re-dispense any medication which has been previously dispensed." "Unless otherwise permitted by law or regulation, a licensee may not accept, store, dispense, package, label or compound any medication that was previously processed or dispensed by another pharmacy."

[192] N.J.A.C. § 13:39–3.10.

[193] Ga. Code Ann. § 26–4–119.

products; (iii) address the return of any prescription medications not delivered or administered to the patient; (iv) assure the confidentiality of patient information; (v) obtain consent from the patient for using such a delivery process through white bagging; and (vi) provide lowest number of vials wherever possible, so as to avoid excess closed-system-transfer requirements and potential USP <800> exposures.

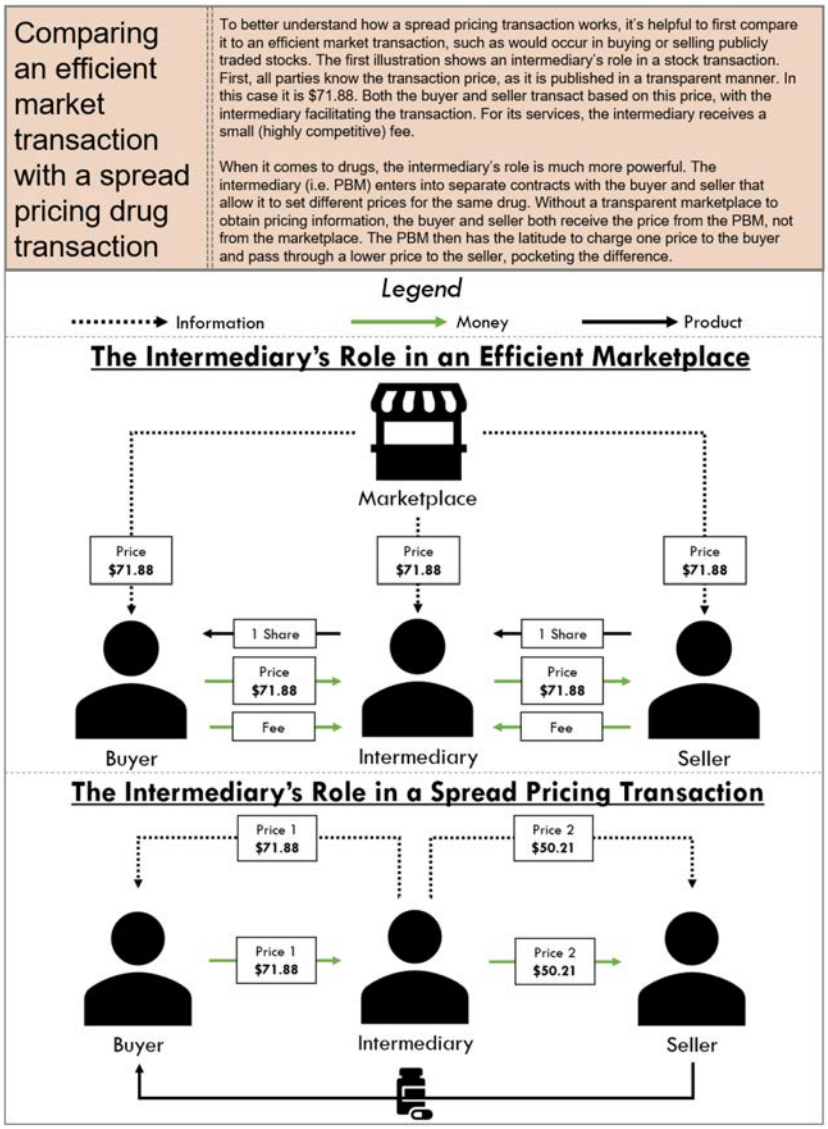
- Practical Considerations
  - Pharmacies providing white bagged medication should be required to assume all liability associated with the applicable medications/prescriptions and defend/indemnify health care providers who accept white bagged medications.
- Plan Sponsor Action
  - Plan sponsors should demand that health plans allow patients to continue to receive administered IV chemotherapy medication provided by their community oncology practice of choice.

10 Spread Pricing and Middleman Profits

Spread pricing occurs when PBMs charge plan sponsors one price for the cost of a patient's drug, while on the other side of the transaction, reimbursing the dispensing community oncology practice or pharmacy at a lower rate, while pocketing the difference, or the "spread," for themselves.[194] It is the classic case of the middleman mark up, but played out in a massive and extraordinarily opaque scale. This practice has recently come to light in the Medicaid context, where PBMs manage benefits for state Medicaid MCOs, and where state governments have uncovered immense spreads in drug claims for Medicaid beneficiaries.[195] Ultimately, spread pricing practices reveal how PBMs are vertically integrated enterprises that control vast swathes of the drug supply chain create an anti-competitive marketplace, ultimately driving up the cost of drugs to public health programs and, ultimately, to patients themselves.

[194] *See, e.g.,* In re Express Scripts, Inc., PBM Litigation, 2008 WL 2952787 *5 (E.D. Mo. July 30, 2008).

[195] *See,* 3Axis Advisors, Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis, January 30, 2020, accessible online: *https://www.3axisadvisors.com/projects/2020/1/29/sunshine-in-the-black-box-of-pharmacy-benefits-management.*



10.1 Who Is Impacted?

10.1.1 Harm to Patients

Spread pricing harms patients by increasing premiums and drug prices.[196] As with many other PBM pricing strategies, spread pricing has the perverse tendency to drive drug prices up as the higher the overall drug cost is, the greater opportunity for the PBM to earn a larger spread. In addition, because pricing strategies put in place by PBMs that are not equitable or uniform across different drugs, and perverse financial incentives can be created, putting patients at risk of having phar-

[196] *See generally,* Neeraj Sood, et al., "The Association Between Drug Rebates and List Prices," 2020, accessible online: *https://healthpolicy.usc.edu/wp-content/uploads/2020/02/Schaeffer Center_RebatesListPrices_WhitePaper.pdf.*

macy providers prioritize certain patients with certain disease states over others based on the arbitrary profitability that a PBM applies to the therapy.[197] Finally, in the context of generic drugs, where patients expect to realize the greatest pricing relief, spread pricing artificially increases the cost of such drugs, thus negating such price relief.[198]

10.1.2 Harm to Plan Sponsors

Plan sponsors, and in particular, state Medicaid programs, have been immensely harmed in the inflated prices they—and ultimately the taxpayers—have paid to PBMs because of spread pricing. Ohio was one of the first states to audit PBMs after a *Columbus Dispatch* exposé revealed the extent of spread pricing in the state's Medicaid program.[199] Shortly after the news broke, the Ohio Department of Medicaid released a summary of its spread pricing analysis which showed PBMs grabbing $223.7 million in hidden pricing spreads within the Medicaid managed care program from Q2 2017 to Q1 2018, accounting for 8.8% of overall (pre-rebate) spending on prescription drugs.[200]

The Ohio revelations have led to other states and the federal government investigating spread pricing practices within their states, as well as independent efforts. State government work in Kentucky, Georgia, Virginia, and Maryland has definitively quantified spread in their states' Medicaid programs, while 3Axis Advisors—an independent pharmaceutical policy think tank—has uncovered evidence of spread pricing in New York, Illinois, Michigan and, notably, a 200-page report on spread pricing in the Florida Medicaid program.[201]

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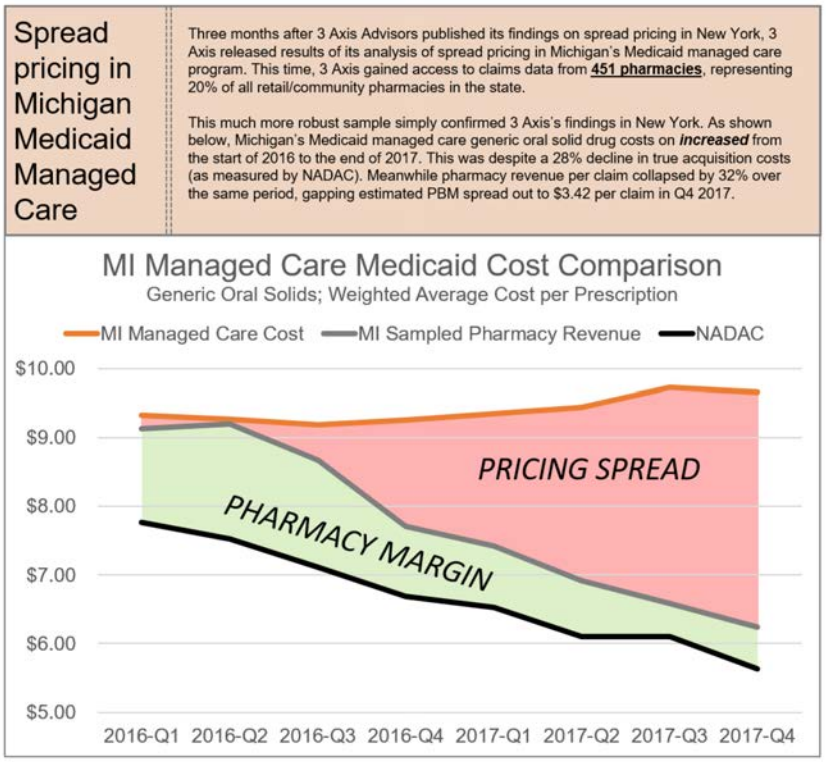
[197] 3Axis Advisors, Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis, 1, 3–4, January 30, 2020 *https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/5e384f26fc490b221da7ced1/1580748598035/FL+Master+Final+Download.pdf. See also,* Community Oncology Alliance, Letter to Defense Health Agency, "The Perverse Financial Impact of Pharmacy Benefit Managers on Our Military Service Members Covered by the TRICARE Program," 2019 (noting how spread pricing incentivizes use of high cost drugs even when less expensive and more efficacious drugs are available).

[198] *See,* 46 Brooklyn, New Pricing Analysis Reveals Where PBMs and Pharmacies Make Their Money, April 21, 2019, *https://www.46brooklyn.com/research/2019/4/21/new-pricing-data-reveals-where-pbms-and-pharmacies-make-their-money* (observing that despite lower payouts to pharmacies and a deflating generic market, Ohio's generic drug unit costs increased 1.8% in SFY 2017 and, of the total state spending on generic drugs, 31.4% went to PBMs via spread pricing).

[199] *See,* Lucas Sullivan and Catherine Candisky, 'Cost-cutting' middlemen reap millions via drug pricing, data show, *The Columbus Dispatch, https://stories.usatodaynetwork.com/sideeffects/cost-cutting-middlemen-reap-millions-via-drug-pricing-data-show/site/dispatch.com/*.

[200] *See,* Catherine Candisky, State report: Pharmacy middlemen reap millions from tax-funded Medicaid, *The Columbus Dispatch, https://stories.usatodaynetwork.com/sideeffects/state-report-pharmacy-middlemen-reap-millions-from-tax-funded-medicaid/*.

[201] *See,* 3Axis Advisors, Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis, January 30, 2020 *https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/5e384f26fc490b221da7ced1/1580748598035/FL+Master+Final+Download.pdf.*



10.1.3 Harm to Providers

Finally, spread pricing has a direct impact on providers, who rely on adequate reimbursement to serve Medicaid patients. In Ohio, the same state to expose $223.7 million in excess charges through spread pricing, many independent pharmacies were reporting such severe loses on Medicaid prescriptions that it made it virtually impossible to continue to participate in the program.[202] The exposure of these abuses led Ohio Medicaid to require certain PBMs, including CVS Caremark, to increase the amount of reimbursements being paid to independent providers (who up until that point, were pocketing the immense spreads).[203]

10.2 What Does the Law Say?

Given the perverse impact of spread pricing upon patients, payers, and providers, CMS' Medicaid and Children's Health Insurance Program (CHIP) managed care's final rule[204] adopted standards for the calculation of Medical Loss Ratios (MLRs).[205] More specifically, the final rule clarified that spread pricing must be re-

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[202] *See, https://www.dispatch.com/news/20180312/cvs-accused-of-using-medicaid-rolls-in-ohio-to-push-out-competition; https://www.ohiopharmacists.org/aws/OPA/pt/sd/news_article/152198/_PARENT/layout_interior_details/false; https://www.dispatch.com/news/20191210/1600-pharmacies-call-on-ohio-to-fix-medicaid-reimbursements.*

[203] Lucas Sullivan and Catherine Candisky, "Medicaid orders drug price changes after more abuse reported," *The Columbus Dispatch, https://www.the-review.com/news/20181031/medicaid-orders-drug-price-changes-after-more-abuse-reported.*

[204] Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability; Final Rule, 81 Fed. Reg. 27498 (May 6, 2016); available at: *https://www.federalregister.gov/documents/2016/05/06/2016-09581/medicaid-and-childrens-healthinsurance-program-chip-programs-medicaid-managed-care-chip-delivered.*

[205] *See,* Medical Loss Ratio (MLR) Requirements Related to Third-Party Vendors, CMCS Informational Bulletin; available at: *https://www.medicaid.gov/federal-policy-guidance/downloads/cib051519.pdf.*

ported and included in the calculation of MLRs, which represents the percent of premium revenue that goes toward actual claims and activities that improve health care quality, as opposed to administrative costs and profits. CMS regulations require Medicaid and CHIP managed care plans to report a MLR and use and MLR target of 85 percent in developing rates.

A number of states have implemented measures to prevent PBMs from utilizing spread pricing schemes when contracting with state Medicaid managed care plans. For example, Ohio Medicaid directed its five managed care plans to terminate contracts with PBMs with spread pricing model and enter into new contracts with PBMs with transparent "pass-through" model in 2018.[206] In similar vein, Nevada has enacted transparency bill specifying that a PBM has a fiduciary duty to a third party that contracts with the PBM for pharmacy benefit management services and must notify the third party in writing of any activity, policy, or practice of the PBM that creates a conflict of interest that interferes with the PBM's ability to discharge its fiduciary duty.[207] New York is also planning to no longer use PBMs and instead, to use fee for service to pay for its prescription drugs.[208]

10.3 What Can Be Done?

The practice of spread pricing by PBMs has recently become an area of focus for plan sponsors seeking to reign in PBM abuses and reduce costs. Potential solutions to spread pricing include:

- Legislation
  - Congress should enact federal legislation that would require pass-through pricing for covered outpatient drug prescriptions in Medicare Part D and in Medicaid (including managed care).
  - States should enact laws like the Nevada law requiring PBMs to be fiduciaries to plan sponsors (*i.e.,* PBMs must act in the plan sponsors' interests) and providing plan sponsors with a cause of action against PBMs if they utilize opaque pricing not in the plan sponsors' best interest or favor the PBMs' wholly-owned or affiliated pharmacies over independent pharmacies or community oncology practices, if this would ultimately be detrimental to the plan sponsors.
  - States should enact laws requiring PBMs to report drug costs charged to and paid by plan sponsors and disclosure of such reports to providers.
- Regulatory
  - Like in Ohio, state regulators should take immediate action, where such action is permitted under enabling statutes, to prevent state Medicaid plans from contracting with PBMs using spread pricing methodology.
  - The FTC should enhance oversight and revise antitrust guidance defining impermissible vertical integration structures which could, at the very least, curb the most blatant PBM anti-competitive behavior.
- Plan Sponsor Action
  - Plan sponsors should implement robust Request for Proposal procedure to select transparent PBMs.
  - Plan sponsors should review and negotiate transparent contract terms including, without limitation, an exclusive pricing benchmark.
  - Plan sponsors should require PBMs to provide reporting of reimbursements paid to the pharmacies on pharmacy claims and the corresponding charges made to the plan sponsor.

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[206] *See,* Guidance for Managed Care Plans, August 14, 2018, Ohio Department of Medicaid; available at: *https://issuu.com/thecolumbusdispatch/docs/mco_pass_through_ltr_8.14.18.*

[207] Senate Bill No. 539; available at: *https://www.leg.state.nv.us/Session/79th2017/Bills/SB/SB539_EN.pdf.*

[208] *See, https://health.ny.gov/health_care/medicaid/redesign/mrt2/pharmacy_carve_out/; https://health.ny.gov/health_care/medicaid/redesign/mrt2/pharmacy_carve_out/docs/carve_out_ffs.pdf.*

11 Copay Accumulators and Maximizers

The increased prevalence of high deductible health plans or plans involving patient coinsurance[209] has left more and more Americans finding themselves with significant annual out-of-pocket copayments, coinsurance obligations or deductibles for their medications. Many patients struggle to meet their deductible and pay the copays for the high-cost drugs they need to treat serious, sometimes life-threatening, illnesses like cancer. In a study published in the *Journal of Clinical Oncology,* the researchers found that drug abandonment and adherence problems are increasingly prevalent in patients prescribed an oral cancer medication due to higher out-of-pocket costs.[210] To help offset these costs—especially in the oncology space, where copayments can range in the thousands of dollars—many drug manufacturers have created copay discount cards to reduce the net out-of-pocket amount to a figure that is affordable to many patients.

However, beginning in 2018, several large insurance companies and PBMs began to implement a nefarious new set of schemes called "copay accumulator programs." Copay accumulator programs restrict manufacturer contributions to copay discount cards from being applied to patients' annual deductibles and out-of-pocket maximums.[211] Normally, the contributions from the drug manufacturer's copay card would not only help offset the patient's copay at the point-of-sale but would count toward fulfilling the patient's out-of-pocket obligations (*i.e.,* the deductible). Thus, after several fills of a high-cost specialty medication, the deductible would be exhausted, and the patient's out-of-pocket would be lowered to an affordable amount. This is important, because many drug manufacturers' copay coupon programs have annual limits or caps, preventing patients from receiving unlimited copayment assistance. Without copay accumulator programs, patients are able to afford their prescriptions throughout the whole year.

Conversely, when a copay accumulator program is implemented, the amounts of the patient's copay that have been funded by a drug company (through a copay coupon program) no longer count towards the patient's out-of-pocket limits. The result is that, after the patient exhausts the benefits from the manufacturer's copay coupon program, the patient is still left with excessively high copayment obligations.

The financial impact of copay accumulator programs is demonstrated well in an example. Consider an example where a patient is prescribed a drug that costs $36,000 per year, or $3,000 per month. The patient obtains a copay coupon card from the drug's manufacturer, with an assistance limit of $12,000 per year. The patient's benefit plan has a $3,000 deductible and, after the deductible has been met, a monthly copay of $500.[212] Without the copay accumulator program, the drug manufacturer would cover the $3,000 deductible in month one (January), and $500 per month each month thereafter. The patient would never run out of benefits under the copay coupon program, and would never be saddled with excessive out-of-pocket costs, significantly reducing the risk of therapy abandonment.

With the copay accumulator program in place, however, the patient would use the copay coupon to cover the monthly drug costs in months one through four (*i.e.,* January through April), and would have no out-of-pocket expenses during those first 4 months of the year. However, because the copay accumulator program would prevent the amounts received through the coupon from applying toward cost-sharing requirements, the patient would still be required to pay the full deductible amount ($3,000) in month five (May), and monthly copays of $500 per month thereafter. In essence, the maximum benefits under the copay coupon program would have been exhausted at the end of April (having funded $3,000 per month).[213] Here, when the patient is now saddled with a $3,000 bill to continue therapy he or she has been on for four months, there is tremendous risk of therapy abandonment.

These programs have been called a variety of things by different entities, including "Out-of-Pocket Protection Programs" (Express Scripts), "True Accumulation" (CVS

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[209] *https://www.shrm.org/resourcesandtools/hr-topics/benefits/pages/high-deductible-plans-more-common-but-so-are-choices.aspx.*

[210] Association of Patient Out-of-Pocket Costs With Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents, Jalpa A. Doshi, Pengxiang Li, Hairong Huo, Amy R. Pettit, and Katrina A. Armstrong, *Journal of Clinical Oncology* 2018 36:5, 476–482.

[211] *https://spondylitis.org/spondylitis-plus/copay-accumulator-programs-what-they-are-and-how-they-might-impact-your-out-of-pocket-costs/.*

[212] *https://www.managedhealthcareexecutive.com/view/coupon-accumulators-and-coupon-maximizers-explained.*

[213] *https://www.managedhealthcareexecutive.com/view/coupon-accumulators-and-coupon-maximizers-explained.*

Caremark), and "Coupon Adjustment: Benefit Plan Protection Program" (UnitedHealthcare).[214] However, the main thrust has been to place financial roadblock in the way of patients receiving necessary care, with dubious savings being realized by plan sponsors.

Another related concept that has emerged in response to the negative patient impact from accumulators is that of "copay maximizer programs." Like copay accumulator programs, copay maximizer programs are designed to allow payers to "extract the full value of the manufacturer's copay support,"[215] but in reality, swap the "financial cliff" that the patients face under accumulator programs, in favor of a slow and steady drain of resources, without any marked benefits to the patient.

For example, assume again a situation where a patient is prescribed a drug that costs $36,000 per year, and there is a manufacturer-sponsored copay coupon with an assistance limit of $12,000 per year (or $1,000 per month). In the context of a copay maximizer, the patient will still have a deductible of $3,000, but instead of a standard copay, the plan will set the monthly copay to slightly more than the coupon's value, to, say, $1,200 per month. Each month, the patient will be responsible for $200 out-of-pocket (the difference between what is covered by the copay coupon and the set copay amount).[216]

Worse yet, to the extent maximizer programs do actually deliver copay savings to the patient, it invariably comes with underhanded restrictions, obligating the patient to obtain the prescription exclusively from the PBM-owned or affiliated pharmacy, and allowing PBM subsidiaries to reap additional revenue.[217] PBMs have created "secretive and independent private companies" to operate these specialty drug maximizer programs, who sometimes take fees equal to 25% of the manufacturer's copay support program.[218]

In each of these scenarios, however, the patient is either forced to go over the "financial cliff" in the middle of the year (when their copays skyrocket) and risk drug abandonment, or is forced to utilize a PBM-owned or affiliated pharmacy with limited real financial benefits (or face exorbitant out-of-pocket costs).

11.1 Who Is Impacted?

Copay accumulator and maximizer programs have clear negative impact on all stakeholders.

11.1.1 Harm to Patients

The harm of copay accumulators and maximizer programs is felt most acutely by patients—especially cancer patients. Unlike instances where there might be lower cost generics available to be used as alternatives when a brand manufacturer's copay coupon benefits expire, there are no alternatives for the high-priced oncology medications, and when manufacturer copay coupon programs run out as a result of copay accumulator programs, "the individuals who need assistance the most will be unable to receive it, and will end up paying more for their treatments."[219]

"This poses an adverse impact on adherence to medication regimens, especially when a support mechanism is not in place."[220] Studies have shown that patients impacted by copay accumulator programs fill their prescription 1.5 fewer times than patients who are not impacted.[221] More critically, data has shown that patients impacted by copay accumulator programs have experienced a 13% drop in adherence—that is, they've fallen off therapy—between month 3 and month 4 of a plan year (coinciding with when they reach the annual cap for manufacturer-sponsored copay

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[214] *https://www.goodrx.com/blog/copay-accumulator-programs-cms-ruling/.*

[215] *https://www.drugchannels.net/2020/05/why-do-cvs-and-express-scripts-rely-on.html.*

[216] *https://www.managedhealthcareexecutive.com/view/coupon-accumulators-and-coupon-maximizers-explained.*

[217] *https://pharmaceuticalcommerce.com/brand-marketing-communications/copay-maximizers-have-murky-financial-implications-says-drug-channels/.*

[218] *https://www.drugchannels.net/2020/05/why-do-cvs-and-express-scripts-rely-on.html.*

[219] *https://www.hepb.org/blog/copay-accumulators-mean-prescriptions/#:~:text=In%20order%20to%20afford%20the,paying%20more%20for%20their%20treatments.*

[220] *https://www.drugchannels.net/2019/04/addressing-rising-impact-of-co-pay.html#:~:text=Co%2Dpay%20accumulators%20often%20block,mechanism%20is%20not%20in%20place.*

[221] *https://www.drugchannels.net/2019/04/addressing-rising-impact-of-co-pay.html#:~:text=Co%2Dpay%20accumulators%20often%20block,mechanism%20is%20not%20in%20place.*

coupon programs).[222] This is significant as over 75% of impacted patients have said that their adherence will suffer as a result of these programs.[223]

These findings and observations of direct patient harm have been backed up by literature. In a study published in the *American Journal of Managed Care,* the authors found that after the implementation of copay accumulator programs, Health Savings Account patients on certain high-cost specialty drugs had "significantly lower monthly fill rates, higher risk of discontinuation, and lower [percentage of days covered]," suggesting that copay accumulator programs have "the potential to negatively affect specialty drug use."[224] This rings true in the cancer context as well. According to a study in the *Journal of Clinical Oncology,* nearly half of patients with cancer abandon their prescriptions when out-of-pocket costs reach $2,000.[225] Nonadherence can have dire consequences to patients, and accounts for 10% of hospitalizations and 125,000 deaths each year.[226]

Perhaps the best evidence of patient harm is the stories from the patients themselves. In one instance, a nurse case manager from Ohio with multiple sclerosis had long managed her disease with medications, and was able to afford them through copay coupon programs.[227] However, in May 2018, she discovered that her health plan had instated a copay accumulator program, that required her to pay $3,600 per month for her prescription drugs until she met an $8,800 deductible, forcing her to consider rationing her medication that allowed her to function in her daily life.[228] In another well-publicized incident, a 27-year-old hemophilia patient had been able to afford the $38,000 for his maintenance drugs with the assistance of manufacturer copay coupon programs.[229] However, once his health plan instituted a copay accumulator program, he was unable to afford the $6,350 deductible.[230] As a result of his immediate and unforeseen inability to afford the medications, he was left with untreated bleeds, resulting in internal bleeding, and needing additional surgeries to correct.[231] "The patient has been in and out of the hospital, is currently in a wheelchair, and is not working, all at a cost of $3.5 million."[232]

One of perhaps the most sinister aspects of copay accumulator and maximizer programs for patients is the overall lack of transparency. These programs lack any semblance of transparency, and are "often implemented without a patient's knowledge or full understanding of their new 'benefit.'"[233]

Ultimately, because patient receiving medications that have lower-cost generic products have the ability to switch to such generic products in the face of copay accumulator and maximizer programs, it is the sickest patients requiring the highest-priced drugs that are most egregiously affected by these programs, and are in essence "subsidizing the patients who are adequately served by lower-cost pharmaceuticals that have low or no copays."[234]

11.1.2 Harm to Plan Sponsors

When the PBMs created and rolled out copay accumulator programs, they were billed as a cost savings tool for plans sponsors, such as employers. In theory, it does make sense when applied to high-cost branded medications, when a lower-cost, equally effective generic product is available. These programs counteract manufacturer efforts to retain market share for brand drugs once generics have become available, and further the interests of pushing patients to lower cost alternatives.

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[222] *https://www.drugchannels.net/2019/04/addressing-rising-impact-of-co-pay.html#:~:text=Co%2Dpay%20accumulators%20often%20block,mechanism%20is%20not%20in%20place.*

[223] *https://www.mmm-online.com/wp-content/uploads/sites/2/2018/09/AccumulatorAdjustmentProgramsThroughPatientsEyes.pdf.*

[224] Sherman B.W., Epstein A.J., Meissner B., Mittal M., Impact of a co-pay accumulator adjustment program on specialty drug adherence. *Am J Manag Care.* 2019;25(7):335–340, available at *https://pubmed.ncbi.nlm.nih.gov/31318506/*.

[225] Association of Patient Out-of-Pocket Costs With Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents, Jalpa A. Doshi, Pengxiang Li, Hairong Huo, Amy R. Pettit, and Katrina A. Armstrong, *Journal of Clinical Oncology* 2018 36:5, 476–482.

[226] *https://fortune.com/2020/07/22/copay-accumulator-adjustment-programs-coronavirus/*.

[227] *https://fortune.com/2020/07/22/copay-accumulator-adjustment-programs-coronavirus/*.

[228] *https://fortune.com/2020/07/22/copay-accumulator-adjustment-programs-coronavirus/*.

[229] *https://www.pharmexec.com/view/making-sense-copay-accumulators.*

[230] *https://www.pharmexec.com/view/making-sense-copay-accumulators.*

[231] *https://www.pharmexec.com/view/making-sense-copay-accumulators.*

[232] *https://www.pharmexec.com/view/making-sense-copay-accumulators.*

[233] *https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2019-AccumulatorsPolicyBrief.pdf.*

[234] *https://pharmaceuticalcommerce.com/brand-marketing-communications/copay-maximizers-have-murky-financial-implications-says-drug-channels/*.

However, in the oncology space, cancer care is for life saving treatment and does not have the same risks of "overutilization," nor are there cheaper alternatives available.

Instead, the result of copay accumulator or maximizer programs is that the harms and additional costs to plan sponsors caused by drug abandonment and non-adherence will far outweigh any potential savings to be gained from them. From increased hospitalizations, additional treatments, and more catastrophic care, it is well-established that plan sponsors save money when patients stay adherent to the drugs they are prescribed. This is especially true in the cancer context, where studies have suggested that the increased plan costs caused by non-adherence due to copay accumulator programs was more than double than that of all other disease groups.[235]

Worse yet, many employers and plan sponsors do not even know what they are getting or whether such programs have been instituted. While nearly 20% of commercial medical insurance policies sold in 2018 will have copay accumulator/maximizer programs built in, "most employers who have purchased/are purchasing these plans are unaware these programs are present in the coverage" and "have no idea how it will adversely affect their employees' care."[236] This is especially alarming considering the secretive operations of copay maximizer programs, where the prescription is typically required to be filled at the PBM-owned or affiliated pharmacy, and related or affiliated companies take up to 25% of the copayment assistance made available by the manufacturer.

For example, with Express Scripts' SaveonSP program, a commercial plan sponsor declares specialty drugs to be "non-essential health benefits," making them covered by the plan, but not subject to out-of-pocket maximums mandated by the Affordable Care Act.[237] In turn, the patients' out-of-pocket costs are set to the maximum annual value of a manufacturer's copay coupon program.[238] "For instance, a program with a total value of $20,000 in copayment support would require a patient to pay $20,000 annually for their drugs, without regard to the plan's out-of-pocket maximums."[239] Thereafter, to avoid these inflated costs, the beneficiaries must enroll separately in the SaveonSP program, and have their prescriptions filled exclusively by Express Scripts' Accredo specialty pharmacy.[240] SaveonSP then charges a fee equal to 25% of the copayment support, or $5,000 in the above example.[241] This is in addition to the profit generated by Express Scripts' wholly-owned pharmacy by filling the prescription.[242]

Ultimately, while copay accumulator and maximizer programs might seem like a good short-term solution, the devil is in the details, and in reality, these programs will ultimately increase costs for plan sponsors in the long run, including increased hospitalizations, additional care, and overall increases to drug prices.

11.1.3 Harm to Providers

Finally, community oncology practices are harmed by manipulative copay accumulator and maximizer practices as well. When physicians prescribe a particular oncology treatment to be dispensed out of the community oncology practice, they undertake a "difficult and time-consuming process" involved in finding financial assistance for their patients.[243] This includes finding manufacturer-sponsored copay coupon programs, providing resources to patients, and potentially providing supporting documentation to these programs. The copay accumulator and maximizer programs will add additional complexities in the patient coverage process and will only increase "the administrative burden on practice staff, who will now need to understand the nuances of co-pay accumulators and maximizers; as well as help explain

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[235] Cutler, R.L., Fernandez-Llimos, F., Frommer, M., Benrimoj, C., and Garcia-Cardenas, V. (2018). Economic impact of medication non-adherence by disease groups: A systematic review. *BMJ open,* 8(1), e016982. *https://doi.org/10.1136/bmjopen-2017-016982.*

[236] Who's Stealing My Savings?, by Peter Pitts, January 4, 2018.

[237] *https://www.drugchannels.net/2020/05/why-do-cvs-and-express-scripts-rely-on.html.*

[238] *https://www.drugchannels.net/2020/05/why-do-cvs-and-express-scripts-rely-on.html.*

[239] *https://www.drugchannels.net/2020/05/why-do-cvs-and-express-scripts-rely-on.html.*

[240] *https://www.drugchannels.net/2020/05/why-do-cvs-and-express-scripts-rely-on.html.*

[241] *https://www.drugchannels.net/2020/05/why-do-cvs-and-express-scripts-rely-on.html.*

[242] *https://www.drugchannels.net/2020/05/why-do-cvs-and-express-scripts-rely-on.html.*

[243] *https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2019-AccumulatorsPolicyBrief.pdf.*

to patients why some of the assistance is not helping them to reach their deductible."[244]

In addition, community oncology practices are further impacted when their patients discontinue prescribed therapy due to cost. Many community oncology practices are contracted with payers under value-based arrangements, where they take responsibility—and sometimes risk—for the outcomes of patients. If a patient stops taking his or her therapy once the copay coupon program is exhausted, that patient may wind up in the hospital or needing additional care. This will in turn negatively impact community oncology practices' performance under value-based contracts.

11.2 What Does the Law Say?

Federal statutory law is silent on the issue of copay accumulator and maximizer programs.

However, in 2019, HHS finalized the Notice of Benefit and Payment Parameters for 2020 (NBPP 2020), which only allowed health plans to implement copay accumulator programs when both a brand and generic medication were available. In essence, this would have allowed plans to steer patients to less costly, generic medications when possible, but would provide protections for patients—including cancer patients—who did not have access to alternative, less costly medications.[245]

However, on May 7, 2020, HHS released its Notice of Benefit and Payment Parameters for 2021 Final Rule, which clarified certain confusion created by different agencies' guidance, and now allows health plans to implement copay accumulator programs regardless of whether or not a generic alternative is available. When patients cannot afford their medications, they may rely on copay assistance (*i.e.,* coupon cards from drug manufacturers). These coupon cards not only contribute toward the patient's copay but also count toward the patient's annual deductible.[246] Thus, as of July 30, 2020, HHS has not only allowed health plans to implement these programs but has removed key protections for cancer patients.

Fortunately, however, several states have enacted their own laws governing copay accumulators (importantly, in NBPP 2021, HHS explicitly stated that the Final Rule does not preempt state laws that govern the use of copay accumulator programs in state-regulated health plans). At this time, four states (Illinois, West Virginia, Virginia, and Arizona) have enacted copay accumulator legislation. While these apply to state-regulated plans (and not to Exchange-based health plans), they provide protection against certain PBM conduct.

For example, Virginia Statute § 38.2–3407.20 requires health plans to include any amount paid by or on behalf of a plan enrollee when calculating an enrollee's overall contribution to any out-of-pocket maximum or any cost-sharing requirement to the extent permitted by federal law and regulation. Likewise, in Illinois, 215 Ill. Comp. Stat. Ann. 134/30 requires health plans to apply any contributions (*i.e.,* third-party payments, financial assistance, discount, product vouchers, or any other reduction in out-of-pocket expenses) for prescription drugs made by or on behalf of an enrollee toward that person's deductible, copay, or cost-sharing responsibility, or out-of-pocket maximum.

An additional eight states have some form of legislation pending to address copay accumulator/maximizer programs.

11.3 What Can Be Done?

- Legislative
    - States should enact laws that require health plans to include any amount paid by or on behalf of a plan enrollee when calculating an enrollee's overall contribution to any out-of-pocket maximum or any cost-sharing requirement.

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[244] *https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2019-AccumulatorsPolicyBrief.pdf.*

[245] *https://aimedalliance.org/hhs-allows-plans-to-implement-copay-accumulators-without-any-patient-protections/#:~:text=NBPP%202020%20would%20have%20only,and%20generic%20medication%20were%20available.&text=It%20limits%20patients'%20access%20to,costs%20to%20the%20health%20system.*

[246] *See,* 45 CFR § 156.130(h); *https://www.federalregister.gov/documents/2020/05/14/2020-10045/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2021.*

- Regulatory
  - HHS should rescind the Notice of Benefit and Payment Parameters for 2021 Final Rule, and institute Notice of Benefit and Payment Parameters that, at the very least, reinstates, strengthens, and clarifies the protections for patients receiving medications without lower cost alternatives.
- Plan Sponsor Action
  - Plan sponsors should inquire with PBM whether copay accumulator and/or maximizer programs are being employed, and demand that protections be given for oncology medications that lack lower cost alternatives.

12 Maximum Allowable Cost (MAC) Pricing

Maximum Allowable Cost pricing, or "MAC," is one of the most significant and challenging issues facing independent pharmacies throughout the United States today. While not as impactful to community oncology practices providing cancer care as many of the other topics addressed in this exposé, MAC has nevertheless become one of the most manipulated and opaque methods by which PBMs control reimbursement to independent pharmacies and has become a catalyst for legislative efforts to rein in PBM conduct.

MAC is typically defined as the maximum amount of money that PBM will pay a pharmacy for certain multi-source drugs, typically multi-source generic drugs.[247] It is well established that generic drugs make up the vast majority of drugs dispensed throughout the United States. For example, according to the Association for Accessible Medicines, generic drugs account for approximately 89% of all prescription drugs dispensed in the United States.[248] Thus, generic drugs constitute the majority of drugs dispensed to patients throughout the United States meaning MAC pricing present a significant issue as it pertains to provider reimbursement.[249]

MAC began as a mechanism to save money in health care and incentivize selective and intelligent purchasing practices, but MAC has since evolved over time into a PBM tool that can be manipulated by PBMs to increase revenues in several different ways.[250] MAC pricing is a PBM created pricing benchmark—MAC prices and MAC lists are prepared exclusively by PBMs and considered by the PBMs to be proprietary and confidential.[251] Moreover, PBM-set MAC rates need not have any relationship to a drug's market clearing acquisition cost.[252] As such, the creation and publication of PBM MAC prices and MAC lists are shielded from the public and avoid public scrutiny.[253]

PBMs' ability to keep MAC lists and MAC prices from the public has enabled PBMs to utilize MAC pricing to increase their revenues and to effectuate certain PBM practices that lead to higher revenues, including the PBM practice of spread pricing, wherein a PBM reimburses a pharmacy provider one price for a drug but collects a higher amount from the plan sponsor and retains the difference.[254] The fact that MAC pricing is shrouded in secrecy, and there is no requirement for MAC rates to have any basis in real costs, creates substantial profit opportunities for PBMs and

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[247] *See, e.g.,* NY Pub Health § 280–a(1)(b).

[248] Association for Accessible Medicines, Generic Drug Access and Savings in the U.S., 2017, *https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf.*

[249] *See, id., see also PCMA v. Rutledge,* 240 F.Supp.3d 951, 961 (E.D. Ark. 2017) (noting that the parties agree that 70% to 90% of all prescriptions are for generic drugs, which utilize MAC pricing); Eugene A. DePasquale, Bringing Transparency and Accountability to Drug Pricing (December 11, 2018), *https://www.paauditor.gov/Media/Default/Reports/RPT_PBMs_FINAL.pdf* (noting that generic drugs make up roughly 85 percent of all prescriptions filled annually nationwide).

[250] *See, e.g.,* Linda Cahn, Don't Get Caught By PBMs' MAC Mousetraps (September 1, 2008), *https://www.managedcaremag.com/archives/2008/9/don-t-get-caught-pbms-mac-mousetraps.*

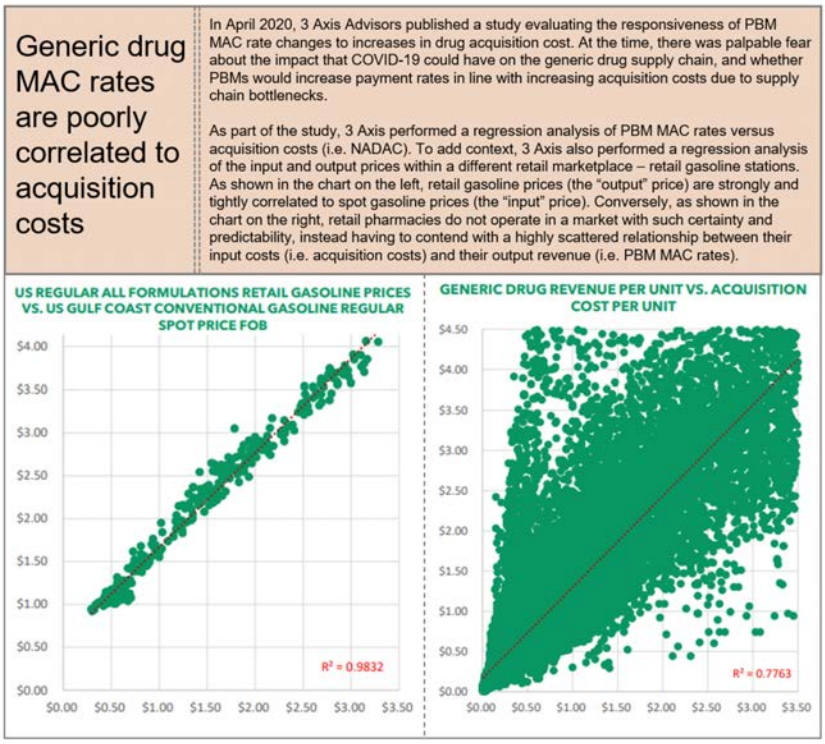
[251] *See, e.g.,* 3AXIS Advisors, Analysis of PBM Spread Pricing in Michigan Medicaid Managed Care (April 2019), *https://www.michiganpharmacists.org/Portals/0/resources/3AA%20MI%20Medicaid%20managed%20care%20analysis%20-%20Final%2004.10.19.pdf?ver=2019-04-30-064856-343&ver=2019-04-30-064856-343; see also* Eugene A. DePasquale, Bringing Transparency and Accountability to Drug Pricing (December 11, 2018), *https://www.paauditor.gov/Media/Default/Reports/RPT_PBMs_FINAL.pdf* (noting that PBMs consider their formulas for reimbursement of generic drugs to be proprietary information that amounts to trade secrets).

[252] *https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/5e95dd726f6f770b5fc85d04/1586879871828/2020_04+Research+Brief+FINAL.pdf.*

[253] *See, id.*

[254] *See, e.g.,* Eugene A. DePasquale, Bringing Transparency and Accountability to Drug Pricing (December 11, 2018), *https://www.paauditor.gov/Media/Default/Reports/RPT_PBMs_FINAL.pdf.*

has resulted in substantial challenges for independent pharmacy providers over the past several years.



12.1 Who Is Impacted?

PBMs' secretive MAC pricing tactics have caused harm to payers, providers, and most critically to patients.

12.1.1 Harm to Patients

The improper use of MAC pricing tactics harm patients throughout the United States by limiting patient care access—this specific issue is on display in the case *Rutledge v. PCMA* which successfully went before the Supreme Court of the United States in December of 2020.[255] In *Rutledge,* Arkansas enacted a law, Act 900, with the purpose of addressing this patient-based issue, which was especially pronounced in rural areas.[256] MAC pricing appears to often disproportionately harm patients in rural areas, who often do not have access to a broad catalogue of different (sometimes cheaper) products, thereby harming these patients specifically.[257] "MAC methodologies are resulting in pharmacies closing down, especially in rural areas . . . [and] approximately 44% of Arkansans live in rural areas."[258] The potential for patient harm based upon improper pricing and reimbursement tactics, including MAC pricing combined with spread pricing was also discussed at length in the Pennsylvania Auditor General's Report on PBMs, wherein it was noted that "small pharmacies often see the most vulnerable patients . . . [a]nd if small pharmacies are forced out of business, these patients will have to travel greater distances to get the medications they need[.]"[259] Thus, there is ample objective evidence that PBMs'

[255] *See, e.g., PCMA v. Rutledge,* 240 F.Supp.3d 951, 960–61 (E.D. Ark. 2017).
[256] *Id.*
[257] *Id.* at 960.
[258] *Id.*
[259] Eugene A. DePasquale, Bringing Transparency and Accountability to Drug Pricing (December 11, 2018), *https://www.paauditor.gov/Media/Default/Reports/RPT_PBMs_FINAL.pdf.*

MAC pricing tactics are causing harm to patient populations throughout the United States and that this harm may be particularly pronounced in rural settings.

12.1.2 Harm to Plan Sponsors

In addition to harming patients, improper MAC pricing tactics by PBMs also potentially harm all payers including Medicare, Medicaid, employers, and taxpayers, although studies indicate this may be particularly pronounced in the Medicaid context.[260] "PBMs' control of MAC definitions allows them to manipulate the MAC concept in whatever ways they choose."[261] Thus, MAC lists do not afford payers and sponsors with the ability to have predictability or in any way guarantee savings but instead give PBMs unfettered discretion to control precisely which drugs are on a particular MAC list and to ensure only those drugs which they are making money on remain on the list and those which they are not are removed from the list. In assessing potential harm of PBMs' MAC pricing tactics, it is important to note that MAC pricing applies to drugs, most commonly generics, and *not* to specific programs (*e.g.,* Medicaid).[262] The implication is that improper MAC pricing tactics can affect all payers, including federal and state governments, and by extension, taxpayers.[263]

As mentioned, MAC pricing is one of the primary methods by which PBM spread pricing is effectuated, wherein the PBM bills a plan sponsor one price and reimburses the pharmacy provider a lower amount.[264] Several studies have shown that improper MAC pricing tactics, in connection with spread pricing, has been prominent in the Medicaid context, including in Florida, Georgia, Illinois, Kentucky, Maryland, Michigan, New York, Ohio, and Virginia.[265] Pennsylvania's report on PBMs noted that in 2017 "three PBMs made between $2 million and nearly $40 million on spread pricing, earning average profits between 28 cents and almost $13 per Medicaid prescription filled."[266]

In order to implement spread pricing via MAC pricing, PBMs create numerous different MAC lists including separate MAC lists for each individual payer as well as separate MAC lists for PBM network providers which enables a PBM to bill a plan sponsor one rate but pay the pharmacy a separate and frequently a much lower rate.[267] Florida, Michigan, New York, and Ohio are three states that exemplify the harm caused by PBM MAC pricing tactics to state specific Medicaid programs.

12.1.3 Harm to Providers

Finally, improper MAC pricing tactics by PBMs also harm providers due to unsustainable reimbursement by PBMs.[268] In *Rutledge,* the District Court acknowledged that numerous pharmacies had been harmed by these tactics and were closing down,[269] noting that "[i]ndependent community pharmacies have had to eliminate employees during the last 5 to 10 years due to the financial hardships they have faced."[270] The court further noted that "[i]ndependent community pharmacies in Arkansas are in economic distress."[271]

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[260] *See, e.g.,* 3Axis Advisors, Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis (January 2020), *https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/5e384f26fc490b221da7ced1/1580748598035/FL+Master+Final+Download.pdf.*

[261] Linda Cahn, Don't Get Caught By PBMs' MAC Mousetraps (September 1, 2008), *https://www.managedcaremag.com/archives/2008/9/don-t-get-caught-pbms-mac-mousetraps.*

[262] *See, e.g.,* NY Pub Health § 280–a(1)(b).

[263] *See* 3Axis Advisors, Analysis of PBM Spread Pricing in Michigan Medicaid Managed Care (April 2019), *https://www.michiganpharmacists.org/Portals/0/resources/3AA%20MI%20Medicaid%20managed%20care%20analysis%20-%20Final%2004.10.19.pdf?ver=2019-04-30-064856-343&ver=2019-04-30-064856-343.*

[264] *See, e.g.,* Eugene A. DePasquale, Bringing Transparency and Accountability to Drug Pricing (December 11, 2018), *https://www.paauditor.gov/Media/Default/Reports/RPT_PBMs_FINAL.pdf.*

[265] 3Axis Advisors, Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis (January 2020), *https://www.3axisadvisors.com/projects/2020/1/29/sunshine-in-the-black-box-of-pharmacy-benefits-management.*

[266] Eugene A. DePasquale, Bringing Transparency and Accountability to Drug Pricing (December 11, 2018), *https://www.paauditor.gov/Media/Default/Reports/RPT_PBMs_FINAL.pdf.*

[267] 3Axis Advisors, Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis (January 2020), *https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/5e384f26fc490b221da7ced1/1580748598035/FL+Master+Final+Download.pdf.*

[268] *See, e.g., PCMA v. Rutledge,* 240 F.Supp.3d 951, 955, 960–61 (E.D. Ark. 2017).

[269] *Id.* at 955–56.

[270] *Id.* at 955.

[271] *Id.* at 960.

These unreasonably low MAC prices are further exacerbated by the fact that PBMs are often slow to make price adjustments to MAC drugs when there are market conditions that would result in the PBM reimbursing a higher amount (*i.e.,* an increase in acquisition cost), but relatively quick to make price adjustments based on market conditions that would result in the PBM reimbursing a lesser amount (*i.e.,* a decrease in acquisition cost).[272]

12.2 What Does the Law Say?

Given its prevalence in commercial insurance contracts and Medicaid programs, MAC pricing has largely been regulated by the states. Currently, 36 states have some form of MAC law or MAC appeal law in place.[273] While the different state laws vary in the level of protections they afford to pharmacies regarding MAC, there are several general characteristics in these state MAC laws. Typically, robust MAC laws will establish criteria for placing a drug on a MAC list, establish an appeal process for challenging questionable MAC pricing, and set requirements for updating MAC lists. Texas and Georgia are example of such laws.[274] In Texas, a PBM may not include a drug on a MAC list unless: (1) the drug: (A) has an "A" or "B" rating in the most recent version of the United States FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book; or (B) is rated "NR" or "NA" or has a similar rating by a nationally recognized reference; and (2) the drug is: (A) generally available for purchase by pharmacists and pharmacies in [Texas] from a national or regional wholesaler; and (B) not obsolete.[275] Further, the PBM must develop a process for pharmacies to appeal MAC prices of a drug on or before the 10th day after the claim is submitted and the PBM must respond within 10 days.[276]

Texas' MAC appeal requirements also require that when an appeal is successful, the PBM must (1) adjust the MAC that is the subject of the appeal effective on the day after the date the appeal is decided; (2) apply the adjusted MAC price to all similarly situated pharmacies as determined by the PBM; and (3) allow the pharmacy that succeeded in the appeal to reverse and rebill the pharmacy benefit claim giving rise to the appeal.[277] When appeals are not successful, the PBM must identify and disclose (1) each reason the appeal was denied; and (2) the NDC number from the national/regional wholesalers from which the drug is generally available for purchase by pharmacies in Texas at the MAC price that is the subject of the appeal.[278] Moreover, in Texas, there are separate guidelines governing MAC in the Medicaid context.[279] Although there are some functions an MCO may delegate to a PBM in Texas, there are also certain functions for which an MCO is ultimately responsible despite the delegable nature of the function.[280] These expressly include "negotiation and establishment of pharmacy provider reimbursement rates [and] cultivation and maintenance of MAC pricing lists."[281] Thus, certain laws in the Medicaid context potentially provide additional recourse against payers in addition to PBMs as is the case in Texas.

12.3 What Can Be Done?

Effective responses to improper MAC pricing by PBMs require action at various levels:

- Legislative
  - Congress should enact legislation at the federal level prohibiting MAC manipulation including a requirement as to transparency in MAC pricing on both sides of the PBM—at the plan sponsor side as well as the provider side.
  - States must take more aggressive action against PBMs' MAC pricing tactics and enact new laws or else enhance existing laws that mandate trans-

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[272] *See generally,* 3Axis Advisors, Responsiveness of Maximum Allowable Cost to Generic Drug Inflation (April 3, 2020), *https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/5e95dd726f6f770b5fc85d04/1586879871828/2020_04+Research+Brief+FINAL.pdf.*

[273] *Rutledge v. PCMA,* Pet'r Br. p. 5; *see also,* National Conference of State Legislatures, 2018 Enacted State Laws Affecting Pharmaceutical Costs, Pricing and Payment (February 2019), *https://www.ncsl.org/portals/1/documents/health/2018EnactedLawsPharmaceuticalCosts.pdf.*

[274] Texas, V.T.C.A. § 1369.353; 1369.357.

