

Submitted Written Testimony on:

*Pharmacy Benefit Managers and the Prescription Drug Supply Chain:
Impact on Patients and Taxpayers*

United States Senate Committee on Finance

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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% 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 & Medicaid Services (CMS) has 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 five 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 five percent combined administrative and data fee is likely close to \$20 billion. I want to emphasize how substantial in scope that five 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 five 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 five 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% of all specialty drugs dispensed in the United States. Express Scripts and UnitedHealth's specialty pharmacies control another 23% and 14% respectively. That is **not** because of PBM-owned specialty pharmacies' clinical superiority, 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 co-pay, 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% 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% 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% less than the previous year's rates, other PBMs

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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.

Dated: March 27, 2023

Respectfully submitted,



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Submission to the U.S. Senate Committee on Finance

**How Pharmacy Benefit Managers Adversely Impact
Patients, Taxpayers, and Other Medicare
Stakeholders**

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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 guidance¹ 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

¹ E.g., Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50.3.

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.

- **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 prior³), 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 shifting 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.

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 (Mar. 16, 2007, 4:59 PM), http://www.forbes.com/2007/03/16/caremark-approves-update-markets-equity-cx_er_0316markets29.html.

⁶ Jon Kamp, *Medco Faces Loss of Blue Cross Customer*, Wall St. J. (Aug. 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. (Jul. 21, 2011, 8:34 AM), <http://blogs.wsj.com/deals/2011/07/21/unitedhealths-answer-to-express-scripts-medco-merger/>.

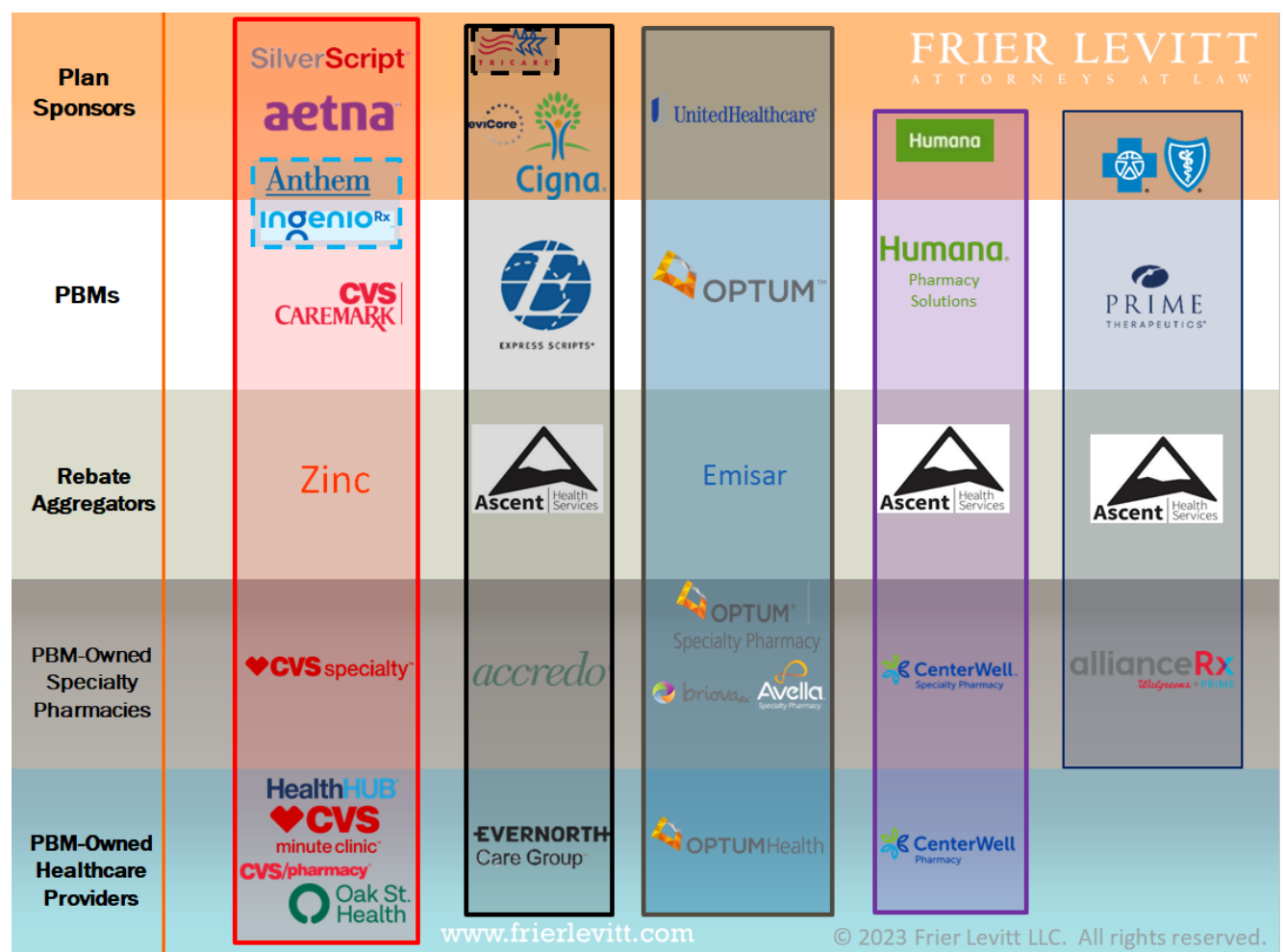
⁸ Reed Abelson and Natasha Singer, *F.T.C. Approves Merger of 2 of the Biggest Pharmacy Benefit Managers*, N.Y. Times (Apr. 2, 2012), <http://www.nytimes.com/2012/04/03/business/ftc-approves-merger-of-express-scripts-and-medco.html>.