[275] *Id.*

[276] *Id.*

[277] *Id.*

[278] *Id.*

[279] Texas HHSC Report on PBMs in Medicaid, Revised September 30, 2019.

[280] *Id.*

[281] *Id.*

parency in reimbursement which should include robust laws that protect both plan sponsors and providers from manipulative MAC pricing practices, especially as it pertains to claims that are paid from taxpayer dollars, *e.g.,* Medicare and Medicaid.[282]

- For legislative efforts to be effective, the laws enacted must provide a deterrent beyond solely relying on government enforcement. Thus, it is imperative that states enact laws or enhance existing laws by including or adding "private rights of action" to ensure plan sponsors and providers have recourse against improper PBM MAC pricing tactics and also make violation of MAC laws by PBMs an unfair or deceptive trade practice act in accordance with existing state law.[283]
- State laws should strive for greater uniformity, including in how MAC is defined to prevent inconsistencies in reimbursement practices throughout the country, greater/broader appeal rights (requiring that the drug utilized as the basis for the MAC rate is readily available and conforms with the state's prescription substitution laws), and to ensure that PBMs cannot take liberties in placing drugs that do not meet a uniform definition of a MAC drug on a MAC list.[284]
- MAC laws should permit providers to choose how MAC appeals are filed rather than permitting PBMs to force providers to use a pharmacy services administrative organization (PSAO)—this ensures that if PSAOs are not responsive to MAC issues, pharmacy providers can pursue the appeals on their own or hire third parties that may be more effective at addressing MAC issues.[285]

- Regulatory
  - There should be increased scrutiny over PBM MAC pricing tactics at the federal level through CMS/OIG audits.
  - Increased scrutiny over PBM MAC pricing tactics should happen at the state level through audits by both the Departments of Insurance and Departments of Health and/or state Boards of Pharmacy.
- Plan Sponsor Action
  - Plan sponsors must demand more from PBMs during the contracting process including specific information on how pharmacies are being reimbursed and the use of MAC lists as it pertains to both the plan sponsors' relationship with the PBM as well as pharmacies' relationships with the PBM to understand if spread pricing is being used and/or whether pharmacies are being harmed by improper MAC reimbursement.

13 Effective Rate Reconciliation

In yet another opaque and underhanded ploy, PBMs have created and utilized the concepts of Generic Effective Rate (GER) and Brand Effective Rate (BER) to essentially reprice drugs, and claw back pharmacy reimbursements, sometimes more than a year after drugs are dispensed.[286] GER and BER (collectively known as the "Effective Rate") measure the discount that the PBM contractually must deliver for its client (*i.e.,* plan sponsors) to a benchmark called Average Wholesale Price (versus) for generic prescription drugs and for brand-name prescription drugs, respectively.[287] However, because they are assessed retrospectively and on a network level basis, it is tantamount to giving PBMs unbridled discretion as to how they will pay a given pharmacy, and still technically be in compliance with the reimbursement terms of the agreement.

Worse yet, PBM methods of imposing and recouping Effective Rate assessments are equally deceitful. Not only did many PBMs foist such reimbursement terms on phar-

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[282] *See, e.g.,* Eugene A. DePasquale, Bringing Transparency and Accountability to Drug Pricing (December 11, 2018), *https://www.paauditor.gov/Media/Default/Reports/RPT_PBMs_FINAL.pdf.*

[283] *See, e.g.,* AR ST § 17–92–507(g).

[284] Compare V.T.C.A. § 1369.353 and NY Pub Health § 280–a(1)(b).

[285] *See, e.g.,* N.J.S.A. 17B:27F–4.

[286] *See,* Complaint, *Total Care Rx, Inc. v. Epic Pharmacy Network, Inc.,* No. 1:18–cv–3853 (D.Md. December 14, 2018).

[287] *See* generally, 3Axis Advisors, "Analysis of PBM Spread Pricing in Michigan Medicaid Managed Care," accessible online: *https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/5cc5eb7b24a6944974537e28/1556474768436/3AA+MI+Medicaid+managed+care+analysis+-+Final+04.10.19.pdf.*

macy providers retroactively without their knowledge or consent (for example via retroactive contracts with the pharmacy providers' PSAOs), but in many instances, the pharmacy providers only learned of the Effective Rate reconciliation when the PBMs, either directly or indirectly, simply began withholding payments due to offset the alleged Effective Rate overpayments.[288]

Because of its after-the-fact assessment applied across an entire network of pharmacy providers, Effective Rates allow PBMs to circumvent Maximum Allowable Cost laws enacted by many states (see, Section 12, *supra*), and hinders pharmacy providers' ability to challenge underwater reimbursements on generic prescriptions.[289] At its most basic level, Effective Rate is not reflected at the point of sale and it provides an opportunity for PBMs to take back a substantial amount of reimbursements on prescription drug claims that were already dispensed to patients.[290]

Similarly, PBMs have also created another pricing mechanism called Dispending Fee Effective Rate (DFER) to recoup dispensing fees already paid to providers that provides no purpose to reduce plan sponsors' drug spending.[291] DFER allows a PBM to pay one dispensing fee at the point-of-sale, and afterwards claw-back a portion of this dispensing fee down to the contractually specified DFER. This particularly pernicious type of effective rate undermines the cost-plus pass-through contracts that many state Medicaid programs are contemplating, or moving to, in response to outrage over spread pricing. DFERs could allow the PBM to pass through the state-mandated dispensing fee, only to claw it back after the fact, without the state's knowledge.

13.1 Who Is Impacted?

13.1.1 Harm to Patients

As with many other PBM tactics, including spread pricing (see, Section 10, *supra*), rebates (see, Section 4, *supra*), and DIR fees (see, Section 5, *supra*), Effective Rate reimbursement frameworks have the ability to increase the gross price for medications, notwithstanding a potentially lower net price. For Medicare Part D patients, Effective Rate forces them to reach "donut hole" and pushes patients into "catastrophic coverage" at a much faster rate.[292] As discussed in detail below, this results in the patients being responsible for a greater share of the costs of the medication.

13.1.2 Harm to Plan Sponsors

While it is billed as a "cost containment" and pricing guarantee to payers, in actuality, Effective Rate reimbursement schemes do little to lower the overall costs of drugs. Effective Rate prices are invariably tied to percentage discounts off of reported AWP (as shown in the graphic on page 78, an inherently unreliable pricing benchmark), enabling PBMs to deliver on savings guarantees, while not actually lowering overall costs (as lower generic and brand-name prescription drug costs for plan sponsors would in turn lower overall revenue for PBMs).[293]

An even more pernicious feature of Effective Rate pricing arrangements is that they provide PBMs with the ability to collect "spread" between what they charge their clients (*e.g.,* employers and plan sponsors) and what they pay their providers (*e.g.,* pharmacies and community oncology practices) without having to put their clients in traditional spread pricing contracts. Instead, PBMs can simply sign one contract with a client guaranteeing, say, an 82% discount to AWP and a different contract with their pharmacy network guaranteeing an 87% discount to AWP. Both contracts are highly confidential, so the "buyer" (the employer) and "seller" (the pharmacy)

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[288] *See generally, https://www.dispatch.com/news/20190714/middlemen-poised-to-grab-back-money-theyve-already-paid-to-ohio-pharmacists.*

[289] *See,* Complaint, *Total Care Rx, Inc. v. Epic Pharmacy Network, Inc.,* No. 1:18–cv–3853 (D.Md. December 14, 2018).

[290] *See,* American Pharmacy Cooperative, Inc., "Letter to U.S. Department of Justice Antitrust Division," December 12, 2018, accessible online: *https://www.justice.gov/atr/page/file/1142771/download.*

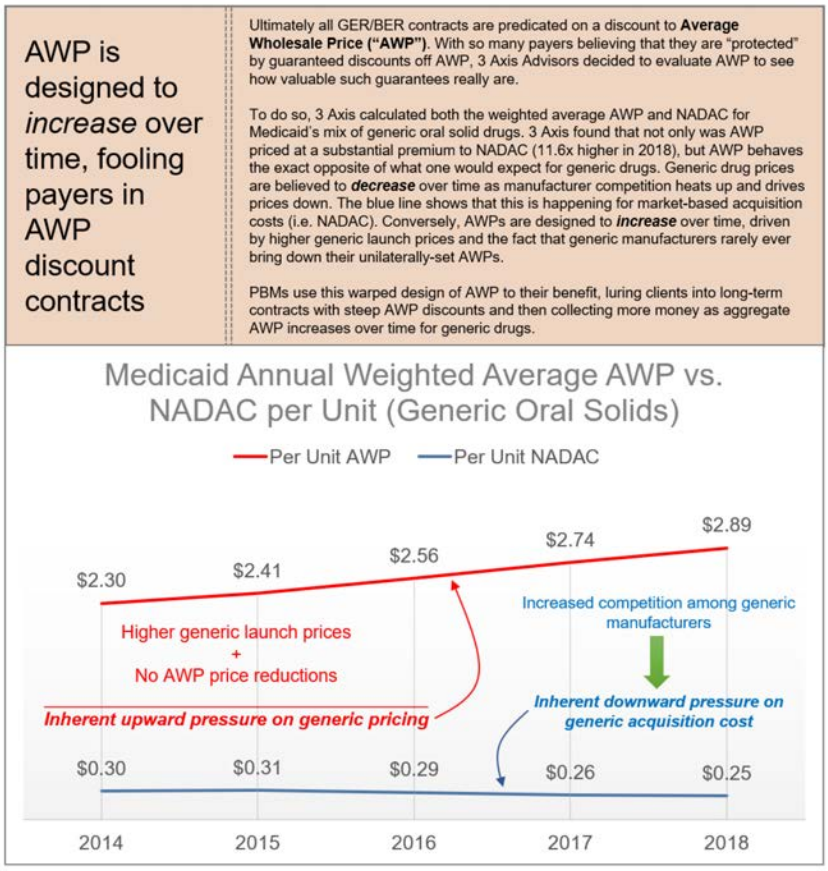
[291] *See,* National Community Pharmacists Association, Letter to United States Senate Committee on Health, Education, Labor and Pensions "Senate HELP Committee request for comments on the Lower Health Care Costs Act of 2019 Discussion Draft," June 5, 2019, accessible online: *http://www.ncpa.co/pdf/qAM/help-discussion-ncpa-comments.pdf.*

[292] *See,* American Pharmacy Cooperative, Inc., "Letter to U.S. Department of Justice Antitrust Division," December 12, 2018, accessible online: *https://www.justice.gov/atr/page/file/1142771/download.*

[293] *See generally,* 3Axis Advisors, "Analysis of PBM Spread Pricing in Michigan Medicaid Managed Care," accessible online: *https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/5cc5eb7b24a6944974537e28/1556474768436/3AA+MI+Medicaid+managed+care+analysis+-+Final+04.10.19.pdf.*

of drugs does not know what each other are paying/receiving. Even if the employer demands a full pass-through contract, in which no spread is taken off the claim, the PBM will simply pass-through what it charges its client to the pharmacy at the time of the transaction, and then claw the overpayment back at a later time through its effective rate adjustments. At the end of the day, in this hypothetical example the PBM has locked in 5% of AWP for its services, regardless if it collects that up front or months after the transaction.

The value of Effective Rate contracts to the PBM does not end there. That's because for generic drugs, AWP is designed to do exactly the opposite of what prices should do over time for generic drugs—AWP is designed to increase, not decrease over time. So, in our hypothetical example, the hidden 5% of AWP locked in by the PBM becomes more and more valuable each year to the PBM as AWPs diverge from true generic acquisition costs.



13.1.3 Harm to Providers

As noted above, Effective Rate reimbursement has had an especially damaging impact on providers. By effectively circumventing MAC laws, PBMs are able to reimburse many pharmacies below water on claims, leaving them without any recourse to challenge such reimbursements through legally-mandated appeals processes. This has particularly effect on providers who only dispense a limited range of generic products, such as community oncology practices. PBMs' reconciliation of Effective Rate is a significant financial hurdle to community oncology practices because oncologists generally treat patients with a handful of drugs compared to other com-

munity retail or chain pharmacies who have a broad and diverse patient population.[294]

13.2 What Does the Law Say?

At the federal level, in addition to the guidance on spread pricing generally (see, section 10, *supra*), GER and BER reconciliations are properly considered direct and indirect remuneration (DIR), which Medicare Part D plan sponsors must report to CMS.[295] This at least, in theory, requires PBMs and Part D plan sponsors to disclose the extent and amount of GER/BER, regardless of whether it is passed-through to the plan sponsor or retained by the PBM.

At a state level, many states have enacted laws that would prohibit these types of post-point-of-sale reconciliations and clawbacks with respect to private health plans. For example, Tennessee law provides that neither a health insurance company nor a PBM may "charge a pharmacist or a pharmacy a fee related to a claim unless it is apparent at the time of claim processing and is reported on the remittance advice of an adjudicated claim."[296] Likewise, Indiana law explicitly regulates the practice of "effective rate of reimbursement," and provides that a PBM may not "[r]educe, directly or indirectly, payment to a pharmacy for pharmacist services to an effective rate of reimbursement. . . ."[297]

Finally, Effective Rate reconciliations may impinge on the multitude of "Prompt Payment" laws that exist in virtually every state in the country. For example, Mississippi's Pharmacy Benefit Prompt Pay Act requires PBMs to pay electronically submitted claims in full within fifteen days.[298] PBMs' later-in-time retraction of the amounts paid could violate those requirements.

13.3 What Can Be Done?

Effective Rate reimbursement requires a response at many levels:

- Legislative
  - States should enact laws, like Tennessee's[299] and Indiana's[300] that prohibit recoupment of fees on claims that were not reflected at the point-of-sale or otherwise ban Effective Rate reimbursement as a construct altogether.
  - States should enact MAC Appeal Laws (where none exist) or amend existing MAC laws to prohibit health insurers and PBMs from circumventing MAC appeal rights through Effective Rate reimbursement constructs.
  - Laws should be enacted, like New Jersey's Fair Price law,[301] requiring PBM pricing transparency and prohibiting below-cost reimbursement to pharmacies.
- Regulatory
  - CMS should audit Part D plan sponsors and contracted PBMs to determine whether GER/BER is appropriately reported and reconciled to CMS at the end of each Plan Year.
  - State Departments of Insurance should pursue complaints against PBMs and health insurers for violations of Any Willing Provider Laws, stemming from efforts to constructively deny providers the right to participate in pharmacy networks based on unreasonably low, below cost reimbursement rates.
- Plan Sponsor Action
  - As part of the PBM contract, plan sponsors should require PBMs to pass through any and all amounts PBMs received from the pharmacies after the point-of-sale on a claim-by-claim level.

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[294] *See, e.g.,* New York Cancer and Blood Specialists, "PBM Delays for Cancer Drugs May Risk Lives, Warn Oncologists," March 13, 2019, accessible online: *https://nycancer.com/blog/2019/03/13/pbm-delays-cancer-drugs-may-risk-lives-warn-oncolo/*.
[295] *See,* Social Security Act § 1860D–15, 42 U.S.C. [1395w–115].
[296] T. C. A. § 56–7–3115.
[297] Ind. Code. § 27–1–24.5–19(b)(4).
[298] *See,* Miss. Code Ann. § 73–21–155.
[299] T. C. A. § 56–7–3115.
[300] Ind. Code. § 27–1–24.5–19(b)(4).
[301] N.J.S.A. 17b:27f–1 to –10.

- As part of the PBM contract, plan sponsors should require PBMs to seek a permission prior to implementing a contracted-rate with the pharmacies (*e.g.,* GER).

14 Conclusion

The list of PBM abuses and games is seemingly never-ending and evolving. But the reality is that we are only just scratching the surface of understanding what these abusive health care middlemen are doing. Simply put, PBMs have overwhelmingly abused their responsibility to protect Americans from this country's drug pricing crisis, instead exploiting the opacity throughout the drug supply chain to enrich themselves. Their many abuses go well beyond just questionable rebate practices, and hurt patients and plan sponsors (including employers, Medicare, and Medicaid).

Unfortunately, their impact is only becoming more pronounced, especially in oncology. More and more cancer drugs are coming out in oral formulations, further shifting care away from the medical space and into the pharmacy space. These expensive therapies are very attractive to PBM's because of the potential for high prices that yield high rebate revenues, high DIR fees, and eventually, high spreads—all of which are a function of the drug's cost.

And even outside of the pharmacy benefits realm, through vertical integration, PBMs have been able to exert considerably more influence in the other areas, such as injectable biosimilars and intravenous chemotherapies. Not only can PBMs can leverage these for steep originator and rebates (thereby stifling the biosimilar industry for their own gain), but PBMs have instituted mandatory white bagging policies to take even in-office administration out of the hands of community oncology practices.

The bottom line is this: today's drug supply chain is designed for cancer patients to receive inferior treatment, while paying more out-of-pocket.

The time for action to stop PBM abuses is now. Each day that goes by, community oncology patients, practices, and professionals become increasingly powerless because of horizonal PBM consolidation and vertical integration with insurers.

Fortunately, however, solutions do exist. These include legislative efforts at both the state and federal levels. Many states' existing laws serve as prime examples of how they can be successfully implemented to protect the interests of patients and health care payers (like employers, Medicaid programs, and taxpayers). In addition, based on many laws that are currently on the books, regulators (both state and federal) have tremendous tools available to them, that up until this point, have not been widely utilized.

The time is critical that regulators—including CMS, OCR, the FTC, state Boards of Pharmacy and state Departments of Insurance—take much need action to rein in the unchecked power of PBMs.

The time for sitting back and letting market forces address the issues is over. The time for action to stop PBM abuses is now.

QUESTIONS SUBMITTED FOR THE RECORD TO JONATHAN E. LEVITT

QUESTIONS SUBMITTED BY HON. RON WYDEN

Question. How can Congress strengthen the Medicare statute to improve pharmacy access and protect community pharmacies?

Answer. To improve pharmacy access and protect community pharmacies, we recommend as a starting point, amending Medicare's Any Willing Provider Law ("AWPL"), codified at 42 U.S.C. § 1395w–104, to expressly apply to PBMs. This will preclude PBMs from taking the position that the AWPL does not apply to PBMs, a common argument made by PBMs and Part D Plan Sponsor in seeking to avoid the law. We also recommend amending the AWPL to require PBMs to admit all qualified providers and to expressly state that the AWPL requires patients to be permitted the option of using any qualified provider of their choice regardless of whether that provider is a PBM affiliated provider cross referencing to 42 U.S. Code § 1395a (Free Choice by Patient Guaranteed). We further recommend that Congress amend the AWPL to include mandatory "reasonable and relevant" terms and conditions, and to provide a framework for determining reasonable reimbursement for Medicare pharmacy providers. We recommend that a framework include:

- **Reimbursement Rates.** Provide that reimbursement below a pharmacy's drug acquisition cost is per se evidence of a violation of the "reasonable and relevant terms and conditions" standard. Documentation provided by the pharmacy provider showing that reimbursement was below acquisition cost shall result in a presumption that the reimbursement was unreasonable.
    - Reimbursement at or above cost shall be considered but one factor in determining if reimbursement was reasonable.
    - Requirement of a reasonable mandatory dispensing fee to pay for labor, operational, and other overhead costs associated with a provider dispensing a drug to a patient. Prohibition on "$0.00" dispensing fee to fulfill the requirement for a reasonable mandatory dispensing fee. Such dispensing fee shall represent an amount paid for the professional services rendered by a pharmacy and/or pharmacist for dispensing a prescription and shall not include any payment associated with the medication(s) being dispensed.
- **Performance Metrics.** Any PBM implemented "performance metric(s)" that impact reimbursement must be "reasonable and relevant" as applied to a particular pharmacy provider to ensure that: (1) pharmacy providers' performance is being measured on a level playing field (*e.g.,* not measuring specialty pharmacies or community oncology providers' performances against retail pharmacies' performance, not measuring independent pharmacy performance against large chain pharmacies); and (2) performance metrics are clearly reported to the pharmacy provider at the claim level and such performance metrics cannot favor the PBM corporately affiliated pharmacies.
- **Dispute Resolution.** Require PBM contracts to include a practical mechanism for pharmacy providers to resolve disputes regarding: (1) unreasonable reimbursement; and (2) the reasonableness and relevance of PBM terms and conditions. Dispute resolution requirements should include: (i) mandatory minimum timeline for PBMs to respond; (ii) an ability for providers to resolve disputes in a court of competent jurisdiction; (iii) an ability for providers with common disputes to resolve disputes with PBMs on a consolidated basis; and (iv) prohibitions on retaliation, such as network exclusion, punitive reduction of reimbursement, for such disputes.
- **Differential Pricing.** PBMs shall not reimburse corporately affiliated pharmacy operations better than non-owned and/or independent affiliated pharmacy operations.
- **Monetary Penalties.** CMS enforcement mechanism that includes right of pharmacy providers to report PBM non-compliance with these obligations to CMS for further investigation with provider protection from adverse action or retaliation by PBMs for such reporting. Enforcement mechanisms should include the right for CMS to impose monetary penalties for noncompliance.

Question. Do you believe PBMs reimburse PBM-owned pharmacies at higher rates than independent pharmacies or unaffiliated chains? Have you seen evidence of this practice through your work?

Answer. Yes, we have seen evidence that PBMs pay their own pharmacies at higher reimbursement rates than PBMs pay to independent pharmacies. PBMs often state that they have "standard terms and conditions" for providers in their networks. But discovery or investigation has revealed "differential pricing." Differential pricing occurs when PBMs pay their wholly owned pharmacies more than PBMs pay to independent pharmacies. We also see evidence of PBMs granting themselves longer "days' supply" for dispensed quantities, as another favorable term. When a PBM is forced to disclose differential pricing and terms during discovery, PBMs often settle rather than disclose this information. PBMs also assess DIR fees in a discriminatory manner, and engage in patient steering to send a higher volume of prescriptions to their wholly owned pharmacies. By paying unreasonable reimbursement rates to independents, PBMs engage in predatory pricing. The PBM's wholly owned pharmacy can sustain operating at a loss because the PBM makes "spread." Unreasonable reimbursement also helps the PBM decrease competition from independent providers. We know for certain that PBMs, even in Medicare, pay their wholly owned chain or specialty pharmacies better than independents, including possibly in the critical arena of 340B. Gag clauses prevent us from revealing this specific data. Even in Medicaid it has been publicly reported that

PBMs pay their wholly owned pharmacies better than independent pharmacies.[1] The Senate should investigate.

Question. Recent evidence suggests that specialty pharmacy is a growing source of revenue for PBMs. Please describe how PBMs are generating revenue through their specialty pharmacy channels. Additionally, what tactics do PBMs use within Medicare Part D to increase specialty dispensing volume?

Answer. PBMs generate revenue through specialty drug distribution channels in multiple ways. Each of the "Big Three" PBMs owns (directly or indirectly) its own specialty pharmacy, and these three pharmacies—CVS Specialty (affiliated with Caremark), Accredo (affiliated with Express Scripts) and Optum Specialty Pharmacy (affiliated with OptumRx)—combine for a 65-percent market share of all specialty prescription revenues in 2021, and likely more today.[2] Thus, each independent specialty pharmacy competes with each PBM-owned specialty pharmacy for prescription revenue. This is particularly distressing because PBMs are also the gatekeepers for pharmacy networks, so they determine which competitor will be excluded or permitted to compete. The fox is guarding the hen house.

Steering. PBMs also engage in prescription "steering." Because each PBM has a pecuniary interest in sending specialty prescriptions to their affiliate specialty pharmacy, each PBM engages in prescription "steering" or "hijacking."[3] PBMs use their position as claims adjudicators to review patient information and specialty drug claims data submitted by providers. PBMs often reject independent provider specialty claims, and require providers to secure "Prior Authorization" for the claim, then reject the claim again to compel the patient to use the PBM's wholly owned specialty pharmacy.[4] PBMs often engage in substantial misrepresentations to patients in the process of misleading them to their wholly owned pharmacies.[5]

Below Water Reimbursement. PBMs also engage in "Low-Ball" or "Below Water" reimbursement. PBMs use below cost reimbursement to independent specialty pharmacies for specialty drugs to drive competitors out of networks and drive revenue to their own pharmacies.[6] Specialty pharmacies will often not fill below-water prescriptions. PBMs use outsized market power to dictate pharmacy reimbursement, which drives independent specialty providers out of network, thus increasing PBM pharmacy market share.[7]

Vertical Integration and Loss on Pharmacy Side. It makes no difference to PBMs whether their affiliated pharmacies make a profit or loss on reimbursement "up front." The affiliated PBM need only drive prescriptions to their own pharmacies; that is, regardless of the profit to the pharmacy at the point of sale, the vertically integrated PBM will profit through manufacturer discounts or spread pricing in their capacity as PBM.[8]

Definitions as Weapons. PBMs seek to increase their specialty dispensing volume and costs by controlling the definition of medications. The power to define what is categorized as specialty medication on plan formulary is the power to profit. PBMs can characterize specialty drugs as non-specialty for purposes of driving lower reimbursement to pharmacy providers, while continuing to define the same products as "specialty" when contracting with plan sponsors to avoid having to meet cost savings guarantees. PBMs also require patients to "try and fail" certain specialty drugs before moving on to specialty drugs that are not on the PBM's preferred formulary, even if the prescriber already knows the best specialty medication for their patient. Additionally, PBMs have encouraged specialty dispensing in Part D by overpaying

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[1] 3Axis Advisors, *Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis,* 1, 3–4, January 30, 2020. Available at: *https://www.3axisadvisors.com/projects/2020/1/29/sunshine-in-the-black-box-of-pharmacy-benefits-management.*

[2] Drug Channels, DCI's Top 15 Specialty Pharmacies of 2021—And Three Factors That Will Reshape 2022, May 4, 2022 *(https://www.drugchannels.net/2022/05/dcis-top-15-specialty-pharmacies-of.html)*.

[3] Frier Levitt, Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers, at 40 (February 2022).

[4] *Ibid.; see also Trone Health Services, Inc. v. Express Scripts Holding Company,* 974 F.3d 845 (8th Cir. 2020) (detailing complaint by pharmacy against Express Scripts in which Express Scripts took patient information to use for its own benefit).

[5] *Ibid.*

[6] Frier Levitt, PBM Exposé at 47.

[7] *Ibid.*

[8] *Id.* at 51.

on certain specialty drugs and steering those claims to their wholly owned specialty pharmacies. These tactics all contribute to increased specialty costs.

Tying Arrangements. PBMs engage in "tying arrangements" to generate revenue by virtue of their market dominance. Vertical integration of a PBM, Prescription Drug Plan (PDP), specialty pharmacy, and retail pharmacy is a recipe for disaster. PBMs decide which drugs are placed on formulary, that drug's copay "tier," and the reimbursement rate that will be paid to pharmacies. The power to control formulary is the power to control manufacturers and distributors. PBMs routinely exclude pharmacies that compete with the PBM-affilaited specialty and retail pharmacies. A PBM that wants access to a new "exclusive distribution drug" at its affiliate specialty pharmacy can threaten a manufacturer that it must provide the PBM's specialty pharmacy access, lest the manufacturer's product not be included on the PBM's formulary. The PBM could "exclude" the independent specialty pharmacy from the network that has been granted access to the exclusive distribution drug by the manufacturer. The power to exclude pharmacies is the power for PBMs to grow to the largest specialty pharmacies. CVS Health/Caremark dominates the specialty industry with 28 percent market share. Cigna/Express Script's specialty pharmacy controls another 21 percent. UnitedHealthcare/Optum's special pharmacy controls 13 percent. Just these three PBMs affiliated specialty pharmacies control 64 percent of all specialty prescriptions.[9] Because they are the largest pharmacies, they are also the largest purchasers of drugs. Armed with formulary power on the PBM side and market share on the pharmacy side, PBMs insist that manufacturers and distributors give preferential drug acquisition cost pricing to the PBMs' affiliate pharmacies. Manufacturers and distributors earn very low margins selling to the PBM owned pharmacies. Manufacturers and distributors must unfortunately make up for that low margin by selling to independent pharmacies at elevated margins. Higher acquisition cost for independents contributes substantially to the inability of independents to survive. The FTC or Senate must investigate these PBM tying arrangements. All manufacturers and distributors are afraid to come forward because of retaliation with formulary treatment.

QUESTIONS SUBMITTED BY HON. MIKE CRAPO

DELINKING COMPENSATION FROM DRUG PRICES

Question. A growing body of research suggests that compensation and contracting structures across the prescription drug supply chain may risk incentivizing higher list prices for medications by tying stakeholder payments to products' list prices or to list-price-derived benchmarks. In its March 2023 report to Congress, for instance, the Medicare Payment Advisory Commission (MedPAC) contends that "[a]ll levels of the drug supply chain include incentives that drive [point-of-sale] prices higher, particularly when payments are based on a percentage of prices."[10]

The potential for these types of incentives has driven some experts and supply-chain participants to propose eliminating the use of drug prices in establishing payment rates and amounts for PBMs and other stakeholders. A coalition of Idaho-based providers, patient advocates, and job creators, for instance, recently wrote in support of Federal policies aimed at "delinking PBM compensation from the list price of individual medications."[11]

How would Federal policies delinking compensation for pharmacy benefit managers (PBMs) and plan sponsors from drug prices in the context of Medicare Part D affect incentives within the retail prescription drug supply chain, and how would this type of change likely impact beneficiary costs and taxpayer spending?

Answer. When a PBM's compensation, and a plan sponsors financial modeling, is tied to a percentage of drug costs, it has the effect of incentivizing PBMs to push for higher list prices of drugs. A PBM that takes a 15 percent rebate earns more money on a $1,000 drug than a $100 drug. A PBM that charges a 5-percent DIR fee profits more from a $1,000 drug than a $100 drug. A plan sponsor saves money (and actually can earn money) when patients have to pay full costs of a high-priced

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[9] Adam Fein, Drug Channels, DCI's Top 15 Specialty Pharmacies of 2022: Five Key Trends About Today's Marketplace, *https://www.drugchannels.net/2022/05/dcis-top-15-specialty-pharmacies-of.html*.

[10] *See* p. 400, *https://www.medpac.gov/document/march-2023-report-to-the-congress-medicare-payment-policy/*.

[11] *See* Endnotes for a copy of the letter.

drug during the deductible phase, while the plan sponsor retains a large rebate from the manufacturer. There are many different fees that PBMs and their affiliates charge that are tied to the list price of a drug, including: rebates, GPO fees, transaction fees, DIR fees, spread pricing, contract pharmacy dispensing fees, 340B third party administration fees, and mail order pharmacy reimbursement amounts. Policies that directed PBMs and plan sponsors to delink their reimbursement from drug prices could serve to remove the incentive to push for higher list prices. It could mean that PBMs and plans pursue drugs for formulary inclusion based on effectiveness, appropriateness, and overall cost, not based on what they stand to make off the drug. This would also reduce incentives for PBMs and plans to raise the list price, which informs the amount that patients have to pay in coinsurance and deductible and allow patients to better share in the lower net price of the drug.

It is important to note that delinking PBM and plan sponsor reimbursement from drug prices would become far less of a problem if some basic changes are made limiting the amount of PBM retained rebates, reducing the amount of PBM retained spread pricing, and limiting the means and manner of how PBMs could extract fees from drug manufacturers. Importantly, PBMs currently seek to rely on the Discount Safe Harbor to the Federal Anti-Kickback Statute to justify their receipt and retention of rebates. Reconfiguring the Discount Safe Harbor to place limitations on how PBMs can obtain and keep rebates and other payments, other than amounts paid for the fair market value ("FMV") of commercially reasonable administrative services performed by the PBM on behalf of the manufacturer in a manner that does not take into consideration the volume or value of drugs bought and sold via the PBM relationship, would likely have a direct and immediate impact on the cost of drugs.

Question. Apart from PBM payments and services, where else in the supply chain do compensation structures rely on drug pricing benchmarks, and how should policymakers consider addressing these dynamics?

Answer. While PBMs and affiliates stand to profit most from the high list price of drugs—siphoning off as much as 60 percent or more of the cost of drug in certain circumstances—other stakeholders are also compensated based on the price of drugs, and impacts to these stakeholders must be considered in structuring any policy reform. For example, independent pharmacy providers are often compensated based on the list price of a drug in that they are paid "Average Wholesale Price" minus a contracted percentage (*e.g.,* AWP – 18 percent). If list prices are reduced overall without a modification to what is paid to providers, it could drastically reduce what pharmacy providers are able to take home (*i.e.,* a 3-percent margin on a $100 drug results in far lower gross revenue than the same margin on a $1,000 drug). Likewise, there is great variance in the acquisition cost of drugs across different provider types. A large chain pharmacy will certainly acquire drugs at a lower price than a smaller independent provider. Further, different providers have different operating cost structures (for example, a specialty pharmacy may require significantly more overhead than a community retail pharmacy). If there is no mechanism to account for these different costs and pricing structures, such a policy change could result in additional harm to independent providers. Finally, such policy changes must also take note of differences in specific drug products. While a reimbursement of actual acquisition cost plus a fixed fee dispensing fee might work for a low-cost generic maintenance medication, the same principle might not work for a high cost, complex hemophilia medication, requiring home delivery and administration. These concerns must be contemplated in any move towards a model that delinks pharmacy reimbursement from drug costs.

TRANSPARENCY MEASURES

Question. The shortage of meaningful transparency across the prescription drug supply chain emerged as a key theme throughout the March 30th hearing. Most hearing attendees signaled that patients, policymakers, providers, plans, and researchers require additional information and data points in order to inform decision-making and reduce costs.

With respect to Medicare Part D, what additional information could PBMs and their subsidiary organizations supply to plan sponsors in order to enhance competition and drive down consumer costs without compromising credibly proprietary trade secrets?

Answer. Plan sponsors must be given statutory rights to audit PBMs and their subsidiary GPOs or "rebate aggregators." Part D plans need to know the total amount that the PBM or aggregator "retains." Rebate aggregators are PBM subcon-

tracted (and affiliated) entities that serve as intermediaries between a PBM, pharmaceutical manufacturer and plan sponsor. The aggregator negotiates and collects rebates and other manufacturer derived revenue. PBMs must be compelled to disclose to Part D Plans all rebates and other manufacturer revenue, including, for example, administrative fees and data fees, their rebate aggregators have received on their behalf, regardless of whether they have been retained or passed on to the Part D Plan. Of note, the annual DIR Reports submitted by plan sponsors to CMS contemplate PBM disclosure of both rebates and fees [12] retained by PBMs. However, the DIR Reports fall short of requiring disclosure of rebates retained by rebate aggregators and do not mention other types of fees that manufacturers remit to PBMs and rebate aggregators (*e.g.,* data fees, price protection fees, access fees, etc.). These forms of manufacturer derived revenue should not qualify as trade secrets, which would allow PBMs to avoid disclosure. All manufacturer derived revenue other than reasonable manufacturer administrative fees should be provided to the Plan Sponsors.

Question. What additional information could policymakers direct plan sponsors, PBMs, and other supply-chain participants to supply to beneficiaries in order to improve consumer choice and access?

Answer. Unlike nearly every other market, where a consumer can easily compare the costs of one product against a competitor, patients seeking to make informed decisions regarding their health care (and how they will pay for it) are largely unable to discern the true costs of their health care. PBMs, as middlemen, have access to information that would enhance competition and improve consumer choice. Yet, they keep this information largely hidden from the public eye and scrutiny.

It is recommended that PBMs be required to report to both manufacturers and plans all "retained rebates" by the PBM (or its affiliated or contracted rebate aggregator). Policymakers should mandate that PBMs disclose instances where beneficiaries are pushed to high cost, highly rebated brand medications rather than generic alternatives to plan sponsors and beneficiaries. PBMs use copay tiering, formulary exclusion and rebates to push highly rebated drugs to the exclusions of cheaper, generic alternatives, often increasing the cost to both beneficiaries and the Plan. Likewise, PBMs should be mandated to provide an expansive network of specialty and mail-order pharmacies. PBMs should not be able to "market" to Medicare or Medicaid beneficiaries suggesting the beneficiary should switch pharmacies. HIPAA should be clarified to prevent communication from PDPs or PBMs to Medicare/Medicaid beneficiaries that are truly "marketing" the PBM's affiliate pharmacy. Regularly, PBMs require beneficiaries utilize PBM-affiliated mail-order and/or specialty pharmacies, regardless of cost or the best interest of the patient. PBMs should disclose to plan sponsors the rebate and spread pricing profits the PBM and its affiliated pharmacy earn by servicing the plan's beneficiaries, compared to an independent pharmacy. Differential pricing (described above) should be banned. Plan sponsors need accurate data to determine whether utilizing PBM-affiliated pharmacies is cost effective and in the best interest of beneficiaries, compared to independent pharmacies. We further recommend that policymakers mandate that PBMs submit a report of all pharmacies that have been denied access into the PBMs' mail-order or specialty pharmacy networks, on an annual basis.

PHARMACY ACCESS

Question. In your written testimony, you noted that statutory and regulatory "any willing pharmacy" requirements have created ambiguities and challenges, particularly for community pharmacies. How, specifically, should Congress and/or relevant Federal agencies clarify or otherwise update "any willing pharmacy" standards to ensure beneficiary access and meaningful market competition?

Answer. As was mentioned in response to a question posed by Senator Wyden, we believe there are several steps that can be taken by Congress and/or the appropriate Federal agencies to clarify and update "any willing pharmacy" standards under Medicare. Such steps would achieve the laudable goals of (1) ensuring beneficiary access, and (2) allowing for and increasing "healthy" market competition. As a threshold recommendation, Medicare's Any Willing Provider Law ("AWPL"), which is codified at 42 U.S.C. § 1395w–104, should be amended to expressly apply to PBMs—it currently expressly applies to PDPs. This change will preclude PBMs from taking the position that the AWPL does not apply to PBMs, a common argument. We also recommend amending the AWPL to require PBMs to admit all qualified

[12] These fees are either reported as DIR or fees that are in excess of bona fide service fees.

pharmacy providers and to expressly state that the AWPL requires patients to be permitted the option of using the pharmacy provider of their choice regardless of whether that provider is a PBM affiliated provider. This modification is without cost to the government because such a requirement is already codified in 42 U.S.C. § 1395a. We further recommend that Congress amend the AWPL to include mandatory "reasonable and relevant" terms and conditions and to provide a framework for determining reasonable reimbursement for Medicare pharmacy providers. We recommend that a framework include:

- Amending Medicare Part D laws, including Medicare's Any Willing Provider Law ("AWPL"), codified at 42 U.S.C. § 1395w–104, to expressly extend such requirements directly to PBMs.
- Prohibit reimbursement to pharmacy providers below their drug acquisition cost. If a PBM reimburses a pharmacy provider below its acquisition cost, documentation provided by the pharmacy provider showing that reimbursement was below acquisition cost shall result in a presumption that the reimbursement was unreasonable. This is already set forth to a degree within the Part D Manual and would be largely codifying and strengthening existing Medicare guidance.
- Reimbursement at or above cost shall be considered but one factor in determining if reimbursement was reasonable.
- PBMs cannot meet the obligations of the AWPL by merely maintaining a network with "convenient access" to retail pharmacies. This ensures the PBMs cannot point to the fact that their wholly-owned pharmacies have agreed to participate as evidence that terms and conditions are reasonable and relevant.
- Expand the scope of the application of the AWPL to other health-care providers and not limited to licensed pharmacies.
- Requirement of a mandatory reasonable dispensing fee reflective of the value the health-care provider added in dispensing the medication with prohibitions on "$0.00" dispensing fees. These dispensing fees must take into account the type of medication (a dispensing fee for a straightforward maintenance medication should not be the same as the dispensing fee for a high-touch, complex specialty medication), as well as the type of provider (the cost structure for a dual-accredited specialty pharmacy will not be the same for a PBM-owned chain retail pharmacy).
- To the extent any performance metrics are implemented by PBMs that impact reimbursement, such performance metrics must be "reasonable and relevant" as applied to a particular pharmacy provider to ensure (1) that pharmacy providers' performance is being measured on a level playing field, *e.g.,* not measuring specialty pharmacies or community oncology providers' performances against retail pharmacies' performance; not measuring independent pharmacy performance against large chain pharmacies; and (2) performance metrics should be clearly reported at the claim level and cannot favor the PBM corporately affiliated pharmacies.
- Require PBM contracts to include a practical mechanism for pharmacy providers to resolve disputes regarding: (1) unreasonable reimbursement, and (2) the reasonableness and relevance of PBM terms and conditions. Requirements should include (i) mandatory minimum timeline for PBMs to respond, and (ii) prohibitions on retaliation, including network exclusion for such challenges. This again codifies and strengthens existing regulatory and subregulatory guidance from CMS indicating that disputes around reasonableness and relevance are fact sensitive inquiries best left to be resolved by the parties.
- PBMs shall not reimburse corporately affiliated pharmacy operations in a more beneficial manner as compared to non-owned and/or affiliated pharmacy operations, which shall include, but not necessarily be limited to, prohibiting reimbursing an owned and/or affiliated pharmacy operation more than non-owned and/or affiliated pharmacy operations.
- CMS enforcement mechanism that includes right of pharmacy providers to report PBM non-compliance with these obligations to CMS for further investigation with provider protections from adverse action or retaliation by PBMs for such reporting. Enforcement mechanisms should include the right for CMS to impose monetary penalties for noncompliance.
- Prohibit any retaliation by a prescription drug plan or any entity acting on behalf of a prescription drug plan against health-care providers challenging whether the terms and conditions are reasonable or relevant, including by prohibiting health-care providers from participating in prescription drug plan

networks when raising challenges to the reasonableness and relevance of terms and conditions.

Question. What other steps should Congress consider taking to mitigate the risk of patient steering or other alleged practices that undermine competition?

Answer. To mitigate the risk of patient steering and other PBM practices that undermine competition, Congress can enact legislation banning PBM patient steering. In fact, several States have enacted such legislation which provides a good template for legislation on the issue of patient steering. One such example is Georgia. Specifically, Georgia's anti-steering law, Ga. Code Ann. § 26–4–119, prohibits pharmacies from presenting claims for reimbursement that were received pursuant to a referral from an affiliated PBM, and Ga. Code Ann. § 33–64–11 prevents PBMs from forcing patients to get their prescriptions filled at a PBM-affiliated pharmacy including specialty pharmacies, with a limited exception regarding certain limited distribution drugs. Although pharmacies can often bring a claim against a PBM based on compliance with laws contractual provisions, some PBMs have been successful in defeating these kinds of claims.[13]

As with any legislation governing PBMs, pharmacies would need a way to enforce such laws, either through a private right of action, or a direct complaint process to the agency responsible for enforcing the law (or both) which would require the agency to investigate complaints. Such a process would also include a reasonable deadline for a final decision, and a right of judicial review for aggrieved parties. At the same time, Congress should require PBM contracts with pharmacy providers to include a practical mechanism for pharmacy providers to resolve disputes regarding: (1) unreasonable reimbursement, and (2) the reasonableness and relevance of PBM terms and conditions. This is a codification and strengthening of existing CMS regulations and sub-regulatory guidance.

Additionally, Congress can enact a ban on the use of patient information to engage in trolling and hijacking activity, like that conduct at issue in the *Trone Health Services v. Express Scripts* matter that the Eighth Circuit failed to find gave rise to a cause of action.[14] Congress can and should create a prohibition on PBMs requiring patient information that is not necessary to adjudicate claims, because this is the information that PBMs use to troll and hijack patients to force them into the PBMs' own specialty pharmacies. Additionally, the Health Insurance Portability and Accountability Act ("HIPAA") should be clarified to prevent communication from PDPs or PBMs to Medicare/Medicaid beneficiaries that are truly "marketing" the PBMs' affiliate pharmacies.

With respect to the greater overall problem of PBM market dominance that itself undermines competition, Congress should consider strong antitrust legislation that prevents the kind of consolidation causing these issues, and legislation that mitigates the oversized market power currently recognized by PBMs, such as legislation guaranteeing reasonable reimbursement for pharmacies, and creating causes of action for pharmacies that suffer these kinds of abuses.

Question. Innovative contracting mechanisms can drive better value for consumers and taxpayers. That said, performance-based contracts should assess providers on meaningful metrics aligned with both clinical and cost considerations. How, specifically, could Federal policymakers provide sufficient flexibility for performance-based contracting between PBMs and pharmacies while increasing clarity and cohesion?

Answer. To the extent any performance metrics are implemented by PBMs that impact reimbursement, such performance metrics must be reasonable and relevant as applied to a particular provider to ensure (1) providers' performance is being measured on a level playing field, (*e.g.,* not measuring specialty pharmacies or community oncology providers' performances against retail pharmacies' performance; not measuring independent pharmacy performance against large chain pharmacies); (2) performance metrics should be clearly reported at the claim level and cannot favor the PBM associated pharmacies; and (3) providers are not penalized financially for medical decision making that is in a patient's best interest and, in many cases medically necessary.

As noted above, Federal policymakers should require PBM contracts to include a practical mechanism for providers to resolve disputes regarding (1) unreasonable reimbursement, and (2) the reasonableness and relevance of PBM terms and condi-

[13] *See, e.g., United/Xcel-RX, LLC v. Express Scripts, Inc.,* 2019 WL 5536806, at *4 (E.D. Mo. Oct. 25, 2019).

[14] *Trone Health Services, Inc. v. Express Scripts Holding Company,* 974 F.3d 845 (2020).

tions. Requirements should include (i) mandatory minimum timeline for PBMs to respond; (ii) an ability for providers to resolve disputes in a court of competent jurisdiction; (iii) an ability for providers with common disputes to resolve disputes with PBMs on a consolidated basis; and (iv) prohibitions on retaliation for such disputes, such as network exclusion or punitive reduction of reimbursement.

PBMs must not be permitted to reimburse wholly owned and/or affiliated pharmacy operations in a more beneficial manner as compared to non-owned and/or affiliated pharmacy operations which shall include, but not necessarily be limited to, prohibiting reimbursing an owned and/or affiliated pharmacy operation more than non-owned and/or affiliated pharmacy operations.

Congress should provide CMS with enforcement mechanisms that include a right of providers to report PBM non-compliance with these obligations to CMS for further investigation with provider protections from adverse action or retaliation by PBMs for such reporting. Enforcement mechanisms should include the right for CMS to impose monetary penalties for noncompliance.

PBM-OWNED GROUP PURCHASING ORGANIZATIONS/REBATE AGGREGATORS

Question. Recent years have seen the emergence of a number of PBM-owned or affiliated group purchasing organizations (GPOs), often known as rebate aggregators, through which certain PBMs have reportedly outsourced some of their functions, including with respect to manufacturer negotiations. How do these organizations differ from traditional GPOs, what are their implications for the broader prescription drug supply chain (and for patients), and what additional information should policymakers seek to collect and/or monitor with respect to these entities?

Answer. Rebate aggregators owned by or affiliated with PBMs are not purchasing an item or service and do not share any meaningful similarities with traditional GPOs. Traditional GPOs were established to help recognize cost savings and efficiencies by aggregating purchasing volume. Rebate aggregators owned by PBMs, which are sometimes misleadingly referred to as GPOs, are aggregating claims to extract rebates from the manufacturers. Rebate aggregators do not meet the definition of GPO under the AKS GPO Safe Harbor, which specifically states, "[n]ote that for purposes of paragraph (j) of this section, the term *group purchasing organization* (GPO) means an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health-care programs, and who are neither wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity)." In many instances (if not all) instances, rebates and fees paid by manufacturers to the rebate aggregators are not visible to the plan sponsors/plans (unless the plans are PBM-owned/affiliated plans). The rebates and fees that are retained by the rebate aggregators contribute to ever increasing drug spend and patients' out-of-pocket expense.

It was reported that the gross-to-net bubble would exceed $200 billion in the calendar year 2021.[15] The term "gross-to-net bubble" refers to the dollar gap between gross sales of brand-name drugs at list prices and their sales at net prices after rebates and other reductions. In other words, the gross-to-net bubble is demonstrative of the rebates paid by manufacturers to PBMs in exchange of having their drugs on the PBM's drug formulary. However, it is clear that at least a portion, if not most of these rebates are retained at the PBM level, rather than passed through to the benefit of plans and patients.

The Securities and Exchange Commission should mandate that PBMs disclose in their SEC filings revenue and expense derived from rebate aggregators including the rebates and the rebates passed through to plans. The retained rebate should be considered profit, no matter how creatively the PBM defines the revenue. Also, policymakers can require PBMs and their rebate aggregators—regardless of whether they maintain headquarters in foreign countries—to report the same data to government agencies and plan sponsors. By way of example, the Consolidated Appropriations Act can be modified to impose prescription drug spend reporting obligations upon PBMs and rebate aggregators (the current version of the Act imposes reporting obligations upon the plans). Those reporting obligations should be a plan specific

[15] Drug Channels, Warped Incentives Update: The Gross-to-Net Bubble Exceeded $200 Billion in 2021, *https://www.drugchannels.net/2022/03/warped-incentives-update-gross-to-net.html#:~:text=March%2022%2C%202022-,Warped%20Incentives%20Update%3A%20The%20Gross%2Dto%2DNet%20Bubble%20Exceeded,after%20rebates%20and%20other%20reductions.*

and not on an aggregate basis. Similarly, the Employee Retirement Income Security Act of 1974 requires entities like PBMs to disclose the sources of all direct and indirect compensation that PBMs and their subcontractors (which would include rebate aggregators) will receive. However, this provision would be strengthened by explicitly requiring PBMs to disclose the precise amount of compensation rebate aggregators retain from manufacturers rather than an aggregated total amount of compensation. Such disclosure requirements should also be extended to brokers and/or consultants.

QUESTIONS SUBMITTED BY HON. MARIA CANTWELL

MARKET MANIPULATION

Question. The three largest PBMs control 80 percent of the total market share by adjusted claims. We know that market competition leads to lower prices and better quality outcomes for consumers, and the PBM market is no different. In addition to consolidating market share, PBMs have also been merging with other players in the drug distribution chain. Today, the four largest PBMs also own their own affiliate insurers and pharmacies, which creates an obvious conflict of interest. PBMs are responsible for developing and maintaining formularies for health insurers, while contracting with individual pharmacies to reimburse for drugs dispensed.

How are PBMs supposed to act in good faith when there is a clear financial incentive to, for example, include higher priced drugs in their formularies even though a cheaper generic is available, so that its affiliate insurers can charge a higher premium or coinsurance? The answer is, they don't.

With their massive market influence and vertically integrated structure, the big PBMs exert pressure on every part of the drug distribution chain. They can demand more rebates from manufacturers, exclude pharmacies from their networks if they don't fully comply with their one-sided terms, and require insurance companies to utilize step therapy or prior authorization. All of this means that the patient at the end receives inferior care, while also paying more.

I am very concerned about the situation where PBMs use anticompetitive tactics such as spread pricing to drive smaller independent pharmacies out of business. Then they buy the pharmacies to integrate them into their sprawling businesses.

I am working on a bill with Senator Grassley, the Pharmacy Benefit Manager Transparency Act, which would shine a light on bad PBM practices. Does my bill have adequate enforcement authority to address the anticompetitive practices PBMs use on pharmacies that I mentioned?

Answer. The Pharmacy Benefit Manager Transparency Act of 2023 would make material improvements to the transparency of the U.S. health-care system, including by eliminating the use of spread pricing and arbitrary, unfair, and deceptive fees and reimbursement reductions on providers. The bill provides the Federal Trade Commission and the States (through State Attorney Generals or other State officials) authority to enforce the provisions of the Act. The Act also provides for whistleblower protections for employees reporting violations of the Act to government officials. However, PBMs have demonstrated a record of refusing to comply with applicable laws or challenging the implementation of any law that negatively impacts them financially. As such, Congress should consider including private enforcement mechanisms into the statutory text of the Act. Reliance on the Federal Trade Commission and State officials is not enough, as in many cases the specific parties injured by PBM violations of the Act will be health-care providers who are at the forefront of providing care to patients. In addition, Congress should include anti-retaliation protections for providers who assert claims under the Act against PBMs, similar to the protections included in the current text of the bill offered to whistleblowers.