⁹ Michael J. De La Merced, *SXC Health Solutions to Buy Catalyst Health for \$4.4 Billion*, N.Y. Times, (Apr. 18, 2012, as updated 3:07 PM), <http://dealbook.nytimes.com/2012/04/18/sxc-health-solutions-to-buy-catalyst-for-4-4-billion/>.

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

Figure 1. Vertical Integration of PBMs and Health care Conglomerates



¹⁰Rite Aid Completes Acquisition of Leading Independent Pharmacy Benefit Manager EnvisionRx, Bus. Wire (Jun. 24, 2015), <http://www.businesswire.com/news/home/20150624005906/en/Rite-Aid-Completes-Acquisition-Leading-Independent-Pharmacy>.

¹¹Bruce Japsen, *Cigna-Express Scripts Merger's A Done Deal*, Forbes, Dec. 19, 2018, <https://www.forbes.com/sites/brucejapsen/2018/12/19/cigna-express-scripts-merger-a-done-deal-by-thursday/#261d98a55688>.

¹²See <https://medcitynews.com/2019/12/express-scripts-strikes-partnership-with-prime-therapeutics/>

¹³See <https://www.primetherapeutics.com/en/news/pressreleases/2019/release-prime-express-scripts-collaboration.html>

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 Harbor¹⁷, 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 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 Health¹⁹ – 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

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)

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/>.

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 concerning 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

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.

²⁴ See <https://www.blueandco.com/cvs-health-has-acquired-340b-software-provider-wellpartner-inc/>

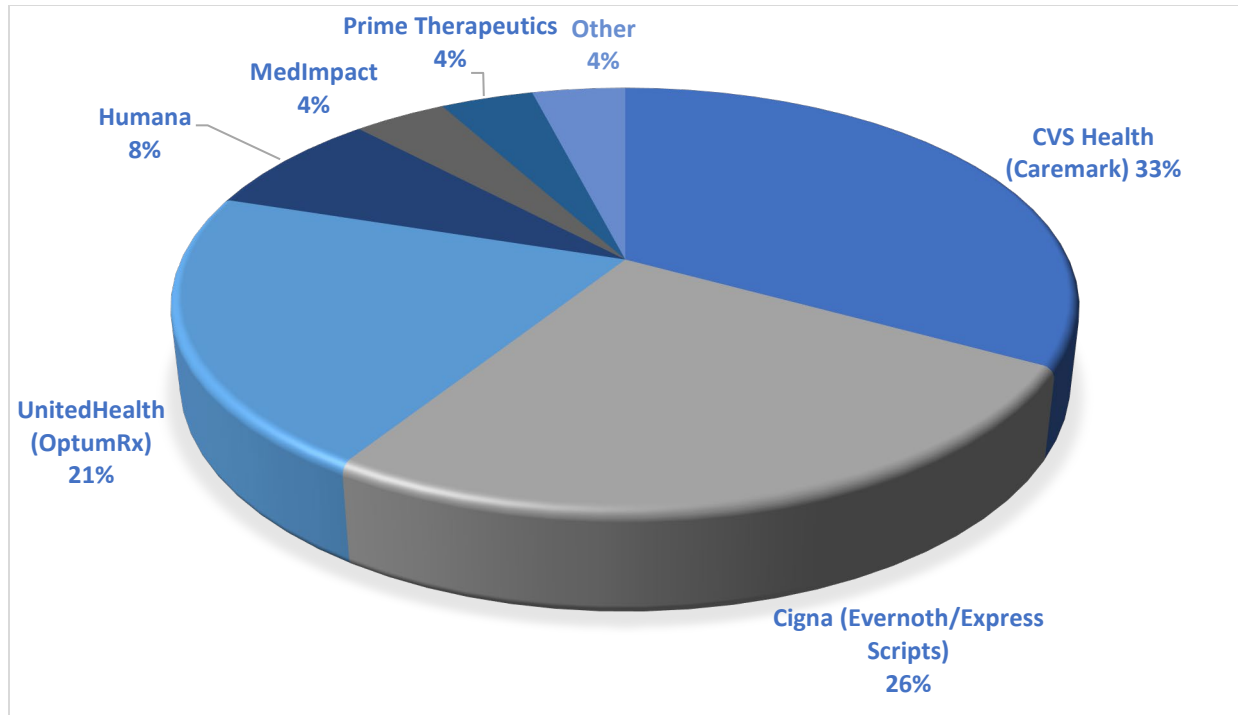
²⁵ See <https://ag.ny.gov/press-release/2022/attorney-general-james-sues-cvs-harming-new-york-safety-net-hospitals-and-clinics>

²⁶ See <https://www.prnewswire.com/news-releases/express-scripts-closes-acquisition-of-edicore-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=593f7ec7ccc9>

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>

Figure 2. Market Share by PBM in U.S. Prescription Benefits Market in 2021²⁹



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 not 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 programs³¹ 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. Through vertical

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 coupon program. This aims to ensure that the full value of the manufacturer’s copay savings program is extracted for the benefit of the plan.

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

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

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 reduce 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) fees⁴⁰, 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.

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 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_PBM_FINAL.pdf.