Question. Which other part of the drug distribution chain can this bill be used to address anticompetitive practices on?

Answer. The Pharmacy Benefits Transparency Act of 2023 addresses many of the significant anticompetitive practices used by PBMs including, but not limited to, arbitrary and unfair fees and clawbacks charged to unaffiliated pharmacies, complicated and opaque provider reimbursement methodologies, and formulary rebates. The Federal Trade Commission's PBM Inquiry seeks information related to these same anticompetitive practices. In addition, the Act could be used to address PBM

anticompetitive practices related to patient steering; a practice whereby PBMs directly or indirectly channel patients and prescription volume to PBM-affiliated pharmacies and away from unaffiliated pharmacies. These practices include, but are not limited to, requiring patients to use a particular mail-order pharmacy, exclusive provider networks, "preferred" provider networks that are only accessible by PBM-affiliated pharmacies, and discounts to patients offered only if they receive their prescription from a PBM-affiliated pharmacy. Note that due to the limited distribution model of the specialty drug distribution chain, certain exceptions might be necessary for limited distribution specialty drugs.

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. The Pharmacy Benefit Manager (PBM) Transparency Act (S. 127) requires transparency reporting by PBMs (or an affiliate, subsidiary, or agent of a PBM) to shine sunlight on prices and fees associated with prescription drugs. Why is transparency reporting by middlemen, such as PBMs, important to ensuring taxpayers and patients are getting the lowest drug price and associated fees possible?

Answer. Transparency reporting by PBMs is critical for patients to make fully informed decisions about all options truly available to them, not just the options available according to the patient's PBM. True transparency will facilitate a better understanding of the true and actual costs of patients' medications. Once a patient has such an understanding, they can select the provider of their choosing. The current lack of transparency in the PBM industry has led to hidden fees (such as DIR fees assessed on pharmacies and manufacturers but improperly excluded from Medicare Part D Bids), inflated drug prices, and conflicts of interest. PBMs negotiate drug prices with manufacturers, set reimbursement rates for pharmacies, and decide which drugs are covered under a plan's formulary, but hold no obligation to share this highly relevant information with the patients and public it impacts. In the absence of transparency, it is difficult for patients, providers, and plan sponsors to understand the factors that influence drug pricing and access to medications.

Question. The Prescription Pricing for the People Act (S. 113) and PBM Transparency Act (S. 127) require the Federal Trade Commission (FTC) to look into the vertical integration that is occurring in the pharmaceutical supply chain. Why is that important?

Answer. Requiring the FTC to look into vertical integration in the pharmaceutical supply chain is important because the FTC is the agency, next to the DOJ, best equipped to understand the anticompetitive effects of vertical integration. The FTC also is charged with enforcing section 5 of the FTC Act prohibiting Unfair Competition and is therefore the appropriate agency to enforce any violations. Using this enforcement power, the FTC should focus specifically on the unfair trade practices PBMs use to dominate the marketplace and further consolidate power to the exclusion of independent providers.

These unfair trade practices include, but are not limited to PBMs' power to control formularies for plans, thereby channeling lucrative rebates to themselves and affiliated plans; controlling network access for independent pharmacies that the PBMs compete with through their affiliate pharmacies; controlling benefit design to their own advantage; profiting from "no-bid" contracts from affiliate plans; setting draconian and inefficient purchasing limits and restrictions on who network providers may source drugs from; and engaging in "differential" pricing that advantages their affiliated pharmacies over competitors. All of these unfair trade practices and more can be investigated, and the FTC can use its section 5 authority to regulate against such practices.

Question. How does vertical integration impact the prices patients and taxpayers pay for prescription drugs?

Answer. Evidence suggests market consolidation, including vertical integration, has contributed to rising costs and lower-quality care.[16] Vertical integration affects the prices patients and taxpayers pay for drugs in multiple ways. When vertically integrated payers use their market leverage to demand higher rebates from manufacturers, distortions occur. Manufactures that do not comply with the PBM's rebate demands will see their drugs have higher copay, prior authorization, step edits or

[16] Purchaser Business Group on Health, Vertical Integration Isn't Great for Health Care Consumers or Purchasers, August 23, 2021, *https://www.pbgh.org/despite-claims-vertical-integration-isnt-great-for-health-care-consumers-or-purchasers/*.

claims denials. More efficacious, less toxic, and cheaper drugs are often disincentivized by PBMs in exchange for more highly rebated drugs. This results in other less rebated drugs—including generic and biosimilar drugs—being placed on lower formulary tiers, or having higher copay, step edit, prior authorization or being entirely excluded.[17] Drugs with a lower list price are excluded from formulary because the PBM receives a higher rebate from a more expensive drug. This costs patients and taxpayers more when their coinsurance is based on the list price, or when patients with a high-deductible plan must pay out of pocket for drugs at list price. In the context of Medicare Part D, higher list prices for covered prescription drugs pushes beneficiaries through the Part D benefit phases quicker, and into the Part D "donut hole" and catastrophic coverage phases, where patients, taxpayers and drug manufacturers pick up large portions of the tab, while the plan sponsors pay less.

Question. Do spread pricing and clawbacks performed by PBMs (or an affiliate, subsidiary, or agent of a PBM) impact the prices patients and taxpayers pay for prescription drugs? If so, how? Additionally, how do spread pricing and clawback practices differ within the commercial insurance market compared to within the Medicaid/Medicare programs?

Answer. Yes, both spread pricing and clawbacks harm patients and taxpayers by raising prices at the point of sale "pharmacy counter." Spread pricing increases premiums and drug prices for patients.[18] Because spread pricing creates a perverse incentive for PBMs to set an overall higher price for drugs, including generic drugs (from which patients normally expect to see the highest savings), patients face higher prices than they would if the PBM was not incentivized to raise prices in this manner.[19]

Clawbacks, including DIR fees and "effective rates" (Generic Effective Rates, or GER, and Brand Effective Rates, or BER), also harm patients through raising their out-of-pocket costs in multiple ways. With DIR, recall that the price reported to CMS as the "negotiated price" at the point of sale does not include the DIR fees. Therefore, the patient pays coinsurance (which is a percentage of the list price) based on the higher list price, which is later reduced by DIR after the patient paid their coinsurance. If the patient paid coinsurance on the lower, post-DIR price, the patient would have a lower coinsurance. DIR fees would otherwise lower the negotiated price if applied at the point of sale—but from 2016 through 2023, PBMs were able to profit from DIR. This means patients—especially vulnerable patients with the most serious disease states—pay a higher out-of-pocket coinsurance based on the artificially inflated prices paid at the point of sale, created by the DIR. This harms the patient, but also harms taxpayers, because it forces the patient into the "donut hole" and catastrophic coverage more quickly, where the government bears a higher price burden and PBMs bear a lower burden.[20]

Effective rates also harm patients in the same way DIR fees do—by raising the gross price of medications and forcing patients to pay higher out-of-pocket fees at the point of sale before the effective rate is clawed back from the PBM.[21] Unlike DIR fees, which apply only to Part D, effective rates affect commercial patients as well as Medicare beneficiaries.

Question. Does the current consolidated PBM market hurt or help community pharmacies who serve rural or underserved areas? When a community pharmacy closes or a patient cannot access a community pharmacy due to being out of network, how does this impact patient access?

Answer. The current PBM market hurts community providers in rural areas. PBMs' excessive market power results in low reimbursement that often does not cover the cost of goods.[22] Such low reimbursement from PBMs means that these pharmacies cannot sustain their business. Additionally, rural pharmacies are disproportionately affected by MAC pricing, because these pharmacies typically do not have access to the products receiving lower MAC pricing, causing underwater reim-

[17] Frier Levitt, PBM Exposé at 12.
[18] Frier Levitt, PBM Exposé at 60.
[19] *Id.*
[20] Frier Levitt, PBM Exposé at 25.
[21] Frier Levitt, PBM Exposé at 76.
[22] Frier Levitt, PBM Exposé at 47.

bursement for the pharmacies.[23] This results in rural pharmacies being forced to close.[24]

Additionally, even urban pharmacies can represent underserved communities. One such pharmacy—Mission Wellness, based in San Francisco—is a minority- and woman-owned pharmacy serving a population of underprivileged, often unhoused persons suffering from HIV/AIDS and hepatitis. In 2019, Mission Wellness brought an arbitration against Caremark because the underwater rates caused by Caremark's DIR program was putting the pharmacy out of business. Mission Wellness eventually won an award of its full damages and attorneys' fees against Caremark, but Caremark has moved to vacate that award (as is typical for Caremark when it loses in arbitration), thus prolonging Mission Wellness's wait for the infusion of money it desperately needs to remain afloat. All this information is available—including the arbitration award—on the public docket in the Federal action to confirm (and Caremark's cross-motion to vacate) the arbitration award. The case and related proceedings can be found at *Mission Wellness Pharmacy LLC v. Caremark LLC et al.,* No. CV–22–00967–PHX–GMS (Dist. Ariz.).

When a community pharmacy closes or a patient cannot access the pharmacy, this negatively affects patient access. "[S]mall pharmacies often see the most vulnerable patients . . . [a]nd if small pharmacies are forced out of business, these patients will have to travel greater distances to get the medications they need[.]"[25]

Question. Since 2017, 23 States have passed various forms of prescription drug transparency laws that require PBMs to report certain data (according to National Academy for State Health Policy). Do any of these States have effective PBM transparency laws that should be replicated at the Federal level? Why are they effective?

Answer. Although Senator Grassley's and Cantwell's PBM Transparency Bill is thorough and would provide much-needed PBM transparency in its present form, State transparency laws are particularly effective to the extent they give providers audit rights. For example, Indiana passed an act (2020 Ind. Legis. Serv. Pub. L. 68–2020 (S.E.A. 241)), effective July 1, 2020, which, among other things, prohibits PBMs from reimbursing PBM-affiliated pharmacies more than unaffiliated pharmacies, requires PBMs to disclose the amount of rebates they receive for drug products, and provides yearly audit rights for all parties contracting with a PBM to view the rates at which any other pharmacy in the network is being reimbursed and the amount of rebates a PBM has received for drug products. This provides for some direct transparency to independent pharmacies and plans, allowing each to independently determine whether the PBM is complying with the law. This level of transparency at the Federal level would greatly strengthen transparency for both providers and plans.

Question. Beginning in 2016, the Texas Department of Insurance began public reporting on the use of manufacturers' rebates and other payments to PBMs. Similarly, beginning in 2020, the Iowa Insurance Division began publicly reporting on the use of manufacturers' rebates and other payments to PBMs. Other States have conducted similar public reporting. According to an analysis of the Texas data *(https://www.tdi.texas.gov/reports/report3.html),* PBMs retained 7 percent to 21 percent of manufacturers' rebate and other payments between 2016–2021. Similar data has been reported in Iowa *(https://iid.iowa.gov/pbm-annual-reports).* Is this public reporting accurately capturing the amount of rebates and other payments retained by PBMs (or an affiliate, subsidiary, or agent of a PBM)? If not, how might policy makers accurately capture the amount of revenue retained by PBMs (or an affiliate, subsidiary, or agent of a PBM)?

Answer. The public reporting does not always fully or accurately capture the amount of rebates and other payments retained by PBMs and rebate aggregators. For example, the Texas Insurance Code section 1369.502 requires PBMs to file a report with the Texas Insurance Commissioner concerning rebates, fees, and other payments received by a PBM. However, the statute only requires PBMs to submit, among other things, the aggregated rebates, fees, price protection payments, and any other payments collected from pharmaceutical drug manufacturers to PBMs.[26] Thus, portions of manufacturer revenue retained by PBM affiliates, subsidiaries, or agents are not captured by the mandatory reports. States should require plan spe-

[23] *See, e.g., PCMA v. Rutledge,* 240 F.Supp.3d 951, 960 (E.D. Ark. 2017).
[24] *Id.*
[25] Eugene A. DePasquale, Bringing Transparency and Accountability to Drug Pricing (December 11, 2018), *https://www.paauditor.gov/Media/Default/Reports/RPT_PBMs_FINAL.pdf.*
[26] *See* Tx. Ins. Code § 1369.502.

cific, NDC-level reporting of rebates and fees paid by manufacturers to PBMs and PBMs' rebate aggregators.

Question. Why do PBMs own or operate affiliated organization such as group purchasing organizations or rebate aggregators? What do these entities do?

Answer. PBMs created rebate aggregators as another level of opacity and possibly to avoid mandatory statutory reporting that expressly applies to PBMs, but has not "caught up to" the creation of rebate aggregators. See above for the problem as it relates to Medicare reporting of retained rebates. PBM contracts with plan sponsors are carefully drafted by PBMs. PBMs contractually promise to turn over to the plan sponsor all "rebates" *that the "PBM receives."* PBM contracts conceal that the PBM has subcontracted to its affiliate company—the rebate aggregator—the task of actually receiving the rebate from the manufacturer. PBMs do not reveal to the plan sponsor the amount of rebate retained by the aggregator.

The advent of the rebate aggregator may also be connected to a desire by PBMs to avoid the reach of United States laws. Two of the major rebate aggregators are based in foreign countries. (Express Scripts/Ascent Health Services in Switzerland; OptumRx/Emisar Pharma Services in Ireland).

It is also worth noting that, in the Ohio Attorney General's complaint recently filed against Ascent Health Services, among others, the Attorney General alleges that Express Scripts and Prime created Ascent Health Services to "use it as a vehicle to share pricing, to the detriment of other market participants, including individual purchasers of medications like insulin." Indeed, PBMs often utilize affiliated rebate aggregators as a means to keep certain manufacturer derived revenue, including, but not limited to rebates, hidden from their plan sponsor clients to preserve the illusion that plan sponsors are receiving 100 percent of rebates paid by manufacturers. Regularly, PBM-affiliated rebate aggregators retain a portion of rebates paid by manufacturers, but PBMs keep the rebate aggregator-retained portion hidden from plan sponsors. This occurs with respect to Medicare Part D plans as equally as it does in commercial contexts.

Question. In 2013, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) published a report (titled, "Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions") recommending that each Medicare Part D plan's Pharmacy and Therapeutics Committee (P&T) have members who are free of conflict from PBMs. HHS OIG specifically recommended that a Medicare Part D plan's P&T committee should be free of conflict with any PBM that manages the plan's prescription drug benefit. Since this recommendation was issued in 2013, CMS updated some conflict of interest policies, but not this recommendation. Should CMS require some (or all) P&T committee members be free of conflict with any PBM?

Answer. Yes. CMS should require Medicare Part D Plan P&T committee members to be free of conflict with any PBM. P&T committee are primarily responsible for making formulary decisions, significantly affecting beneficiary access to specific prescription drugs. PBMs use formulary exclusion and rebates to push highly rebated drugs to the exclusions of cheaper, generic alternatives, often increasing the cost to both beneficiaries and the Plan. This preference for high-cost brand drugs stems from consistently increasing drug rebates from manufacturers, which PBMs typically only earn on branded drugs. Thus, because of the perverse incentives for PBMs to select expensive branded medications over cheaper alternatives, CMS should require that Medicare Part D P&T committee members—who are directly responsible for the selection of which branded and generic medications will be covered on the formulary—be free of any conflict with any PBM.

QUESTIONS SUBMITTED BY HON. TIM SCOTT

Question. I have heard concerns from Federally Qualified Health Centers in my State that some PBMs may be intentionally reimbursing 340B pharmacies at lower rates than non-340B pharmacies for prescription drugs simply because these health centers receive a 340B discount. Is this the case and, if so, why is that and how common is this practice?

Answer. The 340B program's purpose is "to enable covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and pro-

viding more comprehensive services."[27] It is fundamental to 340B that Covered Entities, which include Federally Qualified Health Centers, are credited for their ability to "provide direct clinical care to large numbers of uninsured Americans" regardless of the patient's ability to pay.[28] The Health Resources and Services Administration ("HRSA"), the agency charged with administering 340B, has opined that 340B is designed so that Covered Entities would "pass all or significant part of the discount to their patients."[29] Thus, the clear purpose of 340B is that uninsured, poor, and otherwise vulnerable patients would benefit by receiving discounted drugs or charity care.

PBMs, however, have warped the incentives of the 340B program by intentionally reimbursing 340B pharmacies at rates lower than the PBM's reimbursement rates for non-340B claims. Relatedly, many PBMs also require 340B pharmacies to identify which claims are 340B at the time of claim adjudication, to enable the PBM to apply the reduced 340B reimbursement rate. These practices are common across many of the Nation's largest PBMs.

For example, the PBM OptumRx's 2023 Provider Manual, which is a publicly available document, explicitly States that OptumRx has the right to adjust its reimbursement rates for 340B pharmacies:

> To the extent Network Pharmacy Provider, during the term of any renewal term of the Agreement, is owned operated or contracted with an eligible 340B [Covered Entity] to purchase outpatient Drug Products from drug manufacturers or wholesalers at reduced prices for use by eligible members under the Public Health Service Act, section 340(B) program, Network Pharmacy Provider shall immediately provide [OptumRx] with written notice of such eligibility.
>
> The parties acknowledge/agree [OptumRx] shall be entitled to modify the rates, fees, as well as other reimbursements offered to Network Pharmacy Provider hereunder in accordance with the [Provider Manual] and/or Agreement to the extent Network Pharmacy Provider becomes eligible to purchase Drug Products under the Public Health Service Act, section 340(B) program. Failure of Network Pharmacy Provider to notify [OptumRx] of its 340(B) eligibility as stated above shall constitute a material breach of the Agreement.[30]

The OptumRx Provider Manual is a quintessential contract of adhesion, offered to pharmacies on a take it or leave it basis, and with no opportunity to meaningfully negotiate. Similarly, the PBM Express Scripts Inc. issued notice in February 2021 requiring 340B pharmacies to retrospectively identify 340B claims. Thereafter, Express Scripts began to impose significantly lower reimbursement rates for 340B claims, essentially usurping the savings that should have flowed to Covered Entities, even when a PBM-owned or -affiliated pharmacy may not have been the Contract Pharmacy.

Contrary to the stated intent of the 340B program, reducing reimbursement to 340B pharmacies allows the *PBMs* to capture the prescription drug revenues intended to benefit the 340B Covered Entities and the poor, uninsured, and otherwise indigent patients they serve. In effect, PBMs are essentially transferring the benefit of the 340B program from safety net providers to for-profit payors. Notably, although many States have enacted legislation prohibiting PBMs from reducing 340B pharmacy reimbursement, there is currently no Federal analogue to prohibit these PBM practices. As such, these practices provide a particular area of concern that could be appropriately addressed through Federal legislation and rulemaking regarding the Federal 340B drug pricing program.

Question. Regarding dispensing, what barriers exist for patients seeking to purchase their preferred medication at their pharmacy of choice? What patient groups are most impacted?

Answer. There are several barriers that exist for patients. For example, patients are regularly steered away from their preferred provider and instead are pushed to PBM-owned pharmacies. Patients are also limited in their availability to seek care from their preferred providers when PBMs pay unreasonably low reimbursement to

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[27] H.R. Rep. No. 102–384, pt. 2 at 12 (1992).
[28] *See* H.R. Rep. No. 102–384, pt. 2, at 12 (September 22, 1992).
[29] HRSA, *Notice Regarding section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services,* 61 Fed. Reg. 43551 (August 23, 1996).
[30] *See* 2023 OptumRx Provider Manual, section V.U, 340(B) Program.

independent pharmacies. When a pharmacy cannot operate with a reasonable profit, patients may be referred over to PBM owned pharmacies even if this is not preferred.

Unfortunately, the most impacted patient groups are among the sickest members of society that require closely coordinated care utilizing specialty medications. This includes patients with cancer as well as those experiencing health conditions only treated by specialty medications that are often some of the costliest medications, which is typically indicative of the complex conditions they treat.

QUESTIONS SUBMITTED BY HON. JAMES LANKFORD

FINGER-POINTING

Question. In this industry, the blame for high drug prices is always on someone else:

- The pharmaceutical manufacturers blame PBMs for increasing their list prices through rebates.
- The PBMs blame the pharmaceutical industry for setting prices too high, the PSAOs for taking a cut of the rebate and not working appropriately on behalf of their pharmacy clients, and health plans for demanding certain access and pricing standards.
- PSAOs and pharmacies certainly blame both PBMs and health plans for setting low reimbursement rates, for decreasing patient access to certain drugs, and for clawing back DIR fees.
- Meanwhile, patients do not know who to blame and they likely do not care as long as prices remain high. Patients primarily want to be able to afford the drugs that their doctor prescribed to them and to be able access those drugs at the pharmacy of their choice.

When many of the players in the supply chain are making claims in direct opposition of one another, consumers are more confused and more frustrated. Which of the above arguments are true? Are they all partially true?

Answer. While all of the stakeholders mentioned in the above question owe sacred obligations to patients and taxpayers to ensure the costs of health care are reasonable, the three largest PBMs (which control 80 percent of the prescription drug marketplace) are owned by corporations which also own (a) health insurance plans; (b) retail and/or mail order pharmacy operations; (c) massive specialty pharmacy operations; (d) drug wholesalers; and (e) rebate aggregators. As one example, CVS Health, as a parent corporation, currently owns and operates the following entities: Aetna and SilverScript (health insurance plans); CVS Caremark (largest PBM); CVS Retail Pharmacy Operations (approximately 9,600 locations); CVS mail order pharmacy operations; CVS Specialty Pharmacy; and Zinc (rebate aggregator).

PBMs bear the brunt of responsibility for the high drug prices. PBMs are uniquely situated (and heretofore uniquely unchecked) to extract money from every other stakeholder in the chain of pharmacy operations or alternatively ensure that money that changes hands remains in one of the corporately affiliated entities' "pockets" identified above. PBMs benefit from high list prices set by pharmaceutical manufacturers because a drug with a high list price can afford higher rebates to secure favorable placement on drug formulary. PBMs leverage their control and influence over nearly every aspect of the prescription drug supply chain to force unfavorable pricing on pharmacies and PSAOs (the pharmacies' contracting agents). The companies that own PBMs also own a substantial portion of national insurance companies (benefiting from lower provider reimbursement), and even where PBMs and plan sponsors are separate entities, PBMs still benefit from high drug prices through spread pricing practices and by retaining outsized portions of drug manufacturer rebates though the use of rebate aggregators/GPOs. Ultimately, patients lose out because PBM revenue is used to enrich the largest US companies instead of decreasing drug prices at the pharmacy counter. PBMs further decrease patients' options to obtain care from independent providers and instead force patients to receive medications from their wholly owned pharmacy (often through mail order).

DIR FEES

Question. I have worked with my colleagues on and off this committee to end the abusive practice of DIR fee clawbacks for several years. I am very thankful that CMS took some level of action with their final rule last year, which goes into effect at the start of next year, requiring that pharmacy price concessions be moved to the

point of sale. However, CMS did not go as far as I would argue is necessary by not including all fees in a definition of "negotiated price," by not establishing standardized pharmacy performance metrics, and by not requiring PBM transparency.

Do you agree that the standardization of how pharmacies are treated by PBMs and transparency of a PBM's reimbursement to a pharmacy is a necessary final step in making the impact of the CMS DIR final rule truly impactful to patients and pharmacies?

Answer. Yes. CMS's actions to change the definition of "Negotiated Price" did not go far enough to curb PBM abuses. In fact, recent Part D network enrollment forms offered for 2024 include new kinds of fees being charged against pharmacies that may prove to violate the new definition of "negotiated price," though the customary lack of transparency from the PBM that created the new network makes it difficult to determine the legality of the program, short of litigation and discovery. The fact that PBMs have created a program they believe is justifiable under the new "negotiated price" definition that nevertheless continues to take additional fees from pharmacies above and beyond the point of sale reimbursement underscores the incomplete nature of the new definition and Rule.

Additionally, with respect to standardization—to the extent that PBMs should measure metrics in a manner that is standard and approved by reputable organizations that employ peer-reviewed and proven methods for performance measurement—yes, CMS should further require such standards. To the extent that these metrics are employed for all pharmacies, regardless of whether that pharmacy is a corner retail pharmacy or a sophisticated community oncology provider, we disagree that the same metrics should be applied to all. Retail metrics simply do not and cannot apply to specialty providers, and PBMs refuse to develop metrics that can apply to such providers. This appears to be the case going into 2024, as the new programs lack transparency, uniformity, and predictability, and treat specialty pharmacies as though they are retail.

Congress and CMS should take steps to ensure that current law clearly applies to PBMs, mandate additional transparency, prohibit PBM practices that provide preferential treatment to their own pharmacies—including differential pricing and steering—to the detriment of patients and independent providers, and requiring greater transparency across the board to prevent PBM abuses. Legislators and CMS should take steps to prohibit confidential arbitrations of disputes regarding Medicare Part D, explicitly allow a private right of action by those harmed by PBM actions, prohibit class action waivers and allow disputes to be heard in Federal courts to increase necessary transparency in the industry, among other recommended changes.

TIERING

Question. Currently, some plans have no real order to their formulary tiers—placement is simply based on who gave them the highest rebate—whether the product is a low-cost generic or a high-cost brand-name drug. When a branded drug is rebated so heavily that it is placed on a more favorable tier than a generic, patients not only lose out on a lower-cost drug and often end up paying more in coinsurance, but the market for generics is deteriorated.

The government has worked on policies and the pharmaceutical market has put in years of work to incentivize the creation of more accessible and affordable generic and biosimilar products. However, the current system is sending a message to generic manufacturers—that no matter how cheap you sell a drug for, you will still lose out to branded drugs and patients will lose out on access to low-cost drugs because an artificially lower price through rebates is more affective at reaching patients than an *actual* lower price because of PBM practices.

How would changes to the way plans and PBMs are structuring formularies open up possible savings to patients and what incentives may it provide for the increased production of lower-cost generic products?

Answer. The anticompetitive effects and downstream consequences faced by beneficiaries of Federal health plans caused by PBMs' manipulation of plan formularies to favor branded medications is well documented. As a result, although the Federal Government's policies have expanded the availability of generic drugs in the marketplace, patients are precluding from fully realizing the financial benefits of generic medications in part through PBM formularies that are profit oriented. These PBM formularies prioritize branded medications over the cheaper generic alternatives because these branded medications carry significant rebates with them, which the

PBMs are paid by the branded manufacturers in exchange for favorable formulary placement. PBMs keep a share of these rebates, increasing their bottom lines, and pass the remainder on to the plans they manage. Notably, generic medications, on the other hand, typically do not pay rebates to PBMs. As a result of this rebate structure, PBMs are incentivized against managing their formularies to obtain the most cost effective benefits for the plan and its beneficiaries.

Although this issue is complex and multifaceted, the following represent areas where, if material changes are made, the perverse incentives for the preference of expensive branded medications on PBM formularies can be alleviated:

1. Federal restrictions on the rebates PBMs may retain (directly or indirectly) from drug manufacturers would remove the financial incentive for PBMs to prefer branded medications over generics. These Federal restrictions could take the form of a minimum aggregate rebate amount that a PBM may retain from drug manufacturers, or a prohibition on the retention of rebates entirety. If PBMs are restricted by Federal law from retaining manufacturer rebates, there is less financial incentive for PBMs' preference of the costly branded drugs that carry these rebates.
2. Impose fiduciary requirements on PBMs to act in the best interests of the plan sponsors and their beneficiaries.
3. Federal legislation that sets standard and fixed methodologies through which PBMs can calculate and collect their fees. For example, and generally speaking, PBM contracts with plan sponsors often provide that the PBM's fees are calculated based on a percentage of drug cost. Thus, PBMs are further incentives to place higher cost medications on their formulary, and capture a higher fee from the plan.
4. Federal requirements that PBMs include at least one generic alternative at or above the same formulary tier as the branded drug analogues.
5. Promote transparency to shed light on the manufacturer rebates the PBM is receiving through use of pass-through contracting, which requires the amount charged to the PBM from the plan to be equal to amount paid to the provider, net any rebates.

PREPARED STATEMENT OF KAREN VAN NUYS, PH.D., SENIOR FELLOW, LEONARD D. SCHAEFFER CENTER FOR HEALTH POLICY AND ECONOMICS; AND EXECUTIVE DIRECTOR, VALUE OF LIFE SCIENCES INNOVATION PROGRAM, UNIVERSITY OF SOUTHERN CALIFORNIA

Key Points:

- PBMs play a central role in the economic system that distributes and pays for lifesaving drugs in the United States. Evidence indicates they leverage their position to extract profits in ways that are detrimental to patients, payers, and the drug innovation system more broadly.
- PBMs in some cases increase drug costs to patients and taxpayers; our study suggests Medicare pays 21 percent more for the most common generic drugs than they would if purchased at Costco.
- The rebate system by which PBMs negotiate with manufacturers to gain market access distorts incentives; indeed, it increases list prices for brand drugs, which can have significant adverse impact on patients.
- PBMs sometimes steer patients toward more expensive drugs; there are many examples of PBMs providing more favorable formulary placement to expensive brand drugs than to lower cost generics, presumably in exchange for larger rebates.
- Research on the economic rents earned by different sectors of the distribution system indicates PBMs and other intermediaries earn excess returns after adjusting for risk.
- Increased transparency could shed light on how widespread such practices are, and their overall impact on drug prices and spending. Greater transparency could also provide purchasers better information about the prices and alternatives they face, and help lower costs to patients and taxpayers.

Chairman Wyden, Ranking Member Crapo, and honorable members of the committee, thank you for the opportunity to testify today about the practices of pharmacy benefit managers (PBMs) and their impacts on patient costs and drug spending. My name is Karen Van Nuys, and I am an economist and senior fellow at the Leonard D. Schaeffer Center for Health Policy and Economics at the University of Southern California, where I also direct the Value of Life Sciences Innovation research program. The opinions I offer today are my own, and build on previous statements made to the Federal Trade Commission [1] and in other publications.

BACKGROUND

At the Schaeffer Center, my colleagues and I have been studying prescription drug markets for well over a decade, with particular emphasis on the economic system that distributes and pays for lifesaving drugs. That system includes several intermediaries or "middlemen," who each play a role in getting the physical product (the drugs) from the manufacturer to the patients who need them, and then managing the financial flows that ensure that everyone along the way is paid for playing their part in that system. The Schaeffer Center was among the first research institutions to highlight this complex market and quantify its role in drug prices, with one of our earliest studies [2] demonstrating that, out of $100 spent on retail pharmaceuticals in 2013, $41 went to distribution system intermediaries.

Pharmacy benefit managers (PBMs) play an important role in that system. They can, and often do, provide much-needed services to drug companies, insurers, employers and patients. PBMs sit in the middle of nearly all of the financial transactions in that drug delivery system, a position that provides them with extraordinary information access and leverage.

Their position has only solidified as PBMs have merged with other distribution system participants over the last decade, resulting in an industry that has become more vertically integrated. The top three PBMs are each part of a corporate structure [3] that also includes an insurer, specialty pharmacy, and health-care provider. Some include retail pharmacies as well. Those three companies ranked #4, #5 and #12 on Fortune's list [4] of the largest public companies in America last year. Using a different yardstick, the top three PBMs handle 80 percent of all U.S. prescription volume.[5]

While their size may make PBMs more formidable when negotiating with drug manufacturers and enable them to bring about lower drug prices, it can also position them to suppress competition, capture excess profits and raise drug costs. Which of these two possibilities prevails is ultimately an empirical question that much of our research seeks to answer.

Estimating pharmaceutical market money flows can be challenging, because much of the data on pharmaceutical prices is confidential, proprietary, masked, or otherwise opaque to outside researchers. Without transaction prices, it is difficult to conduct a broad, comprehensive analysis that could prove definitively whether PBMs are lowering drug costs. Instead, drug price researchers like myself must conduct studies using the incomplete data available to us to shine slivers of light into the dark corners of the system, and from these glimpses, assemble a kind of collage of the overall picture. I summarize some pieces of the picture here:

PBMS' IMPACT ON GENERIC DRUG COSTS

An analysis we published in *JAMA Internal Medicine* in 2021 [6] compared what Medicare paid for 184 of the most common generic drugs with what those same prescriptions would have cost cash-paying members at Costco. We found that Medicare could have saved $2.6 billion in 2018 on just those 184 drugs if they had been purchased without insurance at Costco. Somehow, involving the PBM and the health plan in the transaction increased drug costs by 21 percent.

PBMs use several commercial tactics that together may explain those higher costs. One is the copay clawback, in which PBMs collect a patient copay that ex-

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[1] *https://healthpolicy.usc.edu/article/comments-to-the-federal-trade-commission-on-pharmacy-benefit-managers/.*
[2] *https://healthpolicy.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system/.*
[3] *https://www.drugchannels.net/2022/12/drug-channels-news-roundup-december.html.*
[4] *https://fortune.com/ranking/fortune500/.*
[5] *https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html.*
[6] *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2781810.*

ceeds the total cost of the drug, keeping the excess. My colleagues and I used data from a short-lived Federal survey in 2013 (the national average retail price, or NARP) to compare patients' copayments with the reimbursement pharmacies collected to settle the claims. We found[7] that 23 percent of prescriptions incurred a copayment that exceeded the PBM's cost of the drug. When an overpayment occurred, it averaged $7.69 per claim, which went to the PBM. The practice was especially common on generic prescriptions, with 28 percent of generic scripts involving a clawback. Many of the most common generic prescriptions involved overpayments[8] on more than half of claims, including prednisone (50 percent), simvastatin (52 percent), amlodipine besylate (60 percent) and zolpidem tartrate (60 percent).

Federal legislation passed in 2018 banned the gag clauses that prevented pharmacists from telling clients when their copayment exceeded the cash price of their prescription. This has likely curbed some copay clawback activity, but the fact that Federal legislation was necessary to stop PBMs from blocking pharmacists who wanted to help patients save money is telling. PBMs frequently claim they are "on patients' side,"[9] but gag clauses, and the one in four prescriptions with a copay clawback, appear to favor PBMs rather than patients.

A second PBM tactic that raises drug costs is "spread pricing," in which the PBM pays the pharmacy one price to fill a prescription, then charges the health plan a higher price to settle the same claim, pocketing the difference. The Ohio State auditor found[10] that PBMs charged, on average, 31 percent spreads for generic drugs in that State's Medicaid managed care program between 2017 and 2018.

THE FLOW OF MONEY: PBMS IMPACT DRUGS' LIST PRICES

While PBMs may increase the cost of generic prescriptions, branded drugs account for most of drug expenditures,[11] making PBM impacts on prices in those markets especially important. To better understand how middlemen impact brand drug markets, my Schaeffer colleagues and I studied the money flows to distribution intermediaries[12] from insulin sales between 2014 and 2018. We found that insulin list prices rose 40 percent in 5 years while the average net price—what manufacturers received after all rebates, fees and discounts—decreased by 31 percent. At the same time, the total amount spent per 100mL of insulin barely changed, growing just 3 percent.

PBMs frequently tout the role they play in negotiating lower prices from drug manufacturers. Given that insulin manufacturers received lower net prices between 2014 and 2018, PBMs were clearly successful in negotiating steep price concessions. But they were evidently not passing those savings along to patients, since total insulin expenditures for consumers and taxpayers remained flat. Instead, intermediaries in the distribution chain, including PBMs, were capturing the savings: out of every $100 spent on insulin, intermediaries claimed $31.29 in 2014, climbing to $53.27—more than half—by 2018. PBMs' share alone grew 155 percent, from $5.64 in 2014 to $14.36 in 2018. Price discounts do not benefit patients or premium payers if they don't result in lower expenditures. Patients care about the total amount they spend per 100mL of insulin, not whether their money is going to manufacturers or to other entities in the distribution system.

Manufacturers do not determine list prices on their own. List prices are the result of a complicated dynamic that involves both PBMs and manufacturers. The 40-percent growth we observed in insulin list prices is the result of strong incentives for list price increases that are embedded in the current rebate system. Manufacturers compete with one another for preferred formulary placement on the basis of both list prices and rebates. PBMs consider manufacturers' offers, knowing that they will get the rebate, while the manufacturer will get (roughly) the list price minus the rebate (the net price). All other things equal, PBMs have a clear financial incentive to prefer larger rebates (either because they retain a share, or because their clients prefer higher passed-through rebates), so if insulin manufacturers want to stay on the formulary, they need to offer high rebates. This results in upward pressure on list prices: as PBMs seek higher rebates, manufacturers increase their list prices to

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[7] *https://jamanetwork.com/journals/jama/fullarticle/2674655.*
[8] *https://healthpolicy.usc.edu/research/overpaying-for-prescription-drugs/.*
[9] *https://onyourrxside.org/.*
[10] *https://ohioauditor.gov/auditsearch/Reports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.*
[11] *https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022.*
[12] *https://jamanetwork.com/journals/jama-health-forum/fullarticle/2785932.*

accommodate those rebates. PBMs may also collect administrative fees from manufacturers that are calculated as a percentage of list prices, strengthening their incentives to push for higher list prices.

Schaeffer researchers published a study in *JAMA Network Open* in 2021[13] that demonstrated the broader impact of these price negotiation dynamics. They find that the most competitive drug classes, those with both brand and generic competitors, feature the fastest growth in list prices, presumably because PBMs can negotiate most aggressively when there are multiple competitors to pit against one another. The ratio of list price to net price grew fastest for drugs in that class as well, from 2.7 in 2014 to 3.4 in 2018, compared with drugs with only branded competitors and those without any competition. In other words, as competition increases, manufacturers vie for preferred formulary placement by offering PBMs larger rebates, which creates upward pressure on list prices. This runs counter to conventional wisdom—we typically expect greater *downward* pressure on prices the more competitive the market. With drugs, we see greater *upward* pressure on list prices in more competitive markets.

REBATE-DRIVEN INCREASES IN LIST PRICES HURT PATIENTS

Increasing list prices are not purely an accounting phenomenon, they have real consequences. Patients without insurance may pay list prices directly, while patients who are insured may be exposed to list prices while they are in the deductible phase of their benefit. And coinsurance amounts paid by patients are frequently defined as a function of the list price. The same 2021 *JAMA Network Open* study[14] found that Medicare Part D participants who were exposed to cost-sharing based on the list price had out-of-pocket spending that grew 50-percent faster for drugs with branded competitors compared with drugs with no competition.

PBMs have deflected blame for these rebate and list price dynamics by pointing out[15] that they pass through most of the rebates they collect to health plans, who may then use them to keep premiums low for beneficiaries. But the ultimate result of such practices is to decrease the effective generosity of insurance by reducing premiums while increasing out-of-pocket costs—effectively, this transfers resources from sick people to healthy premium-paying beneficiaries. This is of course the opposite of insurance,[16] which is supposed to pool funds from a large, mostly healthy group of beneficiaries and use it to defray the costs of those who experience the misfortune of falling ill.

PBMS CAN STEER PATIENTS TOWARD MORE EXPENSIVE DRUGS

These list price/rebate dynamics can distort formulary design in ways that raise total spending. Most dramatically, this occurs when patients are steered to expensive brand medications, even when a lower cost generic equivalent is available. Researchers studying Medicare Part D formularies[17] found that 72 percent of them placed at least one branded product in a lower cost-sharing tier than its generic product; 30 percent of formularies adopted fewer utilization controls on the branded product than its generic equivalent for at least one drug. Among the 222 drugs studied, the median branded product price was 3.9 times higher than the generic price.

Other examples abound. In 2019, well before their patents were due to expire, Gilead introduced[18] authorized generic versions of their branded hepatitis C cures Epclusa and Harvoni. These versions were identical to the branded products, but had greatly reduced list prices and rebates, giving PBMs the choice to prefer the high list/high rebate branded version or the lower list/lower rebate authorized generics on their formularies. At the time, the manufacturer noted that patients in Medicare plans covering the authorized generics could save up to $2,500 in out-of-pocket costs.

And yet, when the Office of the Inspector General studied Medicare formulary placement[19] for these drugs, it found that "[i]n 2020, nearly half of Part D plans

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[13] *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2779453.*
[14] *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2779453.*
[15] *https://www.fiercehealthcare.com/payer/cvs-caremark-express-scripts-pbm-pass-through-cigna-merger.*
[16] *https://www.forbes.com/sites/tomasphilipson/2014/04/01/double-jeopardy-in-american-health-insurance/?sh=37b38e954f72.*
[17] *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2728446.*
[18] *https://www.gilead.com/news-and-press/company-statements/authorized-generics-for-hcv.*
[19] *https://oig.hhs.gov/oei/reports/OEI-BL-21-00200.pdf.*

covered Epclusa or Harvoni but did not cover the authorized generic versions that were specifically launched to reduce patient costs." By the end of 2020, less than 20 percent of Medicare patients receiving either branded Harvoni or its authorized generic were receiving the cheaper version.

Recent experiences with the pricing of new biosimilar versions of expensive biologics demonstrate the same perverse formulary dynamics. FDA recently approved the first insulin biosimilar that is interchangeable[20] with Lantus, an expensive branded insulin. The manufacturer, Viatris, launched two versions of the drug—branded Semglee, with a list price just 5 percent below that of Lantus, and an authorized but unbranded version, Glargine, with a 65-percent lower list price than Lantus. Both are interchangeable with the originator Lantus product. The net prices to the manufacturer are likely similar across the two versions, with the branded Semglee offering substantially larger rebates than Glargine. Express Scripts announced[21] that they would prefer the biosimilar on their largest formulary, covering 28 million lives, in 2022 and would exclude the originator Lantus product. But the preferred product chosen was the high list price/high rebate Semglee, while the low list price/low rebate Glargine was excluded from the formulary.

More recently, in January, Amgen launched[22] Amjevita, the first biosimilar to the blockbuster rheumatoid arthritis drug Humira. As in the Semglee example, Amgen also went with two options—a high list/high rebate version at a 5-percent discount to Humira, and a low list/low rebate version at a 55-percent discount. Shortly thereafter, Optum released its formulary changes for February 2023.[23] On both its Premium and Select formularies, Optum placed the high-list-price version on Tier 2 (preferred brand), preferring it over the low-list-price version. The low-price version was excluded altogether from the Premium formulary, and placed on Tier 3 for the Select formulary, requiring that patients first try and fail the high-priced biosimilar and the still higher priced Humira before gaining access to the low-list-price biosimilar.

PBMS EARN EXCESS RETURNS

In market economies, a firm's quest for profit is both expected and, in most cases, desirable. But this quest for profits can be harmful if the profits generated are not commensurate with the value delivered to society; in such cases, policymakers may be expected to intervene. In the present case, the question is whether the profits earned by PBMs are justified. To answer it, we must evaluate whether the money they make is "excessive" in some risk/reward sense. High returns may be justified if large risks are undertaken to earn them; manufacturers' high profit margins are often justified by the large risks involved in developing new drugs, most of which fail to make it to market.[24] By contrast, PBMs' contracts with health plans do not typically expose them to financial risk for drug spending, nor do they assume significant inventory risk; in the retail drug market, PBMs do not even take possession of the product.

Schaeffer researchers studied the risk-adjusted returns of distribution system participants in 2013–2018. Comparing the adjusted return on invested capital to firms' weighted average cost of capital, they found[25] that pharmaceutical manufacturers' excess returns fall below those of the S&P 500 (1.7 percent vs. 3.6 percent), while those for biotech manufacturers (9.6 percent), wholesalers (8.1 percent), and insurers/PBM/retailers (5.9 percent) remain significantly above them. (PBMs could not be disaggregated from the insurer/PBM/retailer category since so many of the companies in the sample were integrated across these parts of the distribution system.) They also found that excess returns for the insurer/PBM/retailer sector increased over the study period, when both horizontal and vertical consolidation were also increasing. Broadly, these results suggest that the returns earned by companies in that category, including both standalone and integrated PBMs, are not explained by the risks they bear, and may instead reflect anticompetitive commercial tactics.

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[20] *https://www.drugchannels.net/2021/11/why-pbms-and-payers-are-embracing.html.*
[21] *https://www.prnewswire.com/news-releases/express-scripts-will-unlock-20-million-in-savings-for-clients-in-2022-by-preferring-the-first-interchangeable-insulin-biosimilar-301404121.html.*
[22] *https://www.reuters.com/business/healthcare-pharmaceuticals/amgen-launches-biosimilar-version-abbvies-humira-2023-01-31/.*
[23] *https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/resources/pdfs/PharmacyPassages_Standard_Feb_2023_FINAL.pdf.*
[24] *https://academic.oup.com/edited-volume/34491/chapter-abstract/292630954?redirectedFrom=fulltext.*
[25] *https://link.springer.com/article/10.1007/s10754-020-09291-1.*

CONCLUSION: GREATER TRANSPARENCY AND OVERSIGHT IS WARRANTED

The tactics illustrated here demonstrate some of the methods PBMs use to leverage their market power and the opacity of the system in ways that harm consumers and taxpayers. While it is true that PBMs also provide valuable services, the information asymmetry inherent in their position in the distribution system, the misaligned incentives that govern their behavior, and the trend towards increased vertical consolidation, should all be concerning to policymakers and regulators.

Increased transparency that gives market participants visibility into the prices they are facing would enable them to make more informed economic decisions and help level the playing field. And stricter reporting requirements for more granular transaction data would allow regulators (and potentially researchers) to analyze specific markets and tactics, identify problems more quickly, and offer more targeted solutions.

QUESTIONS SUBMITTED FOR THE RECORD TO KAREN VAN NUYS, PH.D.

QUESTION SUBMITTED BY HON. RON WYDEN

Question. What recommendations do you have for how and where to increase transparency throughout the prescription drug supply chain? Please specify both the transaction and the stakeholders in your response.

Answer. The current drug pricing system is characterized by a lack of transparency at almost every point, which enables sellers to extract profits without fear of competitive consequences (for example, loss of volume if they charge higher prices than competitors). Increased price transparency in such situations helps buyers to understand when they are being overcharged (or sellers to understand when they are being underpaid), and where they should go for better deals. This essential dynamic, in which buyers and sellers compare the deals they are being offered to what alternative providers are offering, keeps prices in check in competitive markets, but is too often missing in drug markets. Increased transparency could strengthen this competitive dynamic at several points in the drug distribution system, if high-quality price benchmarks were available to market participants. Outside researchers could also use them to identify trends and anomalies that warrant further investigation. For example:

Pharmacy reimbursement from PBMs: PBM reimbursements to pharmacies for filling scripts vary widely, and pharmacies lack quality benchmarks to understand whether they are being paid a fair price for their services. Pharmacies are now typically reimbursed based on average wholesale price (AWP), which is not based on actual transaction prices and is subject to manipulation and creates distorted incentives.

A better benchmark would be a national average of actual reimbursements received by pharmacies, collected regularly and posted publicly, similar to the National Average Drug Acquisition Cost (NADAC)[1] price series that CMS currently publishes. To construct NADAC, pharmacies are surveyed about the prices they pay to acquire prescription drugs; a similar survey could gather data about the reimbursements pharmacies receive. Average reimbursement values could be posted by type of payer (commercial plan, government plan, cash pay) and type of pharmacy (independent, chain affiliated with a PBM, unaffiliated chain, mail order, etc.) without revealing sensitive trade secrets.

Interestingly, a series similar to this (called National Average Retail Price, or NARP) was launched alongside NADAC in 2012,[2] but was quickly withdrawn for reasons that are not clear. NARP was a national survey of pharmacies that documented average drug reimbursements received by pharmacies from payers; 6 months of data were published. Schaeffer researchers were able to use the NARP data that were briefly available to establish that 23 percent of commercial pharmacy claims involved a patient copayment that exceeded the total cost of the prescription.[3] At the time, PBM representatives were claiming that they did not support

[1] *https://data.medicaid.gov/nadac.*
[2] *https://www.drugchannels.net/2012/10/transparency-is-here-cms-exposes.html.*
[3] *https://jamanetwork.com/journals/jama/article-abstract/2674655.*

such practices, and that if they happened, they were "outliers."[4] Following our NARP analysis and resulting media attention, in 2018 Congress enacted legislation banning the use of gag clauses[5] in PBM contracts that prevented pharmacists from alerting patients when their copay exceeded the cash price of the drug. Ironically, because NARP data are no longer available, we cannot confirm whether the situation has improved for patients since gag clauses were banned.

As originally implemented, NARP did not capture retroactive fees such as the DIR clawbacks that have since become widespread in Medicare Part D. Any new pricing benchmark would ideally capture these important revenue flows between PBMs and pharmacies, which would be difficult to do if those fees are imposed retroactively. Fortunately, CMS is planning to eliminate retroactive DIR fees beginning next year, requiring that any DIR fees and other concessions be reflected in the negotiated price at the point of sale. Thus, a NARP-like price benchmark implemented after January 2024 could capture all revenue flows at the point of sale and would constitute a more comprehensive measure.

Another complicating factor is that pharmacies that are vertically integrated with PBMs can report almost any reimbursement from their affiliated PBMs, since the amount could be set arbitrarily, simply shifting money from one pocket to the other for the parent company. Thus, other changes, such as additional oversight of vertically integrated entities, or limiting vertical integration, might also be necessary, and pricing benchmarks should be reported separately for those pharmacies affiliated with a PBM. But even an imperfect measure provides market participants (and outside researchers) with more tools than we currently have to make more informed economic choices, and to better understand how money flows in the drug distribution system.

Plan payments to PBMs: Health plans could be surveyed about the rates they pay to settle claims, and responses averaged and publicly posted by NDC or product, with sub-group results for different payer types (Medicare, commercial, etc.) and different PBM types (large/small, integrated with plan/unaffiliated with plan).

As above, this measure is also imperfect. Vertically integrated organizations could again set payments arbitrarily to realize the revenues in whichever unit is most advantageous. Subgroup reporting, comparing rates between plans that are and are not affiliated with a PBM, would help disentangle this effect. Additional oversight of vertically integrated organizations may also be useful.

Note: Any data measures collected via survey would be more useful and closer to "true" transaction prices if survey responses were made mandatory. This is true of the current NADAC survey, for which response is now voluntary. Studies comparing NADAC to similar values collected through a mandatory survey suggest that NADAC may overstate generic drug acquisition costs by roughly 20 percent. Thus, Congress should require participation in these pricing benchmark surveys as a condition of participating in the Medicare/Medicaid programs.

Manufacturer net prices: Drug manufacturers could also be surveyed semiannually about the average net prices they receive, after rebates and discounts, on each of their products by NDC, and the information made available publicly.

Medicare Part D rebate payments: CMS currently collects data from plans about how much they receive in direct and indirect remuneration (DIR), including manufacturer rebates. These values could be made public. To address potential concerns about reporting proprietary information, some degree of aggregation could be applied.

Premiums for Medicare Advantage–Part D plans (MA–PDs): CMS makes information on Part D premiums publicly available, which is useful for researchers and analysts to study how competition is working in the Part D market (including, for example, the extent to which manufacturer rebates are being used by plans to offset premiums). However, the premium data reported for MA–PDs are net of any "supplemental rebate buy-down" applied by the MA plan. (The terminology can be confusing, because this is a different type of "rebate" than those negotiated between PBMs and drug manufacturers.) When an MA plan bids below the benchmark to

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[4] Testimony of Mark Merritt, CEO of PCMA, to Senate HELP Committee, October 17, 2017. (*See* exchange with Senator Susan Collins beginning at 1:15:55), *https://www.help.senate.gov/hearings/the-cost-of-prescription-drugs-how-the-drug-delivery-system-affects-what-patients-pay-part-ii.*

[5] *https://kffhealthnews.org/news/no-more-secrets-congress-bans-pharmacist-gag-orders-on-drug-prices/.*

cover the medical benefits for its enrollees, it receives a portion of that difference in the form of a "supplemental rebate," which the plan then uses to enhance benefits and/or reduce cost sharing or premiums. It is very common for MA–PDs to use a portion of that supplemental rebate to offset some or all of the Part D premium that enrollees would otherwise pay. Indeed, in 2022, 69 percent of MA–PD enrollment[6] was in a plan that fully paid the Part D premium with these supplemental rebates. Because CMS reports Part D premium data net of any buy-down for MA–PDs, that 69 percent of MA–PD enrollees is reported as having a $0 premium. To answer certain research questions it is useful to know what beneficiaries actually pay, but these data provide limited insight into market competition overall; this is particularly limiting because the majority of Part D enrollment is in an MA–PD. If CMS were to also make available the data on Part D premiums *before* supplemental rebates are applied (as they do with stand-alone Part D plans), this would allow for better evaluation of dynamics in the Part D market overall.