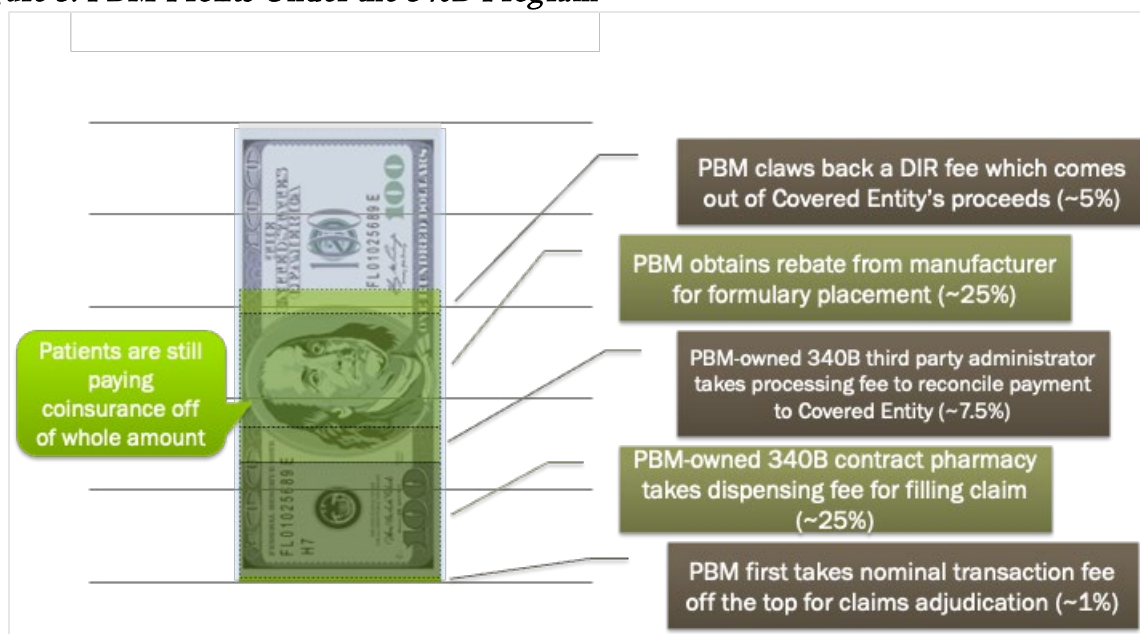
³⁷ Federal Trade Commission, Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products at 1 (June 16, 2022).

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/>

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 viability 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 report⁴² 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.

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.

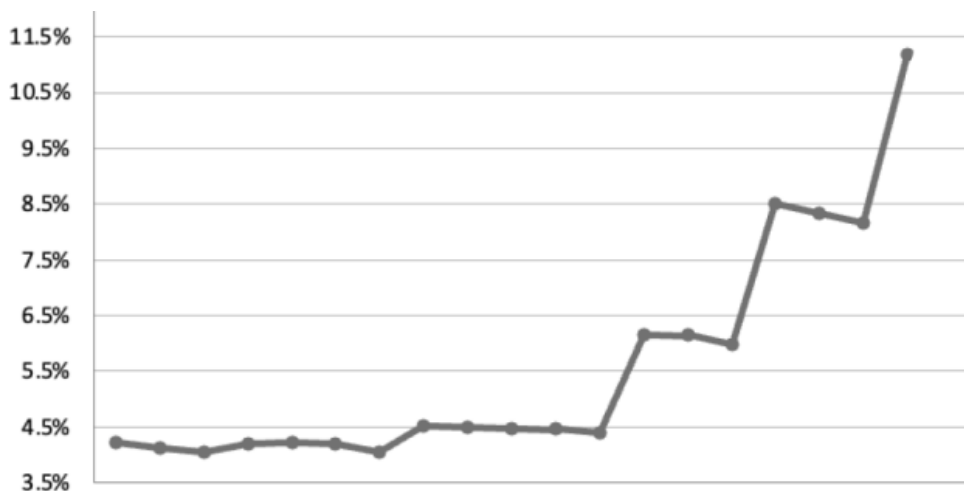
⁴² The Department of Health and Human Services Assistant Secretary for Planning and Evaluation, Office of Science & Data Policy, Trends in Prescription Drug Spending, 2016-2021 (September 2022). Available at <https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fc2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf>.

⁴³ <https://www.drugchannelsinstitute.com/files/Fein-Long-Asembia-03May2022.pdf>.

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 pharmacies⁴⁵ 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 █% with the true range of up to █% 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.

Figure 4. DIR Fees as a Percentage of Ingredient Cost Experienced by a Single Provider from 2016-2022:



⁴⁴ █

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

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

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

⁴⁹ Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50.3.

⁵⁰ 87 FR 1842, 1911.

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%
BrioRx 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%
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 (Advanced 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 Economic Report on Retail, Mail, and Specialty Pharmacies*, Drug Channels Institute, January 2016. Available at http://drugchannelsinstitute.com/products/industry_report/pharmacy/

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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 2018⁵¹ and 2019⁵² respectively. Further, Prime

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., (Dec. 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>

Therapeutics and Walgreens entered a joint venture to form AllianceRx,⁵³ and later Prime Therapeutics entered a joint venture with Express Scripts⁵⁴ 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%
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 BrivoRx.