QUESTIONS SUBMITTED BY HON. MIKE CRAPO

DELINKING COMPENSATION FROM DRUG PRICES

Question. A growing body of research suggests that compensation and contracting structures across the prescription drug supply chain may risk incentivizing higher list prices for medications by tying stakeholder payments to products' list prices or to list-price-derived benchmarks. In its March 2023 report to Congress, for instance, the Medicare Payment Advisory Commission (MedPAC) contends that "[a]ll levels of the drug supply chain include incentives that drive [point-of-sale] prices higher, particularly when payments are based on a percentage of prices."[7]

The potential for these types of incentives has driven some experts and supply-chain participants to propose eliminating the use of drug prices in establishing payment rates and amounts for PBMs and other stakeholders. A coalition of Idaho-based providers, patient advocates, and job creators, for instance, recently wrote in support of Federal policies aimed at "delinking PBM compensation from the list price of individual medications."[8]

How would Federal policies delinking compensation for pharmacy benefit managers (PBMs) and plan sponsors from drug prices in the context of Medicare Part D affect incentives within the retail prescription drug supply chain, and how would this type of change likely impact beneficiary costs and taxpayer spending?

Answer. Delinking PBM and plan sponsor compensation from drug list prices (for example by prohibiting fees and rebates that are set as a share of list price) would reduce the upward pressure we now see on drug list prices, which should translate into lower patient out-of-pocket spending. The impact on beneficiary costs and taxpayer spending of such moves is less clear, as it depends on several factors, including the impact on manufacturer net prices and aggregate PBM fees. If PBM and other intermediary fees are reduced by more than any increase in drug net prices, spending could decrease. On the other hand, if drug net prices increase by more (perhaps because PBMs have weaker incentives to negotiate prices after delinking), overall costs and spending could increase.

Separately however, beneficiary costs and taxpayer spending would change as a result of delinking, because such a move would restore the generosity of the Part D benefit. Since the Part D standard benefit design is tied to list prices, as list prices have become increasingly inflated, the value of Part D insurance coverage has declined over time. Delinking PBM and plan compensation from list prices would reduce upward pressure on list prices (and, more specifically, reduce the wedge between list and net prices). On its own, reducing this wedge would increase taxpayer costs because it would restore the generosity of the Part D benefit. Restoring the generosity of that benefit to more closely reflect net prices would increase premiums (because it is a more valuable benefit), which would increase taxpayer costs. However, it would also lead to more generous coverage and reduce out-of-pocket spending, particularly for some beneficiaries.

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[6] *https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-premiums-out-of-pocket-limits-cost-sharing-supplemental-benefits-prior-authorization-and-star-ratings/*.

[7] *See* p. 400, *https://www.medpac.gov/document/march-2023-report-to-the-congress-medicare-payment-policy/*.

[8] *See* Endnotes for a copy of the letter.

Question. Apart from PBM payments and services, where else in the supply chain do compensation structures rely on drug pricing benchmarks, and how should policymakers consider addressing these dynamics?

Answer. Pharmacies are typically reimbursed for brand, generic and specialty medications as a percentage of Average Wholesale Price (AWP), a benchmark that is not tied to the drug's actual acquisition cost. This creates incentives for pharmacies to sell not the lowest cost drug, but the one that maximizes the difference between AWP and its acquisition costs. For brand drugs, AWP is calculated at 120 percent of WAC (wholesale acquisition cost), the list price set by a drug's manufacturer. For generic drugs, AWP can vary widely across similar drugs, creating incentive distortions. Basing reimbursements on an alternative benchmark that reflects actual transaction prices and that is publicly available, such as the National Average Drug Acquisition Cost (NADAC), as Dr. Gibbs from Capital Rx suggested in his testimony, would reduce these distortions.

ACCESS TO AFFORDABLE BIOSIMILARS

Question. As more biosimilars have come to market, including for Part D-covered biologics, some experts have expressed concerns over the resulting coverage policies, as a number of plans have opted to advantage reference products or biosimilars with higher list prices over lower-priced biosimilars, despite the fact that beneficiaries often pay cost sharing under Part D as a percentage of a list-price-based benchmark. This pattern could curb incentives for biosimilar development and market entry, undermining competition.

What concrete steps could Congress take to ensure that Part D enrollees can benefit from lower-priced biosimilar options, as well as to bolster cost-cutting competition among biologics and biosimilar market entrants?

Answer. The same issues that are noted above with branded drugs—that rebates and cost sharing linked to list prices create pressure to increase drug prices and patient costs—apply to biosimilars in Part D as well. The current model, in which manufacturers compete to offer the highest rebates rather than the lowest net price, is responsible for these dynamics. If Congress were to pursue broader reforms that reduce incentives for high list-price, high-rebate drugs over lower-net-cost drugs, this would give lower-cost biosimilars an advantage over higher-cost biosimilars or reference products in Part D. But such a change will decrease rebate payments to plans, and put upward pressure on premiums, in large part because it would shift beneficiary spending away from out-of-pocket costs (among users) to premiums (for all). While this may be politically uncomfortable, it will shift financial obligations away from sick people (lower out-of-pocket expenses) to healthy people (higher premiums), which is the point of insurance.

Indeed, in Part B drug markets, where dynamics are driven by post-rebate ASP prices, we have seen biosimilar entrants capture significant market shares and drive prices down,[9] as expected from increasing competition, without requiring direct regulatory intervention.

Congress can also work with the FDA to streamline the process for biosimilar approval and entry.

REPORTING MEASURES

Question. During the March 30th hearing, you referenced the value of additional aggregated cost and payment reporting requirements at various junctures of the prescription drug supply chain, given the potential transparency benefits of the resulting information for policymakers, researchers, and stakeholders.

If Congress were to pursue policies to establish these types of reporting and transparency measures, how should legislators go about structuring them (*i.e.,* at what junctures of the supply chain should the measures be instituted, what information should be collected, and what level of aggregation and publication would be most helpful)?

Answer. Please see my response to question 1 from Senator Wyden, above, specifically regarding pharmacy reimbursements from PBMs and plan payments to PBMs.

[9] *https://www.ajmc.com/view/provider-differences-in-biosimilar-uptake-in-the-filgrastim-market.*

Question. What other types of reporting (*i.e.,* to Federal agencies, from PBMs to plan sponsors, from agencies to the public, etc.) would help to improve prescription drug benefits under Federal health programs? Response: Please see my response to question 1 from Senator Wyden, above, specifically regarding manufacturer net prices, Medicare Part D rebate payments, and premiums for Medicare Advantage–Part D plans.

CONSUMER OVERPAYMENTS

Question. In a number of past reports, you and your colleagues at the Schaeffer Center have identified circumstances under which insured patients have paid more than their PBMs and plans for certain prescriptions, including with respect to some generic drugs.

What dynamics or practices seem to drive these types of occurrences, and where in the supply chain do we see markups that increase consumers' out-of-pocket costs? What steps could Congress take to address these patient burdens?

Answer. In one study[10] published in *JAMA* in 2018, we found that patient copays exceeded the total cost of the claim on nearly one in four prescriptions in a commercially insured population (and nearly one in three generic prescriptions). Lack of transparency contributes to this practice, because patients have no idea what their prescriptions actually cost their insurers, and therefore do not know when their copayment is too high. Gag clauses in the contracts between PBMs and pharmacies facilitated such practices, because they prevented the pharmacist from notifying the patient when their copayment was greater than what the drug would cost with cash. Federal legislation in 2018 banned these gag clauses, although we no longer have access to the data that would let us establish if or how much the practice has declined as a result.

In a second study,[11] published in *JAMA Internal Medicine* in 2021, we found that Medicare overspent on claims for the most common generic drugs by 20.6 percent compared to what Costco members would have paid in cash for the same drugs. Some of this may have been the result of copay clawbacks as described above, but more was likely due to spread pricing, in which the PBM charges the Medicare plan more than what it pays the pharmacy to settle the claim, or vertically integrated PBMs reimbursing their affiliated pharmacies more generously. Again, lack of transparency is the root culprit for these practices, as plans don't know what their PBM is paying the pharmacy to settle the claim, so they have no way to judge whether they are being overcharged. Legislation that bans or otherwise limits spread pricing could help, but PBMs that are vertically integrated with pharmacies could easily reduce spread payments by altering their internal transfer prices to realize profits in the pharmacy division instead.

Since much of the Part D market is made up of plans that use their own PBM (UnitedHealth, Humana, and CVS Health are the three largest Part D carriers and each uses its own PBM), a better understanding of whether such overspending reflects generous payments to PBM-owned pharmacies is needed. Therefore, a solution that provides increased price transparency, such as collecting better drug price benchmarks (including their variation across PBM-affiliated vs. non-PBM-affiliated entities) and making them publicly available (as suggested above), may be a more robust approach.

QUESTIONS SUBMITTED BY HON. MARIA CANTWELL

REBATE TRANSPARENCY

Question. The PBM rebate system was originally designed as a way to leverage the PBMs' central position in the drug distribution chain to reduce costs for consumers and patients. In theory, PBMs negotiate rebates with drug manufacturers, and the rebates are then passed through to the patient at the pharmacy counter. I am a big proponent of the thinking that "when you buy in bulk, you should receive a discount." However, the rebate system is not working like it was intended to.

Let's take insulin as an example. Insulin has been used to treat diabetes for 100 years, and a vial of insulin costs $2 to $4 to make. In the study that you conducted, you discovered that between 2014 to 2018, the average list price of several insulin products rose 40 percent, from $19 to $27 per unit. At the same time, total con-

[10] *https://jamanetwork.com/journals/jama/article-abstract/2674655?redirect=true.*
[11] *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2781810.*

sumer insulin expenditures remained the same, while the share of rebates and other expenditures accredited to PBMs increased by a whopping 155 percent. This means that PBMs are demanding and keeping more of the rebates, and drug manufacturers respond by increasing the list price. The consumer ultimately does not get the full benefit of this system because the PBMs pocket most of the rebates.

To complicate this issue further, we know relatively little about the interactions and negotiations between drug manufactures and PBMs. The PBMs claim that the information on the amount of rebates received, and the amount passed through, are considered trade secrets that cannot be disclosed. This shroud of secrecy is contributing to sky-high drug prices and hampering our efforts to rein in bad practices.

I am leading a bill with Senator Grassley, the Pharmacy Benefit Manager Transparency Act, which would crack down on PBM's opaque rebate practices and ensure that PBMs pass on the full amount of rebates that they receive. It would also mandate transparency disclosures to the Federal Trade Commission so that PBMs are accountable in this process.

Do you think that my bill is a good start to tackling the opaque practices that PBMs have hidden from the public?

Answer. I do believe it is a good start, as it places the fundamental issue of transparency front and center. Your bill with Senator Grassley should make it more difficult for PBMs to hide profits from regulators, and reveal anti-competitive practices such as differential DIR clawbacks that provide an unfair advantage to pharmacies that are vertically integrated with PBMs. However, any proposed policy should also consider how PBMs and other supply chain entities are likely to respond. We have already seen the large, vertically integrated PBMs respond to proposed legislation, such as the 2019 "rebate rule," with changes (*e.g.,* re-labeling rebate revenues as fees and concessions, or creating offshore GPOs/rebate aggregators) that would circumvent the proposed legislation without addressing the underlying issue.

Question. In your opinion, what else can we do to crack down on the complicated web of bad practices that PBMs engage in?

Answer. I believe other steps should also be taken to create a more comprehensive solution. By themselves, laws that focus on one or two practices or revenue flows (like spread pricing, or DIR fees, or rebates) are likely to be gamed by the large and highly sophisticated, vertically integrated entities that now dominate PBM markets. For example, a prohibition on spread pricing can be sidestepped by a PBM integrated with pharmacies by (1) steering patients to affiliated pharmacies and (2) increasing reimbursements to affiliated pharmacies to realize any profits in the pharmacy rather than as spread.

For this reason, I believe it is equally important that vertically integrated entities be carefully studied to better understand and quantify the impacts of their integration and, if needed, design policy to limit their scope for such evasive moves and ensure robust competition in health plan, PBM, and pharmacy markets.

Question. PBMs have argued that increased transparency will ultimately lead to collusion in the industry and decreased competitiveness. Do you agree with the statement? If not, why do you disagree?

Answer. The truth is that no one is sure, as we don't have any evidence from pharmaceutical markets. But I am not so concerned about this issue that I would let it scuttle all efforts to increase transparency in these industries. In the current situation, most buyers have almost no idea what the "true" prices are in these markets, so they have no hope of making informed economic choices about which alternatives offer the greatest value. And that dynamic—agents making informed choices among competing alternatives—is the main channel through which competitive forces work to lower prices. Without that transparency, and the channels it will open, the current dynamics are a near-complete mystery, but they certainly don't *appear* to be reducing health-care costs. And when one hears anecdotes about PBMs designing formularies that prefer higher-cost versions of a drug when an identical but lower-cost version is available, forcing patients to bear higher out-of-pocket costs, I become even more skeptical that more transparency will hurt rather than help.

I also do not find much of the evidence behind the claim that increased transparency will increase collusion particularly germane or compelling. My colleagues at USC Schaeffer and I have pointed out that one of the often-cited empirical examples

for this claim is a study[12] of the Danish ready-mix concrete industry in the early 1990s. As one of the study's authors noted:[13] "I'm sure there are some similarities between pricing of various health care services and ready-made concrete in Denmark in the early 1990s, but I'm also sure there might be huge differences." Indeed, one very substantial difference is that ready-mix concrete—much like retail gasoline, another oft-cited example—is identical no matter who is selling it, but branded pharmaceuticals typically differ from one another in various ways. The economics literature[14] has found that collusion is much more likely in industries with homogeneous goods than differentiated ones. (When firms sell identical goods, they have more to gain from tracking their rivals' price increases identically too. By contrast, firms selling differentiated goods often benefit from pricing and marketing in accordance with the unique advantages of their own product.)

Finally, the critique of price transparency rests on the quaint notion that confidential rebates yield benefits for consumers. The evidence suggests otherwise. Powerful PBMs may extract confidential discounts, but they do not systematically pass those savings downstream to consumers.[15]

Ultimately, the theoretical risks of rebate transparency—to the extent they exist at all—need to be weighed against the real costs of the current system, which provides leverage to powerful and profitable intermediaries.

QUESTIONS SUBMITTED BY HON. THOMAS R. CARPER

Question. Last year, Congress passed and President Biden signed into law the Inflation Reduction Act—which capped insulin prices for Medicare beneficiaries at $35 per month. Thanks to President Biden's leadership, drug manufacturers like Eli Lilly have followed suit and have voluntarily capped the price of insulin at $35 per month in the commercial market as well.

What are your thoughts on expanding the insulin price cap to other classes of drugs—for example, drugs that are older, highly rebated, and/or treat chronic conditions? What are the key things that Congress should think about when considering this type of policy? What are the tradeoffs and how can we prevent costs from ballooning in other parts of our health-care system when designing such a policy?

Answer. The recently passed Inflation Reduction Act (IRA) capped out-of-pocket (OOP) prices (*i.e.,* copayments) for insulin at $35. Capping OOP costs for other drugs would create new dynamics. First, while patients' spending for those drugs would likely fall, to the extent those drugs continue to be highly rebated, capping OOP costs could increase premiums (similar dynamics to what would happen if OOP costs were tied to net prices). Second, it could also result in higher drug prices if the current system that ties OOP costs to list prices is depressing those prices because patients will buy less of them when their OOP costs increase. Market and policy factors may mitigate this effect.

Overall, capping OOP payments will produce benefits for a certain set of patients who rely on the chosen drugs. More patients would benefit if the overall dysfunctional rebate dynamics that drive the current system could be addressed instead.

Question. Thanks to the testimony of our witnesses and questions from my colleagues, we heard a good amount of discussion about the perverse incentives that exist in the market due to how PBMs make their money. To summarize, a significant source of revenue for PBMs are rebates and administrative fees that are often based on a drug's list price. This creates bizarre and perverse incentives that have been found to lead to increased drug list prices and higher-priced drugs on formulary lists so that PBMs can bring in more revenue. That's bad for patients and its bad for taxpayers. Dr. Gibbs in his testimony talked about the transparent, flat-fee pricing model that Capital Rx has put in place.

Can we as policymakers learn from Capital Rx's pricing model and what proposals would you recommend we pursue to align pricing incentives in the various parts of the drug supply chain?

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[12] *https://doi.org/10.1111/1467-6451.00057.*
[13] *https://www.nytimes.com/2019/06/24/upshot/transparency-medical-prices-could-backfire.html.*
[14] *https://www.aeaweb.org/articles?id=10.1257/002205106776162681.*
[15] *https://jamanetwork.com/journals/jama-health-forum/fullarticle/2785932.*

Answer. Capital Rx's business model contains several elements that should be considered as you seek to align incentives in the drug supply chain:

No vertical integration: Capital Rx is a stand-alone PBM that does not own pharmacies or health plans. This means they cannot shift revenues among business units to hide profits from scrutiny and regulation. Whatever profits Capital Rx reports are earned solely through their activities as a PBM, and can be benchmarked against what other PBM operations are earning, to understand whether they are making excessive profits.

Meaningful, verifiable pricing benchmarks: Capital Rx uses NADAC, a national average pricing series that is derived from actual transaction prices, to determine what they pay pharmacies and what they charge health plan clients. This ensures transparent and consistent prices that can easily be explained and verified across the entire business, and that potential clients can compare across alternative providers.

Transparent, pass-through model: Capital Rx passes through 100 percent of manufacturer rebates, fees and discounts to their health plan clients, so clients know and benefit directly from any price reductions received. They charge their clients what they pay pharmacies, so there is no spread.

Flat fees: Capital Rx charges for its services via flat fees rather than as a share of drug costs, eliminating any incentive to steer patients towards more expensive drugs.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

Question. You mention in your testimony that PMBs are "essentially practicing medicine through 'fail first' step therapy, prior authorization requirements, or formulary exclusions, many of which favor not the least expensive medication, but the most profitable one for the PBM."

Can you discuss how these practices impact patient access to medication prescribed by their health care provider?

Answer. I believe the quote above comes from Mr. Levitt's testimony rather than mine, but I agree with it. Of these "utilization management" (UM) practices used by PBMs, formulary exclusions are the most extreme. When a drug is excluded, the PBMs' beneficiaries cannot access it using their insurance—they must pay cash or go without. And over the last decade, the three largest PBMs have steadily increased the number of drugs on their exclusion lists.[16]

Prior authorization and step therapy practices also impede patient access. A growing literature demonstrates that when patients face utilization management requirements like these, they experience delays in starting new medications, miss doses, and may experience negative health consequences as a result. These effects have been documented in diseases ranging from epilepsy[17] to asthma[18] to atrial fibrillation.[19]

In theory, UM practices could help PBMs manage the cost of care by ensuring that patients use the most cost-effective alternatives, and only use more expensive alternatives if cheaper ones don't work. But this argument ignores the conflicting financial incentives many PBMs currently face to use UM tools to increase their profits, and is directly undermined by formulary examples[20] where expensive branded drugs are preferred over therapeutically identical authorized generic versions that cost less.

Question. You mention in your testimony that there is evidence that some PBMs engage in a tactic known as "spread pricing," which occurs when PBMs charge health plans a higher amount than what the PBM actually reimburses the pharmacy for a dispensed drug—with the PBM retaining the difference. Almost 20

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[16] *https://www.drugchannels.net/2023/01/the-big-three-pbms-2023-formulary.html.*

[17] *https://www.sciencedirect.com/science/article/abs/pii/S0887899418301516?casa_token=qjlHcSN5jKEAAAAA:MoVHLWDJqzIBr5UHwmSuNcDQMApCOr_fZq2C5ygMgc3-IrQIOslBNY6oucrSrQnrLxVaCwXAtVk.*

[18] *https://pubmed.ncbi.nlm.nih.gov/33404389/.*

[19] *https://www.ajmc.com/view/formulary-restrictions-and-stroke-risk-in-patients-with-atrial-fibrillation.*

[20] *https://oig.hhs.gov/oei/reports/OEI-BL-21-00200.asp.*

States, including my home State of Maryland, have prohibited spread pricing in their Medicaid managed care programs.

Can you discuss how spread pricing in public health care programs impacts patients and taxpayers?

Answer. Spread pricing permits PBMs to earn money on each prescription filled without disclosing the amount earned to their clients. As a result, PBMs have been found to capture large profits that cost Medicaid managed care programs millions of dollars through inflated drug costs. For example, in a 2018 audit of Ohio State Medicaid managed care programs, auditors found that the State paid $225 million in spread in 1 year; for generic scripts, the average spread was 31 percent. The practice and the excess costs it generates is not limited to Ohio; similar audits in other State Medicaid programs have produced similar findings.

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. The Pharmacy Benefit Manager (PBM) Transparency Act (S. 127) requires transparency reporting by PBMs (or an affiliate, subsidiary, or agent of a PBM) to shine sunlight on prices and fees associated with prescription drugs. Why is transparency reporting by middlemen, such as PBMs, important to ensuring taxpayers and patients are getting the lowest drug price and associated fees possible?

Answer. The process of making, distributing, and paying for prescription drugs involves numerous entities, including manufacturers, wholesalers, insurers, PBMs, and pharmacies. Knowing the real transaction prices, including rebates and discounts, at each stage is essential to understanding where profits are taken across the supply chain. Without this information, it is more challenging to target effective policy solutions at the segments that are making excessive profits.

Transparency is especially important in PBM transactions because of the likelihood of hidden costs and markups due to the complex and opaque nature of their pricing practices, and to the information advantage they enjoy because of their involvement in several key transactions in the system. The PBM Transparency Act would require detailed reports from the PBMs, a major step toward ensuring patients and taxpayers are getting the lowest prices for medicines. Increased PBM transparency will promote competition and drive down costs as pharmacies, insurers and drug makers gain information that will enable them to negotiate better prices and discounts.

Question. The Prescription Pricing for the People Act (S. 113) and PBM Transparency Act (S. 127) require the Federal Trade Commission (FTC) to look into the vertical integration that is occurring in the pharmaceutical supply chain. Why is that important? How does vertical integration impact the prices patients and taxpayers pay for prescription drugs?

Answer. Vertical integration in the pharmaceutical supply chain can have several anticompetitive effects in PBM, health insurance and pharmacy markets:

First, a PBM that is vertically integrated with a pharmacy (specialty, mail, or retail) may require patients to fill the most profitable prescriptions at its affiliated pharmacy, while allowing less profitable prescriptions to be filled at independent pharmacies. By steering more profitable business to its own pharmacy, the vertically integrated PBM systematically disadvantages independent pharmacies, who face more competitive pressure and may go out of business as a result. This leads to increased concentration in pharmacy markets, higher consumer prices and reduced patient access to pharmacy services.

Second, an integrated PBM/pharmacy organization can arbitrarily choose to realize profits in either business unit, which gives them great scope for avoiding legislation that places restrictions or reporting requirements on tactics like spread pricing. Suppose the pharmacy acquires a drug for $10 and, when a patient fills a prescription for it, the PBM charges the health plan $100. The total profit to the integrated PBM/pharmacy is $90, but where it is realized is determined by the (arbitrary) rate chosen to reimburse the pharmacy. If the reimbursement is set at $10, the full $90 will be realized as spread in the PBM unit. But the organization can sidestep spread pricing restrictions by setting the pharmacy reimbursement at $100, thereby realizing the entire $90 profit in the pharmacy unit, with no reported spread.

Third, a PBM vertically integrated with a health plan can offer PBM services to other health plans which compete with the PBM's own health plan. The vertically

integrated PBM has incentives to provide poor quality or high cost services to rival health plans, since disadvantaging rivals will lead to higher market share for its own health plan. Such so-called "input foreclosure" leads to reduced competition in the health plan market, increasing premiums for patients and taxpayers.

Finally, a health plan integrated with a PBM will not seek PBM services from independent PBMs. This limits the size of the market for independent PBMs, leading to limited entry, reduced competition and higher prices for PBM services.

Question. Do spread pricing and clawbacks performed by PBMs (or an affiliate, subsidiary, or agent of a PBM) impact the prices patients and taxpayers pay for prescription drugs? If so, how? Additionally, how do spread pricing and clawback practices differ within the commercial insurance market compared to within the Medicaid/Medicare programs?

Answer. PBMs' spread pricing and clawback[21] tactics result in patients and taxpayers paying more for prescription drugs than necessary. When a PBM engages in spread pricing, it charges the health plan more than it pays the pharmacy to settle the claim, and keeps the difference. The practice has been well documented in Medicaid programs—in Ohio, the State auditor found average spreads of 31 percent[22] for generic drugs in its Medicaid managed care program; other States have documented similar results.

Using Medicare claims, my Schaeffer colleagues and I found that Medicare overpaid by 21 percent[23] on the most common generic prescriptions in 2018, compared to what Costco members paid for the same drugs with cash. The resulting $2.6 billion overpayment was more likely due to spread and/or vertical integration than to copay clawbacks, as the latter appeared to be relatively uncommon in our data. I am unaware of any empirical study establishing the frequency or magnitude of spread practices in commercial plans.

In a copay clawback, the patient's copayment exceeds the total cost of the prescription, and the PBM keeps the difference. In one study of commercial claims, we found that patient copays exceeded the total cost of the claim on nearly one in four prescriptions, and nearly one in three generic prescriptions. Federal legislation in 2018 banning gag clauses in commercial and Medicare plans may have diminished the use of these tactics, although we lack the data to confirm this conjecture.

Lack of transparency contributes to these cost-increasing tactics. In the case of spread pricing, neither the payer nor the pharmacy is aware of what the other is paid or charged, and don't see when the PBM is capturing excessive profits from the transaction. In the case of copay clawbacks, patients do not know the actual cost of their medication, so they cannot see when their copayment is being siphoned off to enrich the PBM. In the case of vertical integration, the PBM has an incentive to pay its own pharmacies higher prices. In all these cases, PBMs are inflating costs in the drug supply system. The amount of money in each transaction might be small, but spread over billions of prescriptions each year the cost to payers is significant.

Question. Does the current consolidated PBM market hurt or help community pharmacies who serve rural or underserved areas? When a community pharmacy closes or a patient cannot access a community pharmacy due to being out of network, how does this impact patient access?

Answer. In a recent study,[24] Schaeffer colleagues and others found that the total number of community pharmacies, after increasing steadily since 2010, began declining in 2018. This timing coincided with increasing consolidation in the PBM industry, with the CVS/Aetna merger in 2017 and the Cigna/Express Scripts merger in 2018. Net pharmacy closures were only observed among chain pharmacies, and were primarily observed in rural areas and in predominately Black/Latinx urban neighborhoods.

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[21] With the term "clawback," I am referring to a copy that exceeds the total cost of the prescription, with the PBM keeping the overage, as described in our *JAMA* 2018 article. The term clawback is also used to describe the direct and indirect remuneration (DIR) fees that PBMs charge pharmacies after a drug claim is settled. These are different from the type of clawback I am referring to here.

[22] *https://ohioauditor.gov/auditsearch/Reports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.*

[23] *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2781810.*

[24] *https://academyhealth.confex.com/academyhealth/2022arm/meetingapp.cgi/Paper/53833.*

A second study[25] exploring a national cohort of older Americans using cardiovascular medications found that pharmacy closures have an immediate and persistent effect on medication adherence, including among patients fully adherent prior to their pharmacy closing. These declines were greater among patients living in low-access neighborhoods.

Question. Since 2017, 23 States have passed various forms of prescription drug transparency laws that require PBMs to report certain data (according to National Academy for State Health Policy). Do any of these States have effective PBM transparency laws that should be replicated at the Federal level? Why are they effective?

Answer. I have not studied recent State transparency laws, or what impact they are having. That said, I am somewhat skeptical. In 2019, my Schaeffer colleagues analyzed 166 State drug pricing laws that were passed between 2015 and 2018, of which 35 had a clear transparency component. They concluded that only 7 laws passed in 6 States could be labeled "informative," meaning they would result in disclosure of previously unavailable information. Furthermore, since sophisticated, vertically integrated PBMs can shift revenues internally among business units, they can skirt reporting requirements that focus on individual revenue flows (such as rebates, spread pricing, or clawbacks) in isolation. To the extent that these State transparency laws are looking at flows in isolation, I suspect they may be circumvented by large, vertically integrated PBMs.

Question. Beginning in 2016, the Texas Department of Insurance began public reporting on the use of manufacturers' rebates and other payments to PBMs. Similarly, beginning in 2020, the Iowa Insurance Division began publicly reporting on the use of manufacturers' rebates and other payments to PBMs. Other States have conducted similar public reporting. According to an analysis of the Texas data *(https://www.tdi.texas.gov/reports/report3.html)*, PBMs retained 7 percent to 21 percent of manufacturers' rebate and other payments between 2016–2021. Similar data has been reported in Iowa *(https://iid.iowa.gov/pbm-annual-reports).* Is this public reporting accurately capturing the amount of rebates and other payments retained by PBMs (or an affiliate, subsidiary, or agent of a PBM)? If not, how might policymakers accurately capture the amount of revenue retained by PBMs (or an affiliate, subsidiary, or agent of a PBM)?

Answer. It is hard to know if these reports are accurate, although I have my doubts. There were 66 PBMs in the U.S.[26] in 2022, while the Texas reports contain data from 19 PBMs in 2019, 23 in 2020, and 13 in 2021. This seems like a relatively small number of respondents, and I can't think of a reason why the number would fall so much between 2020 and 2021. I do not believe the reports are audited. We have also seen PBMs engage in some evasive tactics when rebates are in the spotlight. When policymakers began paying more attention to rebates around 2018–2019, some PBMs responded by proliferating the number of "fees," "concessions," and "allowances" collected from manufacturers, without labeling them "rebates." The suspicion is that by relabeling the rebate revenue stream, PBMs were shielding it from new rebate reporting requirements. Such seemingly evasive maneuvers raise my suspicion that State rebate reports are not capturing the full story.

Question. Why do PBMs own or operate affiliated organizations such as group purchasing organizations or rebate aggregators? What do these entities do?

Answer. These frequently offshore entities negotiate for and collect rebates from drug manufacturers, retain a portion of that revenue and distribute the remainder to their affiliated PBMs. Those PBMs then generally pass that rebate revenue to their health plan clients. Over time, health plan clients have been negotiating for an increasing share of rebates—many of them have contracts that specify 100 percent rebate pass-through. By creating the offshore GPO which retains a portion of the manufacturer revenue before it is passed to the PBMs, these integrated organizations are able to keep more of the manufacturer revenue for themselves, while still claiming to pass through "all" or "most" of the rebates to health plans. Indeed, they may pass through 100 percent of the rebates that the PBMs get, but they are not passing through 100 percent of the rebates that the manufacturers pay, because the GPO is retaining a share. There may be tax advantages as well.

Question. In 2013, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) published a report (titled, "Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions") recommending that each Medi-

[25] *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2730785.*
[26] *https://content.naic.org/cipr-topics/pharmacy-benefit-managers#:~:K:text=Today.*

care Part D plan's Pharmacy and Therapeutics Committee (P&T) have members who are free of conflict from PBMs. HHS OIG specifically recommended that a Medicare Part D plan's P&T committee should be free of conflict with any PBM that manages the plan's prescription drug benefit. Since this recommendation was issued in 2013, CMS updated some conflict of interest policies, but not this recommendation. Should CMS require some (or all) P&T committee members be free of conflict with any PBM?

Answer. Yes, I believe CMS should require P&T committee members to be free of conflict with any PBM. Current rules only define conflicts of interest in relation to pharmaceutical companies and plan sponsors, but PBMs can also exert influence on P&T decision-making in a way that harms beneficiaries. Because PBMs may benefit from manufacturer rebates, they may recommend high rebate drugs that have higher list prices, thereby exposing beneficiaries to higher out-of-pocket costs.

Furthermore, negotiated rebates are confidential, making it impossible for PBM-conflicted members to disclose their conflicts related to specific drugs and manufacturers to enable committee deliberations to specifically take those financial interests into account. That is, disclosure—a common conflict of interest remedy—is not a feasible remedy for conflicts in this case. Requiring that members be free from a PBM conflict would be an efficient way to remove potential bias from the financial influence of PBM rebates.

If a PBM's perspective is required to make a formulary decision, it can be obtained through other channels, without requiring PBM-conflicted members on the P&T committee. Outside stakeholder perspectives are routinely gathered by P&T staff for specific issues and presented to the committee for consideration. A PBM's perspective, if needed, could be collected and presented in the same way.

QUESTIONS SUBMITTED BY HON. JOHN CORNYN

Question. Your testimony indicates that more oversight and transparency of the PBM industry is needed as a result of the concentrated market and the opaque system that they operate in.

What other solutions do you need as appropriate? Do you think consolidation of the industry is the main driver of some of these issues?

Answer. I do believe consolidation, and especially vertical integration in this industry, has been very problematic. It has led to many of the commercial tactics we are concerned with today, that reduce transparency, inhibit competition, and raise health-care costs for patients and taxpayers. It has also increased the scope these large and sophisticated organizations have to evade transparency and other requirements that could be effectively brought to bear if they were standalone businesses.

For other suggested solutions I believe appropriate, please see my responses to Senator Wyden's question 1 above.

Question. During the hearing, you mentioned one idea to take generics out of health insurance coverage. In your *Washington Post* op-ed, you write "yet insurance coverage has enabled middlemen to feast on billions of these prescriptions each year, keeping prices higher than they need to be."

Are there other intermediaries in the supply chain that are contributing to this issue excluding PBMs?

Answer. Some pharmacies may also be contributing to the issue here, although it is hard to disentangle definitively, especially because we do not have good data on pharmacy DIR fees. We compared what Medicare paid for common generic prescriptions to what Costco members paid with cash, and found a 21-percent difference.[27] Costco's pharmacy was still earning a margin on those cash scripts—Costco's pharmacy margins are not included in the 21-percent overage. But if other pharmacies are taking a larger margin than Costco (and I find that plausible), then that 21-percent overpayment may include some pharmacy margin as well.

Question. Do you think biosimilars should remain a part of health insurance coverage?

Answer. Yes. Most biosimilars are still rather expensive, and many patients would struggle to pay for them without insurance. While health insurance coverage

[27] *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2781810.*

through the existing system probably increases the costs of these drugs overall, those drawbacks must be weighed against the significant benefits of insuring patients from large, unpredictable health-care costs. By contrast, the majority of common generic prescriptions can be purchased for less than $20 at Costco, so insuring them does not protect patients from large, unpredictable expenditures.

QUESTION SUBMITTED BY HON. TIM SCOTT

Question. HHS's Office of the Inspector General issued a report in 2022 that concluded that Medicare Part D, a highly successful program, could realize significant spending reductions with increased biosimilar use. Additionally, an ERISA Industry survey released that same year found that employers are concerned about rebate gamesmanship and prefer all biosimilars to be included on formularies.

If formulary access for biosimilars continues to be restricted, will patients see any significant savings in out-of-pocket costs?

Answer. A growing literature has demonstrated that in Medicare Part B, biosimilar entry corresponds with greater availability and use of lower-priced alternatives to the reference product, and falling prices for the reference product. Forthcoming Schaeffer research additionally finds that biosimilar prices—as measured by both the average sales price and net manufacturer price—continue to fall the longer the biosimilar products are on the market, particularly in markets with multiple biosimilar competitors. This evidence suggests that market competition in the biosimilar market is reducing prices, and that competition can help patients see significant savings in out-of-pocket costs. But these dynamics occur in the context of Medicare Part B, where payment is based on the Average Sales Price (ASP), a price benchmark that is net of rebates.

Biosimilars in Medicare Part D are a more recent phenomenon, and may be following a different path. We have seen biosimilar manufacturers launch the same biosimilar product with two prices—a high-list-price/high-rebate version, and a low-list-price/low-rebate version—and PBMs respond by preferring the high-list-price version over the low-list-price version, or excluding the low-list-price version entirely. Such tactics expose patients to high costs when their out-of-pocket expenses are tied to the drug's list price. If new biosimilars are to reduce patients' financial burden, their out-of-pocket costs may need to be decoupled from the drug's list price, either using a flat copayment, or tying out-of-pocket charges to the drug's net-of-rebate price.

QUESTIONS SUBMITTED BY HON. JAMES LANKFORD

VERTICAL INTEGRATION

Question. Many PBMs are now a large part of massive conglomerates that include an insurer, a retail pharmacy chain, the PBM that negotiates between plans and drug manufacturers, and now even physician practices.

How does this ownership structure, where the same company is able to decide what drug is prescribed, whether a lower-cost generic is available to a patient, what drug is covered by insurance and on what formulary tier it is placed, how much the patient's out-of-pocket requirements are for a drug, and where a patient can access their prescription: (1) create an anticompetitive monopoly, and (2) impact patient health?

Answer. Vertically integrated firms have more information and increased opportunities for extracting economic rents at the expense of independent pharmacies and patients. Please see my response to Senator Grassley's question 2 about vertical integration above for more detail.

REBATES

Question. When previous rules have been proposed from an administration regarding the elimination of rebates, hysteria ensued because some estimates showed it would increase costs for the Federal Government and patients' premiums may increase.

Have model systems been created to test what would really happen if rebates were removed from the pharmaceutical pricing supply chain? Do such models show

that pharmaceutical products' list prices will drop and drugs may be able to compete using their prices for formulary placement?

Answer. While I am unaware of any specific model system that would test what would happen if rebates are removed, in general, these kinds of models rely very heavily on assumptions. For example, as my USC Schaeffer colleagues have described, the hysteria to which you refer largely reflected CBO and CMS OACT estimates of the 2019 "rebate rule," which was based on assumptions that manufacturer rebates would be reduced by 15 percent in Medicare Part D. We do not know how CBO and CMS OACT arrived at those assumptions, but alternative assumptions—such as those modeled in an analysis [28] conducted by Milliman prepared for the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services—projected potential *Federal savings* from the rule. In the Federal Register, DHHS noted [29] that they engaged multiple analyses from OACT and actuarial firms precisely because "it is difficult to predict manufacturer and Part D plan behavior in response to this regulation."

In fact, CBO estimates of other proposals have projected savings from policies intended to increase transparency in PBM markets. For example, in 2019, CBO scored [30] the Lower Health Care Costs Act. Section 306 would have required PBMs operating in commercial health-care markets to (in short) provide information on costs, aggregate rebates, and fees; fully pass rebates, fees, discounts, or other remuneration to plan sponsors; and prohibit spread pricing. CBO estimated these provisions would *reduce* average premiums in the private insurance market and *decrease* the deficit by $1.7 billion over the 2019–2029 period.

PREPARED STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON

The Finance Committee meets this morning to continue our longstanding efforts to lower the cost of health care for taxpayers and patients. Today the committee focuses on pharmacy benefit managers, in particular the new strategies—like charging administrative fees tied to the price of a drug—that these multibillion-dollar corporations have aggressively adopted in the last 4 years since the Finance Committee previously held a hearing about PBMs.

Pharmacy benefit managers had a strong case for themselves back in the 1980s and 1990s. The original goal was to use their access to limited data to negotiate lower drug prices on behalf of their clients—insurance companies and employers. When prescription drug coverage came to Medicare with Part D in the 2000s, PBMs shifted into overdrive with a larger market and more sophisticated drugs.

In recent years, it's increasingly apparent that PBMs are using their data, market power, and know-how to keep prices high and pad their profits instead of sharing the benefits of the prices they negotiate with consumers and the Medicare program. I believe this is an industry that is going in the wrong direction, and that's having a big impact on the prices Americans are paying at the pharmacy counter.

There are serious consequences for the Federal health programs the Finance Committee is responsible for. Between Medicare, Medicaid, CHIP, and the individual health insurance marketplace, the committee oversees health coverage for more than half of all Americans, or roughly 180 million people. Prescription spending for these Americans constitutes a significant portion of the amount that the United States as a whole spends on pharmaceuticals each year—which totaled $577 billion in 2021. That's why it's so critical for this committee to examine what needs to be done to modernize the rules of the road for PBMs.

I'm proud to say that this is a hearing with strong bipartisan interest, and Senator Crapo and I have agreed to take on this issue together. That means looking at pharmacy benefit manager practices with a thorough eye and taking any legislative steps necessary to ensure taxpayers and patients aren't getting a raw deal. The Finance Committee has a long history of tackling big-league issues on a bipartisan basis, and the results speak for themselves.

Before I turn it over to Senator Crapo, I want to illustrate just one example of PBMs practices that result in high prices. In a competitive market, if two products

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[28] *https://www.regulations.gov/document/HHSIG-2019-0001-0002.*
[29] *https://www.govinfo.gov/content/pkg/FR-2019-02-06/pdf/2019-01026.pdf.*
[30] *https://www.cbo.gov/system/files/2019-07/s1895_0.pdf.*

have equal quality, a business should prefer the lower-cost option. However, oftentimes PBMs charge administrative fees to drug makers which are calculated as a percentage of a drug's list price. That means PBMs get a higher payment if they favor higher-cost drugs. In my view, that's a clear example of the perverse incentives PBMs have created that leave so many Americans fed up and outraged at the health-care system in this country.

The consequences of this out-of-whack market are felt by taxpayers and American families every time they pick up a prescription at the pharmacy counter. Discounts negotiated by PBMs play an important role in driving down premiums for seniors. But the games PBMs play behind the scenes also appear to be driving up drug costs for many seniors, who are forced to pay top dollar for their prescriptions at the pharmacy counter while PBMs profit at their expense.

Today's hearing is an important opportunity for committee members to get up to speed on the latest practices being employed by pharmacy benefit managers and the impact these tactics are having on taxpayers and Americans who count on expensive medications for a decent quality of life.

Thank you to our witnesses for joining the committee this morning.

CIVICASCRIPT
2912 W. Executive Parkway, Suite 300
Lehi, UT 84043
888–304–0120

March 28, 2023

Senator Ron Wyden, Chair
Senator Mike Crapo, Ranking Member
Committee on Finance
United States Senate

Dear Chairman Wyden and Ranking Member Crapo,

Thank you for your focus on the pharmacy benefits management (PBM) industry. While PBMs serve several important functions in our system of drug procurement and reimbursement, the dominant business model also creates unintended consequences that are not in the interest of individual consumers. While much attention has been paid to the effect of PBM rebates on the cost of branded drugs, we wish to draw your attention to potential for increased costs to individual consumers, health plans and the Medicare program related to generic specialty drugs.

Civica is a non-profit generic drug company established to reduce drug shortages and ensure a reliable supply of essential medicines to hospitals at fair prices. CivicaScript, a public benefit corporation, is the operating unit of Civica that was established in partnership with health plans to lower costs for consumers at the pharmacy counter. CivicaScript was founded in partnership with 18 BlueCross and BlueShield plans and the BCBS Association. Additional members include health plans Elevance (formerly known as Anthem) and HCSC and two PBMs, Navitus and Emsana Rx.

In 2022, CivicaScript launched abiraterone 250mg. Abiraterone is a generic oral drug used in combination to treat prostate cancer. The average cost of a month's supply of abiraterone 250mg to Medicare Part D in 2021 was over $3,000. However, CivicaScript's selling price is $160. Our recommended maximum price to the consumer, allowing for a fair pharmacy dispensing fee, is $171.[1]

One might hope that our health system would take advantage of the availability of CivicaScript abiraterone at a low cost to lower costs for consumers and for the Medicare program.

Unfortunately, while CivicaScript and its health plan partners have attempted to work with all the major PBMs, most have not been willing to deliver this drug to patients at low cost, and average costs per claim remain high (Table 1).

[1] CivicaScript is the first company to introduce quality affordable generics with a transparent consumer price by making our maximum retail price (MaxRPTM) of $171 publicly available including through a QR code on the packaging.

Based on publicly available pricing information,[2] it is certainly likely that large vertical health-care companies acquire competing products at lower cost than CivicaScript's $160. But if so, the question remains: why are consumers, health plans and Medicare paying such high prices?

Table 1[3]

Manufacturer	Market share (%)	Average Medicare Part D spend per claim
Novadoz	44.3	$2,778
West-Ward/Hikma	9.2	$181
Amneal	8.5	$4,766
Rising	7.6	$3,734
Apotex	7.1	$3,167
Celltrion	6.9	$379
Northstar	6.5	$2,735
Viatris	5.5	$6,703
Wockhardt	1.8	$2,647
Bluepoint	1.5	$3,219
Patriot Pharm	0.6	$3,336
Dr. Reddy's	0.3	$3,377
Glenmark	0.1	$2,466
Teva	0.1	$3,850

One possible reason is that because of its cost, abiraterone is still classified as a "specialty drug," products that are normally dispensed through a "specialty pharmacy." We note that the vast majority of the specialty pharmacy dispensing in the United States occurs through PBM-owned specialty pharmacies. Therefore, the same entity that is theoretically working on behalf of health plans, consumers, and Medicare to reduce drug costs also has an incentive to maximize its revenues from dispensing.

CivicaScript's health plan partners have been creative in their attempts to get PBM-owned specialty pharmacies to dispense CivicaScript abiraterone, proposing a number of models, mechanisms and workarounds to get this drug to consumers at low cost. To date, with the exception of Navitus, a CivicaScript founding member, none of the largest PBM-owned specialty pharmacies have purchased or dispensed CivicaScript abiraterone.

Specialty pharmacy dispensing accounts for an estimated 32 percent of total PBM gross profits.[4] In addition to abiraterone, numerous other specialty drugs have approved generic versions available which should reduce the cost of medications.

Due to the oligopolies that control the generic market and benefit from our complex and opaque system of generic drug purchasing and reimbursement, U.S. patients, health plans and the Federal Government are not realizing the tremendous potential savings that they should.

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[2] On March 25, 2023, the publicly advertised cash prices for abiraterone 250mg ranged from $186.90–$8,661.38 (GoodRx, accessed 27 March 2023). The National Average Drug Acquisition Cost (NADAC) published by Medicaid is $229.10 for 2022.

[3] 2021 CMS Medicare Part D dashboard. Accessed March 27, 2023.

[4] Estimated for 2019. Drug Channels. *https://www.drugchannels.net/2020/07/pbm-owned-specialty-pharmacies-expand.html.* Accessed March 27, 2023.

Please contact Allan Coukell, Civica's Senior Vice President for Public Policy, for additional information: allan.coukell@civicarx.org.

Sincerely,

Gina Guinasso
President
CivicaScript

Witness Biographies

Lawton Robert Burns, Ph.D., MBA

Mr. Burns is the James Joo-Jin Kim professor, a professor of health care management, and a professor of management at the Wharton School, University of Pennsylvania. He is also co-director of the Roy and Diana Vagelos Program in Life Sciences and Management. Mr. Burns teaches on health-care strategy, strategic change, strategic implementation, organization and management, managed care, integrated delivery networks, and the U.S. health-care system.

He has published books on the institutional supply chain, technology sectors in health care, biomedical innovation, and international health-care systems. He recently published a book on the retail supply chain in health care *(The Healthcare Value Chain: Demystifying the Roles of GPOs)* and co-authored an analysis of why many solutions to improve health care do not work. He is the lead editor of a major health-care management text (Healthcare Management: Organization Design and Behavior, 2019).

Robin Feldman, J.D.

Ms. Feldman is the Arthur J. Goldberg distinguished professor of law, Albert Abramson '54 distinguished professor of law chair, and director of the Center for Innovation at UC College of the Law, San Francisco. She is a leading expert on health care and access, particularly as it relates to pharmaceutical competition and innovation. Ms. Feldman clerked for the Honorable Joseph Sneed of the U.S. Court of Appeals for the Ninth Circuit. She is an award-winning scholar who has published four books and more than 70 articles in law journals and leading economic and health-care reviews.

Ms. Feldman frequently testifies before legislative and regulatory bodies. Her work has been cited in the Congressional Record, by the White House, in governmental reports, and in court proceedings. In a recent Supreme Court case, briefs in support of both sides cited her work. She has also contributed to government projects beyond patent and pharmaceutical law, including AI and cyber-threats.

Matthew Gibbs, Pharm.D.

Mr. Gibbs is president at Capital Rx, a full-service pharmacy benefit manager that operates with a transparent, flat-fee pricing model. He oversees several core operations at Capital Rx, such as client services, client operations, benefit administration, customer contact and clinical call centers, and clinical operations and services. Mr. Gibbs is also involved in commercial activities to support sales and the growth of the Pharmacy Benefit Administration segment. Before joining Capital Rx, Mr. Gibbs worked in executive positions at Walgreens, Medco, and Anthem. He also served as president of EnvisionRx and led the Aon pharmacy consulting practice. Mr. Gibbs maintains an active pharmacy license.

Jonathan Levitt, Esq.

Mr. Levitt co-founded Frier Levitt, a health-care law firm, in 2000. Beginning with a 2003 national class action of pharmacies against a publicly traded pharmacy benefit manager (PBM), Mr. Levitt began his career journey to understand the U.S. prescription drug supply chain. He is an experienced trial attorney who represents drug supply chain stakeholders, such as pharmacies, physician-dispensers, provider associations, manufacturers, wholesalers, and plan sponsors. He has represented supply chain stakeholders in numerous law suits, often uncovering PBM tactics used to hide funds, and challenged one-sided contracts drafted by PBMs. Additionally, Mr. Levitt assists Self-Funded Plans with their pharmacy benefit design. He has led numerous litigations and arbitrations involving Medicare Part D "direct and indirect remuneration" (DIR) fees and represents State Medicaid systems conducting PBM audits.

Karen Van Nuys, Ph.D.

Ms. Van Nuys is the executive director of the Value of Life Sciences Innovation program and a senior fellow at the USC Schaeffer Center for Health Policy and Economics. Her research focuses on the pharmaceutical distribution system and the impact of intermediaries' business practices on prescription drug utilization and cost. She has conducted research on the flow of money in the insulin market, the impact of biosimilar entry on cancer drug markets, and the social value of novel therapies for heart failure and hepatitis C. Her work has been published in leading journals in economics, medicine, finance, and health policy, and cited in congressional testimony and policy reports.

Ms. Van Nuys has held positions in both consulting and academia, and she has consulted with Fortune 50 companies ranging from insurers and life sciences companies to automotive manufacturers and media conglomerates.

COMMUNICATIONS

AMERICAN PHARMACISTS ASSOCIATION
2215 Constitution Ave., NW
Washington, DC 20037
800–237–2742
https://pharmacist.com/

Chair Wyden, Ranking Member Crapo, and Members of the Committee:

On behalf of our nations over 310,000 pharmacists, the American Pharmacists Association (APhA) is pleased to submit the following Statement for the Record to the U.S. Senate Committee on Finance hearing "Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers."

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists and pharmacy personnel in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA applauds the Committee's ongoing leadership and recognition federal legislation must be passed to address pharmacy benefit managers' (PBMs) harmful business practices that are increasing prescription drug costs at the expense of patients and creating "pharmacy deserts" in minority and underserved communities, where the neighborhood pharmacy may be the only health care provider for miles.[1] PBMs' business practices have undermined the community pharmacy business model, resulting in many pharmacies having to make the challenging choice of taking a loss when filling a prescription to ensure patients are not denied access to their needed medications. As the most accessible healthcare professional, pharmacists should be able to provide the high-quality care they are trained to provide without fear it will cause them to go out of business. In a February 2023 national survey conducted by APhA, 91.5% of respondents reported that current PBM practices negatively impact their practice and ability to provide patient care.[2] As explained during APhA's recent PBM 101 briefing for congressional staff,[3] there are already mountains of data for Congress to take action from Medicare, Medicaid and commercial plans on PBMs' uncompetitive and deceptive trade practices that target patients with chronic conditions, and force them to use PBM-owned specialty and mail order pharmacies rather than their local pharmacy. It's way past time to put patients over PBM profits, and Congressional action is overdue.

Background

- PBMs originally emerged over 40 years ago as middlemen between health plans and pharmacies to adjudicate claims.

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[1] *https://www.japha.org/article/S1544-3191(22)00230-8/fulltext/.*

[2] *https://www.pharmacist.com/APhA-Press-Releases/apha-releases-survey-results-quantifying-the-impact-of-pbms.*

[3] *https://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Fapha.msgfocus.com%2Fc%2F11HbcOknPGFkG5EnaeGtULx9O4KoUj&data=05%7C01%7Cmbaxter%40aphanet.org%7C93f200d5701a4088bcde08db21aed8a7%7C6577def6f03f4adba697e1535f172506%7C1%7C0%7C638140807069554809%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=hhBrgcsMgLnW4Sg4%2F%2ByGVtZf6qC9XtdCzkz66e0l7UY%3D&reserved=0.*

- Over the years, three PBMs have come to control 80% of the total market share [4] and have vertically integrated with insurers, chain pharmacies and specialty pharmacies.
- Numerous reports from pharmacists and media over the years have documented unfair and anticompetitive practices from PBMs on community pharmacies. These include clawbacks (known under Medicare as direct and indirect remuneration (DIR) fees which PBMs often assess weeks, or even months, after Part D beneficiaries' prescriptions are filled, resulting in pharmacies realizing only long after the prescription was filled that they did not recoup their costs), gag clauses (preventing sharing cash prices with patients), spread pricing (overcharging the payer, underpaying the pharmacy and keeping the spread), patient steering to PBM-owned pharmacies, mandatory mail-order raising patient safety concerns, and many other concerning practices.
- In December 2020, the U.S. Supreme Court unanimously ruled on *Rutledge v. PCMA* in the pharmacy communities favor, opening the door for state oversight of PBMs.[5]

Why PBM Reform is Needed

- The pharmacy reimbursement and drug pricing scheme in the U.S. has grown out of control, with misaligned incentives that neither benefit the patient nor lead to better health outcomes. These misalignments are causing pharmacies across the country to shut their doors, leaving patients without access to their local pharmacies.
- As a result of the predatory practices of PBMs:
  - Patients' access to medications from their local pharmacist across the country has declined,[6]
  - Taxpayer dollars have been funneled into corporate profits,[7] and
  - Generationally owned community pharmacies have been driven out of business.[8]
- Patients' access to their medications and their trusted healthcare professional, the pharmacist, should not be jeopardized due to misaligned incentives in the PBM industry that prioritize profits over patients.
- The unsustainable reimbursement model for medications caused by PBMs has contributed to negative workplace conditions for pharmacists and pharmacy teams.

PBMs are Costing Medicare and the U.S. Taxpayer

- Between 2010 and 2020 the Centers for Medicaid and Medicaid Services (CMS) reports that pharmacy direct and indirect remuneration (DIR) fees increased by more than 107,400 percent.[9] The increase in point-of-sale and retroactive pharmacy price concessions have contributed to an unsustainable environment for community pharmacies to keep their doors open.
- This month, the **Medicare Payment Advisory Commission's (MedPAC) March 2023 report found that pharmacy DIR payments to PBMs in Medicare Part D were an astounding $12.6 billion for 2021—which represents a $3.1 billion (+33%) increase from the 2020 figure of $9.5 billion.**[10]

Congressional Ask

- **Transparency:** APhA supports transparency and accountability in reimbursement and pricing to ensure consistent practices throughout the drug supply chain.

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[4] Pharmacy Benefit Managers: Market Landscape and Strategic Imperatives. Hirc. Available at *https://www.hirc.com/PBM-market-landscape-and-imperatives.*

[5] Supreme Court of the United States. *Rutledge, Attorney General of Arkansas v. Pharmaceutical Care Management Association*. Available at *https://www.supremecourt.gov/opinions/20pdf/18-540_m64o.pdf.*

[6] Rose J., Krishnamoorth R. Why your neighborhood community pharmacy may close. *The Hill.* Available at *https://thehill.com/blogs/congress-blog/healthcare/530477-why-your-neighborhood-community-pharmacy-may-close.*

[7] 3Axis Advisors. Analysis of PBM Spread Pricing in New York Medicaid Managed Care. Available at *http://www.ncpa.co/pdf/state-advoc/new-york-report.pdf.*

[8] Callahan C. Mom-and-pop pharmacies struggle to hang on. *Times Union.* Available at *https://www.timesunion.com/hudsonvalley/news/article/Mom-and-pop-pharmacies-struggle-to-hang-on-16187714.php.*

[9] Medicare Program; Contract Year 2023 Policy and Technical Changes.

[10] Medpac. March 2023 Report to Congress—Medicare Payment Policy. Page 399. *https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_SEC.pdf#page=427.*

- **Sustainability:** APhA supports pricing models that allow for the fair reimbursement of drug products and dispensing fees that can support a sustainable business model within community pharmacies.
- **Accountability:** APhA encourages appropriate oversight from state and federal agencies to prohibit pricing manipulations and anticompetitive practices that harm patient access to their medications and their pharmacist.

Legislation

- APhA supports the amended Pharmacy Benefit Manager Transparency Act (S. 127) that recently passed the Senate Commerce, Science and Transportation Committee. Initial estimates from the Congressional Budget Office (CBO) found that S. 127 saves taxpayers $740 million. We would also support removing the exemption for passing along 100 percent of rebates to health plans or payers as this provision does not guarantee plans and payers will pass these "savings" on to patients or ensure adequate pharmacy reimbursement.
- APhA also supports the Drug Price Transparency in Medicaid Act, which would reign in PBMs' unfair use of "spread pricing." Spread pricing is a practice in which a PBM charges the state or health plan more than they pay the pharmacy for a medication and then keeps the "spread" as a profit, often reimbursing the pharmacy for less than their cost to acquire the drug. This hurts pharmacies' ability to stay in business and provide care to the vulnerable Medicaid beneficiaries whom they serve. This legislation would also move all state Medicaid managed care programs to a market-based reimbursement model that more closely reflects the true acquisition costs of prescription drugs in Medicaid plus a fair professional dispensing fee. APhA previously sponsored a study that found that utilizing a model of Medicaid's National Average Drug Acquisition Cost (NADAC) plus a professional dispensing fee offered an overall point-of-sale spending decrease for prescription drugs at pharmacies, which would result in billions of projected savings to Medicare beneficiaries as a result of their reduced cost-sharing obligations.[11]

Patient Need

- Patients are harmed by insurer and PBM practices that mask the real prices of medications, increase the amount they pay at the pharmacy counter, and interfere with pharmacists' ability to provide patient care.
- As a result of anticompetitive practices, PBMs have caused pharmacies to close, contributing to pharmacy deserts which are especially prominent in racial and ethnic minority communities.[12]
- These practices impact taxpayers as they contribute to inflated prices of medications reimbursed under public health plans. **A study found that PBM tactics forced Oregon Medicaid to overpay $1.9M on a single drug, where PBMs marked up the drug by 800 percent.**[13]

APhA would like to thank the Committee for the opportunity to comment on the importance for Congress to pass PBM reform legislation. APhA looks forward to working with the Committee to restore transparency, accountability, competition, and equity to our nation's supply chain and health care marketplace. Please contact Doug Huynh, JD, APhA Director of Congressional Affairs, at dhuynh@aphanet.org if you have any additional questions or additional information.

AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS
4500 East-West Highway, Suite 900
Bethesda, MD 20814
301–657–3000
https://www.ashp.org/

March 30, 2023

The Honorable Chairman Ron Wyden
U.S. Senate
Committee on Finance
219 Dirksen Senate Office Building

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[11] *https://www.pharmacist.com/About/Newsroom/new-study-medicare-could-save-seniors-billions-by-fixing-part-d-incentives.*

[12] Fewer Pharmacies in Black and Hispanic/Latino Neighborhoods Compared With White or Diverse Neighborhoods, 2007–15. *Health Affairs.* Available at *https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01699.*

[13] *https://oregonpharmacy.org/2022/10/27/oregon-report/.*

Washington, DC 20510–6200

The Honorable Ranking Member Mike Crapo
U.S. Senate
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510–6200

Re: Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers (March 30, 2023).

Dear Chairman Wyden and Ranking Member Crapo:

Pharmacy Benefit Managers (PBMs) play an important role in managing participants, beneficiaries, and enrollees' individual and group plan, as well as Medicare Advantage and Medicaid Managed Care plans, and prescription drug benefits. However, some PBM practices have put participants, beneficiaries, and enrollees' health and safety at risk, as well as restricted underserved individuals' access to safe and affordable prescription drugs. ASHP is the largest association of pharmacy professionals in the United States, representing over 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health-system community pharmacies. Our members have seen firsthand how PBM practices can limit and put at risk patient care.

Bring Transparency to PBM Rebates: Manufacturer drug rebates for patient out-of-pocket (OOP) expenses that are being taken by PBMs are opaque and need greater transparency. At a minimum, rebates intended for patients' OOP expenses should be provided at the point-of-sale (POS) and instituted in a manner designed to simplify reimbursement and promote transparency for both patients and pharmacies. Often the negotiated rate between a PBM and a manufacturer so adversely impacts a pharmacy's ability to cover its acquisition cost for a product, the cost to the pharmacy is greater than a dug's acquisition cost. *POS reimbursement should, in all cases, be sufficient to cover a pharmacy's acquisition cost for a drug. Additionally, we recommend that all contracts clearly outline prescription and pharmacy performance measures, fees, and expectations, as they relate to reimbursement. There should be complete transparency about expectations and comparator benchmarks related to performance and outcomes.*

Pharmacy Fees: Pharmacy fees have increased exponentially over the last few years. According to data released by CMS, "performance-based pharmacy price concessions, net of all pharmacy incentive payments, increased, on average, nearly 170 percent per year between 2012 and 2020 and now comprise the second largest category of DIR received by sponsors and PBMs, behind only manufacturer rebates"[1] These fees were originally created to incentivize quality. However, they have become arbitrary in nature and purpose and quite extensive. For instance, many times the quality metric a pharmacy fee is based on is irrelevant to the setting and medical condition a drug is used to treat. Pharmacy fees are also usually unknown until a drug is dispensed and the claim adjudicated. Until recently, these fees were enforced retroactively, placing pharmacists in financial peril. While the retroactive collection of fees is expected to terminate based on CMS's recent ruling, vague administrative fees and unclear performance measures may not be impacted.[2] *We recommend that no administrative, prescription, quality, performance, or other care-related fees be collected retroactively, but clearly outlined at the POS. We also recommend an individual or group plan, and its PBM, be prohibited from enforcing pharmacy fees except when the quality measure on which a fee based is directly relates to the condition a patient is being treated and is appropriate for the setting the patient is being treated in. Lastly, we recommend that any fee to be collected and related to performance be clearly outlined in scope and magnitude within the contract with a pharmacy, allowing pharmacies to properly forecast budgeting and understand expectations.*

Prohibiting White and Brown Bagging: White bagging occurs when a PBM requires patient medications be distributed through a narrow network of specialty pharmacies that are often affiliated with the PBM before the pharmaceuticals are then sent to a site of care, such as a hospital, where they will be dispensed by a provider. Hospitals have strict quality controls and by circumventing the traditional and regulated hospital supply chain, white bagging raises patient safety risks by enabling diversion and heightening the possibility of drug spoilage/wastage. Brown

[1] Federal Register, Vol. 87, No. 89, Monday, May 9, 2022, Rules and Regulations; page 27834.
[2] *Id.*

bagging occurs when a PBM ships medications to a patient, who then must take the pharmaceutical to the provider for administration. These medications typically require special storage and handling. White bagging and brown bagging put pharmaceuticals at risk of spoilage, contamination, and diversion, putting patients' health at risk. *We recommend Congress prohibit PBMs from imposing white and brown bagging.*

Protecting the 340B Program and Providers Against Discrimination: Safety net hospitals rely on the 340B Drug Pricing Program to provide healthcare services, including care for uninsured and underinsured patients. However, PBMs have been discriminating against 340B providers, including excluding them from networks or making them use their software and other services at additional costs with the intent of reducing reimbursements for 340B purchased drugs. *We recommend Congress prohibit PBMs from discriminating against 340B providers with the intent of reducing reimbursements for 340B purchased drugs, including such practices as excluding 340B providers from networks or requiring payment of fees or the use of specific claims software as a means of increasing drug costs beyond 340B levels.*

Expanding Access to Biosimilars: Uptake of biosimilars lags behind coverage of small molecule generic drugs. Insurers and their PBMs typically only cover one preferred brand of any given biologic product, excluding all other biosimilar products. This is contrary to how plans cover small molecule drugs where they are required to cover all commercially available generics. *We recommend Congress require that an individual or group plan, and its PBM, that covers multiple generic small molecule drugs in a formulary, treat biosimilars in a similar fashion. Thus, an individual or group health plan, and its PBM, that cover a reference (brand name) biologic or any biosimilar of the reference product, must cover* all *biosimilars of that product.*

ASHP thanks you for considering these recommendations regarding PBMs, which will ensure participants, beneficiaries, and enrollees have access to safe and effective drugs. We look forward to continuing to work with you on this issue. If you have questions or if ASHP can assist in any way, please contact Frank Kolb at fkolb@ashp.org.

Sincerely,

Tom Kraus
Vice President, Government Relations

ASSOCIATION FOR CLINICAL ONCOLOGY
2318 Mill Road, Suite 800
Alexandria, VA 22314
T: 571–483–1300
F: 571–366–9530
https://asco.org/

Statement of Lori J. Pierce, M.D., FASCO, Chair of the Board

The Association for Clinical Oncology (ASCO) is pleased to submit this statement for the record of the hearing entitled, "Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers." ASCO is pleased that the U.S. Senate Committee on Finance is exploring this issue.

ASCO represents more than 45,000 oncology professionals who care for people living with cancer. ASCO works to ensure that all individuals with cancer have access to high quality, equitable care; that cancer delivery systems support optimal cancer care; and that our nation supports robust federal funding for research on the prevention, screening, diagnosis and treatment of cancer.

ASCO has endorsed the Pharmacy Benefit Manager Transparency Act of 2023. This bill, which advanced out of the U.S. Senate Committee on Commerce, Science, & Transportation, would provide transparency and hold pharmacy benefit managers (PBMs) accountable for unfair and deceptive practices that may lead to an increase in prescription drug prices for patients with cancer.

Cancer drugs are a critical component of treatment for many cancer types as well as for the prevention and control of symptoms. They also represent an increasing component of cancer care costs. While PBMs were originally created to serve as third-party administrators of pharmacy claims, they now leverage their market

power to obtain lower prices on drugs, often without passing those savings along to patients.

Further, ASCO members have reported that some patients have had their medication or dosage changed by PBMs without prior approval by or in consultation with the treating physician. PBMs are also increasingly shifting drug dispensing away from physicians and toward pharmacies they own, which can negatively impact patient access to treatment. In these ways, PBMs are interfering with the doctor-patient relationship and lowering the quality of care for people with cancer.

ASCO supports efforts to shed light on PBM practices and prohibit unfair or deceptive practices that impact patients with cancer. For a more detailed understanding of our policy on this issue, we invite you to read the *ASCO Policy Brief: Pharmacy Benefit Managers* by our affiliate, the American Society of Clinical Oncology. We are committed to working with you as Congress continues to have meaningful dialogue about these issues. If you have any questions, please contact Kristine Rufener, Director of Congressional Affairs, at Kristine.Rufener@asco.org or 571–483–1547.

LETTER SUBMITTED BY DAVID BAGOT, RPH

Chairman Wyden, Ranking Member Crapo, and Members of the Committee,

My name is David Bagot. I own and operate a small community pharmacy that services Rural Menard County, in Central Illinois. I want to thank you for holding this hearing today, and implore you to craft bills to curb the damaging business practices used by the PBM industry.

It would take me way longer than the amount of time I have to write this statement to describe all of the things I know about PBMs and how they are degrading the quality of health care in this country while simultaneously driving up the cost. So, I will just make a short statement.

PBMs make brand named medication more expensive by charging Big Pharma companies for formulary access. I do not believe I have to explain why that makes them more expensive. These kickbacks should be illegal and I hope that is the first thing done to reign in PBMs, remove their "Safe harbor" from laws that make kickbacks illegal.

PBMs damage everyone who is involved in the transaction surrounding a patient buying a prescription drug:

- *The patient.* Must pay more for expensive prescriptions, must settle for what drug the PBM wants them to have and not what their doctor wants them to have, are told where and when they can get their prescriptions. Is cut off from medications not paying kickbacks to their PBM.
- *Pharmacy.* The pharmacy is under paid (spread pricing, AWP minus contracts, claw backs like DIR fees . . .), patient steering and the list goes on and on.
- *Drug manufacturer.* Must pay kickbacks to get their drug covered and are then watch their reputation smeared by PBMs saying they alone are the reason for high prices. If they do not pay a high enough kickback their drug doesn't make the formulary and is not used.
- *Payers.* Employers, government and folks purchasing Market Place Plans. Everyone pays higher premiums because drugs cost more than twice as much in the USA than anywhere else in the world.

PBMs have driven the price of many generic medications so low that they are no longer produced in our country. They have done this by under paying pharmacies, who then turn to their wholesaler for cheaper prices who then turn to the manufacturers for lower prices. Pretty soon, the only way the manufacturer can lower their price is by moving production to countries with super cheap labor. This is bad for all the obvious reason.

Please fix our broken health care system, it is way past time!

Thank you again for having this hearing, I look forward to listening in.

David Bagot, RPh

BIG Y FOODS INC.
2145 Roosevelt Ave.
Springfield, MA, 01104
413–504–4494
https://www.bigy.com/

Statement of Steven M. Nordstrom, Director of Pharmacy

Introduction

Big Y Foods, Inc. appreciates the opportunity to submit a statement for the record for the United States Senate Committee on Finance on "Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers."

Big Y is a family owned and operated supermarket chain located in Massachusetts and Connecticut. We operate 72 grocery stores with 33 locations offering pharmacy services. Big Y is one of the largest independently owned grocery chains in New England. The company was started in 1936 by founders Paul and Gerry D'Amour. The third generation of D'Amours are actively involved in the day to day operations of the business.

Great Concern about Pharmacy Benefit Manager Tactics

We are extremely concerned about pharmacy benefit manager (PBM) tactics that have significant negative effects on patients, communities, taxpayers, employers, and pharmacies. PBMs are hired by insurance plans and others to negotiate lower drug prices. Unfortunately, they manipulate the system and keep billions in profits while:

- Forcing patients and others to pay more for their medicines;
- Limiting patients' ability to choose their pharmacist;
- Restricting access to medicines that doctors and other prescribers determine to be right for the patient; and
- Jeopardizing pharmacies' viability—harming not only the pharmacy but also the patients and communities that rely on them.

The dominance of PBMs is significant. Three PBMs control 80 percent of the prescription drug market. These are the practical effects of PBM tactics:

- **Over-payments:** The University of Southern California Leonard D. Schaeffer Center for Health Policy & Economics found that Medicare Part D standalone plans paid $2.6 billion more in one year for 184 common generic medications compared with prices for the same drugs available to cash-paying customers of one retailer.
- **Restricting medications:** Drug Channels analysis found that from 2014 to 2022, 1,357 medications were excluded from at least one PBM formulary for at least one year. The exclusions of drugs from these lists have escalated since starting in 2012.
- **Putting the squeeze on pharmacies:** The Centers for Medicare & Medicaid Services found that direct and indirect remuneration (DIR) fees charged by PBMs and payers to pharmacies have exploded by 107,400% over the last decade.

Big Y continues to grow as a company, building clean modern stores while adding jobs in the communities we serve. Unfortunately, we have not opened any new pharmacy locations in several years due to the incredible financial pressures being placed on the pharmacy industry by unfair PBM practices. As these behaviors go unchecked, operating a pharmacy becomes increasingly more difficult. Many independent pharmacies have been forced to close in our market area, unable to keep the doors open with rising costs and declining reimbursements. Big Y had to make the tough decision to close several pharmacies in 2019 facing those same rising costs and declining reimbursements, making these pharmacies no longer viable. As more and more pharmacies close, customer access to convenient, friendly service is being limited, leaving only the big chains with long lines for many.

During the pandemic, our pharmacy team was a vital part of vaccinating our communities along with providing treatments to those infected and offering test kits as they became available. Incredibly, our 33 pharmacy locations were able to administer 120,000 COVID vaccinations over the last two years. Teams of our pharmacists and technicians visited nursing homes, schools, and businesses to administer a variety of vaccinations, including COVID and Flu. Several of these locations reached out to us as the big chains would not service them because they were unable to meet

the chains' minimum requirements. As independent pharmacies continue to close, this kind of service will go away; people will be left vulnerable and underserved.

At Big Y, the health and wellness of our employees and customers is our highest priority. Offering Pharmacy services is paramount to that goal. We would love to play a larger role providing those services, but we are limited by current PBM practices. Although the industry was excited by the CMS ruling on the elimination of D.I.R. claw backs starting in 2024, we are already seeing PBMs enacting unfair business practices to recoup those lost profits. New contracts are being submitted with reimbursements well below our cost of goods and cost to dispense. These negative terms will force us to decline participation, in some cases limiting consumer access. This could lead to more potential job loss with scripts going to the major chains. Pharmacies need to be protected from these tactics in order to keep us as a viable business model. Our ask is simple; require PBMs reimburse us at a fair rate allowing us to provide our employees great pay and benefits while offering great service to our communities

We want to take this opportunity to define "PBM reform." This is important to maximize the effectiveness of Congress' work in this area for patients, and to rollback the current jeopardy posed by PBMs to pharmacies. For this purpose, we call to your attention the Principles of PBM Reform advocated by the National Association of Chain Drug Stores:

- **Stop explosive retroactive fees.** Stop PBMs and payers from using "DIR fees" and other tactics to grab back the payments made and owed to pharmacies—often many months after the fact and often resulting in below-cost pharmacy reimbursement.
- **Stop below-cost reimbursement.** Adopt a reimbursement rate floor that prevents PBMs and payers from reimbursing pharmacies below the true cost of acquiring and dispensing prescription drugs.
- **Stop gaming of performance measures.** Standardize performance measures to help improve patient outcomes and reduce costs—rather than allowing PBMs and payers to play "gotcha" with pharmacies using arbitrary measures and exorbitant fees.
- **Stop "specialty definitions" from steering patients from their pharmacy.** Prevent PBMs and payers from defining "specialty drugs" in ways that steer patients with rare or complex diseases away from their preferred pharmacy of their choice and toward another pharmacy—including those owned by the PBMs and payers.
- **Stop mandatory mail-order.** Prohibit PBMs and payers from forcing patients to use mail-order pharmacies—including those owned by the PBMs and payers—and prohibit them from imposing penalties on patients for choosing a convenient and trusted pharmacy in their neighborhood.
- **Stop limited networks.** Require PBMs and payers to include in their networks all pharmacies willing to accept terms and conditions established by the PBM.
- **Stop overwhelming audits.** Bring efficiency, transparency, and standardization to the processes by which PBMs audit pharmacies without sacrificing continuity of care.
- **Stop the undercutting of PBM reform laws.** Prioritize the implementation, enforcement, and oversight of PBM reform laws—to maximize results for patients and fairness for pharmacies and other stakeholders, and to ensure laws are not undermined by inaction of PBMs or of government.

Conclusion

In closing, we want to put to rest one of the myths perpetuated by PBMs. It is shocking that they have been able to stave off reform efforts by alleging that premiums will increase. This is nothing short of a scare tactic, and one that cannot be allowed to be used so flippantly and without substantiation. PBM reform will reduce prescription drug costs by cracking down on middlemen's manipulation. It does not follow logically that reductions in prescription drug costs will result in increased premiums. It is time to address the manipulative business practices of PBMs, as well as to end the negative effects of their tactics.

Big Y thanks the Committee for the opportunity to provide our perspective on PBM reform. For questions or further discussion, please contact Steve Nordstrom, at nordstrom@bigy.com or, at 413–222–7653.

BIOSIMILARS FORUM
800 17th St., NW, Suite 1100
Washington, DC 20006
tel: (202) 828–1895
https://biosimilarsforum.org/

Humira® Biosimilars: Opportunities and Barriers for Patient Access Placement

Common Sense Policies for Pharmacy Benefit Manager Reform

At least eight lower-cost, FDA-approved biosimilars for Humira® (adalimumab) are expected to become available to patients by the summer of 2023. Their launches will be consequential in determining the future success of the biosimilars market in the U.S. and could save patients and the U.S. healthcare system more than $5 billion dollars a year, if—and only if—patients can actually access these medications at affordable costs.[1]

As Congress and the Federal Trade Commission (FTC) examine pharmacy benefit manager (PBM) reform, recent biosimilar launches show how PBMs prioritize profits and backend rebates over patients. Most notably, the recent launches of Humira® (adalimumab) and insulin biosimilars highlight the market challenges presented to patients that need them.

Actions must be taken now to accelerate biosimilar preferential placement on formularies as they become available. The following policy solutions and market reforms to address market challenges would increase access to lower-cost biosimilars for patients, promote prescription drug affordability, and support health equity.

Existing PBM Practices: Perverse Incentives for Biosimilar Adoption

As Humira® (adalimumab) biosimilars launch, PBMs are expected to continue to favor the branded Humira® reference product by either placing it on a preferable formulary tier or requiring fewer restrictions for a patient to access it relative to it biosimilar competitors. This lack of access to lower-cost treatment options will stifle free market competition, limit patient savings, and harm the long-term viability of the biosimilars industry.

PBMs also often use rebates from biosimilar manufacturers to control formulary placement and uptake. Biosimilar manufacturers intend to offer patients significantly more affordable treatments options, but they are forced into rebates with PBMs to earn formulary access. These rebates increase the price of the biosimilar and patients' out-of-pocket costs.

Biosimilar developers can be forced to launch biosimilars with high list prices, in order to accommodate PBM demands for the high rebates when the biosimilar developer would prefer to make the treatment available to patients at a lower list price. In an attempt to support patients, dual pricing strategies have emerged from biosimilar manufacturers. These pricing strategies focus on the traditional higher price/high rebate compared to using a lower list price strategy that could lower overall costs for patients and the healthcare system. However, a lower list price strategy will only benefit the patient if the PMB chooses the most competitive lower list price version to place on a preferred position on the formularies. This would mean giving up retroactive rebates in favor of point of sale discounts. When given this choice, the PBM has continued to prefer high WAC options.[2] These PBM schemes thwart robust, transparent competition that will lower overall drug costs for patients and taxpayers.

High List Prices Hurt Patients

- For example, Semglee®, an insulin biosimilar, was launched at two different prices. The unbranded version (insulin glargine) carries a wholesale acquisition cost (WAC) of $147.98 for a package of five 3-ml pens. That price is 65% cheaper than the reference product's list price.

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[1] Rebate walls may thwart biosimilar savings. Published September 13, 2022. Accessed March 23, 2023, *https://www.modernhealthcare.com/supply-chain/humira-biosimilar-savings-may-face-delays.*

[2] Lessons from Semglee: Early Perspectives on Pharmacy Biosimilars. Published November 2022. Accessed March 29, 2023, *https://www.iqvia.com/locations/united-states/library/white-papers/lessons-from-semglee-early-perspectives-on-pharmacy-biosimilars.*

- Brand-name Semglee®, meanwhile, has a WAC of $404.04 per package of five 3-ml pens. That version comes in only slightly cheaper than the reference product, which carries a list price of $425.31 for five pens.
- Uptake for the unlabeled Semglee® was slow for the first 10 months prior to the launch of labeled Semglee®, with Lantus holding onto 99% of the market share through November 2021. After interchangeable Semglee® launched, market share jumped to 15% of commercial prescriptions by March 2022. Authors of a recent IQVIA paper noted that payer formulary constraints were the main driver.[3]
- This dual pricing strategy effectively provides payers with the option to choose between a high price, high rebate product, etc., that carries a lower price and features a lower rebate.
- A recent study showed that patients would rather pay slightly higher insurance deductibles to save out-of-pocket costs at the pharmacy.[4]

Opaque volume-based rebate agreements that favor high list prices that do not save patients money when there is a lower list price option available is contrary to the intent of the U.S. healthcare system. Biosimilar manufacturers want to serve patients, but when our customers are plans and PBMs that have opposite goals than that of the patient, that task is impossible. The end result of not rebalancing the market will jeopardize healthcare costs long term.

Changes Required to Promote a Path Forward for Biosimilar Access

- PBMs must be willing to place biosimilars on their formularies—as they are approved, including mid-year—in preferred positions without restrictions and make them accessible to patients and providers.[5] Merely listing biosimilars on a formulary at parity with the brand biologic is not enough to ensure full patient access or maximum affordability.
- PBMs must prioritize patients over profits and backend rebates by placing Humira® (adalimumab) biosimilars on formulary tiers that are affordable and unrestricted for patients. This will achieve full cost-savings for patients, instead of using them as leverage for larger rebates. For example, as it stands, brands may have opaque agreement that guarantees volume in exchange for a retroactive rebate at the end of the year. This takes decision-making away from patients and providers and disallows multiple points of competition from biosimilars.
- This situation results in limited formulary coverage for the biosimilar, as the reference product is "preferred" on formularies because of sizeable and anti-competitive volume contracting strategies.
- Currently, the launch of the first wave of pharmacy benefit biosimilars (Semglee® and Amjevita™) has shown list prices close to that of the brand necessary to gain access to the PBM formulary. This may continue with the launch of additional Part D biosimilars and is not conducive to lowering drug prices for patients in 2023, as the patient will pay a percentage of high-rebated list price and lose most of the savings they could have had with the low-rebate list price

Policy Solutions Needed

Lawmakers must lead in looking at savings in the long-term, which will be achieved with robust free-market competition, even if there are short-term costs with changing the current system. Increased patient access and cost-savings can be achieved by the following strategies.

Congress Should Demand the Federal Trade Commission (FTC) Immediately Investigate PBM Actions Specifically Toward Biosimilars

- PBM rebate walls create de facto exclusivity and foreclose biosimilars from effectively competing with the reference product. The FTC's policy statement on Section 5 of the Federal Trade Commission Act (FTC Act) (15 U.S.C. 45) states

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[3] Lessons from Semglee: Early Perspectives on Pharmacy Biosimilars. Published November 2022. Accessed March 29, 2023, *https://www.iqvia.com/locations/united-states/library/white-papers/lessons-from-semglee-early-perspectives-on-pharmacy-biosimilars.*

[4] Faced with High Cost Sharing for Brand Medicines, Commercially Insured Patients with Chronic Conditions Increasingly Use Manufacturer Cost-Sharing Assistance. Published June 2020. Accessed March 23, 2023, *https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Faced-with-High-Cost-Sharing-for-Brand-Medicines.pdf.*

[5] Rebate walls may thwart biosimilar savings. Published September 13, 2022. Accessed March 23, 2023, *https://www.modernhealthcare.com/supply-chain/humira-biosimilar-savings-may-face-delays.*

that "de facto . . . exclusive dealing, or loyalty rebates that use market power in one market to entrench that power or impede competition in the same or a related market" is anticompetitive and a clear violation of Section 5.[6] We encourage the FTC to act quickly and decisively to bring challenges to this anticompetitive behavior.
- The FTC must require PBMs to issue a market share report of patient uptake, by plan and drug mix, to establish biosimilar Humira access and uptake by January 1, 2024, with a final report and recommendations by January 1, 2025.

Policymakers and Regulators Must Implement Commonsense Solutions to Promote Biosimilar Access in Medicare Part D

- The Biden Administration, Congress, and federal regulators must ensure biosimilars are available to Medicare patients by allowing them the chance to compete on list price for preferred positions on formularies.
- CMS and policymakers must support a clear and expedited pathway to add biosimilars to Medicare Part D formularies.
  - Policies must not support artificial barriers that do not allow replacement of the reference product from Part D formularies.
  - Policies should not favor the ability for formularies to prefer reference products and interchangeable products over biosimilars without the interchangeable designation. This includes policies related to biosimilar formulary substitution and utilization management that favor reference products and interchangeable biologics over biosimilars.

Enact Federal Legislation for Point-of-Sale Rebates to be Passed to Patients

- Congress must pass legislation to remove barriers that prevent patients from accessing lower-cost biosimilars. These efforts could include:
  - De-linking fees for PBMs that have a direct relationship with high list prices.
  - Promoting health equity and patient convenience by disallowing anticompetitive vertical integration maneuvers, such as driving patients to specialty pharmacies owned by the corresponding PBMs and plans.
  - Charging PBMs more if they use other providers.
- Lawmakers must mandate that rebates are provided at the point of sale so that patients benefit from the cost-savings—not PBMs.
- Policymakers must promote transparency to patients, and employers on what agreements are taking place between PBMs, plans, and manufacturers.

Biosimilars Provide Significant Potential Cost-Savings

- Humira® has had a 470% price increase[7] since first introduced. Humira® and Enbrel® (etanercept) accounted[8] in 2019 for more than $5.7 billion in Part D spending—more than 14 times the $405 million that Part D spent that year for reference products with available biosimilars.
- Medicare could have saved[9] an estimated $2.19 billion on Humira® over 4 years had biosimilar competition been available.
- Part D spending on biologics with available biosimilars could have decreased[10] by $84 million, or 18%, if biosimilars had average uptake.

The Biosimilars Forum

The Biosimilars Forum is a nonprofit organization working to advance biosimilars in the United States with the goals of expanding access and availability and improving healthcare outcomes. Since its inception, the Forum has worked to expand the

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[6] Federal Trade Commission, Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act, Commission File No. P221202 (November 10, 2022) at 14.

[7] House committee uncovers how Humira's price spiked by 470% as AbbVie execs cashed bonuses tied to the hikes. Endpoint News. Published May 18, 2021. Accessed July 2022, *https://endpts.com/house-committee-uncovers-how-humiras-price-spiked-by-470-as-abbvie-execs-cashed-bonuses-tied-to-the-hikes/*.

[8] Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use. U.S. Department of Health and Human Services Office of Inspector General. Published March 29, 2022. Accessed July 2022, *https://oig.hhs.gov/oei/reports/OEI-05-20-00480.pdf*.

[9] Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use. U.S. Department of Health and Human Services Office of Inspector General. Published March 29, 2022. Accessed July 2022, *https://oig.hhs.gov/oei/reports/OEI-05-20-00480.pdf*.

[10] Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use. U.S. Department of Health and Human Services Office of Inspector General. Published March 29, 2022. Accessed July 2022, *https://oig.hhs.gov/oei/reports/OEI-05-20-00480.pdf*.

uptake of biosimilars throughout the healthcare system through policies that will increase access for patients and lower costs through increased competition. Forum members represent companies with the most significant U.S. biosimilars development portfolios.

FOR IMMEDIATE RELEASE
March 30, 2023

Biosimilars Forum Applauds the U.S. Senate Finance Committee for Holding PBMs Accountable for Prioritizing Profits over Patients

Juliana M. Reed, executive director the Biosimilars Forum, released the following statement about the United States Senate Finance Committee hearing "Pharmacy Benefit Managers (PBMs) and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers." At least eight lower-cost, FDA-approved Humira® (adalimumab) biosimilars are expected to become available to patients by the summer of 2023. Their launches will be consequential in determining the future success of the biosimilars market in the U.S. and could save patients and the U.S. healthcare system more than $5 billion dollars a year, if—and only if—patients can actually access these medications at affordable costs.

"The members of the Biosimilars Forum and I applaud the Senate Finance Committee for holding PBMs accountable for their opaque and anti-competitive pricing schemes that force higher prices on patients, while denying them access to the treatments they need.

"Biosimilars can save the health care system $133 billion by 2025 if they are fully available and accessible to the patients who need them. Unfortunately, PBMs often prevent patients from accessing these lower-cost, FDA-approved treatments by forcing biosimilar manufacturers to launch biosimilars with high list prices and high rebates to gain access on their formularies. PBMs have proven time and time again that they prioritize higher list prices with high rebates over making treatments more affordable and accessible for patients.

"PBMs must be willing to support free market competition and place biosimilars on formularies—as they are approved, including mid-year updates—in preferred positions without restrictions. Particularly, PBMs must prioritize patients over profits and backend rebates by placing biosimilars—especially Humira® (adalimumab) biosimilars—on formulary tiers that are affordable and unrestricted for patients.

"Even though biosimilar manufacturers would prefer to make treatments available to patients at a lower list price, they are often forced to meet PBM demands for higher rebates to gain formulary access. This has led to dual pricing structures that focus on the traditional higher price and high rebates compared to using lower list prices for patients. These PBM schemes thwart robust, transparent competition.

"PBM transparency is not enough. Lawmakers and regulators must ensure biosimilars have preferential placement on formularies as they become available. This would increase access to lower-cost biosimilars for patients, promote prescription drug affordability, and support health equity."

For more information on the Biosimilars Forum's work to increase access to lower-cost biosimilars, visit *biosimilarsforum.org*.

MEDIA CONTACT:

Scott Lusk
Signal Group, Vice President
202–288–3233; slusk@signaldc.com

CENTER FOR FISCAL EQUITY
14448 Parkvale Road, #6
Rockville, Maryland 20853
fiscalequitycenter@yahoo.com

Statement of Michael G. Bindner

Chairman Wyden and the Ranking Member Crapo, thank you for the opportunity to submit these comments for the record.

This testimony relies on my experience as a member of the Cost Management Systems project of what was then called Computer-Aided Manufacturing—International, now the Consortium for Advanced Management—International. The project produced *Cost Management for Today's Advanced Manufacturing.* I created a handbook based on the project, the *U.S. Air Force Orientation Guide to Advanced Cost Management.*

A key concept in cost management, supply chain management and cost accounting is non-value-added cost. Pharmacy Benefit Managers are a non-value-added cost. While they do have an impact on the price manufacturers can charge, they are the primary, if not the sole, beneficiaries.

The answer to this problem is some form of single payer healthcare, whether it be through Medicare for All, an expanded Public Option (to replace Medicaid) or having employers pay for medications, healthcare workers (and education) and specialist/hospital care either directly or as a part of the organization. Please see our Single Payer Attachment for more on this issue.

The other significant driver of drug prices is the question of funding orphan drugs. The answer is easy. Keep control of orphan drug intellectual property in the hands of the National Institutes of Health. Let them, and other agencies such as the National Science Foundation, fund grants and research contracts to generate breakthroughs, as well as to manage clinical trials for FDA approval (if appropriate for the population that needs the drug). When the drug is approved, NIH can then contract for its manufacture and distribution.

This methodology will get more done faster, without relying on profiteering to do what is necessary to help our most vulnerable patients.

Thank you for the opportunity to address the committee. We are, of course, available for direct testimony or to answer questions by members and staff.

Attachment: Single Payer discussion from HHS Budget FY 2022

We address the funding of the Affordable Care Act, the need for an immediate COLA for retirees, funding the Social Security Administration's non-fund costs, and the idea of cost savings for Social Security.

So far, the Administration has not yet addressed changes to the **Affordable Care Act,** at least not publicly. We suggest that the Committee ask the Secretary about any such plans.

At minimum, the individual and employer mandates, with associated penalties, that were repealed must be restored. The President campaigned on restoring and perfecting the Act, adding a public option. We agree, although the public option need not be self-supporting. It must be subsidized through a broad-based consumption tax. Such a tax burdens both capital and wage income.

The current funding stream seems to have been designed to draw opposition from wealthier taxpayers. It is an open secret that the Minority does not oppose most of the Affordable Care Act (which was designed by their own Heritage Foundation as an alternative to Mrs. Clinton's proposals). Broaden the tax base to fund the program and the nonsense on repeal will end.

The current funding stream from student loan initiation and interest, which was included in the baseline, should also be ended. Graduates (and non-graduates) with student loan debt cannot afford both their loan payments and insurance payments under the Affordable Care Act. When they apply for lower loan payments, which are always granted, they face either a balloon interest payment or capitalized interest, which makes their funding situation worse. No one should have to retire with student loan debt, yet quite a few soon will (or already have).

Forgive capitalized interest and apply any overpayments to principal. There should not be a one-size-fits-all subsidy. Also, when payments are deferred, return to the practice of deferring interest (or allow debts to be discharged, at least partially, in bankruptcy).

To deal with these issues, whatever is budgeted for analytical support in the Department should likely be doubled.

The following analysis comes from the Single Payer attachment that has previously been provided. Because of the President's preference for establishing the public option, we will repeat those analyses here. Aside from a broader base of funding, other compromises are necessary to enact a public option.

To set up a **public option** to end protections for pre-existing conditions and mandates. The public option would then cover all families who are rejected for either pre-existing conditions or the inability to pay. In essence, this is an expansion of Medicaid to everyone with a pre-existing condition. As such, it would be funded through increased taxation, which will be addressed below. A variation is the expansion of the Uniformed Public Health Service to treat such individuals and their families.

The public option is inherently unstable over the long term. The profit motive will ultimately make the exclusion pool grow until private insurance would no longer be justified, leading-again to Single Payer if the race to cut customers leads to no one left in private insurance who is actually sick. This eventually becomes Medicare for All, but with easier passage and sudden adoption as private health plans are either banned or become bankrupt. Single-payer would then be what occurs when insurance companies are bailed out in bankruptcy, the public option covers everyone and insurance companies are limited to administering the government program on a state by state basis.

The financing of the Affordable Care Act should be broadened. It should neither be funded by the wealthy or by loan sharking student loan debtors. Instead, it should be funded by an employer-paid consumption tax, with partial offsets to tax payments for employer provided insurance and taxes actually collected funding a Public Option (which should also replace Medicaid for non-retirees). Medicaid for retirees and Medicare should be funded by a border adjustable goods and services tax, which should be broad based.

Why the difference? The goal is to not need a public option as employers do the right thing and cover every worker or potential worker. Using an employer-based tax is an incentive to maximize employee coverage. Medicare, however, is an obligation on society as a whole.

CHRONIC CARE POLICY ALLIANCE
1001 K St., 6th Floor
Sacramento, CA 95814
916–444–1985
https://chroniccarealliance.org/

Re: Full Committee Hearing: Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers

Dear Chairman Wyden and Ranking Member Crapo:

On behalf of patients with chronic conditions, the Chronic Care Policy Alliance applauds the Finance Committee's focus on Pharmacy Benefit Managers (PBMs) and the role they play in the healthcare marketplace. While patients and families struggle to access the medications needed to manage their health and chronic conditions, PBMs exacerbate those challenges by driving up costs, limiting access to medications, and instituting harmful policies that limit the usefulness of financial assistance. We urge this committee to investigate the role of PBMs and institute policies that protect against measures that shift cost burdens to patients.

While PBMs were originally designed to create greater efficiency in processing pharmacy claims, their role has expanded over time. Taking advantage of a lack of transparency and oversight into their role, PBMs have implemented policies that create barriers for patients seeking to access medications and shift a greater share of the cost burden onto patients, all in the interest of increasing profits for PBMs.

For example, PBMs negotiate rebates on prescription drugs with manufacturers in the interest in lowering costs. Unfortunately, rather than pass these rebates on to patients, PBMs instead recoup the profits of these rebates. Meanwhile, patients who are already struggling to afford needed medications are left paying the original, undiscounted price for their medications.

Additionally, PBMs work alongside insurers to implement policies within health plans that further limit patient access to medications. Practices including limited drug formularies, adverse tiering, requirements for prior authorizations, and other discriminatory practices make it more difficult for both doctors and patients to identify effective therapies and maintain drug treatments.

Alongside these policies, we have also seen a sharp increase in copay accumulator rules within health plans. These rules exclude certain copay assistance programs from counting towards patient deductibles and out-of-pocket maximums. Millions of

patients rely on copay assistance programs to help them afford their critically needed medications; therefore, these copay accumulator policies drive up patient costs and, in some instances, can put medications out of reach for patients.

If PBMs continue to have the ability to implement discriminatory practices and fail to share rebates with patients, they will be partially responsible for millions of patients foregoing their treatment regimens. Therefore, we urge this committee to protect patients by bringing transparency to these operators.

Sincerely,

Liz Helms
Founder/Director

CYSTIC FIBROSIS FOUNDATION
4550 Montgomery Avenue, Suite 1100N
Bethesda, MD 20814
301–951–4422
800.FIGHT.CF
Fax: 301–951–6378
https://www.cff.org/

April 12, 2023

The Honorable Ron Wyden
Chairman
U.S. Senate
Committee on Finance
221 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mike Crapo
Ranking Member
U.S. Senate
Committee on Finance
239 Dirksen Senate Office Building
Washington, DC 20510

On behalf of the nearly 40,000 children and adults with cystic fibrosis in the United States, we write to share additional perspectives on the topics discussed at the recent hearing on pharmacy benefit managers (PBMs), including concerns about the opaque influence of PBMs and the confusing, labyrinthian system they have created for patients.

The Cystic Fibrosis Foundation is a national organization dedicated to curing cystic fibrosis (CF). We invest in research and development of new CF therapies, advocate for access to care for people with CF, and fund and accredit a network of specialized CF care centers. Cystic fibrosis is a life-threatening genetic disease that causes the body to produce thick, sticky mucus that clogs the lungs and digestive system, which can lead to life-threatening infections. As a complex, multi-system condition, CF requires targeted, specialized treatment and medications. If left untreated, infections and exacerbations caused by CF can result in irreversible lung damage, and the associated symptoms of CF lead to early death, usually by respiratory failure. Transformative therapies—such as CFTR modulators—have been paramount in changing what it means to live with CF. However, PBM cost containment strategies have created a convoluted system that patients struggle to navigate and often results in significant barriers to care.

PBMs manage prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, large employers, and other payers. By negotiating with drug manufacturers and pharmacies to determine drug coverage and reimbursement, PBMs can exert significant control over total drug costs for insurers, patients' access to medications, and how much pharmacies are paid.[1] PBMs often focus cost mitigation strategies on specialty drugs because of their high cost but low utilization within the overall population. PBM practices and the opacity of the system are extremely problematic and burdensome for chronic conditions like CF that primarily use specialty drugs.

CF Community's Experience with PBMs

Overall, PBMs cause significant barriers to care for people with CF in navigating insurance. This is largely due to the lack of understanding of the role of PBMs in coverage decisions and evolving strategies that PBMs put in place to mitigate their own costs and those of their clients, which add out-of-pocket costs or administrative burden for patients.

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[1] *https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/healthpolicybrief_178-1660136543567.pdf.*

Transparency

There is a lack of transparency on the role of PBMs, insurers, and subcontracted third-party entities in coverage and cost-sharing decisions, especially in the self-funded insurance market. This causes confusion on the appropriate point of contact for coverage decisions, increasing administrative burden on both patients and their care teams, and causing gaps in access to important therapies. PBMs and insurance companies both regularly claim that the other entity makes the final determinations on coverage for a therapy, resulting in an avoidance of responsibility from both parties and delays and confusion for the patients they cover. Patients and care teams frequently report being "passed back-and-forth" between the two entities when seeking to understand coverage decisions. The result is that people with CF do not know who is ultimately responsible for decisions about their drug coverage, or where to appeal in order to access their essential treatments.

Third-party entities such as maximizers—many of which are owned by PBMs—and alternative funding programs add complexity to an already opaque system. Maximizers often outsource a patient's drug coverage to a third-party entity that sets the patients' cost-sharing at a level to maximize use of manufacturer copay assistance. Alternative funding programs also rely on third-party entities that seek to enroll patients in manufacturer patient assistance programs that provide free drugs, which are usually intended for people without insurance. Without transparency on the decision-maker (PBM vs. payer vs. third-party), patients often face unnecessary, confusing, and time-consuming administrative barriers and unacceptable and inappropriate treatment gaps. New coverage tactics emerge frequently, requiring patients and care teams to consistently learn and adapt to new, opaque, and confusing policies. PBMs are often at the center of these challenges.

Increased Out-of-Pocket Costs

In addition to maximizers and alternative funding programs, PBMs and insurers are increasingly implementing accumulator programs—which prevent third-party payments from counting towards deductibles and out-of-pocket limits and therefore increasing out-of-pocket costs for patients. Many people with CF rely on third-party financial assistance to cover some of the costs associated with their care, as CF is an expensive disease. The CF Foundation recognizes that copay that copay assistance programs mask bigger cost and affordability issues; however, cost containment strategies like accumulator programs that further burden patients are unacceptable.

Recommendations

The CF Foundation appreciates the committee's attention to this issue. We urge Congress to ensure that the legislative proposals seek to improve the experience for patients, in addition to regulating the business and financial structure of PBMs. We provide the following recommendations:

HELP Copays Act: The CF Foundation recommends including the Help Ensure Lower Patient Copays Act (HELP Copays Act; HR 830) in to any PMB reform legislation. This bill reduces patient administrative and financial barriers imposed by PBMs and payers by (1) requiring payers to apply third party assistance to out-of-pocket maximums and other patient cost-sharing requirements; and (2) ensuring any item or service covered by a health plan is considered part of their essential health benefits (EHB) package. Together, these policies would prohibit accumulators, maximizers, and alternative funding programs in federally-regulated insurance plans, eliminating some of the most problematic PBM practices for patients.

Transparency: CF Foundation recommends Congress direct the FTC and HHS to expand transparency measures for PBMs and insurers to ensure patients receive better information about coverage policies for specialty drugs, including relationships with third-party entities. Specifically, Congress should direct the FTC and HHS to require PBMs and payers to provide enrollees with notices and disclosures on which entity is responsible for coverage determinations and provide clear contact information.

Oversight and Enforcement: The CF Foundation supports efforts by Congress to require the FTC to determine whether there is more information about PBMs that should be available to consumers and whether there are any legal or regulatory obstacles the FTC currently faces in enforcing the antitrust and consumer protection laws in the PBM marketplace.

Thank you for your leadership on this important issue. The CF Foundation stands ready to work with you to ensure patients' health and financial well-being are not

sacrificed in the ongoing systemic debate among payers, PBMs, and drug manufacturers.

Sincerely,

Mary B. Dwight
Chief Policy and Advocacy Officer
Senior Vice President, Policy and Advocacy

EMPLOYERSRX COALITION: EMPLOYERS' PRESCRIPTION FOR AFFORDABLE DRUGS ET AL.

U.S. Senate
Committee on Finance

Chairman Wyden, Ranking Member Crapo, and Members of the Committee, on behalf of the Employers' Prescription for Affordable Drugs (EmployersRx), and our undersigned members, we want to thank you for holding this important and timely hearing on Pharmacy Benefit Managers (PBMs) and the drug supply chain. We offer our appreciation to all of the witnesses and Members focused on the impact unaffordable prescription drugs have on Americans and thank you for your actions in support of meaningful PBM reform. EmployersRx stands ready to help as you begin this critical work.

EmployersRx is a nationwide effort led by the Purchaser Business Group on Health that includes The ERISA Industry Committee (ERIC), American Benefits Council, National Alliance of Healthcare Purchaser Coalitions, Silicon Valley Employers Forum, HR Policy Association, and the Small Business Majority. Our members share a common goal—to bring more transparency to health care, ensuring employers and their employees are empowered by information. This is especially important with regards to PBM transparency to ensure employees have access to affordable prescription drugs.

Growing awareness around the lack of transparency, layers of complexity, and the many activities PBMs have devised that contribute to our country's spiraling drugs costs has created an unprecedented opportunity to compel change. The U.S. has a health care affordability crisis and employers, workers, and clinicians are all struggling in a health care system that incentivizes high cost, low quality care.