3. On Dec. 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).

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Already in 2023, there have been additional consolidations. For example, in February, CarepathRx sold its specialty pharmacy, BioPlus, to Elevance⁵⁵ (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

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/>

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>

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, because 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 remaining 74.5% based on bids submitted 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 CMS 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.

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/>

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/>

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); (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

⁶² See generally Medicare Managed Care Manual, Chapter 7 – Risk Adjustment.

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. Oct. 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. Dec. 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 C.F.R. § 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 C.F.R. § 423.505(f)(3)(iii).

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-owed 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 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

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).

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., Sept. 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. Mar. 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 Psychcare Servs., Inc.*, 6 P. 3d 669, 690 (Cal. Sup. Ct. 2000).

negotiations were possible.⁷³ Substantive unconscionability occurs when the terms of the contract are overly 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 [REDACTED]

[REDACTED]. 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. [REDACTED] network enrollment forms typically advise that “[y]ou will be enrolled as a Provider [...] under the terms detailed in the attached [REDACTED] [REDACTED] Forms unless you notify [REDACTED] Caremark in writing (via facsimile) [...] that you do not want to enroll.” [REDACTED]

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:

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. Mar. 15, 2023).

[REDACTED]

See [REDACTED]

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. [REDACTED]

[REDACTED]. 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, [REDACTED] requires that disputes be filed “[REDACTED]

See [REDACTED]

Further, [REDACTED]

requires that such [REDACTED]

See [REDACTED]

[REDACTED] 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. [REDACTED] requires that [REDACTED]

See [REDACTED]

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. [REDACTED]

[REDACTED] 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. [REDACTED]

[REDACTED] Coupled with fee shifting clauses, providers are heavily dissuaded from pursuing their rights against PBMs because of these exorbitant costs. [REDACTED]

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

⁷⁷ [REDACTED]

⁷⁸ [REDACTED]

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., [REDACTED]; [REDACTED]). 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. [REDACTED]

[REDACTED]. 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). [REDACTED]

[REDACTED] 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. [REDACTED]

[REDACTED], [REDACTED]. 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 co-insurance.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. [REDACTED]

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

⁷⁹ See 87 FR 89 at 27850.

⁸⁰ 42 C.F.R. 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.

⁸² 87 FR 89 at 27834.

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. [REDACTED]

[REDACTED]. 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. [REDACTED].

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[.]” [REDACTED]

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. [REDACTED]

(demonstrating the mean imputed assessment of non-specialty DIR fees against [REDACTED] [REDACTED] was legally prohibited from dispensing those drugs). Thus, applying the AWPL regulation at 42 C.F.R. 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. [REDACTED]

[REDACTED]. This metric is measured by taking all the 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. [REDACTED]

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 § 6807 (“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 seventy-two hour supply of drugs, except for: . . . the dispensing of drugs pursuant to an oncological or AIDS protocol.”).

██████. 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.

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.*

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-SPI, 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. Sept. 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.

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.

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. [REDACTED] 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 C.F.R. § 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 C.F.R. § 423.505(b)(19) (incorporating 42 C.F.R. § 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 C.F.R. § 423.505(b)(19) (incorporating 42 C.F.R. § 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 [REDACTED], 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. [REDACTED]

[REDACTED]. 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. [REDACTED]

[REDACTED]. 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. [REDACTED], Order Approving Respondents' Withdrawal Of Termination Notice. Yet other Specialty Pharmacies have been threatened with termination for bringing similar claims. [REDACTED]. Retaliation is a real and continuing problem, and PBMs can hide these retaliative acts behind the cloak of confidentiality.

V. PBM Conduct Conflicts With Plan Sponsor Interests By Imposing Spread Pricing to Increase Plan Sponsor Costs 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

⁹⁰ For example, 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.

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 uniform 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 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

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>).

⁹⁷ *See Id.*, at 61.

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 NADAC¹⁰⁰ 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 context¹⁰², 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 programs¹⁰⁷, making it difficult to grasp the full

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

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

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.).