This crisis is greatly exacerbated by health care industry consolidation, including the fact that the three largest PBMs, which control 80 percent of the market, are now integrated with the country's largest health insurers as well as affiliated pharmacies and provider organizations. Their collective market power to determine where patients receive care, which drugs they can access, how much they pay and where their prescriptions are filled raises real questions about conflict of interest.

PBMs and their insurer parents exert enormous and often-harmful influence over drug cost and access for the 158 million Americans receiving health care through employer-sponsored coverage.[1] Employers have a legal responsibility as plan fiduciaries—we are bound by law to act in the best interest of the plan beneficiaries and to be financially responsible of plan assets. For PBMs, the exact parameters of their responsibilities should align with the best interest of plan beneficiaries.

Selecting and monitoring good health care services for workers and their families and paying for reasonable plan expenses is not only an employer's obligation under the law, but also good business as it helps companies recruit and retain top talent. However, despite being the primary customers for PMBs and even some of the country's largest companies and purchasers of health care—employers are no match against PBMs' significant market power. Employers continue to encounter barriers to PBM pricing and other data and simply lack the bargaining power to require it.

For all these reasons, employers strongly believe the market is not functioning as intended and Americans are being denied access to affordable health care, including needed medicines. Therefore federal action is essential to address the anticompetitive aspects of the PBM business model by establishing clear regulatory oversight of the industry.

These actions should include:

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[1] "Improving and Strengthening Employer-Sponsored Insurance," Bipartisan Policy Center, October 2022, *https://bipartisanpolicy.org/download/?file=/wp-content/uploads/2022/10/BPC-Improving-and-Strengthening-Employer-Sponsored-Insurance-Oct-2022.pdf.*

1. **Strong transparency and reporting requirements.** Transparency for the primary customers of PBMs—employers—is a critical aspect to reform. Contracts between PBMs and employers typically do not provide details about fee or rebate schedules or amounts, prices, and fees generated from manufacturers and other parties, drug definition criteria, or amounts charged to pharmacies. Sometimes PBM control of information extends to an employer's effort to enforce contract compliance, as they may either prohibit an employer from auditing the PBM or require a PBM-designated auditor.
2. **Prohibition or limits on spread pricing.** PBMs should not be allowed to charge employers, health plans, or patients more for a drug than the PBM paid the pharmacy for that drug. Confidentiality clauses make it difficult for employers to identify what pharmacies pay and vice versa. This strategy has been especially profitable to PBMs, as exposed in numerous state Medicaid program audits.
3. **Pass-through of 100 percent of all rebates and volume or access-based administrative fees by PBMs.** The exploitation and manipulation of manufacturer rebate revenues and fees charged to employers for an ever-growing array of service and administrative fees has historically been a critical aspect of a PBM's business model. Due to significant pressure to pass rebate funds through to employers, PBMs are creating and/or increasing fees (over and above rebates) on manufacturers, pharmacies, other supply chain entities, and employers.
4. **Prohibition on all "workarounds."** Falling rebate revenues has led to the creation of group purchasing organizations (GPOs), or rebate aggregator entities by the big three PBMs—of which two are established outside of the U.S. These workarounds must be addressed in any legislation put forward this year to guard against current and future gamesmanship of a PBM's legal requirements.
5. **Transparency regarding PBM-owned pharmacies.** American workers and their families rely on local pharmacies in many communities, especially in rural and low-income neighborhoods. PBMs should be required to submit information regarding transactions between the PBM and any pharmacy wholly or partially owned, including mail-order, specialty and retail pharmacies, by the PBM.
6. **Definition and regulation of bona fide service fees.** PBMs should be required to disclose the fees they receive from drug manufacturers for nonspecific services affecting plan design and costs to employers and their plan beneficiaries.
7. **Establishment of clear regulatory oversight.** Employers are required as plan fiduciaries to ensure they are good stewards of the health care benefits they provide for their employees. To fulfill that obligation, employers believe any legislation must require clear oversight and accountability of PBMs and specify the exact parameters of PBM responsibility.

The Senate Finance Committee has a key role in both uncovering the concerning practices of the PBM industry, as well as leadership in addressing this important issue. We support and applaud the committee's desire to act. We also encourage you to work with your colleagues in the other Senate and House committees of jurisdiction to ensure this important legislation lays the critical foundation and groundwork to reduce spending on prescription drugs and make health care more affordable and attainable for America's workers and their families.

EmployersRx looks forward to working with you to design and enact bipartisan, commonsense legislation that can pass Congress and be signed into law by President Biden. Together, we can bring true accountability and reform to the PBM industry. Please contact Alan Gilbert, Vice President for Policy, The Purchaser Business Group on Health at agilbert@pbgh.org for further information on this or any other matter of mutual concern.

Sincerely,

Purchaser Business Group on Health
National Alliance of Healthcare Purchaser Coalitions
The ERISA Industry Committee (ERIC)
American Benefits Council

Silicon Valley Employers Forum
HR Policy Association
The Small Business Majority

HARMON CITY, INC.
3540 S 4000 W, Suite 500
West Valley City, Utah 84120
801–969–8261
www.HarmonsGrocery.com

Statement of Gregory J. Jones, R.Ph., MBA, Director of Pharmacy and Health/Wellness, Harmon City, Inc.

Introduction

Harmon City, Inc. appreciates the opportunity to submit a statement for the record for the United States Senate Committee on Finance on "Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers."

Harmons is a family owned chain of 20 grocery stores. 19 of the grocery stores also have pharmacies. We have served the residents of Utah since 1932, including pharmacy patients since 1945.

Great Concern about Pharmacy Benefit Manager Tactics

We are extremely concerned about pharmacy benefit manager (PBM) tactics that have significant negative effects on patients, communities, taxpayers, employers, and pharmacies. PBMs are hired by insurance plans and others to negotiate lower drug prices. Unfortunately, they manipulate the system and keep billions in profits while:

- Forcing patients and others to pay more for their medicines;
- Limiting patients' ability to choose their pharmacist;
- Restricting access to medicines that doctors and other prescribers determine to be right for the patient; and
- Jeopardizing pharmacies' viability—which obviously harms the pharmacy and also the patients and communities that rely on them.

The dominance of PBMs is significant. Three PBMs control 80 percent of the prescription drug market. These are the practical effects of PBM tactics:

- **Over-payments:** The University of Southern California Leonard D. Schaeffer Center for Health Policy & Economics found that Medicare Part D standalone plans paid $2.6 billion more in one year for 184 common generic medications compared with prices for the same drugs available to cash-paying customers of one retailer.
- **Restricting medications:** Drug Channels analysis found that from 2014 to 2022, 1,357 medications were excluded from at least one PBM formulary for at least one year. The exclusions of drugs from these lists have escalated since starting in 2012.
- **Putting the squeeze on pharmacies:** The Centers for Medicare & Medicaid Services found that direct and indirect remuneration (DIR) fees charged by PBMs and payers to pharmacies have exploded by 107,400% over the last decade.

We want to take this opportunity to define "PBM reform." This is important to maximize the effectiveness of Congress' work in this area for patients, and to rollback the current jeopardy posed by PBMs to pharmacies. For this purpose, we call to your attention the Principles of PBM Reform advocated by the National Association of Chain Drug Stores:

- **Stop below-cost reimbursement.** Adopt a reimbursement rate floor that prevents PBMs and payers from reimbursing pharmacies below the true cost of acquiring and dispensing prescription drugs.
- **Stop gaming of performance measures.** Standardize performance measures to help improve patient outcomes and reduce costs—rather than allowing PBMs and payers to play "gotcha" with pharmacies using arbitrary measures and exorbitant fees.
- **Stop "specialty definitions" from steering patients from their pharmacy.** Prevent PBMs and payers from defining "specialty drugs" in ways that steer patients with rare or complex diseases away from their preferred phar-

macy of their choice and toward another pharmacy—including those owned by the PBMs and payers.

- **Stop mandatory mail-order.** Prohibit PBMs and payers from forcing patients to use mail-order pharmacies—including those owned by the PBMs and payers—and prohibit them from imposing penalties on patients for choosing a convenient and trusted pharmacy in their neighborhood.
- **Stop limited networks.** Require PBMs and payers to include in their networks all pharmacies willing to accept terms and conditions established by the PBM.
- **Stop overwhelming audits.** Bring efficiency, transparency, and standardization to the processes by which PBMs audit pharmacies without sacrificing continuity of care.
- **Stop the undercutting of PBM reform laws.** Prioritize the implementation, enforcement, and oversight of PBM reform laws—to maximize results for patients and fairness for pharmacies and other stakeholders, and to ensure laws are not undermined by inaction of PBMs or of government.

Conclusion

In closing, we want to put to rest one of the myths perpetuated by PBMs. It is shocking that they have been able to stave off reform efforts by alleging that premiums will increase. This is nothing short of a scare tactic, and one that cannot be allowed to be used so flippantly and without substantiation. PBM reform will reduce prescription drug costs by cracking down on middlemen's manipulation. It does not follow logically that reductions in prescription drug costs will result in increased premiums. It is time to address the manipulative business practices of PBMs, as well as to end the negative effects of their tactics.

Harmon City, Inc. thanks the Committee for the opportunity to provide our perspective on PBM reform. For questions or further discussion, please contact Gregory J Jones, R.Ph., MBA, Director of Pharmacy and Health/Wellness, at gregjones@ harmonsgrocery.com or, 801–957–8454.

HY-VEE, INC.
5820 Westown Parkway
West Des Moines, Iowa 50266
515-695-3087
https://www.hy-vee.com/

Introduction

Hy-Vee, Inc. appreciates the opportunity to submit a statement for the record for the United States Senate Committee on Finance on "Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers."

Hy-Vee is an employee-owned company operating more than 280 retail pharmacy locations across eight Midwestern states—Illinois, Iowa, Kansas, Minnesota, Missouri, Nebraska, South Dakota and Wisconsin—with sales of more than $12.5 billion annually. We have more than 80,000 employees in our region serving millions of customers and patients each week. We also care for patients through our national specialty pharmacy, Amber Specialty Pharmacy, which serves vulnerable patients across the nation who often are facing severe illnesses that can only be treated by rare and speciality drugs.

PBM Concerns

We are extremely concerned about pharmacy benefit manager (PBM) strategies that have significant negative effects on patients, communities, taxpayers, employers, and pharmacies. PBMs are hired by insurance plans and others to negotiate lower drug prices. Unfortunately, they manipulate the system in a way that potentially keeps billions in profits while also:

- Forcing patients and others to pay more for their medicines;
- Limiting patients' ability to choose their pharmacist;
- Restricting access to medicines that doctors and other prescribers determine to be right for the patient; and
- Jeopardizing pharmacies' viability—which harms the pharmacy, and the patients and communities who rely on them.

The astronomical increase of DIR fees, in particular, continues to have a devastating impact on our patients as well as our company. Our communities rely on us as often

the closest provider of health care services; however, the economic impact of the current PBM landscape is becoming unmanageable. Hy-Vee has incurred a 309.44 percent increase in DIR fees over the past four years, and continual increases are unsustainable.

Hy-Vee stores serve a number of smaller, rural communities and see other businesses in these areas struggle under the unsupportable weight of increasing DIR fees. These fees are placing the ecosystem that boasts unparalleled access to care—where 90% of Americans are within 5 miles of a pharmacy—in jeopardy. According to the RUPRI Center for Rural Health Policy analysis report (Update on Rural Independently Owned Pharmacy Closures in the United States, 2003–2021), the total number of retail pharmacies in micropolitan and noncore areas declined by 836 between 2003 and 2021, and the number of independently owned retail pharmacies in micropolitan and noncore areas decreased by 9.1% and 16.1%, respectively.

The recent Centers for Medicare and Medicaid Services (CMS) rulemaking (Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; CMS–4192–P) fell short of expectations and will further disadvantage those pharmacists who serve the customers directly.

Critical elements were neglected in the final rulemaking, and we ask Congress to address these key principles of PBM reform to maximize the effectiveness of any proposed legislation and help keep our current pharmacy network strong and stable for all Americans:

- **Stop below-cost reimbursement.** Adopt a reimbursement rate floor that prevents PBMs and payers from reimbursing pharmacies below the true cost of acquiring and dispensing prescription drugs.
- **Stop gaming of performance measures.** Standardize performance measures to help improve patient outcomes and reduce costs—rather than allowing PBMs and payers to play "gotcha" with pharmacies using arbitrary measures and exorbitant fees.
- **Stop "specialty definitions" from steering patients from their pharmacy.** Prevent PBMs and payers from defining "specialty drugs" in ways that steer patients with rare or complex diseases away from their preferred pharmacy of their choice and toward another pharmacy—including those owned by the PBMs and payers.
- **Stop mandatory mail-order.** Prohibit PBMs and payers from forcing patients to use mail-order pharmacies—including those owned by the PBMs and payers—and prohibit them from imposing penalties on patients for choosing a convenient and trusted pharmacy in their neighborhood.
- **Stop limited networks.** Require PBMs and payers to include in their networks all pharmacies willing to accept terms and conditions established by the PBM.
- **Stop overwhelming audits.** Bring efficiency, transparency, and standardization to the processes by which PBMs audit pharmacies without sacrificing continuity of care.
- **Stop the undercutting of PBM reform laws.** Prioritize the implementation, enforcement, and oversight of PBM reform laws—to maximize results for patients and fairness for pharmacies and other stakeholders, and to ensure laws are not undermined by inaction of PBMs or of government.

Conclusion

Our Hy-Vee pharmacies continue to be a trusted, convenient, and equitable access point for health and wellness in urban and rural communities. We remain a critical access point for prescription drugs, chronic care management, wellness and prevention services, testing, vaccines, and health and wellness education. PBM reform is crucial to preserving pharmacies' role in their communities and to retain this vital health care access for all patients. Without action in the near future, our pharmacies will suffer.

In closing, we want to put to rest one of the myths perpetuated by PBMs. It is unfortunate that reform efforts have been thwarted by alleging that premiums will increase. PBM reform will reduce prescription drug costs by addressing the middlemen's tactics. It does not follow logically that reductions in prescription drug costs will result in increased premiums. It is time to address the business practices of PBMs, as well as to end the negative effects of these tactics.

Hy-Vee, Inc. thanks the Committee for the opportunity to provide our perspective on PBM reform. For questions or further discussion, please contact Stacey Johnson, Vice President, at staceyjohnson@hy-vee.com.

LETTER SUBMITTED BY EDWARD KITLOWSKI

U.S. Senate
Committee on Finance

Re: Poor Health Care for Federal Employee

I am writing on behalf of my wife Mary Kitlowski, a Federal employee with the Patent and Trademark Office. Mary is a GS12 at the PTO and has won two Bronze medals for exemplary work. All her ratings have been classified as exceptional. She works from home. The complaint is with the Federal Carefirst, Blue Choice Insurance plan which has denied covering two prescriptions Mary had when covered by Blue Cross/Blue Shield Federal insurance. Mary's health is deteriorating and will probably entail hospitalization in the coming week.

I am writing as she is exhausted from the scenario I will describe. As background, she was born with a genetic condition called Primary Ciliary Dyskinesia (PCD). Persons with this condition have flaccid cilia, meaning the mechanisms in our body which protect and expel irritants from the nasal and pulmonary systems do not work. This causes infections in the sinuses and lungs which build up. The infections cause damage to the lungs called bronchiectasis. My wife has a daily routine that is very similar to a person with Cystic Fibrosis. PCD is considered a rare disease, which complicates treatment. It is also a progressive disease. More information on the disorder can be found at Living with PCD—PCD Foundation Website.[1]

As previously stated, it is a progressive disease. She now has only 30% lung capacity. She requires supplemental oxygen when walking and even sleeping. She is under the supervision of Dr. O'Donnell of Georgetown Medical and Dr. Shah of Johns Hopkins Transplant Center. On several occasions, she has had prescriptions denied by insurance companies, and fought to receive the treatment ordered by her doctor. Dr. O'Donnell monitors Mary's medical care which involves prescriptions, and medical devices.

When the annual health insurance renewal for Federal employees opened, she re-evaluated her plan which was the Federal Blue Cross/Blue Shield. She enrolled in the Federal Carefirst Blue Choice plan believing it provided the same level of care but with different levels of deductions. What she did not expect was the new plan denied the prescriptions she had been taking for many years. Her health has been deteriorating because of the policies of the insurance company.

One of the medications is Theo 24. She had been taking one tablet of 200mg a day. Carefirst denied covering the prescription. She was informed by phone of the denial without the name and title of the medical person who made the denial. Mary was told Theo 24 was not part of their medical formulary. Dr. O'Donnell is a recognized expert on PCD and Theo 24 has specific properties that are ideal for patients with PCD. Mary has been paying out of pocket to continue taking the medication. Carefirst has been unresponsive in responding to Mary's appeal and contacting both Dr. O'Donnell and Mary to cover this necessary medication. They have made statements unsubstantiated by Dr. O'Donnell's office and do not return calls by Mary. Meanwhile, time passes, and she is not covered for the necessary medication.

A second prescription that was denied is Budesonide, an inhaled steroid. Mary has been taking this for over five years. It reduces bronchospasms and allows for easier expiration of mucus from the lungs, alleviating breathing and reducing the scarring of lung tissue, (bronchiectasis). Again, Carefirst not has been responsive to phone calls and emails. Mary's health has been compromised by Carefirst's inaction.

Mary uses an Airway Clearance System, an inflatable vest attached to a machine which provides oscillation to loosen the mucus and pus in her lungs to facilitate expiration. There is a new device called the Volara System which has preliminary results and anecdotal reports of increased lung capacity from its use. It is currently classified as experimental by the FDA, which allows insurance companies the ability to deny coverage. Mary was denied the device by an RN. I have included informa-

[1] *https://pcdfoundation.org/living-with-pcd/*.

tion on the system and review of the efficacy by members of the American College of Chest Physicians.

This scenario raises numerous issues in the health insurance business, as it is a for-profit enterprise, and specifically of a policy for Federal employees. Insurance companies should be required to maintain current prescriptions for transferred patients for a period of possibly two months. When Mary reviewed the two plans, there was little to no transparency on the prescriptions covered. Mary would not have changed plans if she knew Carefirst would deny two of her prescriptions. Mary is possibly going to have to be hospitalized, a cost much higher than the price of the prescriptions. Insurance companies should not have the preponderance of judgement in patient care.

Mary is a Federal employee having problems with a health insurance plan for Federal employees. I believe Mary's suggestion of legislation requiring insurance companies to continue prescriptions for at least 2 months and not be allowed to deny ongoing medical coverage is brilliant.

Senators, I am watching my wife's health deteriorate. The frustrations with dealing with Carefirst are contributing to the decline along with the lack of medical care. I suggest Mary is not the only person experiencing the same issue. I am a retired Baltimore County teacher, experiencing my own trials and tribulations with health care plans. As a country, we can do better. I know you believe the same.

Respectfully,

Edward Kitlowski

I have included descriptions of the disease and medications from The Cleveland Clinic, NIH, and the PCD Foundation.

Bronchiectasis is a condition where damage causes the tubes in your lungs (airways) to widen or develop pouches. It makes it hard to clear mucus out of your lungs and can cause frequent infections. Coughing a lot with pus and mucus is the main symptom of bronchiectasis. **Bronchiectasis can't be cured but can be managed with treatment.**

Theophylline is used to treat lung diseases[2] such as asthma[3] and COPD[4] (bronchitis,[5] emphysema[6]). **It must be used regularly to prevent wheezing[7] and shortness of breath.** This medication[8] belongs to a class of drugs known as xanthines. It works by relaxing the muscles around the airways so that they open up and you can breathe more easily. **It also decreases the lungs' response to irritants.**

One drug Carefirst said is covered is Salmeterol (Serevent)

Long-acting beta agonists (LABAs)

These bronchodilator medications open airways and reduce swelling for at least 12 hours. They're used on a regular schedule to control moderate to severe asthma and to prevent nighttime symptoms. *Although they're effective, they've been linked to severe asthma attacks.* For this reason, LABAs are taken only in combination with an inhaled corticosteroid.

Volara System

Purpose: The Volara System is a novel device that is intended for the mobilization of secretions, lung expansion therapy, and the treatment and prevention of pulmonary atelectasis. Oscillation and lung expansion (OLE) therapy can be used in the acute care as well as the home setting, in patients with cystic fibrosis [CF], chronic obstructive pulmonary disease [COPD], Bronchiectasis, neuromuscular disease [NMD], and other conditions requiring airway clearance therapy. In this study, we aimed to evaluate the trends in clinical outcomes in patients started on OLE, as documented in the OLE patient reported outcomes data repository.

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[2] *https://www.webmd.com/lung/lung-diseases-overview.*
[3] *https://www.webmd.com/asthma/what-is-asthma.*
[4] *https://www.webmd.com/lung/copd/10-faqs-about-living-with-copd.*
[5] *https://www.webmd.com/lung/understanding-bronchitis-basics.*
[6] *https://www.webmd.com/lung/copd/what-is-emphysema.*
[7] *https://www.webmd.com/asthma/understanding-wheezing-basics.*
[8] *https://www.webmd.com/drugs/2/index.*

Conclusions: Patients receiving at home OLE therapy showed improved self-reported clinical outcomes in various disease states, as evidenced by the reduction in hospitalizations and antibiotic use, and subjective improvement in ease of breathing in the first 6 months of therapy. This was accompanied by high levels of patient satisfaction and adherence to therapy. Longer term studies with established correlation with EMR data as well as clinical studies are needed to support these findings.

Huynh T.T., Liesching T.N., Cereda M., Lei Y., Frazer M.J., Nahouraii M.R., Diette G.B., Efficacy of Oscillation and Lung Expansion in Reducing Postoperative Pulmonary Complication, *Journal of the American College of Surgeons* (2019).

DOI: *https://doi.org/10.1016/j.chest.2021.07.1670*

NATIONAL ASSOCIATION OF CHAIN DRUG STORES
1776 Wilson Blvd., Suite 200
Arlington, VA 22209
703–549–3001
https://www.nacds.org/

Statement of Steven C. Anderson, FASAE, CAE, IOM, President and Chief Executive Officer

Introduction

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to submit a statement for the record for the Senate Committee on Finance's hearing, "Pharmacy Benefit Managers (PBM) and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers." NACDS appreciates the Committee's work to explore PBMs' lack of transparency and standardized performance measures, inflationary effects on drug prices, restrictions on patient access, and unfair pharmacy reimbursement practices that threaten pharmacies and the patients who rely on them for access. The prescription drug supply chain is largely controlled and manipulated by the three largest PBM-insurers, with significant consequences for patients and taxpayers.

Retail pharmacies are critical healthcare access destinations for patients and population health. The nation called on pharmacies to deliver COVID–19 testing, vaccinations, and other critical care services to communities during the pandemic. Pharmacies seamlessly rose to the challenge, in large part due to more than a decade of pandemic preparedness and collaborative planning. Consider, the nation's pharmacies administered over 300 million COVID vaccines, performed more than 42 million tests, dispensed nearly 7 million antiviral courses, and were the top provider of over-the-counter COVID tests in CMS' demonstration program. Using conservative estimates, pandemic interventions by pharmacists and pharmacy personnel averted more than 1 million deaths, more than 8 million hospitalizations, and $450 billion in healthcare costs.

A poll of adults conducted March 4–6, 2022, by Morning Consult and commissioned by NACDS found that retail pharmacies received the highest ratings for ease of access among the destinations tested. Of note, 79 percent of those surveyed also support pharmacists helping patients prevent chronic diseases. America's pharmacies have been dealing with these legacy issues for over a decade and it has been exacerbated by the absence of oversight and understanding of the offensive and competition-eroding practices of PBMs that impact timely patient access, pharmacy sustainability, and pharmacy's innovative vision to empower patients' total health and wellness.

NACDS applauds Chairman Wyden and Ranking Member Crapo for keeping this issue top of mind on a bipartisan basis and for their continued commitment to fight for meaningful reform. Comprehensive reform is needed to instill increased transparency and accountability for PBM's, to help ensure the economic viability of pharmacies, and to foster increased access to care and improved health outcomes for the patients they serve.

The Pharmacy Benefit Manager Marketplace and Impact on Pharmacies

Prescriptions filled by patients who are paying cash without any form of insurance or discount card account for only about 3% of the total volume of prescriptions.[1]

[1] Source: IQVIA, National Prescription Audit and RxInsight, June 2022; Approximately 5.4% of patients use a discount card to assist with payment.

While approximately 91% of prescriptions filled have a payment component coming from Medicare Part D, Medicaid, or a commercial insurance plan, these plans are ordinarily administered by PBMs. The top three PBMs manage about 80% of the volume.[2] The top six PBMs and plans manage about 96% of the volume.[3] Five of those six PBMs are owned by large national health insurers. This business environment makes it very difficult for pharmacies to negotiate fair business practices and transparency because the PBMs and health insurers have more commercial market power and leverage in the relationship due to their size and scale. This creates a one-way street with negative consequences for patients, pharmacies, employers, taxpayers, and communities—seemingly for all but the PBMs and payers.

Retail pharmacies are in crisis, facing unsustainable financial pressures as they are increasingly reimbursed by payers below the cost of buying and dispensing prescription drugs. Dire financial pressures have forced an alarming number of pharmacies to take drastic steps, such as possibly paring back hours and placing on hold innovative care services that otherwise could improve health outcomes. Payers have increasingly reduced reimbursements; in many cases, pharmacies dispense prescriptions below cost. Retroactive fees and claw backs often occur weeks or months after a transaction closes, when a payer decides to recoup a portion of the pharmacy's reimbursement. These fees have made the economic viability of community pharmacies increasingly difficult, due to the unpredictability of reimbursement and the increased damage to bottom lines.

It is important to look at the pre-COVID pharmacy closures. According to IQVIA, between December 2017 and December 2020, almost 2,200 pharmacies closed nationwide.[4] Some of the PBMs' abuse of pharmacies were abated during the pandemic and the nation's reliance on pharmacies over the past three years further mitigated pharmacy closures. However, the ominous situation for pharmacies is worse than ever before.

The epidemic of pharmacy closures is reducing access to vital healthcare services, especially in rural areas where options are already limited. Communities across the nation depend on neighborhood pharmacies among all healthcare destinations. A recent study published in the Journal of the American Medical Association also found that pharmacy closures led to a significant drop in medication adherence for older adults taking cardiovascular medications, which has obvious implications for patient health and healthcare costs. Preserving patient access to robust pharmacy provider services and networks like health screenings, disease state management, vaccinations (*e.g.,* flu, COVID–19), patient counseling, medication adherence, and testing—all in addition to essential medication access can help improve health outcomes and generate overall healthcare savings for Americans.

We look forward to continuing to work with Congress to stop the manipulation by PBM go-betweens that increases patients' medication costs, limits patients' choice of pharmacies, restricts access to medicines that are right for them, and jeopardizes the pharmacies and pharmacy teams on whom patients rely.

To that end, please see below NACDS' policy recommendations to increase transparency and ensure comprehensive reform of harmful PBM tactics and practices:

I. Help to Preserve Patient Access to Pharmacies by Addressing PBM's Retroactive Pharmacy Fees

Retroactive DIR Fees/Claw Backs—Pharmacy access can be undermined when health plans and their middlemen, PBMs, arbitrarily "claw back" fees retroactively from pharmacies weeks or months after a claim has been adjudicated/processed. This manipulation of pharmacy reimbursements may diminish access to care *(e.g., pharmacies being forced to close their doors or pare back hours and healthcare services)* when PBMs are unpredictable, not transparent, and payment falls below a pharmacy's costs to acquire and dispense prescription drugs. Policymakers should consider enacting laws that prohibit payers or PBMs from retroactively reducing and/or denying a processed pharmacy drug claim payment and obligating them to offer predictable and transparent pharmacy reimbursement to better protect pharmacies as viable and reliable access points of care for patient services.

II. Provide Fair and Adequate Payment for Pharmacy Patient Care Services

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[2] *https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html.*
[3] *Id.*
[4] IQVIA Data, 2020. Closures disproportionately impacted rural areas.

Reasonable Reimbursement and Rate Floor—Pharmacy access remains at risk when PBMs reimburse pharmacies below the cost to acquire and dispense prescription drugs. Pharmacy reimbursement that falls below the costs to acquire and dispense prescription drugs threatens future sustainability for pharmacies to continue providing valuable medication and pharmacy care services to communities. Policymakers should enact laws to adopt a reimbursement rate floor that requires PBMs to use comprehensive reimbursement models that are no less than the true cost to purchase and dispense prescription drugs to help maintain robust public access to pharmacies.

Standardized Performance Measures—A crucial part of comprehensive DIR fee reform is advancing pharmacy quality that improves outcomes for beneficiaries and drives value in care which are essential to controlling costs in the healthcare system. Arbitrary performance measures developed by PBMs assess the performance of the pharmacy without pharmacies' input and create a moving target for pharmacies to show value and improve health outcomes. Measures vary across the various plans and dictate DIR fees (or claw backs at the State level) imposed on pharmacies, as well as help create substantial system dysfunction and unnecessary spending in the Part D program. Policymakers should enact laws to standardize PBM's performance measures for pharmacies to help set achievable goals for pharmacies before signing a contract to promote harmonization in the healthcare system and improvements in health outcomes.

III. Protect Patient Choice of Pharmacies

Specialty—Some PBMs require patients with rare and/or complex diseases to obtain medications deemed "specialty drugs" from designated "specialty pharmacies" or mail-order pharmacies which impedes patient access to their convenient local neighborhood pharmacies where specialty drugs are filled as well. Prescription drugs should not be classified as "specialty drugs" based solely on the cost of the drug or other criteria used to limit patient access and choice—instead, should focus on clinical aspects such as requiring intensive clinical monitoring. Policymakers should enact laws to establish appropriate standards for defining and categorizing specialty drugs to ensure comprehensive and pragmatic patient care and access and prohibit PBMs from steering patients to only specialty pharmacies, including those owned by the PBMs, for their prescription needs.

Mail Order—Medication access and care can be weakened when PBMs manipulate the system by requiring patients to use mail-order pharmacies only. Some plans impose penalties such as higher copays or other financial disincentives for choosing a retail pharmacy instead of a mail-order pharmacy which is often owned by the PBM. Policymakers should support patient choice and access by enacting laws to prohibit PBMs from requiring or steering patients to use mail-order pharmacies.

Any Willing Pharmacy—Due to PBMs' network and contract barriers, pharmacies willing and ready to serve patients may be ineligible to provide important pharmacy services and patients may experience unnecessary delays and interruptions in patient care. Patients should have the choice and flexibility to utilize the pharmacy that best meets their healthcare needs. Policymakers should enact laws that require PBMs and plans to include any pharmacies in their networks if the pharmacy is willing to accept the terms and conditions established by the PBM to help maximize patient outcomes, and cost savings and ensure patient access to any willing pharmacy of their choice.

IV. Enforce Laws to Stop PBM Manipulation and Protect Pharmacies and Patients

Audits—PBMs routinely conduct audits to monitor a pharmacy's performance and reverse or claw back pharmacy payments when there are alleged issues with a particular pharmacy claim. PBM audits interrupt the pharmacy workflow, can extend wait times, and detract attention from the quality-of-care patients receive. Policymakers should enact laws that support fair pharmacy audit practices to ensure timely patient care delivery at community pharmacies and bring efficiency, transparency, and standardization to the PBM audit process.

Oversight Authority—There are growing concerns that pro-pharmacy and pro-patient legislative successes might be undercut if PBMs fail to comply with such laws and/or states fail to fully enforce these laws. Such failure could significantly impact pharmacy reimbursement and overall patient access. Policymakers should establish and enforce laws already on the books to regulate

harmful PBM reimbursement practices that may harm patients and the healthcare system as we know it, especially at the pharmacy counter, and empower state regulators to do the same to enforce PBM transparency and fair and adequate pharmacy reimbursements.

Conclusion

NACDS thanks the Committee for the opportunity to provide our perspective on PBM reform[5] and our support for your dedicated work. We implore you to act on these principles[6] and ensure proper safeguards are established to protect pharmacies and Americans from PBMs and to promote transparency, accountability and fairness in the prescription drug supply chain. For questions or further discussion, please contact NACDS' Christie Boutte, Senior Vice President, Reimbursement, Innovation and Advocacy at CBoutte@NACDS.org or 703–837–4211.

NATIONAL ASSOCIATION OF SPECIALTY PHARMACY
300 New Jersey Avenue, NW, Suite #900
Washington, DC 20001
703–842–0122
https://naspnet.org/

Statement of Sheila Arquette, President and CEO

Chairman Wyden, Ranking Member Crapo and Members of the Committee:

I write today on behalf of the National Association of Specialty Pharmacy (NASP) to express support for the Senate Committee on Finance's efforts to address unfair and anticompetitive practices that narrow the pharmacy marketplace and negatively impact patients. Thank you for holding today's hearing and for all of your efforts to work with specialty pharmacy.

NASP represents the entire spectrum of specialty pharmacy industry stakeholders, including the nation's leading specialty pharmacies and practicing pharmacists; nurses; technicians; pharmacy students; non-clinical healthcare professionals and executives; pharmacy benefit managers (PBMs); pharmaceutical manufacturers; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; patient advocacy organizations; independent accreditation organizations; and technology, logistics and data management companies. With more than 170 corporate members and 3,000 individual members, NASP is the unified voice of specialty pharmacy in the United States.

What is Specialty Pharmacy

Specialty pharmacies support patients who have complex health conditions like rheumatoid arthritis, multiple sclerosis, hemophilia, cancer, organ transplantation and rare diseases. Specialty pharmacies operate as independent pharmacies, academic medical center and hospital-health system based pharmacies, regional and national chain pharmacies, grocery store owned specialty pharmacies, health plan-owned specialty pharmacies and home infusion pharmacies. The medications a specialty pharmacy dispenses are typically expensive. Historically, there are limited generic or biosimilar alternatives to brand specialty drugs. Specialty prescription medications are not routinely dispensed at a typical retail pharmacy because the medications are focused on a limited number of patients and require significant patient education and monitoring on utilization and adherence. Typical retail pharmacies are not designed to provide the intense and time-consuming patient care services that specialty medications require. Though many specialty medications are taken orally, still many need to be injected or infused. The services a specialty pharmacy provides include patient training in how to administer the medications, comprehensive treatment assessment, ongoing patient monitoring, side effect management and mitigation, and frequent communication and care coordination with caregivers, physicians and other healthcare providers. A specialty pharmacy's expert services drive patient adherence, proper management of medication dosing and side effects, and ensure costly and complex drug therapies and treatment regimens are used correctly and not wasted.

Anticompetitive Practices and Impact on Specialty Pharmacy

While the number of specialty medications only comprises 2.2 percent of the total number of prescriptions dispensed in the United States, these medications represent

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[5] *https://accessagenda.nacds.org/defendaccess/.*
[6] *https://www.nacds.org/pdfs/NACDS-PBM-Reform-Principles-2-2023.pdf.*

approximately 50 percent of overall drug spend in the U.S., which by the end of 2021, was estimated to be about $600 billion. Distribution for most specialty medications is limited, with payers working to keep them even smaller. The market is heavily dominated by the largest PBMs and the health insurers that own those PBMs.

Over the years, anticompetitive market practices, including the escalation in pharmacy DIR claw back fees have led to a significant narrowing of pharmacy networks. Efforts by Congress are needed to address comprehensive pharmacy DIR reform and ensure patient access to specialty pharmacies.

Pharmacy DIR Fees and Implications for Patient Access to Specialty Pharmacies

For many years, Medicare Part D Plans and their Pharmacy Benefit Managers (PBMs) have opted for higher negotiated prices to pharmacies, and in some cases, even preferred a higher net cost drug over a cheaper alternative because they plan to collect retroactive fees from pharmacies and rebates from manufacturers. Receipt of such fees and rebates contributes primarily to plan profits and does nothing to lower drug costs or drug cost sharing requirements for beneficiaries.

Retroactive fees on pharmacies include "Direct and Indirect Remuneration" fees—commonly known as "DIR Fees." Pharmacy DIR fees are collected through retroactive claw back charges on specialty pharmacy providers and other pharmacies months and sometimes a year after the pharmacy has dispensed the drug and after a beneficiary has already purchased the drug at a higher price. The Centers for Medicare and Medicaid Services (CMS) issued a Medicare Part D rule in 2022, showing that pharmacy DIR fees grew from $8.9 million collected in 2010 to $9.5 billion in 2020.[1] Fees on pharmacies *grew more than 107,400 percent,*[2] with much of that growth occurring after Part D sponsors stood up so-called DIR "performance-based metrics" for pharmacy payment arrangements. CMS data shows that pharmacies are hardly ever paid for meeting performance metrics and are instead financially penalized in relation to performance measures. For specialty pharmacies, nearly all of the metrics utilized by Plans/PBMs are irrelevant to the drugs specialty pharmacies dispense or services they provide.

In the 2022 Medicare Part D rule, CMS took some initial steps in addressing pharmacy DIR fees by eliminating the regulatory loophole (exception) that has permitted the significant growth of pharmacy DIR fees. Beginning in January 2024, CMS will require that all pharmacy price concessions—as newly defined for the first time—be counted at the point-of-sale, when a beneficiary receives their prescription. The specific purpose of this change is to ensure that patient out-of-pocket costs are assessed with all concessions applied, giving the beneficiary the lowest possible price, and therefore, the lowest possible co-pay. However, **the 2022 Part D rule did not eliminate the practice of pharmacy DIR claw back fees, allowing Plans to continue to impose claw backs and the rule did not establish any standards or protections to ensure that the negotiated price inclusive of all price concessions paid to pharmacies is reasonable to cover a pharmacy's costs.**

NASP supports CMS' effort to reduce prescription drug prices for Medicare Part D beneficiaries by removing the reasonably determined regulatory exception and adopting a revised definition of "negotiated price" for a covered Part D drug that includes all pharmacy price concessions, requiring them to be applied at the point of sale. It is our hope that doing this will better align marketplace competition with the interests of Medicare beneficiaries and lead to lower out-ofpocket costs. However, NASP is concerned that the final rule did not address comprehensive DIR reform, which is necessary to meet patient needs. To prevent anticompetitive DIR practices, we request further action by Congress.

Impact of the Part D Rule on Beneficiary Access to Pharmacies

Over the years, pharmacy DIR claw back fees have significantly harmed specialty pharmacies forcing many to decline participation in Medicare Part D networks, resulting in limiting beneficiary access and pharmacy choice; restructuring their operations, laying off staff and cutting back on higher-cost inventory; and ending the stocking and dispensing of certain drugs to treat certain conditions. Other specialty pharmacies have been forced to sell their pharmacies or be acquired due to the harm caused by excessive pharmacy DIR claw back fees.

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[1] XIL Consulting. Policy Alert: Payers and PBMs Profit from Obscure Pharmacy Fees, While Seniors See No Relief in Prescription Costs. February 11, 2020. *https://www.xilang consulting.com/post/policy-alert.*

[2] 87 FR 1910.

While the Calendar Year Part D rule is viewed as a first step toward needed pharmacy DIR reform, we want the Committee and CMS to understand the problems that are negatively impacting pharmacy network participation and patient access persist. Specialty pharmacies have faced significant 2023 upfront reimbursement reductions and continue to see terms in their contracts that say their pharmacies will continue to be subject to retroactive DIR claw backs.

Congress can help address these significant concerns by taking action to pass legislation that would allow for comprehensive pharmacy DIR reform. **NASP recommends that the Senate Finance Committee work to advance legislation that will:**

- Encourage CMS to ensure pharmacy reimbursement does not violate the any willing provider statute and is reasonable to ensure network participation by pharmacies;
- Require the standardization and oversight of Part D pharmacy performance measures; and
- Ensure pharmacies are provided pricing transparency.

Any Willing Provider Statute—Reasonable Pharmacy Reimbursement to Support Pharmacy Network Participation

NASP is very concerned that the Calendar Year 2023 Medicare Part D rule continues to permit post-sale pharmacy price concessions. That allowance in addition to the continued significant reductions to the "negotiated price" pharmacies receive, could continue to escalate pharmacy acquisitions and closures. CMS provides no regulatory protections for ensuring that pharmacies will not be reimbursed at such a low level that they are unable to remain in a network, and therefore, accessible to patients.

In other Medicare Part D rules issued over the years, **CMS has recognized that any willing provider statutory requirements permit the agency to regulate reasonable reimbursement provisions.**[3] **NASP has commented to CMS that the agency exercise its authority in enforcing this part of the statute to protect pharmacy payments going forward.** CMS acknowledged these comments, stating in the final Calendar Year 2023 Part D rule that the agency would consider future rulemaking to address stakeholder concerns over CMS establishing safeguards to guarantee that pharmacies participating in Medicare Part D receive a reasonable rate of reimbursement.[4] Considering that the final rule did not address the impact that retroactive DIR fees have had on pharmacy viability and beneficiary access to pharmacies, we are pleased that CMS acknowledged the need for this long-overdue rulemaking, and we urge the Senate Finance Committee to request that the agency begin the rulemaking process immediately through legislative action or direct request.

Pharmacy Performance Evaluations and Metrics

The final Calendar Year 2023 Part D rule continues to permit contract agreements between pharmacies and plans that allow for performance-based evaluations to determine price concessions and/or incentive payments. Also, the final rule provided no incentives for plans/PBMs to offer incentive-based opportunities to pharmacies and the rule did not establish any process for standardizing pharmacy performance metrics or any parameters to ensure pharmacy performance evaluations are appropriate, fair, and relevant based on the drugs a pharmacy dispenses and the services a pharmacy provides. In the absence of these important issues being addressed by CMS, pharmacy cannot expect or rely on incentive payment opportunities to address reimbursement concerns and there is serious concern that metrics will continue to be abused in an effort to claw back fees from pharmacies.

NASP continues to advocate for the standardization of pharmacy performance-based metrics. We also want to ensure that there are CMS requirements for fair pharmacy performance evaluation, and regulatory incentives for plans to offer pharmacy performance-based agreements to pharmacies. We believe it is important that CMS immediately work with pharmacy stakeholders to conduct a review to ensure pharmacy performance evaluations are fair and are associated with Part D plans' Star Ratings, thus aligning incentives for Part D plans and pharmacies toward better quality, equity, and reductions in preventable spending for beneficiaries.

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[3] 79 Fed. Reg. 1918, 1970 (January 10, 2014).
[4] 87 Fed. Reg. at 27845 (May 2022).

Specifically related to action we believe CMS can and must take immediately, in the 2023 Part D final rule, CMS stated the following:

> We addressed reporting of pharmacy performance measures to CMS in the January 2021 final rule (86 FR 5864). In the January 2021 final rule, we finalized a proposal to give CMS the authority to establish a Part D reporting requirement for Part D sponsors to disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreements. This authority to establish a reporting requirement is effective January 2022; however, the actual data elements must be proposed through the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) process in a future package.[5]

CMS' delay in exercising its authority to establish a Part D reporting requirement for Part D sponsors to disclose the pharmacy performance measures they use is especially disconcerting, given the concerns expressed by the pharmacy community and CMS' reporting that such measures have directly resulted in the substantial growth of pharmacy DIR fees. We implore the Committee to address this delay and urge CMS action to conduct this oversight. **We also urge the Committee to request that CMS work in collaboration with the Federal Trade Commission on this review, as the FTC considers anticompetitive market practices impacting pharmacies that are not affiliated with plans or PBMs.**

Part D Bidding Process

Under the current Medicare Part D bidding process, Plans are encouraged to underestimate their DIR fees, which they submit to determine the total bid amount, the direct subsidy payment the Plan will receive from Medicare, and the premiums that beneficiaries pay. If a Plan underestimates their pharmacy DIR fees, they can keep subsidy overpayments up to five percent, this process has encouraged Plans to underestimate their DIR fees to make a profit.[6] Current regulations concerning the bid and reconciliation processes do not meaningfully protect unaffiliated specialty pharmacies (those not owned by Plans/PBMs) from post-sale price concessions or unreasonably low reimbursement.

The overbidding (and underestimation of DIR fees) directly harms beneficiaries by inflating the premiums they pay. This is because CMS calculates premiums based on the Plan's bid amount. CMS uses approved Plan bids to calculate a national average monthly bid which determines CMS's subsidy payments to Plans and a national base beneficiary premium.[7] The base premium is then used to determine the actual beneficiary premium for each Plan.[8] For example, if a Plan's bid exceeds the national average bid, its beneficiaries are responsible for the excess through a higher monthly premium which the beneficiary must pay. The bid-reconciliation profit incentive harms: beneficiaries through inflated premiums, pharmacies through unreasonable post-sale price concessions that are used to generate overpayments, and taxpayers through retained Medicare overpayments through reconciliation.

As the pharmacy negotiated price/DIR provisions of the Calendar Year 2023 Part D rule go into effect in 2024, **NASP urges the Committee to require CMS to closely review plan bid estimations and the reporting of pharmacy DIR and other fees placed on pharmacies. CMS must disincentivize plans from underestimating prospective DIR during their bid submissions and should be overseeing this process to understand to what extent plans are retaining overpayments obtained from DIR and administrative or other fees that are in excess of their DIR bid estimates. Ultimately eliminating this practice should be a priority focus of Congress and CMS.**

Transparency Regarding Pharmacy Claims Processes

In the 2023 Part D Rule, CMS notes that one of the purposes of the regulations addressing pharmacy negotiated price and remuneration is to foster price transparency and consistency among pharmacies with respect to their reimbursement.[9] The 2023 Part D rule is intended to require Plans to calculate the lowest possible reimbursement to lower the patient's out-of-pocket costs; however, the Rule does not explicitly state whether the lowest possible price will be disclosed to pharmacies.

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[5] 87 Fed Reg. at 27704 (May 2022)

[6] Neither the Bid Pricing Instructions nor Part D bid regulations *strictly* prohibit Plans from under-projecting expected DIR fees.

[7] 42 CFR § 423.279(a) (2021).

[8] 42 CFR § 423.286 (2021).

[9] Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. at 1914.

Such information is of critical importance if CMS' goal of ensuring transparency with respect to pharmacy reimbursement is to be recognized. This data will be critical to business planning for specialty pharmacies who today and going forward have no understanding how or to what extent their reimbursement will be altered after the point of sale.

NASP requests that the Committee work with CMS to address the lack of clarity in the final 2023 Part D rule regarding pharmacy claims processes and information transparency to pharmacies. To ensure full transparency for pharmacies at the point-of-sale, we request that CMS clarify that Part D plans must provide a mechanism for pharmacies to know the lowest possible reimbursement at the point-of-sale. Part D plans must ensure that the appropriate fields are included and populated in the claims response so that this information is provided to the pharmacy.

Conclusion

NASP is pleased that with the Chairman's support and the efforts by the Senate Finance Committee on a bipartisan basis, initial efforts have been made to address pharmacy DIR fees and needed Part D reforms to reduce beneficiary drug costs. **We now want to work with the Committee and ultimately CMS to achieve needed comprehensive pharmacy DIR reform that will support the viability of pharmacies, network competition, and allow for beneficiary access to the pharmacy of their choice.** We urge the Committee to take additional action this year to establish protections as detailed in this testimony to ensure pharmacies are no longer exploited by Plans or their partners, particularly as the Calendar Year 2023 Medicare Part D rule addressing negotiated price and pharmacy remuneration (DIR fees) goes into effect in January 2024.

NASP appreciates the opportunity to provide testimony for the record for today's hearing. If we can provide additional information as the Committee proceeds with its review of anticompetitive pharmacy market practices, please contact our organization.

NATIONAL COMMUNITY PHARMACISTS ASSOCIATION
100 Daingerfield Road
Alexandria, VA 22314–2888
703–683–8200 Phone
703–683–3619 Fax

Chairman Wyden, Ranking Member Crapo, and members of the committee:

Thank you for conducting this hearing on pharmacy benefit manager practices and their impact on patients and taxpayers. In this statement, the National Community Pharmacists Association will offer support and suggestions on several policy considerations that would lower out-of-pocket costs for patients' prescription drugs, provide certainty for pharmacies, and protect taxpayers by bringing more transparency to prescription drug spending.

NCPA represents America's community pharmacists, including the owners of more than 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care settings. Together, our members represent a $78.5 billion health care marketplace, employ 240,000 individuals, and provide an expanding set of health care services to millions of patients every day. Our members are small business owners who are among America's most accessible health care providers.

Our pharmacies and the patients they serve have long had concerns about pharmacy benefit managers (PBMs), their anticompetitive practices, and the role they play in ever-increasing drug costs. These concerns have been further exacerbated because of the COVID-19 pandemic's effects on small businesses. Independently owned pharmacies have served as lifelines as essential businesses during the pandemic. However, PBM practices are causing these small businesses to struggle to remain viable and keep doors open to provide continued access and care.

NCPA and the University of Southern California School of Pharmacy and Leonard D. Schaeffer Center for Health Policy and Economics have collaborated to develop a web tool that shows pharmacy shortage areas at the neighborhood level and generates information on pharmacy closures and populations affected. High-level findings include:

- Twenty-five percent of the U.S. population (81,203,948) lived in pharmacy shortage areas across urban, suburban, and rural areas in 2020.
- Only one-third of pharmacy shortage areas calculated within the web tool carry the Health Resources and Services Administration designation of Medically Underserved Areas, or MUAs. This means that two-thirds of pharmacy shortage areas are unaccounted for when considering low access to health care in geographical areas under the MUA definition.
- Populations with the highest pharmacy shortage area population were Black (37.1 percent), Medicaid (33.2 percent), and low-income (36.7 percent).
- States with the highest percentage of census tracts calculated as pharmacy shortage areas are Alaska, Mississippi, Montana, New Mexico, North Dakota, South Dakota, and Wyoming.
- Independent pharmacies were the most dynamic factor in terms of creating and closing pharmacy shortage areas.

Pharmacies have also faced significant closures in recent years:

- From 2012 to 2019, over 1,000 independent pharmacies closed, going from approximately 23,000 to less than 22,000.[1]
- Both chain and independent pharmacies closing contribute to creating pharmacy shortage areas, but in most states, independent pharmacies closing contribute far more gaps than chains.[2]
- Independent pharmacies are at greater risk of closure than chains in urban and non-urban areas. Additionally, pharmacies serving disproportionately low-income and uninsured populations are at greater risk of closure.[3]
- Kaiser Heath News cited a Rural Policy Research Institute study showing that due to over 1,000 pharmacy closures since 2003, 630 communities are now without a pharmacy.[4]

We appreciate the efforts of the chair and ranking member to discuss PBM practices and their effect on drug prices for patients.

PBMs are not transparent about the rebate process and their profit margins. Moreover, we often do not know how much the PBMs make on administrative service fees and spread pricing (the difference between how much they reimburse the pharmacy and the higher price they charge the plan for the same prescription). More accurate reporting is needed to provide this transparency. To get a complete picture of PBM financials, we also need greater clarity on:

- Complicated and opaque methods to determine pharmacy reimbursement.
- Methods to steer patients towards PBM-owned or affiliated pharmacies.
- Fees and clawbacks charged to pharmacies.
- Potentially unfair audits of independent pharmacies.
- The prevalence of prior authorizations and other administrative restrictions.
- The use of PBM-defined specialty drug lists and associated specialty drug policies.
- The effect of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients.

Bring transparency to the Medicaid program and prevent the use of spread pricing by PBMs

H.R. 1613, the Drug Price Transparency in Medicaid Act, was introduced by Reps. Buddy Carter (R–GA), Vicente Gonzalez (D–TX), Rick Allen (R–GA), Jake Auchincloss (D–MA), Elise Stefanik (R–NY), and Deborah Ross (D–NC). It would bring transparency to the Medicaid program by:

- Prohibiting spread pricing/requiring a full pass-through in all Medicaid managed care programs.
- Requiring that pharmacy reimbursements in all state Medicaid managed care programs be at a rate of pharmacy's average acquisition costs and the state's Medicaid fee-for-service dispensing fee.
- Limiting payments to PBMs to solely administrative fees.
- Mandating National Average Drug Acquisition Costs reporting to the Centers for Medicare and Medicaid Services by all pharmacies participating in state

[1] From historic NCPA Digest data.
[2] Data from 2018 to 2020, from University of Southern California School of Pharmacy and Leonard D. Schaeffer Center for Health Policy and Economics.
[3] Assessment of Pharmacy Closures in the United States From 2009 Through 2015, Clinical Pharmacy and Pharmacology, JAMA Internal Medicine, JAMA Network.
[4] How Rural Communities Are Losing Their Pharmacies, Kaiser Health News *(khn.org).*

Medicaid programs. This provision would provide much needed transparency in drug pricing and allow reimbursements to reflect the true acquisition costs of prescription drugs in Medicaid.