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>.

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 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,

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> (Oct. 14, 2022).

¹¹³ 42 U.S.C. § 256b(a)(1), (4).

¹¹⁴ See H.R. Rep. No. 102-384, pt. 2, at 12 (Sept. 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 (Aug. 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 & Human Servs.*, 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.

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 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

¹²³ See 61 F.R. at 43,549.

¹²⁴ *Id.* at 43,551.

¹²⁵ See 75 F.R. 10,272-01 (Mar. 5, 2010).

¹²⁶ See *infra*, Section II.D., Figure 3.

¹²⁷ Karen Mulligan, PhD, University of Southern California, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, (Oct. 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 & 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, PhD, University of Southern California, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, (Oct. 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.*

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 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

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.

¹³⁸ See *Sanofi Aventis, U.S. LLC v. United States Dept. of Health and Human Servs.*, 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*, (Feb. 4, 2014), at 5, <https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf>

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 themselves 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

¹⁴² BRG, *For-Profit Pharmacy Participation in 340B Program*, at 4 (Oct. 2020), <https://bit.ly/36X0eUG>; see also AIR340B, *The Impact and Growth in 340B Contract Pharmacy Arrangements – Six Years Later*, at 8, <https://340breport.com/wp-content/uploads/2020/12/AIR340B-Report-on-the-Impact-of-Growth-in-340B-Contract-Pharmacy-Arrangements.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.

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 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:

¹⁴⁷ Rhiannon Klein, cv340b, *Express Scripts Issues 340B Claims Identification Requirements*, (Mar. 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>

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

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ATTORNEYS AT LAW

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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 percent 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 horizontal 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 3 Axis 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 program, 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

¹ See, *CZ Servs. v. Express Scripts Holding*, Case No. 3:18-cv-04217-JD, Dkt. No. 301-3.

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-medicare-pharmacy-benefit/>

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 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 particularly 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.

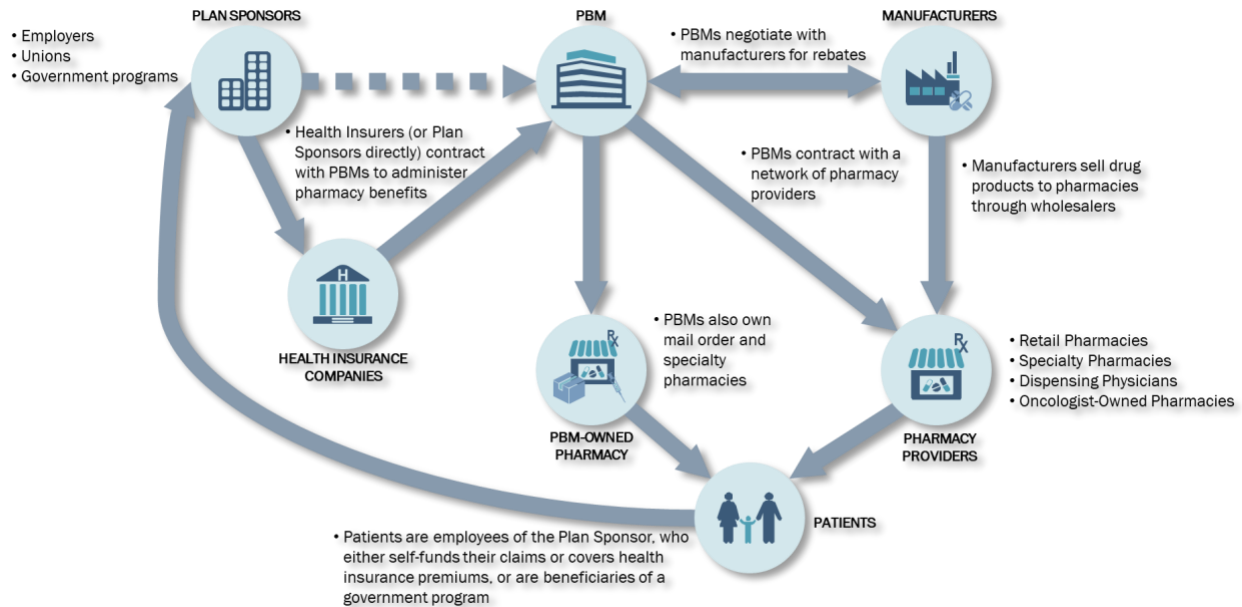
The final piece of the puzzle is the PBM. PBMs are third-party administrators of prescription drug programs covered by a plan sponsor. The PBM is primarily responsible for processing and paying prescription drug claims submitted by participating providers on behalf of covered beneficiaries. However, 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