Bring transparency for employers and consumers and greater enforcement authorities

S. 127, the Pharmacy Benefit Manager Transparency Act of 2023, introduced by Senators Maria Cantwell (D–WA) and Chuck Grassley (R–IA), would increase drug pricing transparency for employers and plan sponsors and hold PBMs accountable for unfair and deceptive practices that drive up the costs of prescription drugs at the expense of consumers. The bill:

- Prohibits deceptive, unfair pricing schemes, including spread pricing and arbitrary clawbacks of payments made to pharmacies.
- Incentivizes transparent PBM practices by making clear that a PBM would not be in violation of the law if it:
  - Passes along 100 percent of rebates to the health plan sponsor; AND
  - Provides the full disclosure of cost, price, reimbursement and all charged fees, mark-ups, and discounts to the plan sponsor and pharmacy; OR
  - Provides the aggregate remuneration fees it receives from drug makers to health plans, payers, and any federal agency.
- Mandates transparency by requiring that PBMs file an annual report with the Federal Trade Commission, including the total amount they pocket through spread pricing and pharmacy fees.
- Clarifies the enforcement authority of the FTC and state attorneys general to prohibit unfair or deceptive business practices PBM-insurers use in commercial health insurance.

On March 22, 2023, the Senate Committee on Commerce, Science, and Transportation marked up the legislation in an executive session. An amendment by Senators Jon Tester (D–MT) and Shelley Moore Capito (R–WV) was adopted that closes a loophole which could have allowed PBMs to continue to engage in the abusive practice of clawbacks and protects the CMS direct and indirect remuneration final rule regarding post-adjudication clawbacks. S. 127, as amended, advanced out of the committee on a bipartisan 18–9 vote. NCPA hopes the full Senate will promptly take up this legislation to ensure PBM business practices that impact employers, patients, and pharmacies are fair and transparent.

Ensure patient access to pharmacies and pharmacy market competition

Opaque and convoluted PBM and insurance plan pricing structures prevent pharmacies from being able to plan their business operations, as they are currently unable to understand what they will be reimbursed for a given drug or the services they provide for dispensing a given drug. Pharmacy performance/quality measures are being abused by plans/PBMs to secure fees from pharmacies rather than to fairly assess pharmacy performance.

Draft legislation in development by Reps. Morgan Griffith (R–VA), Vicente Gonzalez (D–TX), Buddy Carter (R–GA), Lisa Blunt Rochester (D–DE), and others would improve patient access to pharmacies and pharmacy market competition. This bill requires:

- The secretary of the Department of Health and Human Services to promulgate regulations to ensure Medicare Part D prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA–PDs) reasonably reimburse pharmacies.
  - This regulatory effort would help to ensure total reimbursement paid—net of all price concessions, fees, incentive payments, and any other form of remuneration is reasonable for a pharmacy to acquire and dispense drugs and provide necessary pharmacy services.
- PDP sponsors and MA–PD plans, beginning on January 1, 2024, to only use standardized measures established by the secretary and relevant to the performance of a pharmacy based on the drugs a pharmacy dispenses.
- PDP sponsors and MA–PD plans to promptly furnish all pricing components to pharmacies, so that a pharmacy understands its final reimbursement and the purpose of any adjustments in reimbursement.

We are grateful CMS has finalized its rulemaking which applies all pharmacy price concessions at the point of sale after years of congressional efforts in support of DIR fee reform. However, while the final rule is a good start, additional statutory authority and clarity is needed that would allow CMS to address other issues, such as adequate pharmacy reimbursement. We hope Congress will work with us to en-

sure that more comprehensive pharmacy DIR fee reform can be implemented in 2024.

More on PBM practices

PBMs protect profits at the expense of competition and consumer welfare. Our additional comments below demonstrate the staggering scope of such practices. NCPA believes Congress and CMS could correct many of these harms by focusing immediate attention on adhesion contracts between PBMs and independent community pharmacies, patient steering to PBM-affiliated pharmacies, and discriminatory reimbursement.

The effect of PBM rebates and fees on net drug prices to patients, employers, and other payers

NCPA has sought reforms on rebates and fees for more than 10 years to address ballooning expenses for patients. NCPA is hopeful that CMS' attempt to bring transparency to pharmacy DIR fees through the recently issued final rule[5] is a step in the right direction. With vertical integration both upstream and downstream, there is a need to level the playing field between independent pharmacies and PBM-affiliated pharmacies to protect patients from paying too much at the counter. NCPA believes it is incumbent on Congress to engage with CMS to address PBM market power exacerbated by rebates and clawback fees. The vertical integration of PBMs into monoliths with an affiliated upstream insurance provider and downstream pharmacies has only increased the incentives for PBMs to disfavor independent pharmacies. The current CMS fee and rebate structure creates incentives for PBMs to disfavor competing independent pharmacies, resulting in pharmacy deserts and increased patient costs. The final CMS rulemaking, however, also illustrates that CMS is not equipped to address the issues without the assistance of Congress.

Utilization management, other "cost controls," and the effect on patients and independent pharmacy

Due to contractual obligations with PBMs, NCPA members frequently must explain to their patients that due to "utilization management" (*e.g.,* prior authorization and step therapy) and formulary exclusions, patients are unable to get access to their prescribed medication. While described as "payer controls," used to "control costs," PBMs, through their offshore group purchasing organizations (GPOs) Ascent Health Services (Cigna/Express Scripts), Zinc Health Services (Aetna/CVS Caremark) and Emisar Pharma Services (United Healthcare/Optum), use these cost controls to direct utilization to the drug with the best manufacturer rebate, which is often not the best drug for the patient, while also using the GPOs to hide rebates from plan sponsors.[6] PBMs also use these "cost controls" to control manufacturer access to the market, creating a "pay-to-play" game to get new drugs to the marketplace. In a recent analysis by IQVIA, two-thirds of patients who want to start a new prescribed drug were unable to do so because of these controls, with the largest PBMs blocking about 450 products.[7]

On Monday, March 27, 2023, Ohio Attorney General Dave Yost filed a lawsuit against Cigna/Express Scripts, Prime Therapeutics, and Ascent. In the complaint, Yost accuses PBMs Express Scripts and Prime Therapeutics of colluding with Ascent, based in Switzerland, to illegally drive up drug prices which resulted in higher out-of-pocket costs for patients. Additionally, the state of Ohio argues, "PBMs also use their market power to hurt competing pharmacies, and particularly independent pharmacies."

Ascent is one of the new contracting entities, or GPOs, that Cigna/Express Scripts has added to their vertically integrated corporate structure, adding another layer of confusion and deception to drug pricing. The three largest PBMs (Caremark, Optum, and Express Scripts) have all created their own contracting entities or GPOs. Two of these entities are located in Ireland and Switzerland. Many believe

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[5] Medicare Program; 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, CMS 4192–F, May 9, 2022, *2022-09375.pdf (govinfo.gov).*

[6] PBMs claim that they no longer retain rebates but that is because the rebates have shifted to their offshore GPOs.

[7] Greenwalt, L. (2022). Payer Controls: Goodbye, Old Assumptions for Access and Uptake. *Iqvia.com.* Retrieved 26 March 2023, from *https://www.iqvia.com/locations/united-states/blogs/2021/09/payer-controls-assumptions-for-access-and-uptake.*

these GPOs are corporate shells created for the purpose of hiding the actual amount of rebates PBMs receive from pharmaceutical manufacturers.

PBM drug substitutions and their effect on patient costs

PBMs operating in the commercial, Medicare Part D, and Medicaid spaces alike contribute to artificially inflating drug costs using expensive name brand medications when less expensive generic alternatives are available. For example, PBMs continue to require the use of the more expensive brand asthma inhaler Symbicort over the generic budesonide; Symbicort costs over $150 per month more. One PBM mandated that a state Medicaid program use Lamictal, at over $16.50 a tablet, which is significantly more expensive than its generic counterpart that costs less than $0.10 a tablet. PBMs similarly give wasteful, preferential treatment to other brand medications like Advair, Concerta, Colcrys, Ventolin, Adderall XR, and Focalin XR. Common sense would dictate that where you have a choice between two equivalents, you take the less expensive one, unless there is a compelling reason not to.

In these cases, PBMs claim that they secure large rebates from the manufacturer to bring the net cost of the product down to below the cost of the generic. Even if this were true (which would require complete transparency and a 100 percent pass-through of all monies that flow from a pharmaceutical manufacturer to a PBM), it does not negate the consumer harm that exists to patients when they are in the deductible phase and paying more out of pocket for their medication costs. PBMs will also blame these formulary placements on plan sponsors, but plan sponsors like others in this industry are at the mercy of PBMs and their constant threats of rate hikes.

PBMs' use of potentially unfair, deceptive, or anticompetitive contract terms and all related practices when calculating pharmacy reimbursements and disbursements

NCPA members have received Medicare Part D contract amendments that appear predatory. One PBM offered an anticompetitive contract amendment that would compensate independent pharmacies 10 percent below their wholesale acquisition cost, provide no dispensing fee,[8] and assess a per-transaction performance pool fee. The intended effect of such an amendment and discriminatory pricing can only be to force independent pharmacies to opt out of the Medicare Part D networks or stay in them only to face financial ruin. The end result is the strengthening of PBM-affiliated mail-order, specialty, and retail pharmacies at the expense of independent pharmacies.

It is important to understand the lengths to which PBMs go to obfuscate how they price and reimburse drugs. Such distortion begins with terminology: an average wholesale price (AWP) is generally a mark-up (typically 20 percent) of the wholesale acquisition cost (WAC) and can be thought of as the manufacturer's list price.[9] It is generally accepted that WAC is the amount paid by the wholesaler to the manufacturer.

The maximum allowable cost (MAC) is the amount set by the PBM and is the amount the PBM will reimburse a pharmacy for generic drugs (pharmacy MAC). MAC is also the amount the PBM will charge a plan sponsor for a drug (plan sponsor MAC). The pharmacy MACs and plan sponsor MACs can change by the hour or even minute. The price difference between the pharmacy MAC and the plan sponsor MAC is the "spread." Many understand that the spread is a revenue stream retained by the PBMs. As an example of the amount of money generated by this arbitrage, spread pricing cost the state of Ohio $225 million in 2018.[10]

A generic effective rate (GER) represents a reimbursement baseline calculated as a percentage discount (*e.g.,* 86 percent) off the average wholesale price (AWP) of a generic drug. A PBM will calculate across all generic drugs dispensed for a specified period (*e.g.,* 1 year) either at an individual pharmacy level or often across all the pharmacies represented by a pharmacy services administrative organization (PSAO). However, PBMs reimburse generic claims at varying MAC, WAC or discounts off AWP, not at the GER. Accordingly, at the end of the specified evaluation

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[8] Stoller, M. (2022). The Red Wedding for Rural Pharmacies. *Mattstoller.substack.com.* Retrieved 5 May 2022, from *https://mattstoller.substack.com/p/the-red-wedding-for-rural-pharmacies?s=r.*

[9] Anderson, L. (2022). Average Wholesale Price (AWP) as a Pricing Benchmark. *www.drugs.com.* Retrieved 5 May 2022, from *https://www.drugs.com/article/average-wholesale-price-awp.html.*

[10] Ohio Auditor of State. *Ohioauditor.gov.* (2022). Retrieved 26 March 2023, from *https://ohioauditor.gov/news/pressreleases/Details/5042.*

period, PBMs reduce the AWP of all the individual generic drugs dispensed by the GER discount (*e.g.,* 86 percent) and that number is compared to the actual reimbursement originally paid to a pharmacy. The PBM will then reconcile the total dollar difference. If, after the PBM completes the calculations and determines a pharmacy has received excess reimbursement, the PBM will claw back the money. Given the vast differences between generic reimbursements based on MAC, WAC, and discounts of AWP, it is particularly difficult for pharmacies to know where they stand in comparison to the contracted GERs. Notably, PBMs do not refund clawbacks to patients; the PBMs retain the clawbacks for themselves. Brand effective rates (BERs) work the same, except the PBMs use them for brand drugs.

This effective rate contracting/payment method allows PBMs to play games with individual drug reimbursements to the detriment of patients, pharmacies, and employers. Effective rate contracts allow a PBM, at its sole discretion, to reimburse a pharmacy artificially high or low knowing the PBM will reconcile the pharmacy reimbursement dollars at the end of the evaluation period to the contracted effective rate, as described above. For patients who have a percentage-based cost share, when a pharmacy dispenses a drug at a higher price artificially inflated by the PBM, based on the point-of-sale adjudication, the patient will pay a higher copayment. The patient will not receive the benefit of the end of the year reconciliation—the PBM will keep that money.

PBMs' use of unconscionable contract terms

PBMs control market access, and they use that control to force unconscionable contract terms. PBM adhesion contracts include random basis audits, aberrant drug list compliance, inventory management limitations, specialty drug limitations, complicated performance metrics, complex pricing schemes, "flexible contracting" (which means unilateral, no-notice contract changes), and other such provisions. The PBM can base an audit off any of those unconscionable contract terms. A PBM audit is an existential threat to an independent pharmacy's business. Nevertheless, it is common for a single pharmacy to face several PBM audits a month. One of the most common audits is an invoice audit. Invoice audits require the pharmacy to prove that it bought the drugs it billed to the PBM. While that sounds reasonable, it is the frequency with which the PBM conducts such audits and the penalties that are not reasonable. If a PBM finds even a minor discrepancy, the pharmacy faces substantial financial penalties, and potentially even termination of the network agreement.

Termination of the network agreement can be fatal. In 92 percent of metropolitan statistical areas (MSAs), at least one insurer with a PBM has a 30 percent market share. In 50 percent of MSAs, one insurer has at least 50 percent market share.[11] With PBMs controlling access to the upstream insurer networks, they are able to control the downstream pharmacy market, and conflicts of interest abound.

PBMs steering patients away from unaffiliated pharmacies and toward PBM-affiliated specialty, mail-order, and retail pharmacies

PBMs use a variety of methods to steer patients away from unaffiliated pharmacies. PBMs create arbitrary lists, such as specialty and aberrant drug lists, to limit independent pharmacies' access to patients. These lists require patients to obtain certain drugs from a PBM-affiliated pharmacy.[12] The PBMs use contract provisions that require independent pharmacies to "walk" their patients to "specialty pharmacies," a term PBMs arbitrarily define. Any independent pharmacy can potentially be a specialty pharmacy, however, the PBMs make the sole determination of who meets the opaque "criteria." If the PBMs do not determine the independent pharmacy meets PBM-established specialty pharmacy accreditation requirements, the pharmacy cannot be part of the specialty pharmacy network. Such a process begs the question: when would a PBM with a downstream affiliated specialty pharmacy ever determine an independent pharmacy is worthy of such designation?

Other methods include refill walk requirements. Below is a screenshot from an independent pharmacy's pharmacy management system. As you will see, the PBM requires the independent pharmacy to inform its patient that the patient must seek

[11] COMPETITION in HEALTH INSURANCE A comprehensive study of U.S. markets. *Ama-assn.org.* (2022). Retrieved 26 March 2023, from *https://www.ama-assn.org/system/files/2020-10/competition-health-insurance-us-markets.pdf.*

[12] Fein, A. (2022). Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?. *Drugchannels.net.* Retrieved 26 March 2023, from *https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html.*

an alternative way of getting their refills. The alternative way is through the PBM-affiliated pharmacy.

Failure to follow these exclusionary procedures often leads to audits and threats of termination of the pharmacy's network agreement. At the very least, PBMs force pharmacies to choose between filling the refill free of charge (real-time claims adjudication would prevent the independent pharmacy from submitting a claim) or letting the patient go untreated until they find a PBM-affiliated alternative.

PBMs' policies and practices related to specialty drugs and pharmacies

On behalf of PBMs, sPCMA, a division of the Pharmaceutical Care Management Association representing the specialty pharmacy industry, released a white paper to defend PBM specialty drug practices.[13] In it, sPCMA admits that the definition of specialty drug continues to evolve. It lists a number of attributes that on the one hand apply to many non-specialty drugs, and on the other hand begs the question: if specialty drugs are used to treat complex or chronic medical conditions that require lab monitoring; additional patient education, adherence and support; and administration technique training beyond traditional dispensing activities, why would a PBM want to send specialty drugs through its affiliated mail-order pharmacy? sPCMA provides the answer—money.[14, 15]

Other criteria cited in this document reveal the lack of differentiation between most designated specialty drugs and more widely used drugs. In fact, sPCMA notes that patients use specialty drugs for a wide range of conditions. When addressing why specialty drugs have limited distribution, sPCMA cites criteria that is relevant with all non-specialty designated drugs too: drug inventory tracking, supply chain integrity, and dosing and lab monitoring. Therefore, the criteria PBMs use is nebulous at best.

The impact on patients is clear. PBMs cut off patients who often have complex or chronic medical conditions from specialty options and force them into mail order at significant risk to their health.[16] The PBM practices prevent patients from accessing prompt care, education, injection training, adherence, and related support that only an in-person pharmacist can provide. Additionally, this practice is hurting consumers because when a mail-order drug fails to arrive at a patient's home, patients are forced to fill their specialty drugs at a pharmacy that is out of network, or not authorized to distribute specialty drugs.

Potential conflicts of interest and anticompetitive effects arising from horizontal and vertical consolidation of PBMs with insurance companies, specialty pharmacies, and providers

In 2018, the auditor of the state of Ohio produced a State Report on Ohio's Medicaid Managed Care Pharmacy Services that spoke to PBM conflicts of interest.[17] In it, the auditor found discriminatory reimbursement because PBMs compensated their affiliated pharmacies at a higher rate than independent pharmacies. This discriminatory reimbursement occurs nationwide, based on evidence reviewed from Arkansas, Florida,[18] and Oklahoma. In fact, in February 2018, the Arkansas Pharmacists Association, joined by Arkansas Lieutenant Governor Tim Griffin and almost half of the General Assembly, held a press conference unveiling data demonstrating that PBMs pay their own affiliate pharmacies more than independent pharmacies.[19] The Arkansas data contained over 200 examples of discriminatory reimbursement. Of the top generic drug prescriptions, Arkansas found that the PBMs were paying themselves, on average, over $60 more per prescription than they were paying independent pharmacies. The PBM was steering patients to its wholly owned affiliate so that it could pay itself more. Such anticompetitive behavior results in increased costs and harm to patients.

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[13] *https://www.spcma.org/wp-content/uploads/2016/06/sPCMA_The_Management_of_Specialty_Drugs.pdf.*
[14] *Id* at 3.
[15] *Id* at 4.
[16] *https://www.npr.org/sections/health-shots/2019/01/07/673806506/extreme-temperatures-may-pose-risks-to-some-mail-order-meds.*
[17] *https://audits.ohioauditor.gov/Reports/AuditReports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.*
[18] Milliman, Florida Agency for Health Care Administration: Pharmacy Benefit Manager Pricing Practices in Statewide Medicaid Managed Care Program (December 2020).
[19] *https://m.youtube.com/watch?v=CDnFSOMAazA.*

Conclusion

Prescription drug prices continue to grow at an alarming rate, while transparency and competition are decreasing. As we have shown above, there are many factors in the pharmaceutical supply chain and delivery system that may contribute to these negative factors, including PBM "middlemen." NCPA stands ready to work with Congress and the administration to implement policies that will lower drug prices at the pharmacy counter for our patients.

NATIONAL MULTIPLE SCLEROSIS SOCIETY
One M Street, SW, Suite 510
Washington, DC 20003
Tel 1–202–408–1500
https://www.nationalmssociety.org/

April 5, 2023

The Honorable Ron Wyden
Chairman
U.S. Senate
Committee on Finance
221 Dirksen Senate Office Building
Washington, DC 20510–6200

The Honorable Mike Crapo
Ranking Member
U.S. Senate
Committee on Finance
239 Dirksen Senate Office Building
Washington, DC 20510–6200

Dear Chairman Wyden and Ranking Member Crapo:

On behalf of the National Multiple Sclerosis Society (Society), thank you for the opportunity to provide a statement for the record for the hearing "Pharmacy Benefit Managers and the Prescription Drug Supply: Impact on Patients and Taxpayers." We appreciate this hearing's focus on examining the role that pharmacy benefit managers (PBMs) play in the American healthcare system and the ways that these entities contribute to the high cost of prescription drugs.

We appreciated this Committee's commitment and focus on passing key provisions of the Inflation Reduction Act that reduce the cost of prescription drugs for Medicare beneficiaries by allowing Medicare to negotiate for a select number of medications, setting a $2,000 cap on what beneficiaries must pay out of pocket, and enacting rebates to Medicare if the cost of a specific prescription drug rises faster than inflation. The IRA was a critical first step at systemically lowering the prices of prescription drugs for Americans. Still, more work remains to ensure that people can get life-changing medications when they need them. We are pleased that the Committee is now turning its attention to advancing solutions that ensure transparency and accountability of PBMs and their practices and that any savings that they negotiate are passed along to the patients and the healthcare system at large.

Multiple sclerosis (MS) is an unpredictable disease of the central nervous system. Currently, there is no cure. Symptoms vary from person to person and may include disabling fatigue, mobility challenges, cognitive changes, and vision issues. An estimated 1 million people live with MS in the United States. Early diagnosis and treatment are critical to minimize disability. Significant progress is being made to achieve a world free of MS. The Society, founded in 1946, is the global leader of a growing movement dedicated to creating a world free of MS. To fulfill this mission, we fund cutting-edge research, drive change through advocacy, facilitate professional education, collaborate with MS organizations around the world, and provide services designed to help people affected by MS move their lives forward.

PBMs have played an increasingly important—but often hidden—role in the U.S. healthcare system. PBMs manage prescription drug benefits for health insurers, Medicare Part D drug plans, large employers, and other payors. Today, PBMs play an outsized role in determining the cost of prescription drugs for payors, influencing the access to medication that people with MS and other patients need, and determining how much pharmacies are paid for these medications.

High-priced MS medications are targets for PBM negotiations—creating both cost and access challenges for people with MS.

MS is a highly expensive disease. The average total cost of living with MS is $88,487 per year.[1] The total estimated cost to the U.S. economy is $85.4 billion per

[1] Bebo, Bruce et al. The Economic Burden of Multiple Sclerosis in the United States: Estimate of Direct and Indirect Costs. Neurology May 2022, 98 (18) e1810–e1817; DOI: 10.1212/WNL.0000000000200150. *https://n.neurology.org/content/98/18/e1810* (accessed May 4, 2022).

year, and the direct medical cost to live with MS is an average of $65,612 more than a person who does not live with MS.[2]

Evidence demonstrates that early and ongoing treatment with an MS disease-modifying therapy (DMT) is the best way to manage the disease course, prevent the accumulation of disability, and protect the brain from damage due to MS.[3] There are now more than twenty DMTs on the market, including generic options. These medications have transformed the treatment of MS over the last 30 years. Unfortunately, these DMTs are incredibly expensive. The full range of MS DMTs represents various mechanisms of action and routes of administration with varying efficacy, side effects, and safety profiles. No single agent is 'best' for all people living with MS[4] and as MS presents differently in each person, every person's response to a DMT will vary. It is common for people with MS to move through several different DMTs throughout their life as they may "breakthrough" on medication or have disease activity and need to try a different DMT.

When the first MS DMT came to market in 1993, the price range was $8,000 to $11,000 for one year of treatment. The price of MS therapies has dramatically risen since that time. As of January 2023 (see appendix I), the median annual price of brand MS DMTs is nearly $98,000. The annual cost for individuals on an MS DMT ranges from $57,202 to $92,719, depending on an individual's age and sex,[5] and people with MS stay on these medications for years. Cost increases have also impacted MS symptom management medications. For example, H.P. ActharGel (Acthar), approved in 1952, is used as a short-term treatment for acute exacerbations of MS. For years, this medication was priced at less than $40 per vial. However, today, a vial of Acthar is priced at around $40,000—approximately 140,000% more expensive than when it was approved 68 years ago. The price increases have made MS medications targets for both PBMs and payors, increasing out-of-pocket costs for people with MS, costs to the system, and creating access issues that impact the health and well-being of those living with MS.

PBMs Impact Access to Medications

PBMs play a powerful role in determining what access people with MS have to their DMTs and symptom management medications. PBMs can determine which medications are covered by payors and, what tier those medications are on, even what pharmacies people can use to get their medications. As the costs for these medications have increased, health plans and PBMs employ increasingly strict utilization management practices, like prior authorization and step therapy, to minimize the use and cost liability for these therapies. These practices present **significant** hurdles for prescribers and cause **real delays and barriers for people with MS in accessing medications that they and their provider decide is right for them.**

While PBMs often cite part of their role as keeping pharmaceutical and health costs down, there are documented examples that PBM practices can add costs to the healthcare system overall and inhibit patient care. Physicians in the United States complete an average of 33 prior authorization (PA) requests every week, taking an average of 14.4 hours to process.[6] Eighty-six percent of surveyed physicians described the burden of PA as either high or extremely high. This burden is detrimentally impacting patients, with 90% of physicians reporting that PA requirements hurt patient clinical outcomes and 74% of physicians reporting that issues associated with PA can lead to patients abandoning or being nonadherent to a recommended course of treatment. Twenty-four percent of physicians report that PA has led to a serious adverse event for a patient in their care, and 16% of physicians

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[2] Bebo, Bruce et al. The Economic Burden of Multiple Sclerosis in the United States: Estimate of Direct and Indirect Costs. Neurology May 2022, 98 (18) e1810–e1817; DOI: 10.1212/WNL.0000000000200150. *https://n.neurology.org/content/98/18/e1810* (accessed May 4, 2022).

[3] Costello, K. et al. MS Coalition. The Use of Disease Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. September 2019. *https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf* (accessed May 20, 2022)

[4] MS Coalition. The Use of Disease Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. *http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color.* Accessed December 26, 2018.

[5] Bebo, Bruce et al. The Economic Burden of Multiple Sclerosis in the United States: Estimate of Direct and Indirect Costs. Neurology May 2022, 98 (18) e1810–e1817; DOI: 10.1212/WNL.0000000000200150. *https://n.neurology.org/content/98/18/e1810* (accessed May 4, 2022).

[6] American Medical Association. 2019 AMA prior authorization (PA) physician survey. *https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.*

say that PA has led to a patient's hospitalization. The healthcare system must do better for patients and providers.

Personal stories from the MS community echo these findings. For the past several years, people with MS and their healthcare providers have described egregious step therapy practices and prior authorization delays that have resulted in MS exacerbations, worsening health, and increased costs to the healthcare system.

MS Activist Marguerite from CA:

> I have had the not-uncommon experience of running out of my critical medication while I wait for my neurologist to jump through the prior authorization hoops. With MS, it's critical to take medication regularly, as scheduled, to avoid progression of the disease and potential disability.

These utilization management practices can include requiring three to five DMTs to fail a person with MS prior to accessing the individual's and their provider's medication of choice, requiring someone to use a DMT they already know does not work for them, and requiring people with needle phobia to use self-injectable medications even though oral medications are available. These practices result in nonadherence and dangerous delays to people getting on the DMTs that will work for them. With every delay, people with MS risk disease activity and underlying progression from which they may not recover. MS Activist Therese from Florida shared her experience:

> I almost gave up in January when it was time to coordinate with insurance, hospitals/doctors, and the specialty pharmacy for my Ocrevus infusion, which happens every 6 months. I almost give up every 6 months. Why? Because it's hard. It's hard to understand the steps that need to happen for approval because they seem to change every time. The people that I speak with on the phone are busy and talk fast, which is difficult for me to understand. I'm spoken down to by representatives, often making me feel dumb or that I'm a burden. And all I want is the medication that I'm already taking and is working. The medication that my medical team and I have deemed appropriate for me. It's nothing new, yet the problems to get it approved and dispensed are always new and ever-changing.

There is often little transparency into how formularies or step therapy protocols are developed, especially for MS DMTs, where no publicly available algorithms describe how to progress through the different MS DMTs. In 2019, in response to a Society funded survey, people with MS reported that the greatest challenge in getting their DMT comes from insurance companies.[7] Too often, formularies designed by PBMs, and health insurers are driven not by medical practice but by rebates in the system. For example, according to a 2020 staff report from the House Committee on Oversight and Reform, Teva Pharmaceuticals pressured PBMs by tying contractual rebates on Copaxone 20 mg/ml to adding Copaxone 40 mg/ml to their formularies.[8]

The combination of vertical integration of PBMs, payors and pharmacies, rebating, and other business-related practices often result in formulary placement of medications that often steers individuals towards more expensive medications, while generics and biosimilars are becoming increasingly available. For example, PBMs often place generic drugs and biosimilars in higher formulary tiers alongside brand medications, thus negating the cost savings to the health system and the patient. We have seen this practice in the MS space, as MS generics, due to higher cost than regular generic medications, are covered more like specialty medications, resulting in higher cost sharing for people with MS.

PBMs may also prefer a higher cost drug because it will increase their revenues; so, despite lower cost alternatives being available, a higher cost product may receive favorable formulary placement. These practices do not serve the best interest of the patient and Congress should act to ensure that what works best for the patient guides all elements of health-care decision-making.

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[7] National MS Society. Quantifying the Effect of the High Cost of DMTs. Market Research Report. August 2019. *https://nms2cdn.azureedge.net/cmssite/nationalmssociety/media/msnationalfiles/advocacy/nmss-research-report-full-access-to-ms-medications.pdf*. (Accessed February 15, 2023).

[8] Drug Pricing Investigation Teva-Copaxone. Staff Report Committee on Oversight and Reform. U.S. House of Representatives. September 2020. *https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Teva%20Staff%20Report%2009-30-2020.pdf* (Accessed May 3, 2020).

Society's Recommendations for PBM Reform

The Society's analysis of policy recommendations is guided by two sets of recommendations, both developed by teams comprised of people affected by MS, MS healthcare providers, policy experts, and Society staff. The Access to High Quality MS Healthcare Principles[9] and the Access to MS Medications Recommendations[10] serve as the basis for the Society's support for any policy proposal and our recommendations to ensure that proposals best meet the needs of people with MS.

The Society's full set of policy recommendations for PBM reform is outlined below, and we support many of the solutions that were raised during the hearing. We believe that comprehensive PBM reform should include the following policies:

- Ensure transparency by requiring disclosure of specific costs, prices, reimbursements, fees, mark ups, discounts and aggregate payments received with respect to their PBM service.
- Prohibit unfair and deceptive pricing models including spread-pricing and arbitrary claw backs of payments.
- Require pass-through pricing models.
- Require oversight and reporting on PBM behavior and allow the FTC to take legal action when a PBM is found in violation of the law.
- Allow for patients to have a choice of the pharmacy where they receive their medications.
- Ban PBMs from using discriminatory formularies.
- Eliminate copay accumulator and similar policies that put greater burden on patients.
- Allow patients to receive the benefits from rebated savings and pay the lesser amount of copay/co-insurance, the amount charged by the PBM to the pharmacy, or the cost of the drug.
- Include a substantial monetary penalty for those PBMs who act in violation of the law.

Recommendations for Medicare and Part D

While many of our recommendations may fall outside the jurisdiction of the Senate Finance Committee, we believe that these areas are an important first step to reform—both in the government and commercial markets.

Transparency and consistency of reporting are key.

As noted above and by many at the hearing, the opaqueness of the American healthcare system makes reform especially challenging. We support policies to improve transparency so that all stakeholders are working with the same level of information. There is increased pressure on people with MS and other chronic health conditions to make informed choices about the cost of their care and prescription drug medications. Yet, there is very little true transparency to provide the level of information needed to guide these decisions. We do not believe data like net price, mark-ups, payments, or rebates should be a trade secret. **The Society supports proposals that would grant CMS the authority to require more granular data in reporting requirements and publish prescription drug prices throughout the year to level the playing field and give all stakeholders access to information necessary to guide their decision-making.**

Additionally, due to the vertical integration between payors and PBMs, **we support Congress granting authority to CMS to define an acceptable profit threshold for PBMs. CMS has a fiduciary duty to its beneficiaries and to taxpayers and this is consistent with the policies that CMS has around profit margins for plans under the Affordable Care Act.**

Align incentives to ensure that PBMs have a responsibility to act on what is best for the patient.

Many members acknowledged during the hearing that PBMs are not charged to act in the best interest of the patient, so they often act in ways that are more profitable for them as a business. Vertical integration has only served to further remove the patient's interest from the center of decision-making. **As mentioned above, the Society supports proposals that would prohibit unfair and deceptive pricing models including spread-pricing and arbitrary claw backs of payments, ban PBMs from using discriminatory formularies, and pass through all sav-**

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[9] *https://www.nationalmssociety.org/Get-Involved/Advocate-for-Change/Take-Action/Access-to-High-Quality-Healthcare/Access-to-High-Quality-MS-Healthcare-Principles.*

[10] *https://nms2cdn.azureedge.net/cmssite/nationalmssociety/media/msnationalfiles/advocacy/recommendations-make-ms-meds-accessible.pdf.*

ings from the system to plans and patients. It is our understanding that these practices stem from PBMs not having a requirement to act on what is best for the patient.

Patients should not be paying the highest prices for any prescription drug.
It is unconscionable that patients are sometimes paying the highest prices for medications, particularly when the role of payors and PBMs is to negotiate for lower costs yet, because so much data on pharmaceutical prices is confidential, researchers and policy makers often have a hard time ensuring that patients really are getting the best deal. **The Society believes and would support proposals that, would allow patients to pay whatever price is the lowest—the copay or coinsurance, the cost not utilizing insurance, or the price charged by the PBM to the pharmacy. Additionally, we would support reforming how coinsurance is calculated and ensuring that amount is calculated based off the rebated price, not the list price.** This change could be truly transformative for people living with MS, where the median annual price of brand MS DMTs is close to $98,000.

Additional Considerations for PBM Policy Reform

The specialty drug market needs further examination.
As noted during the hearing and throughout the Inflation Reduction Act hearing in the 117th Congress, the rise in specialty drugs has transformed the prescription drug and health coverage landscape. Dr. Burns noted in his testimony that "PBMs are not heavily focused on the dispensing of specialty drugs." We believe that the entire specialty market needs examination to truly understand its impact on the prescription drug enterprise and pipeline. There are some significant differences between specialty drugs, and the Society believes that they may not function the same as other types of drugs or follow traditional supply/demand market dynamics, particularly due to their frequent use off-label. **The Society believe that Congress should ask the GAO to examine specialty drugs and the impact on the research, development, and healthcare sector broadly.**

End gaming of the regulatory and patent systems.
As multiple Senators and the panel noted during the hearing, vertical integration has made it more urgent that Congress act to address regulatory and patent gaming of the system. The Society appreciates the attention from the Committee around improving the regulatory process to ensure speedy regulatory approval and access to generic medications and biosimilars. We believe that industries should be compensated fairly for the research and development required to bring innovative products to market. However, market exclusivity and patent protections are vital tools created by Congress to reward innovation, and the Society believes that minor tweaks to existing products should not receive lengthy patent protections. **We support the bills that passed out of the Judiciary Committee in February: S. 79, the Interagency Patent Coordination and Improvement Act of 2023, S. 113, the Prescription Pricing for the People Act of 2023, S. 142, the Preserve Access to Affordable Generics and Biosimilars Act, S. 148, the Stop Stalling Act, and S. 150, the Affordable Prescriptions for Patients Act of 2023. While large scale patent reform and pay for delay legislation should be examined, these bills provide a good first step at addressing common practices that are utilized to delay competition in the prescription drug market which artificially creates higher prices and less choice for patients.**

Conclusion

We are encouraged that the Senate Commerce and Judiciary Committees have already advanced legislation that would align with the Society's recommendations and urge you to pass comprehensive PBM reform out of Committee that provides accountability from PBMs to the Medicare system and for beneficiaries. The Society believes many of these proposals can and should be implemented in the commercial market and will work with your Colleagues in the Senate HELP Committee on complimentary legislation to ensure all patients have access to the life-changing therapies they need to live their best lives.

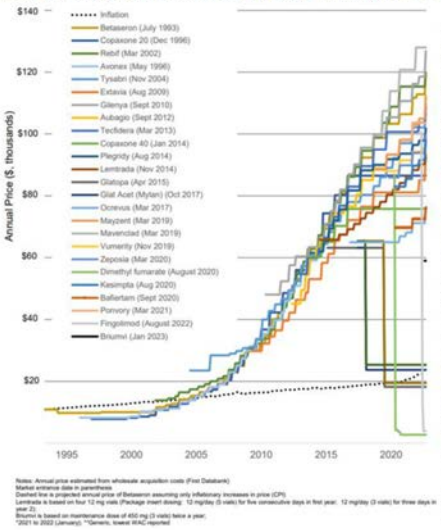
Thank you again for holding this important hearing and your work to address harmful PBM practices that hurt patients and raise costs for them and the healthcare system at large. If you have any questions about our comments or recommendations, please contact Leslie Ritter, AVP of Federal Government Relations at Leslie.Ritter @nmss.org.

Sincerely,

Bari Talente, Esq.
Executive Vice President, Advocacy and Healthcare Access

Appendix I

Trends in annual price for disease-modifying therapies for multiple sclerosis; 1993 to 2023



Drug (manufacturer)	1 Year Change*	Annual Price 2023
Self-administered Injections		
Betaseron (Bayer)	7.1%	$119,610
Avonex (Biogen)	5.5%	$101,796
Rebif (EMD Serono)	4.0%	$119,973
Extavia (Novartis)	15.4%	$93,566
Plegridy (Biogen)	5.5%	$101,796
Kesimpta (Novartis)	9.1%	$97,969
Glatiramer Acetate		
Copaxone 20 (Teva)	0.0%	$86,554
Copaxone 40 (Teva)	0.0%	$75,816
Glatopa (Sandoz)	0.0%	$18,250
Glatopa 40 (Sandoz)	0.0%	$19,500
Glat Acet (Mylan)	0.0%	$23,725
Glat Acet 40 (Mylan)	0.0%	$25,350
S1P Receptor Modulators		
Gilenya (Novartis)	9.1%	$126,812
Mayzent (Novartis)	9.1%	$112,346
Zeposia (Celgene)	6.0%	$99,549
Ponvory (Janssen)	0.0%	$103,660
*Fingolimod (generic)***	NA	$3,893
Fumarates		
Tecfidera (Biogen)	8.1%	$108,896
Vumerity (Biogen)	4.0%	$98,064
Bafiertam (Banner)	5.0%	$76,192
*Dimethyl fumarate (generic)***	0.0%	$2,738
Other Oral DMTs		
Aubagio (Genzyme)	6.0%	$109,862
Mavenclad (EMD Serono)	6.0%	$127,986
Infusions		
Tysabri (Biogen)	4.5%	$106,722
Lemtrada (Genzyme)	4.7%	$92,496
Ocrevus (Genentech)	5.5%	$75,102
Briumvi (TG Therapeutics)	NA	$59,000

Notes: Annual price estimated from wholesale acquisition costs (First Databank)
Market entrance date in parenthesis
Dashed line is projected annual price of Betaseron assuming only inflationary increases in price (CPI)
Lemtrada is based on four 12 mg vials (Package insert dosing: 12 mg/day (5 vials) for five consecutive days in first year; 12 mg/day (3 vials) for three days in year 2).
Briumvi is based on maintenance dose of 450 mg (3 vials) twice a year.
*2021 to 2022 (January). **Generic, lowest WAC reported

National Multiple Sclerosis Society

NEVADA PHARMACY ALLIANCE
11 Sunset Way
Henderson, NV 89014
702–714–1931
www.nevadapharmacyalliance.com

U.S. Senate
Committee on Finance

Introduction

The Nevada Pharmacy Alliance appreciates the opportunity to submit a statement for the record for the United States Senate Committee on Finance on "Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers."

The Nevada Pharmacy Alliance was created to address the need in our state to have an association that focused on the greater good of the pharmacy profession. To make sure that pharmacy professionals were supported so that they are able to take care of their patients. We are committed to connecting, educating, and advocating for the profession of pharmacy to optimize patient care and public health.

Great Concern about Pharmacy Benefit Manager Tactics

We are extremely concerned about pharmacy benefit manager (PBM) tactics that have significant negative effects on patients, communities, taxpayers, employers, and pharmacies. PBMs are hired by insurance plans and others to negotiate lower drug prices. Unfortunately, they manipulate the system and keep billions in profits while:

- Forcing patients and others to pay more for their medicines;
- Limiting patients' ability to choose their pharmacist;
- Restricting access to medicines that doctors and other prescribers determine to be right for the patient; and

- Jeopardizing pharmacies' viability—which obviously harms the pharmacy and also the patients and communities that rely on them.

The dominance of PBMs is significant. Three PBMs control 80 percent of the prescription drug market. These are the practical effects of PBM tactics:

- **Over-payments:** The University of Southern California Leonard D. Schaeffer Center for Health Policy and Economics found that Medicare Part D standalone plans paid $2.6 billion more in one year for 184 common generic medications compared with prices for the same drugs available to cash-paying customers of one retailer.
- **Restricting medications:** Drug Channels analysis found that from 2014 to 2022, 1,357 medications were excluded from at least one PBM formulary for at least one year. The exclusions of drugs from these lists have escalated since starting in 2012.
- **Putting the squeeze on pharmacies**: The Centers for Medicare and Medicaid Services found that direct and indirect remuneration (DIR) fees charged by PBMs and payers to pharmacies have exploded by 107,400% over the last decade.

We hear daily, as medical providers, the struggles that Nevada patients of all ages have affording their prescriptions. One reason that the cost of prescription medications are rising is because of the lack of transparency of PBMs. There are multiple studies that show PBMs are failing to pass saving on to states, insurance companies, and patients. Many of these were highlighted in the 2020 Interim Study Concerning the Costs of Prescription Drugs that happened in the Nevada Legislature.

We hear all of the time, as an association, the negative effects that the big PBMs (the top three have a 80% market share) are having on patient care and non-PBM owned pharmacies being sustainable in Nevada. As you are aware, pharmacies that are not managed by a company that owns a PBM are closing rapidly.

We want to take this opportunity to define "PBM reform." This is important to maximize the effectiveness of Congress' work in this area for patients, and to roll back the current jeopardy posed by PBMs to pharmacies. For this purpose, we call to your attention the Principles of PBM Reform advocated by the National Association of Chain Drug Stores:

- **Stop explosive retroactive fees.** Stop PBMs and payers from using "DIR fees" and other tactics to grab back the payments made and owed to pharmacies—often many months after the fact and often resulting in below-cost pharmacy reimbursement.
- **Stop below-cost reimbursement.** Adopt a reimbursement rate floor that prevents PBMs and payers from reimbursing pharmacies below the true cost of acquiring and dispensing prescription drugs.
- **Stop gaming of performance measures.** Standardize performance measures to help improve patient outcomes and reduce costs—rather than allowing PBMs and payers to play "gotcha" with pharmacies using arbitrary measures and exorbitant fees.
- **Stop "specialty definitions" from steering patients from their pharmacy.** Prevent PBMs and payers from defining "specialty drugs" in ways that steer patients with rare or complex diseases away from their preferred pharmacy of their choice and toward another pharmacy—including those owned by the PBMs and payers.
- **Stop mandatory mail-order.** Prohibit PBMs and payers from forcing patients to use mail-order pharmacies—including those owned by the PBMs and payers—and prohibit them from imposing penalties on patients for choosing a convenient and trusted pharmacy in their neighborhood.
- **Stop limited networks.** Require PBMs and payers to include in their networks all pharmacies willing to accept terms and conditions established by the PBM.
- **Stop overwhelming audits.** Bring efficiency, transparency, and standardization to the processes by which PBMs audit pharmacies without sacrificing continuity of care.
- **Stop the undercutting of PBM reform laws.** Prioritize the implementation, enforcement, and oversight of PBM reform laws—to maximize results for patients and fairness for pharmacies and other stakeholders, and to ensure laws are not undermined by inaction of PBMs or of government.

Conclusion

In closing, we want to put to rest one of the myths perpetuated by PBMs. It is shocking that they have been able to stave off reform efforts by alleging that premiums will increase. This is nothing short of a scare tactic, and one that cannot be allowed to be used so flippantly and without substantiation. PBM reform will reduce prescription drug costs by cracking down on middlemen's manipulation. It does not follow logically that reductions in prescription drug costs will result in increased premiums. It is time to address the manipulative business practices of PBMs, as well as to end the negative effects of their tactics.

The Nevada Pharmacy Alliance thanks the Committee for the opportunity to provide our perspective on PBM reform. For questions or further discussion, please contact Ken Kunke, Executive Secretary, info@nevadapharmacyalliance.com.

Ken Kunke, Pharm.D.
Executive Secretary

PATIENTS FOR AFFORDABLE DRUGS NOW
1120 20th Street, NW
Washington, DC, 20036

Patients For Affordable Drugs Now is the only national patient organization focused exclusively on policies to lower drug prices. We are independent, bipartisan and we do not accept funding from any organizations that profit from the development or distribution of prescription drugs.

Prescription drug prices are set by pharmaceutical companies, and our organization is dedicated to effective implementation of the comprehensive drug price reforms included in the Inflation Reduction Act (IRA) that will hold drug companies accountable by giving the federal government leverage over prices through negotiation and by implementing penalties on companies that price gouge. The policy provisions in the IRA finally authorize Medicare to negotiate prices directly for some of the most expensive prescription medicines; institute a hard cap on out-of-pocket drug costs for people on Medicare; limit copays on insulin for millions of Americans to $35 each month; and limit annual price increases to no more than the rate of inflation.

But drug companies are not the only actors in the drug pricing supply chain, and there is ample evidence that pharmacy benefit managers (PBMs) do not always act to minimize prices and costs for patients as intended under U.S. policy. Our concern about the impact of PBMs—and the need for more oversight and accountability—is why we submitted the following comments in response to the Federal Trade Commission's solicitation for public input on the business practices of PBMs.[1] Our comments urged the FTC to investigate PBMs in order to highlight specific areas needing reform and potential solutions, and we are pleased the FTC has opened an investigation into the major PBMs. But, even while the FTC pursues its work to examine PBM practices, Congress can act now to increase accountability for PBMs by requiring transparency into the secret actions of PBMs, giving the FTC the necessary tools to regulate PBMs, and passing legislation to ensure that PBMs are accountable first to their beneficiaries, rather than their shareholders.

We are grateful for the Committee's attention to lower drug prices, and we submit the following comments for the record in the hope that they will elucidate the patient perspective on PBMs and their impact on drug access and affordability.

Patients For Affordable Drugs Now is the only national patient organization focused exclusively on policies to lower drug prices. We are bipartisan and independent. We don't accept funding from any organizations that profit from the development or distribution of prescription drugs.

Today, pharmacy benefit managers (PBMs) administer prescription drug benefits for more than 266 million Americans, or 80% of the population.[2] While drug prices are set by manufacturers, there is ample evidence that indicates the profit-driven and secretive practices of PBMs play a major role in the cost of and access to drugs for our patient community. In order to better understand PBMs' impact on patients—

[1] *https://www.ftc.gov/news-events/news/press-releases/2022/02/ftc-requests-public-comments-impact-pharmacy-benefit-managers-practices.*
[2] *https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/.*

and to guide future government and industry reforms—we urge the Federal Trade Commission to conduct a study of PBMs.

PBMs Are Shrouded in Secrecy

PBMs are supposed to act as intermediaries, leveraging the buying power of insurers, employers, and government purchasers in order to capture savings, which at the end of the day are supposed to accrue to the benefit of patients and consumers. But because the business practices of PBMs are shrouded in secrecy, policymakers and the public are left in the dark about the amount of savings actually passed on to payers and patients through lower premiums and out-of-pocket costs.[3] While PBMs claim to be utilizing their bargaining power on behalf of patients, they are simultaneously fighting to ensure their rebate practices stay hidden from view.[4] As a result, a patient cannot know if the preferred drug on the formulary is placed there because it is the best, most cost-effective option or because it is the one for which the PBM received a substantial rebate. Without further transparency and accountability, PBM decision-making and its impact on patients will remain a mystery.

Are Patients Actually Paying More for Some Drugs Because of Rebate Practices?

Because larger rebates can be exchanged for more favorable formulary placement, PBM rebate practices may in fact incentivize drug companies to raise list prices in order to be able to provide deep enough rebates to gain and maintain placement. This ongoing cycle demonstrates how rebate practices can contribute to ever-increasing list prices.[5]

Pay-for-position rebate practices also lead to higher costs for patients. A PBM may receive a substantial rebate from a brand-name drug company in exchange for placing that brand-name drug—instead of a less expensive generic option—in a preferred tier. Because patient cost-sharing is most often based on the full, non-discounted price of the drug, this structure exposes insured patients to higher costs even though an equally effective, more affordable option may exist. The impact on uninsured patients is even more severe because they must pay the entire, rebate-inflated list price without the benefit of insurance coverage to absorb some of the costs. The relationship between rebates and higher out-of-pocket costs has been substantiated in academic research.[6]

PBM Practices May Be Used To Block Competition

Our drug pricing system is designed around the expectation that the market entry of generic and biosimilar drugs will generate competition and promote affordability. Unfortunately, PBM practices may make it difficult or impossible for generic and biosimilar drugs to gain uptake in the market. Current incentives in the negotiations between drugmakers and PBMs leave contracts vulnerable to gaming.

For example, as part of drug manufacturer Teva's effort to delay generic competition for its blockbuster multiple sclerosis drug Copaxone, the company developed a higher concentration version of the drug and began efforts to switch patients to this dosage before the existing dosage faced generic competition.[7] The House Committee on Oversight and Reform uncovered documents that show that Teva pressured PBMs "by tying contractual rebates on [the previously marketed concentration] to adding [the newly developed concentration] to their formularies."[8] The participating PBM conceded, seeking the sizable rebates in question. Teva's efforts to impede generic competition resulted in considerable costs to our health system and kept affordable alternatives out of reach for patients. In addition, in 2017, Pfizer filed a lawsuit[9] accusing Johnson & Johnson of offering PBMs larger rebates to incentivize them to place its blockbuster rheumatoid arthritis drug Remicade in a favorable formulary position instead of Pfizer's new biosimilar competitor, Inflectra.[10] Both examples il-

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[3] *https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/.*

[4] *https://www.reuters.com/legal/litigation/pbms-sue-us-keep-prescription-drug-prices-hidden-public-2021-08-12/.*

[5] *https://healthpolicy.usc.edu/article/new-evidence-shows-prescription-drug-rebates-play-a-role-in-increasing-list-prices/.*

[6] *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780950.*

[7] *https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG PRICING REPORT WITH APPENDIX v3.pdf.*

[8] *https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG PRICING REPORT WITH APPENDIX v3.pdf.*

[9] *https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2017/9/pfizer-sues-j-j-over-contracts-blocking-remicade-biosimilars.*

[10] *https://www.statnews.com/2021/01/19/ftc-biden-antitrust-rebates-mergers/.*

lustrate instances in which drug companies worked in tandem with PBMs to hinder market penetration of more affordable generic and biosimilar medications.

PBMs Put Shareholders First, Not Patients

PBMs have become some of the most profitable players in the health care sector. In 2021, PBMs handled more than $422 billion[11] of gross drug revenues in the United States. The profitability of PBMs has risen in recent years as a result of vertical mergers between PBMs, insurance companies, and pharmacies. Almost 90%[12] of those gross revenues in 2021 moved through the "Big Three" alone—CVS, Express Scripts, and OptumRx. The gross profit[13] of PBMs grew 12% between 2017 and 2019, increasing from $25 billion to $28 billion. Because they are profit-driven entities with a duty to shareholders but without a fiduciary responsibility to beneficiaries, additional transparency could clarify whether their practices best serve patients or shareholders. We believe U.S. law and policy should be amended to give PBMs a fiduciary responsibility to beneficiaries, requiring them to put beneficiary health and financial interests first.

Lack of Competition Leads to Profits Over Patients

Concentration in the PBM industry is yet another factor that appears to contribute to a drug pricing system where profits come before patients. Because three large PBMs[14] have a stranglehold on the market, these companies have a disproportionate impact on what medications patients have access to. For example, at the end of last year, CVS Caremark announced[15] that it would no longer cover the blockbuster anticoagulant Eliquis in 2022 and would instead cover only warfarin and Xarelto. This decision had enormous implications for patients since CVS Caremark has the largest market share (34%[16]) of any PBM. As a result, many patients were forced to switch products in order to remain on a covered drug. For some medications—especially biologics—a forced switch can carry with it significant health and safety implications for the patient. Patient choice can be further limited by PBMs, like CVS Caremark, that own retail pharmacies and may be directing or requiring beneficiaries to fill prescriptions with their retail affiliates.

Recent mergers[17] have also made the lines between PBMs and insurance companies increasingly difficult to distinguish. This trend creates conflicting incentives stemming from the fact that PBMs are typically more profitable than insurance companies.[18] Insurers, which are typically motivated by cost-containment, may pivot to direct patients to treatments with higher rebates instead of acting in the best health and financial interests of their beneficiaries. This dynamic could exacerbate all the aforementioned effects that PBMs have on patients and their costs.

Conclusion

PBMs were created with the stated purpose of negotiating on behalf of patients. Today, PBMs handle more than $420 billion[19] and cover more than 266 million lives.[20] Nevertheless, their work is shrouded in secrecy, so their practices remain unclear and their effects on patients are at best uncertain—and at worst deleterious. The Federal Trade Commission should investigate PBMs in order to reveal the practices and effects of these large and growing entities. Such an investigation could be critical for identifying problem areas and an important step in building a foundation for policymakers to utilize as they seek to develop appropriate legislative solutions to ensure PBMs can best serve consumers.

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[11] *https://www.statnews.com/2022/03/22/pharmacy-benefit-managers-revenue-contracts/.*
[12] *https://www.statnews.com/2022/03/22/pharmacy-benefit-managers-revenue-contracts/.*
[13] *https://www.modernhealthcare.com/supply-chain/pbms-profit-swells-sector-consolidates-report-shows?adobe_mc=MCMID%3D10021893709279058923077270792425270302%7CMCORGID%3D138FFF2554E6E7220A4C98C6%2540AdobeOrg%7CTS%3D1649856281&CSAuthResp=1%3A%3A1011632%3A7461%3A24%3Asuccess%3AF1AE116B9E5CA453243ABB636E36C095.*
[14] *https://www.statnews.com/2022/03/22/pharmacy-benefit-managers-revenue-contracts/.*
[15] *https://endpts.com/cvs-takes-a-swing-at-bristol-myers-and-pfizer-excluding-coverage-of-their-megablockbuster-eliquis-in-2022/.*
[16] *https://www.beckershospitalreview.com/pharmacy/pbms-ranked-by-market-share-cvs-caremark-is-no-1.html.*
[17] *https://www.statnews.com/2018/06/01/mergers-health-insurers-pharmacy-benefit-managers/.*
[18] *https://www.statnews.com/2018/06/01/mergers-health-insurers-pharmacy-benefit-managers/.*
[19] *https://www.statnews.com/2022/03/22/pharmacy-benefit-managers-revenue-contracts/.*
[20] *https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/.*

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION
325 7th Street, NW, Suite 900
Washington, DC 20004

Introduction

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to provide this statement about the role of the pharmacy benefit manager (PBM) industry in the market for prescription drugs, focusing on how PBMs benefit patients and taxpayers. PCMA is the national association representing America's pharmacy benefit companies, which administer prescription drug plans and operate home delivery and specialty pharmacies for more than 275 million Americans with health coverage through public and private employers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits (FEHB) program, and the exchanges established by the Affordable Care Act (ACA). Our members work closely with health plans and health insurance issuers to secure lower costs for prescription drugs and achieve better health outcomes.

Pharmacy Benefit Companies Support Policies to Encourage Competition as the Best Way to Lower Prescription Drug Costs

PBMs work to improve prescription drug affordability by providing prescribers with information about less expensive generic alternatives, setting performance standards for pharmacies to encourage generic fills, and ensuring patients are aware of lower cost alternatives. Due in large part to these efforts by PBMs, 90 percent of prescription drug fills are generics.[1] Pharmacy benefit companies also support increased uptake of biosimilars through business decisions, such as preferring both the brand and a biosimilar to ensure patients and providers have the proper incentives to choose lower cost options and the choice to continue with a drug they may be reluctant to move away from, and policy proposals, including eliminating the interchangeability designation to reduce costs and confusion, stopping patent abuses, and making it easier for Medicare Part D plans to update formularies as new biosimilars come to market.

Toward that end, PCMA recently proposed the following three keys in a policy platform supportive of a more sustainable health care future:

> **Key #1: Ensure System Sustainability by Promoting Competition.** Enabling a robust private prescription drug marketplace that promotes competition is the best way to drive down prescription drug costs and make more affordable alternatives available for patients.
>
> **Key #2: Support and Equip Clinicians with Tools and Data to Serve Patients Optimally.** Pharmacy benefit experts support efforts to help clinicians, including pharmacists and other health care practitioners, "practice at the top of their license" to optimize use of their clinical expertise and counseling abilities. Pharmacy benefit companies also work to increase clinicians' administrative efficiency by offering information and tools to help serve patients.
>
> **Key #3: Enhance Patient Outcomes and Improve the Patient Experience.** Pharmacy benefit companies use their prescription drug expertise to support better health outcomes and provide recommendations to meet each patient's needs.

Our *Affordable Future* policy platform proposes numerous solutions to build on the private market system and facilitate collaboration among patients, regulators, PBMs, clinicians, health plans, and pharmacies to work toward a more functional, equitable, and affordable prescription drug market.

PCMA supports numerous bills introduced by members of the Senate. These measures align with the solutions proposed by our organization: the Interagency Patent Coordination and Improvement Act of 2023, the Prescription Pricing for the People Act of 2023, the Stop STALLING Act, the Preserve Access to Affordable Generics and Biosimilars Act, the Affordable Prescriptions for Patients Act, and the Expanding Access to Affordable Prescription Drugs and Medical Devices Act to improve the competitive landscape for prescription drugs.

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[1] AAM. 2021. Available at *https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.*

Pharmacy Benefit Companies Improve Care for Patients

PBMs Simplify the Patient Experience

People with insurance filled more than 6.4 billion prescriptions in retail pharmacies in 2021.[2] Every day, that amounts to nearly 15 million prescriptions, so it is critical that patients can pick up their prescriptions as quickly as possible at the pharmacy counter (or at home via mail delivery) to establish and maintain medication adherence. PBMs perform many essential functions that combine disparate information and expertise, as well as advanced technology to facilitate and streamline getting a prescription filled as seamlessly as possible.[3]

To optimize the patient experience when a pharmacy initiates the process of filling a prescription drug, once the pharmacy enters the prescription into its system, the prescribing information is sent electronically to the patient's PBM, which checks the pharmacy benefit information to confirm the patient's insurance status and cost-sharing amount, as well as the patient's medication history for any errors or possible harmful drug interactions. When a patient uses insurance, their PBM can see all their prescriptions. Technology allows real-time, almost instantaneous access to this information which the PBM uses to determine if there is any reason that a prescribed drug should not be taken by a patient and can alert the pharmacist to any dangerous interactions before the patient receives any medication and pays any associated cost sharing. All of this happens rapidly, seamlessly, and behind the scenes to improve patient safety and care.

Part D plans and the PBMs that administer them are also required to provide real-time benefit tools to give patients and prescribers cost sharing and benefits information at the point of prescribing.

PBMs Lower Drug Costs for Patients

PBMs, working with those providing insurance, encourage patients through formulary design and cost-sharing incentives to use the most affordable drugs, which are usually generics. For brand drugs, PBMs negotiate directly with drug manufacturers, who compete for formulary placement by offering a type of discount called rebates.[4] For drugs on the preferred tier of a plan's formulary, patients typically have lower cost sharing.[5] As competing products enter the market, PBMs gain leverage competitor products to negotiate deeper drug discounts for patients and employers.[6]

PBMs have also created contracts that account for the value of specialty and high-cost medications.[7] Value-based arrangements are at the forefront of new drug payment designs and will be critical to managing the costs of next-generation therapies like cell and gene therapies, orphan drugs, and ultra-expensive specialty drugs. Value-based contracts will better allow plans to manage these high costs, and plan sponsors will need broad flexibility to craft and employ value-based contracts.

The Medicare Part D program, where older Americans and those living with disabilities can choose among private plans to get their drug benefits, is a great example of PBM value. PBMs support Part D plans by negotiating rebates and discounts and promoting better pharmacy quality, passing 99.6 percent of rebates to the Part D plans, which in turn use them to enhance drug benefits and keep premium costs reliably low for beneficiaries.[8]

Savings from PBMs benefit health plans, employers, retirees, and patients directly. Prescriptions cost health plans and employers an average of $1,315 per person per year, with patients paying an average of $180 for their prescriptions, or 14 percent.[9]

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[2] IQVIA. 2022. Available at *https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022.*

[3] PCMA. 2022. Available at *https://www.pcmanet.org/pbm-technology-and-expertise-improves-patient-health-outcomes/.*

[4] Foley Hoag. 2019. Available at *https://foleyhoag.com/publications/ebooks-and-white-papers/2019/march/the-history-of-rebates-in-the-drug-supply-chain.*

[5] CBO. 2020. Available at *https://www.cbo.gov/system/files/2022-01/57050-Rx-Spending.pdf.*

[6] CBO. 2020. Available at *https://www.cbo.gov/system/files/2022-01/57050-Rx-Spending.pdf.*

[7] PBMI. 2021. Available *https://www.pcmanet.org/wp-content/uploads/2021/01/Solving-America%E2%80%99s-High-Drug-Cost-Problem_whitepaper_FINAL2.pdf.*

[8] GAO. 2019. Available at *https://www.gao.gov/products/gao-19-498.*

[9] Visante. 2020. Available at *https://www.pcmanet.org/wp-content/uploads/2020/02/ROI-on-PBM-Services-FINAL_.pdf.*

Without PBMs and the savings they generate, drug costs could be $2,000 per person per year.[10]

Pharmacy Benefit Companies Reduce Costs for Employers

Employers need choice and flexibility when designing prescription drug benefits that meet the health and affordability needs of unique employee populations. Employers and other health plan sponsors vary dramatically in size, resources, and function and serve diverse populations.

PBMs have an established record of negotiating price concessions from drug manufacturers (through formularies and other tools) and pharmacies to reduce drug costs. No employer, union, retiree health plan, pension fund, or other health plan sponsor is required to hire or use a PBM, but virtually all choose to because PBMs lower the cost of providing health care coverage and allow them to better serve the patients they represent. Health plan sponsors choose PBMs through a transparent and highly competitive bidding process. With more than 70 full-service PBMs in the market, including regular new entrants, health plan sponsors have diverse options, allowing them to select the PBM that best meets their unique needs.[11]

For health plan sponsors, it is important to maintain a competitive market that provides choice among PBMs and the ability to decide how to set up drug benefits to best serve their unique populations. Some may choose a PBM based on its scale, ability to negotiate deep discounts or manage the risk of price changes. Others choose to hire PBMs based on their innovative care management programs or different levels of service. For small employers, many of whom may struggle to provide health insurance to employees, PBMs both lower drug costs and provide cost predictability, enabling them to stretch their benefit dollars even further.

Plan sponsors should have the option of determining how they would like to pay the pharmacy benefit company they select for their services. "Spread pricing" is a risk-based contracting model in which employers choose to let the pharmacy benefit company hold the risk that plan participants may use more expensive pharmacies to acquire drugs in exchange for the option to keep the savings when a patient uses a less expensive pharmacy, as well as to take a loss when they use costlier pharmacies. Today, employers can choose spread pricing or "pass-through" contracting, in which the plan sponsor pays whatever the pharmacy charges. While larger employers typically select pass-through contracts, as they have the scale to deal with the variability of pharmacy charges, smaller employers often choose spread contracts because of the pricing predictability and savings they derive.

As a result, PBMs have a pro-competitive influence on the prescription drug marketplace, and PBM services provide a significant and measurable benefit for businesses and others providing health insurance. Without PBMs in the marketplace, those organizations would be left to negotiate drug costs on their own or pay the full costs of these drugs.

PBMs Save Taxpayers Money and Improve the Efficiency of Government Programs

Pharmacy benefit companies play an important role in federal health coverage programs, providing prescription drug benefits to approximately 67 million people across Medicare Part D, TRICARE, and the FEHB program. Pharmacy benefit companies save the Part D program an average of $2,026 per Part D beneficiary per year and will save the program over $430 billion over the next 10 years.[12] In addition to drug savings, pharmacy benefit companies provide important clinical services that help patients lead healthier lives. For example, over the next 10 years, they will prevent 1 billion medication errors.[13] Across the three federal programs, pharmacy benefit companies facilitate affordable prescription drug access to enable better health outcomes.

PBMs Keep Medicare Part D Spending Down

The Medicare Part D program covers 49 million Medicare beneficiaries through private prescription drug plans. Beneficiaries enrolled in original Medicare can choose

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[10] *Ibid.*

[11] PCMA. 2021. Available at *https://www.pcmanet.org/wp-content/uploads/2021/04/PBM-Landscape-2021.pdf.*

[12] Visante. 2023. Available at *https://www.pcmanet.org/wp-content/uploads/2023/01/Pharmacy-Benefit-Managers-PBMs-Generating-Savings-for-Plan-Sponsors-and-Consumers-January-2023.pdf.*

[13] Visante. 2023. Available at *https://www.pcmanet.org/wp-content/uploads/2023/01/The-Return-on-Investment-ROI-on-PBM-Services-January-2023.pdf.*

from 801 (as of 2023) stand-alone prescription drug plans (PDPs),[14] while those with Medicare Advantage (MA) have their benefits prescription drug benefits (MA–PDs) integrated into their plans. Overall, in 2021, Part D had total spending of $110.8 billion.[15]

Part D has grown both in terms of the number of prescriptions filled and expenditures since its inception in 2003. However, despite its growth, during its first ten years in operation, according to the Congressional Budget Office (CBO), total Part D spending was 50 percent lower than expected.[16] Again in 2023, CBO has found that spending in Part D has been much lower than anticipated.[17]

In both 2013 and 2023, one major driver of low spending has been the steady increase in the generic utilization rate among patients participating in the program. Across MA–PDs, the generic dispensing rate with just 63 percent in 2006, but had climbed to 90 percent by 2016.[18] And nationally, when a generic alternative is available, the generic version is substituted for the branded drug 97 percent of the time, a substitution rate that has been stable since 2013.[19] Because of the promotion of generics to beneficiaries by pharmacy benefit companies, an estimated additional 15 percent of drugs are dispensed as generics. Pharmacy benefit companies use formularies as a tool to incentivize beneficiaries to use generic drugs. According to academic research, "Part D plan formularies are designed to encourage the use of generics rather than their brand name counterparts."[20]

In addition to the increased use of generics, lower than predicted Part D net spending—after discounts and rebates—was also in part due to higher rebates negotiated by pharmacy benefit companies. Between 2011 and 2015, the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) found that rebates on brand drugs nearly doubled, while growth in Part D spending was substantially reduced.[21] The average net price of a prescription, after all pharmacy benefit company-negotiated discounts and rebates, fell from $57 in 2009 to $50 in 2018.[22]

Additionally, the Government Accountability Office (GAO) found that rebates negotiated by pharmacy benefit companies kept Part D spending 7 percent lower than it would have been without rebates. And pharmacy benefit companies do not keep rebates in Part D, according to GAO, 99.6 percent of rebates get passed through to plan sponsors. Plan sponsors use these rebates to keep premiums affordable for beneficiaries.[23]

Beneficiary premiums in Part D have been relatively stable since 2010,[24] and the average monthly premium declined by 1.8% to $31.05 in 2023.[25] GAO found that "downward pressure [by rebates] on premiums is one reason that premiums remained relatively unchanged between 2010 and 2015, according to the Centers of Medicare and Medicaid Services (CMS), even though total gross Part D drug costs grew about 12 percent per year in that period." The Medicare Payment Advisory Commission (MedPAC) agrees, finding that growth in rebates has helped keep the average premium affordable for beneficiaries.[26]

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[14] Kaiser Family Foundation. 2023. Available at *https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/*.

[15] MedPAC. 2023. Available at *https://www.medpac.gov/wp-content/uploads/2023/03/Ch12_Mar23_MedPAC_Report_To_Congress_SEC.pdf*.

[16] CBO. 2014. Available at *https://www.cbo.gov/publication/45552*.

[17] CBO. 2023. Available at *https://www.cbo.gov/system/files/2023-03/58997-Whitehouse.pdf*.

[18] AJMC. 2020. Available at *https://www.ajmc.com/view/variation-in-generic-dispensing-rates-in-medicare-part-d*.

[19] IQVIA. 2023. Available at *https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023*.

[20] Health Affairs. 2020. Available at *https://www.healthaffairs.org/doi/10.1377/hlthaff.2019.01694*.

[21] OIG. 2019. Available at *https://oig.hhs.gov/oei/reports/oei-03-19-00010.pdf*.

[22] CBO. 2022. Available at *https://www.cbo.gov/system/files/2022-01/57050-Rx-Spending.pdf*.

[23] GAO. 2019. Available at *https://www.gao.gov/assets/gao-19-498.pdf*.

[24] MedPAC. 2021. Available at *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/meeting-materials/part-d-status-report-medpac-jan-2021.pdf*.

[25] CMA. 2023. Available at *https://www.cms.gov/newsroom/news-alert/cms-releases-2023-projected-medicare-basic-part-d-average-premium*.

[26] MedPAC. 2021. Available at *https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch13_sec.pdf*.

Fully Implementing PBM Tools in Medicaid Could Provide Substantial Savings for the Program

PBMs also manage pharmacy benefits for state Medicaid programs with both health plan and fee-for-service (FFS) coverage. Nationally, PBMs saved Medicaid $22 billion from 2013 to 2018 combined; however, the potential for additional savings remains untapped.[27] In the commercial market, PBMs have the flexibility to drive use of the highest therapeutic quality, lowest-cost drugs and shift utilization from brands to generics as clinically appropriate; develop preferred pharmacy networks; advance evidence-based, clinically effective utilization; and leverage data analytics to detect and prevent fraud, waste, and abuse. As drug prices continue to increase and expensive gene and cell therapies come to market, state Medicaid programs will face increasing budgetary pressures. Optimal use of PBMs tools in state Medicaid programs would save a total of $112 billion over 10 years, $43 billion for states and $69 billion for the federal government.[28]

PBMs Support Meaningful, Actionable Transparency to Enhance Market Competition

Transparency that helps patients and payers is necessary across the entire prescription drug chain. PBMs support and practice actionable transparency that empowers patients, their physicians, those sponsoring health coverage, and policymakers, so that they can make informed decisions that can lead to lower prescription drug costs. Actionable transparency encourages consumers to shop for coverage that best fits their health needs and budgets, and once covered, use the most cost-effective, highest-value health care goods and services. It enables prescribers and patients to avoid pharmacy-counter surprises and helps ensure that physicians can prescribe drugs that are affordable for patients. To that end, PBMs provide patients and prescribers with real-time benefit tools (RTBTs), which provide real-time information on exactly where the patient is with respect to progressing through a deductible or another benefit phase, what drugs are on the patient's formulary, and exactly what cost sharing to expect for a given drug at the pharmacy. PBMs also provide patients with information on in-network pharmacies, premiums, general cost-sharing, and benefits for their prescription drug coverage.

PBMs provide health plans, employer plan sponsors, and consumers with a broad array of accurate, actionable information on price and quality to make efficient purchasing decisions. PBMs' customers are able to set the terms of the transparency and information they want to receive, as well as their audit rights, as part of their contracts.

In recent years, Congress has added more requirements for PBMs to report to federal agencies, as well as public reporting in more aggregated form, in both cases with appropriate protections for confidential data to avoid encouraging tacit collusion, efforts that we support.

The Congressional Budget Office has framed the transparency and disclosure considerations clearly in this often quoted statement:

> The disclosure of drug rebates could affect Medicare spending through two principal mechanisms. First, disclosure would probably make rebates less varied among purchasers, with large rebates and small rebates tending to converge toward some average rebate. Such compression, for reasons discussed below, would tend to reduce the rebates that PDPs received and thus would raise Medicare costs. Second, for a range of medical conditions, drugs appropriate for treatment are available from only a few manufacturers; disclosure of drug-by-drug rebate data in those cases would facilitate tacit collusion among those manufacturers, which would tend to raise drug prices. (CBO March 12, 2007)

Likewise, the Federal Trade Commission has noted that there are limits to the benefits of transparency and unintended consequences that can result.[29] Thus, PBMs encourage the Committee, as it reviews how to improve the prescription drug mar-

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[27] Visante. 2016. Available at *https://www.unitedhealthgroup.com/content/dam/UHG/PDF/2019/UHG-PBM-Medicaid-Savings.pdf.*

[28] *Ibid.*

[29] *See* FTC Staff Comment to the Honorable James L. Seward Concerning New York Senate Bill 58 on Pharmacy Benefit Managers (PBMs), Fed. Trade Comm'n. March 2009. Available at *https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf.*

ket to help lower costs for patients and businesses, to focus its efforts on actionable transparency that reduces drug costs versus transparency that raises them.

PBMs Already Comply with Numerous Disclosure Requirements

Pharmacy benefit companies already operate under federal transparency requirements and adhere to myriad contractually required transparency provisions imposed by their own business and government partners.

PBMs are subject to regulations promulgated by HHS, the Department of Labor, the Department of Treasury, the Food and Drug Administration, and states. PBM practices are overseen by state Medicaid agencies, state-based consumer protection agencies, private accreditation organizations, and their own clients—health plan sponsors and PBMs are directly regulated by state departments of insurance or other state agencies.

Exchange plans must report data on numerous administrative processes like coverage determinations and prior authorization in a way that potential enrollees can access and understand them. Exchange plans must also report data confidentially to CMS regarding generic dispensing rates for retail and mail-order pharmacies; aggregate amounts and types of rebates, discounts, price concessions, and service fees; total prescriptions covered; and the difference between the amount the health plan pays the PBM and the amount that the PBM pays retail and mail-order pharmacies.

Medicare Part D plans must make available to enrollees and potential enrollees all relevant aspects of their benefit design, and report confidentially to CMS the same information as exchange plans, through annual reporting. Part D plans also submit Prescription Drug Event (PDE) data, which is a summary of Part D claims activity with additional data elements including pharmacy dispensing fees. As part of the bid and reconciliation processes, PBMs (via the Part D plans) must report estimated pharmacy and manufacturer Direct and Indirect Remuneration (DIR), including rebates and other price concessions.

It is important to note that government reporting by PBMs is not static but an ongoing, evolving construct. Indeed, CMS routinely updates required Part D filings to encompass more information, including with respect to PDE and DIR filings. For example, new pharmacy DIR rules take effect on January 1, 2024. Under these new rules, the negotiated price for a Part D covered drug must reflect the lowest possible reimbursement a network pharmacy will receive for a drug and must include all pharmacy price concessions. CMS has already issued detailed guidance on how these changes are to be included in PDE and DIR filings, including changes related to calculating beneficiary cost sharing taking into account the application of pharmacy price concessions at point of sale.[30] Also, CMS has several other major expansions underway to the PDE submissions for 2025 related to Inflation Reduction Act implementation, and we expect to see more for 2026.

Moreover, reporting is not limited to federal health care programs and the exchanges. For commercial plans, Departments of Treasury, HHS, and Labor as well as OPM require PBMs to report:

- The 50 most frequently dispensed brand prescription drugs.
- The 50 costliest prescription drugs by total annual spending.
- The 50 prescription drugs with the greatest increase in expenditures from the previous year.
- Prescription drug rebates, fees, and payments by drug manufacturers in each therapeutic class of drugs, as well as for each of the 25 drugs that yielded the highest amount of rebates.
- The premium and out-of-pocket cost impact of prescription drug rebates, fees, and other payments. PBMs may report these data directly to the government or to their clients. The clients (plan sponsors, issuers, and the FEHB program carriers generally) are required to submit this information, along with some of their own data regarding premiums, aggregated at the state/market level, rather than separately for each plan.

The Departments must biannually issue a report based on the data, but otherwise must keep the data confidential and may not release proprietary information.

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[30] CMS HPMS memo. 2022. Available at *https://www.cms.gov/httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memos-wk-2-october-10-14.*

Conclusion

The PBM industry is the only stakeholder in the chain dedicated to seeking lower costs. PBMs do that work for the employer, union, retiree plan, health plan, and government entities who hire them, and, most importantly, for the patients for whom those health plan sponsors provide coverage. As pharmacy benefit experts, PBMs generate tremendous value, estimated at $145 billion annually for society,[31] and save payers and patients an average of $1,040 per person per year.[32] For many years, evidence has also shown a return of 10:1 on investments in PBM services for their private sector and government partners.[33] As a result, PBMs will lower the cost of health care by $1 trillion this year alone.[34]

PBMs are able to negotiate for lower drug costs when they can bring competition between pharmaceutical manufacturers and between pharmacies to bear. PBMs lower prescription drug costs by using these negotiations to deliver discounts and rebates, promoting the use of generic medications, encouraging better pharmacy quality, and offering things like home delivery for those on chronic medications.

Through their work, PBMs are contributing to lower costs for health coverage, lower costs for medications, and better and more affordable access for patients, which means more people getting the medications they need to lead healthier lives.

PCMA would be happy to provide additional information to the Committee on the value pharmacy benefit companies bring to patients, health plan sponsors, and society, and looks forward to working collaboratively with Congress and other stakeholders to build on the existing private market framework to make medications more affordable and accessible for patients.

PHARMACY SOCIETY OF WISCONSIN
701 Heartland Trail
Madison, WI 53717
608–827–9200
www.pswi.org

Introduction

The Pharmacy Society of Wisconsin appreciates the opportunity to submit a statement for the record for the United States Senate Committee on Finance on "Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers."

With "One Voice, One Vision" on January 1, 1998, Wisconsin successfully united all pharmacists, pharmacy technicians, and student pharmacists within one advocating organization. The Pharmacy Society of Wisconsin has championed the cause of helping pharmacists deliver the best care for their patients. Today, with more than 4,000 members statewide, PSW is the professional organization pharmacists, pharmacy technicians, and student pharmacists join to further their careers, advance the standing of pharmacists and improve the care of patients in Wisconsin.

At the Pharmacy Society of Wisconsin, we collaborate with healthcare teams to improve medication use and the health of Wisconsinites and transform pharmacy practice. We provide a unified voice, resources, and leadership to advance the pharmacy profession and improve the quality of medication use in Wisconsin.

Great Concern about Pharmacy Benefit Manager Tactics

We are extremely concerned about pharmacy benefit manager (PBM) tactics that significantly negatively affect patients, communities, taxpayers, employers, and pharmacies. PBMs are hired by insurance plans and others to negotiate lower drug prices. Unfortunately, they manipulate the system and keep billions in profits while:

- Forcing patients and others to pay more for their medicines;
- Limiting patients' ability to choose their pharmacist;
- Restricting access to medicines that doctors and other prescribers determine to be right for the patient; and

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[31] National Bureau of Economic Research. 2022. *https://www.nber.org/papers/w30231.*

[32] Visante. 2023. Available at *https://www.pcmanet.org/wp-content/uploads/2023/01/Pharmacy-Benefit-Managers-PBMs-Generating-Savings-for-Plan-Sponsors-and-Consumers-January-2023.pdf.*

[33] Visante. 2023. Available at *https://www.pcmanet.org/wp-content/uploads/2023/01/The-Return-on-Investment-ROI-on-PBM-Services-January-2023.pdf.*

[34] Visante. 2020. Available at *https://www.pcmanet.org/wp-content/uploads/2020/02/ROI-on-PBM-Services-FINAL_*.pdf.

- Jeopardizing pharmacies' viability—which obviously harms the pharmacy and also the patients and communities that rely on them.

The dominance of PBMs is significant. Three PBMs control 80 percent of the prescription drug market. These are the practical effects of PBM tactics:

- **Over-payments:** The University of Southern California Leonard D. Schaeffer Center for Health Policy and Economics found that Medicare Part D standalone plans paid $2.6 billion more in one year for 184 common generic medications compared with prices for the same drugs available to cash-paying customers of one retailer.
- **Restricting medications:** Drug Channels analysis found that from 2014 to 2022, 1,357 medications were excluded from at least one PBM formulary for at least one year. The exclusions of drugs from these lists have escalated since starting in 2012.
- **Putting the squeeze on pharmacies:** The Centers for Medicare & Medicaid Services found that direct and indirect remuneration (DIR) fees charged by PBMs and payers to pharmacies have exploded by 107,400% over the last decade.

Countless Wisconsin pharmacists reach out to us weekly to share the squeeze unfair PBM practices are putting on their ability to serve their patients. We are seeing pharmacies close across the state, often in rural or medically underserved areas, because they are no longer financially viable, leaving patients without access to timely and necessary medications.

We want to take this opportunity to define "PBM reform." This is important to maximize the effectiveness of Congress' work in this area for patients and roll back the current jeopardy posed by PBMs to pharmacies. For this purpose, we call to your attention the Principles of PBM Reform advocated by the National Association of Chain Drug Stores:

- **Stop explosive retroactive fees.** Stop PBMs and payers from using "DIR fees" and other tactics to grab back the payments made and owed to pharmacies—often many months after the fact and often resulting in below-cost pharmacy reimbursement.
- **Stop below-cost reimbursement.** Adopt a reimbursement rate floor that prevents PBMs and payers from reimbursing pharmacies below the true cost of acquiring and dispensing prescription drugs.
- **Stop gaming of performance measures.** Standardize performance measures to help improve patient outcomes and reduce costs—rather than allowing PBMs and payers to play "gotcha" with pharmacies using arbitrary measures and exorbitant fees.
- **Stop "specialty definitions" from steering patients from their pharmacy.** Prevent PBMs and payers from defining "specialty drugs" in ways that steer patients with rare or complex diseases away from the preferred pharmacy of their choice and toward another pharmacy—including those owned by the PBMs and payers.
- **Stop mandatory mail-order.** Prohibit PBMs and payers from forcing patients to use mail-order pharmacies—including those owned by the PBMs and payers—and prohibit them from imposing penalties on patients for choosing a convenient and trusted pharmacy in their neighborhood.
- **Stop limited networks.** Require PBMs and payers to include in their networks all pharmacies willing to accept terms and conditions established by the PBM.
- **Stop overwhelming audits.** Bring efficiency, transparency, and standardization to the processes by which PBMs audit pharmacies without sacrificing continuity of care.
- **Stop the undercutting of PBM reform laws.** Prioritize the implementation, enforcement, and oversight of PBM reform laws—to maximize results for patients and fairness for pharmacies and other stakeholders and to ensure laws are not undermined by the inaction of PBMs or of government.

Conclusion

In closing, we want to put to rest one of the myths perpetuated by PBMs. Shockingly, they have staved off reform efforts by alleging that premiums will increase. This is nothing short of a scare tactic and one that cannot be allowed to be used so flippantly and without substantiation. PBM reform will reduce prescription drug costs by cracking down on middlemen's manipulation. It does not follow logically that reductions in prescription drug costs will increase premiums. It is time

to address the manipulative business practices of PBMs and end the harmful effects of their tactics.

The Pharmacy Society of Wisconsin thanks the Committee for the opportunity to provide our perspective on PBM reform. For questions or further discussion, please contact Danielle Womack, Vice President of Public Affairs, at dwomack@pswi.org or 608–827–9200.

SPARTANNASH
850 76th St. SW
Grand Rapids, MI 49518–8700
(616) 878–2000
https://www.spartannash.com/

Statement of James Lilly, Vice President of Government Affairs

Introduction

SpartanNash Company greatly appreciates the opportunity to submit a statement for the record for the United States Senate Committee on Finance regarding "Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers."

SpartanNash is a food solutions company that delivers the ingredients for a better life through customer-focused innovation. We operate two complementary business segments—food wholesale and grocery retail. Our global supply chain network serves wholesale customers that include independent and chain grocers, national retail brands, e-commerce platforms, and U.S. military commissaries and exchanges in the United States and abroad. We distribute products for every aisle in the grocery store, from fresh produce to household goods to our OwnBrands, which include the Our Family® portfolio of products. On the retail side, we operate 146 brick-and-mortar grocery stores, in addition to dozens of pharmacies and fuel centers.

Our vast distribution network plays an essential role in the nation's food supply chain, ensuring that communities of all sizes—from densely populated cities to remote rural areas—have access to food, medications, and the household supplies they need. As it relates to patient access, our organization operates 84 corporately owned pharmacies and supports 145 affiliate pharmacies that are independently owned and operated. Combined, our corporate and affiliated pharmacies fill tens of thousands of prescriptions each week.

Sounding the Alarm on Pharmacy Benefit Manager Practices

Like many other organizations that provide care to patients in a pharmacy setting, we are deeply concerned about pharmacy benefit manager (PBM) practices that have significant negative effects on patients, communities, taxpayers, employers, and pharmacies. While PBMs may have originally been created with good intentions to reduce costs by negotiating lower drug prices, that is not the way they operate anymore. PBMs are a significant factor in ever increasing drug pricing. They do little more than manipulate the system and keep billions in profits while:

- Making patients pay more for their medicines;
- Restricting patients' ability to choose their Pharmacy;
- Limiting access to medicines that doctors and other prescribers determine to be right for the patient; and
- Jeopardizing pharmacies' ability to remain in business—which obviously harms the pharmacy and also the patients and communities that rely on them.

Policymakers should be concerned that three PBMs control 80 percent of the prescription drug market, and their impact is extraordinary. These are three practical effects of PBM tactics:

- **Over-payments:** The University of Southern California Leonard D. Schaeffer Center for Health Policy and Economics found that Medicare Part D standalone plans paid $2.6 billion more in one year for 184 common generic medications compared with prices for the same drugs available to cash-paying customers of one retailer.[1]

[1] Trish, E., Gascue, L., Ribero, R., Van Nuys, K., Joyce, G. Comparison of Spending on Common Generic Drugs by Medicare vs Costco Members. JAMA Intern Med. 2021;181(10):1414–1416. doi:10.1001/jamainternmed.2021.3366.

- **Restricting medications:** Drug Channels analysis found that from 2014 to 2022, 1,357 medications were excluded from at least one PBM formulary for at least one year. The exclusions of drugs from these lists have escalated since starting in 2012.[2]
- **Putting the squeeze on pharmacies:** The Centers for Medicare and Medicaid Services found that direct and indirect remuneration fees, also known as DIR fees, charged by PBMs and payers to pharmacies have exploded by 107,400% over the last decade.[3]

Along with filling prescriptions, our pharmacists provide medication counseling for thousands of patients each day. We strive to provide the best medical outcome possible for each patient's condition. Our pharmacists are available nights and weekends to provide these services. During the COVID–19 pandemic, our pharmacies expanded prescription home delivery to assist our patients who needed to avoid contact with others. Our pharmacists also administered thousands of COVID immunizations while working on the front lines during this pandemic.

We need to consider what a future pandemic could look like without this level of pharmacy access because today, many pharmacies are at risk of closing as a result of the anti-competitive behavior of PBMs. PBMs have reached a size and scale that gives them tremendous, unparalleled influence in determining the price and access to prescription drugs for patients.

Allow me to paint a more detailed picture. As you know, DIR Fees are relatively new in our industry. In 2016, the DIR Fees SpartanNash was charged were significant—over $7,048 per pharmacy, and over $578,000 in total. Keep in mind that these were brand new fees that started being assessed only a few years earlier. Fast forward to 2021, and we were charged over $127,000 per pharmacy or $10.7 million in total. That is a dramatic increase in just six years. It would be unthinkable if the price of a hamburger went up from $10 to $180 using the same ratio, in a matter of just five years.

The rate of increase with these astronomical fees undoubtedly contributed to SpartanNash closing its pharmacy operations in West Branch, Coldwater and Grand Rapids, Michigan, as well as in Somerset, Wisconsin. Other independent pharmacy owners in our buying group have closed 17 pharmacies in Michigan, Indiana, Wisconsin, and Ohio. Unfortunately, many of these pharmacies are located in more rural areas where patients do not have as many options for pharmaceutical care. This is unfortunate because in many cases, the pharmacist is the closest clinician and the one the patient interacts with most frequently for health maintenance. SpartanNash and many of the independent pharmacies in our buying group have voiced concerns about their viability if DIR fees and the unfair and anticompetitive practices continue unchecked.

Recently, we were forced to reduce hours in our stores because of cost pressure driven largely by the increase in DIR fees. Most pharmacy locations now close at 7 p.m., and we no longer operate 24-hour pharmacy locations. At our company, we know access to a pharmacist improves medical outcomes for patients, so we do not make these decisions lightly. But, in the absence of congressional intervention and relief, we and others in the industry may be forced to make further reductions in schedules or locations.

So, what can be done? Congress can be especially effective in correcting this market failure. The National Association of Chain Drug Stores has identified the following actions that can be undertaken by Congress:

- **Stop explosive retroactive fees.** Stop PBMs and payers from using "DIR fees" and other tactics to grab back the payments made and owed to pharmacies—often many months after the fact and often resulting in below-cost pharmacy reimbursement.
- **Stop below-cost reimbursement.** Adopt a reimbursement rate floor that prevents PBMs and payers from reimbursing pharmacies below the true cost of acquiring and dispensing prescription drugs.
- **Stop gaming of performance measures.** Standardize performance measures to help improve patient outcomes and reduce costs—rather than allowing PBMs

[2] Fein, A.J., Ph.D., (January 10, 2023). The Big Three PBMs' 2023 Formulary Exclusions: Observations on Insulin, Humira, and Biosimilars. *https://www.drugchannels.net/2023/01/the-big-three-pbms-2023-formulary.html.*

[3] Centers for Medicare and Medicaid Services, Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. at 1842 (January 12, 2022).

and payers to play "gotcha" with pharmacies using exorbitant fees and arbitrary measures that continuously change like a moving target.

- **Stop "specialty definitions" from steering patients from their pharmacy.** Prevent PBMs and payers from defining "specialty drugs" in ways that steer patients with rare or complex diseases away from their preferred pharmacy and toward another pharmacy—including those owned by the PBMs and payers.
- **Stop mandatory mail-order.** Prohibit PBMs and payers from forcing patients to use mail-order pharmacies—including those owned by the PBMs and payers—and prohibit them from imposing penalties on patients for choosing a convenient and trusted pharmacy in their neighborhood.
- **Stop limited networks.** Require PBMs and payers to include in their networks all pharmacies willing to accept terms and conditions established by the PBM.
- **Stop overwhelming audits.** Bring efficiency, transparency, and standardization to the processes by which PBMs audit pharmacies without sacrificing continuity of care.
- **Stop the undercutting of PBM reform laws.** Prioritize the implementation, enforcement, and oversight of PBM reform laws—to maximize results for patients and fairness for pharmacies and other stakeholders, and to ensure laws are not undermined by inaction of PBMs or of government.

Conclusion

PBMs have been able to fight off reform for many years, but their time of manipulating this market can come to an end if Congress acts on the reforms proposed by NACDS and other like-minded associations. Conversely, if nothing is done, more pharmacies will be forced to close their doors or reduce hours, and fewer patients will be able to access the healthcare they need in their communities.

On behalf of SpartanNash, we thank the Committee for the opportunity to provide our perspective on PBM reform. For questions or further discussion, please contact James Lilly, Vice President of Government Affairs, at james.lilly@spartannash.com or, (616) 878–8820.

SPECIALTY CARE RX
408 N. Allen Dr., Suite 100
Allen, TX 75013
Phone: (949) 506–1300 Ext. 270
Fax: (714) 602–9571

April 12, 2023

U.S. Senate
Committee on Finance
219 Dirksen Senate Office Bldg.
Washington, DC 20510–6200

Dear Committee on Finance,

Specialty Care Rx is a specialty pharmacy that takes great pride in servicing our patients with integrity and passion. It is getting more difficult to service our patients because of closed networks, low reimbursement rates, steerage of patients to Pharmacy Benefit Manger (PBM) and Insurance Company owned Specialty Pharmacies and increasing costs due to hidden Direct and Indirect Remuneration (DIR) fees.

As time goes on smaller insurance companies are being absorbed by larger players in the medical insurance industry such as United Healthcare and Aetna. These insurance companies own PBM, Specialty Pharmacy, and manufacture rebate companies. To serve our communities, we must join their networks and most of the time the networks are closed because they have their own Specialty Pharmacy and do not allow choice for their membership. When we are accepted into the network we are forced to accept low reimbursement rates which can be anywhere between AWP-30%–50% and we are unable to accept the patient because of the low rates or we are told that the patient must use PBM or Insurance Company owned Specialty Pharmacies, such as Optum Rx, CVS Specialty and Accredo. So, even though we are contracted we are still not able to service the patient. We can onboard our patient quicker and provide premier service, but we are prevented from doing so at the plan level to keep profit under the insurance company's umbrella.

DIR fees are based on arbitrary performance standards having a lasting negative impact on the overall profitability of the pharmacy. With very low reimbursement rates oftentimes the DIR fees absorb the profit, and the drug cost is not covered leaving the pharmacy to cover the cost. DIR fees are not disclosed upfront and can take months to process causing "claw backs" taken as a percentage of total cost of prescriptions. The percentage can be anywhere from 4%–20%. We are unable to predict the performance standards and the PBM will not explain how the performance based DIR fee is calculated. As a result, during the Intake process it appears the account is profitable when in fact it is not, and we are having to triage patients out months sometimes a year later. This is not only causing hardship on the pharmacy, but it also causes a burden on the patient, because they must start the intake process over with the Insurance company or the PBM's owned Specialty Pharmacy.

The drugs we are delivering to our community are for people with true illness. They should have the option of choice and should be able to select the best provider for their care and the care of their loved ones. Our pharmacy delivers more than just a drug on the doorstep. We have access to nursing, dieticians, financial counselors, and customer care individuals that not only walk the patient through their treatment plan but get them back to doing the things they enjoy in life. Thank you for taking the time to review the issues at hand in hopes to stop the PBM abuse not only to their membership but to independent pharmacies across our country.

Sincerely,

Denise Stechman
Director of Contracts

WEGMANS FOOD MARKETS, INC.
1500 Brooks Ave.
Rochester, NY 14624
1–800–934–6267
https://www.wegmans.com/

Statement of Julie Lenhard, Vice President of Pharmacy

Introduction

Wegmans Food markets, Inc. appreciates the opportunity to submit a statement for the record for the United States Senate Committee on Finance on "Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers."

Headquartered in Rochester, NY, we are a regional chain that operates 97 pharmacies in six states that provides Patient care by providing prescription fulfillment, immunization services, counseling, and other critical patient services.

Great Concern about Pharmacy Benefit Manager Tactics

We are extremely concerned about pharmacy benefit manager (PBM) tactics that have significant negative effects on patients, communities, taxpayers, employers, and pharmacies. PBMs are hired by insurance plans and others to negotiate lower drug prices. Unfortunately, they manipulate the system and keep billions in profits while:

- Forcing patients and others to pay more for their medicines;
- Limiting patients' ability to choose their pharmacist;
- Restricting access to medicines that doctors and other prescribers determine to be right for the patient; and
- Jeopardizing pharmacies' viability—which obviously harms the pharmacy and also the patients and communities that rely on them.

The dominance of PBMs is significant. Three PBMs control 80 percent of the prescription drug market. These are the practical effects of PBM tactics:

- **Over-payments:** The University of Southern California Leonard D. Schaeffer Center for Health Policy & Economics found that Medicare Part D standalone plans paid $2.6 billion more in one year for 184 common generic medications compared with prices for the same drugs available to cash-paying customers of one retailer.
- **Restricting medications:** Drug Channels analysis found that from 2014 to 2022, 1,357 medications were excluded from at least one PBM formulary for at least one year. The exclusions of drugs from these lists have escalated since starting in 2012.

- **Putting the squeeze on pharmacies:** The Centers for Medicare & Medicaid Services found that direct and indirect remuneration (DIR) fees charged by PBMs and payers to pharmacies have exploded by 107,400% over the last decade.

We want to take this opportunity to define "PBM reform." This is important to maximize the effectiveness of Congress' work in this area for patients, and to roll-back the current jeopardy posed by PBMs to pharmacies. For this purpose, we call to your attention the Principles of PBM Reform advocated by the National Association of Chain Drug Stores:

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- **Stop below-cost reimbursement.** Adopt a reimbursement rate floor that prevents PBMs and payers from reimbursing pharmacies below the true cost of acquiring and dispensing prescription drugs.
- **Stop gaming of performance measures.** Standardize performance measures to help improve patient outcomes and reduce costs—rather than allowing PBMs and payers to play "gotcha" with pharmacies using arbitrary measures and exorbitant fees.
- **Stop "specialty definitions" from steering patients from their pharmacy.** Prevent PBMs and payers from defining "specialty drugs" in ways that steer patients with rare or complex diseases away from their preferred pharmacy of their choice and toward another pharmacy—including those owned by the PBMs and payers.
- **Stop mandatory mail-order.** Prohibit PBMs and payers from forcing patients to use mail-order pharmacies—including those owned by the PBMs and payers—and prohibit them from imposing penalties on patients for choosing a convenient and trusted pharmacy in their neighborhood.
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- **Stop overwhelming audits.** Bring efficiency, transparency, and standardization to the processes by which PBMs audit pharmacies without sacrificing continuity of care.
- **Stop the undercutting of PBM reform laws.** Prioritize the implementation, enforcement, and oversight of PBM reform laws—to maximize results for patients and fairness for pharmacies and other stakeholders, and to ensure laws are not undermined by inaction of PBMs or of government.

Conclusion

In closing, we want to put to rest one of the myths perpetuated by PBMs. It is shocking that they have been able to stave off reform efforts by alleging that premiums will increase. This is nothing short of a scare tactic, and one that cannot be allowed to be used so flippantly and without substantiation. PBM reform will reduce prescription drug costs by cracking down on middlemen's manipulation. It does not follow logically that reductions in prescription drug costs will result in increased premiums. It is time to address the manipulative business practices of PBMs, as well as to end the negative effects of their tactics.

Wegmans Food Markets, Inc. thanks the Committee for the opportunity to provide our perspective on PBM reform. For questions or further discussion, please contact Julie Lenhard, Vice President of Pharmacy at Julie.lenhard@wegmans.com or (585) 429–1761.

WYOMING PHARMACY ASSOCIATION
P.O. Box 9, Wheatland, WY 82201
Phone: (307) 257–5197
www.wypha.net

Introduction

Wyoming Pharmacy Association appreciates the opportunity to submit a statement for the record for the United States Senate Committee on Finance on "Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers."

The Wyoming Pharmacy Association (WPhA), founded in 1915, is the only statewide professional organization representing the interests of licensed pharmacists, pharmacy technicians and pharmacy students across all practice settings. Our mission to: Advocating, educating, and connecting to improve the health of Wyoming citizens through the advancement of pharmacy. Our vision is: Pharmacists and technicians in Wyoming will be recognized as caring and competent providers, as part of the greater health care team, who improve the use of medications, assure the safety of drug therapy, and enhance health-related quality of life.

Great Concern about Pharmacy Benefit Manager Tactics

We are extremely concerned about pharmacy benefit manager (PBM) tactics that have significant negative effects on patients, communities, taxpayers, employers, and pharmacies. PBMs are hired by insurance plans and others to negotiate lower drug prices. Unfortunately, they manipulate the system and keep billions in profits while:

- Forcing patients and others to pay more for their medicines;
- Limiting patients' ability to choose their pharmacist;
- Restricting access to medicines that doctors and other prescribers determine to be right for the patient; and
- Jeopardizing pharmacies' viability—which obviously harms the pharmacy and also the patients and communities that rely on them.

The dominance of PBMs is significant. Three PBMs control 80 percent of the prescription drug market. These are the practical effects of PBM tactics:

- **Over-payments:** The University of Southern California Leonard D. Schaeffer Center for Health Policy & Economics found that Medicare Part D standalone plans paid $2.6 billion more in one year for 184 common generic medications compared with prices for the same drugs available to cash-paying customers of one retailer.
- **Restricting medications:** Drug Channels analysis found that from 2014 to 2022, 1,357 medications were excluded from at least one PBM formulary for at least one year. The exclusions of drugs from these lists have escalated since starting in 2012.
- **Putting the squeeze on pharmacies:** The Centers for Medicare and Medicaid Services found that direct and indirect remuneration (DIR) fees charged by PBMs and payers to pharmacies have exploded by 107,400% over the last decade.

We want to take this opportunity to define "PBM reform." This is important to maximize the effectiveness of Congress' work in this area for patients, and to rollback the current jeopardy posed by PBMs to pharmacies. For this purpose, we call to your attention the Principles of PBM Reform advocated by the National Association of Chain Drug Stores:

- **Stop explosive retroactive fees.** Stop PBMs and payers from using "DIR fees" and other tactics to grab back the payments made and owed to pharmacies—often many months after the fact and often resulting in below-cost pharmacy reimbursement.
- **Stop below-cost reimbursement.** Adopt a reimbursement rate floor that prevents PBMs and payers from reimbursing pharmacies below the true cost of acquiring and dispensing prescription drugs.
- **Stop gaming of performance measures.** Standardize performance measures to help improve patient outcomes and reduce costs—rather than allowing PBMs and payers to play "gotcha" with pharmacies using arbitrary measures and exorbitant fees.
- **Stop "specialty definitions" from steering patients from their pharmacy.** Prevent PBMs and payers from defining "specialty drugs" in ways that steer patients with rare or complex diseases away from their preferred pharmacy of their choice and toward another pharmacy—including those owned by the PBMs and payers.
- **Stop mandatory mail-order.** Prohibit PBMs and payers from forcing patients to use mail-order pharmacies—including those owned by the PBMs and payers—and prohibit them from imposing penalties on patients for choosing a convenient and trusted pharmacy in their neighborhood.
- **Stop limited networks.** Require PBMs and payers to include in their networks all pharmacies willing to accept terms and conditions established by the PBM.

- **Stop overwhelming audits.** Bring efficiency, transparency, and standardization to the processes by which PBMs audit pharmacies without sacrificing continuity of care.
- **Stop the undercutting of PBM reform laws.** Prioritize the implementation, enforcement, and oversight of PBM reform laws—to maximize results for patients and fairness for pharmacies and other stakeholders, and to ensure laws are not undermined by inaction of PBMs or of government.

Conclusion

In closing, we want to put to rest one of the myths perpetuated by PBMs. It is shocking that they have been able to stave off reform efforts by alleging that premiums will increase. This is nothing short of a scare tactic, and one that cannot be allowed to be used so flippantly and without substantiation. PBM reform will reduce prescription drug costs by cracking down on middlemen's manipulation. It does not follow logically that reductions in prescription drug costs will result in increased premiums. It is time to address the manipulative business practices of PBMs, as well as to end the negative effects of their tactics.

Wyoming Pharmacy Association thanks the Committee for the opportunity to provide our perspective on PBM reform. For questions or further discussion, please contact Matt Meyer, WPhA President, at info@wypha.org or (307) 257–5197.