⁴ <https://www.shrm.org/hr-today/news/hr-magazine/pages/0909wellsc.aspx>

⁵ See Mark Munger et al., *Emerging Paradigms: Physician Dispensing*, Presentation to the Nat'l Ass'n of Bds. of Pharmacy (May 20, 2014), available at https://www.nabp.net/system/rich/rich_files/rich_files/000/000/338/original/munger-202.pdf.

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.

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.

⁶ See <https://www.latimes.com/business/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html>

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 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

⁷ Evelyn M. Rusli, *Caremark Approves CVS Merger*, *Forbes* (Mar. 16, 2007, 4:59 PM), http://www.forbes.com/2007/03/16/caremark-approves-update-markets-equity-cx_er_0316markets29.html.

⁸ Jon Kamp, *Medco Faces Loss of Blue Cross Customer*, *Wall St. J.* (Aug. 3, 2011, 6:04 PM), <http://www.wsj.com/articles/SB10001424053111903454504576486653127464070>.

⁹ Anna Wilde Mathews, *UnitedHealth's Answer to Express Scripts-Medco Merger?*, *Wall St. J.* (Jul. 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*, *N.Y. Times* (Apr. 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*, *N.Y. Times*, (Apr. 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*, *Bus. Wire* (Jun. 24, 2015, 10:23 AM), <http://www.businesswire.com/news/home/20150624005906/en/Rite-Aid-Completes-Acquisition-Leading-Independent-Pharmacy>.

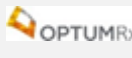
¹³ Dana Mattioli, Michael Siconolfi, and Dana Cimilluca, *Walgreens, Rite Aid Unite to Create Drugstore Giant*, *Wall St. J.* (Oct. 27, 2015, 9:01 PM), <http://www.wsj.com/articles/walgreens-boots-alliance-nears-deal-to-buy-rite-aid-1445964090>.

¹⁴ *Aetna to Acquire Humana for \$37 Billion, Combined Entity to Drive Consumer-Focused, High-Value Health Care*, *Bus. Wire* (Jul. 3, 2015, 2:08 AM), <http://www.businesswire.com/news/home/20150702005935/en/Aetna-Acquire-Humana-37-Billion-Combined-Entity#.VZYpMeTD9OI>.

¹⁵ Michael J. De la Merced and Chad Bray, *Anthem to Buy Cigna Amid Wave of Insurance Mergers*, *N.Y. Times* (Jul. 24, 2015), <http://www.nytimes.com/2015/07/25/business/dealbook/anthem-cigna-health-insurance-deal.html>.

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

2011							
2013							
2015							
2022							

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

¹⁶ Leslie Picker, *U.S. Sues to Block Anthem-Cigna and Aetna-Humana Mergers*, N.Y. Times (Jul. 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, Dec. 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/>

result of the arrangement, Express Scripts will now manage the prescription benefits for more than 100 million Americans.¹⁹

Figure 3. Vertical Integration of PBMs and Health care Conglomerates

Let's Get Vertical: Insurer + PBM + Specialty Pharmacy + Provider



1. Cigna partners with providers via its [Cigna Collaborative Care](#) program. However, Cigna does not directly own healthcare providers.
 2. AllianceRx Walgreens Prime is jointly owned by Prime Therapeutics and Walgreens Boots Alliance.
 Source: Drug Channels Institute research; [The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers](#), Chapter 5.



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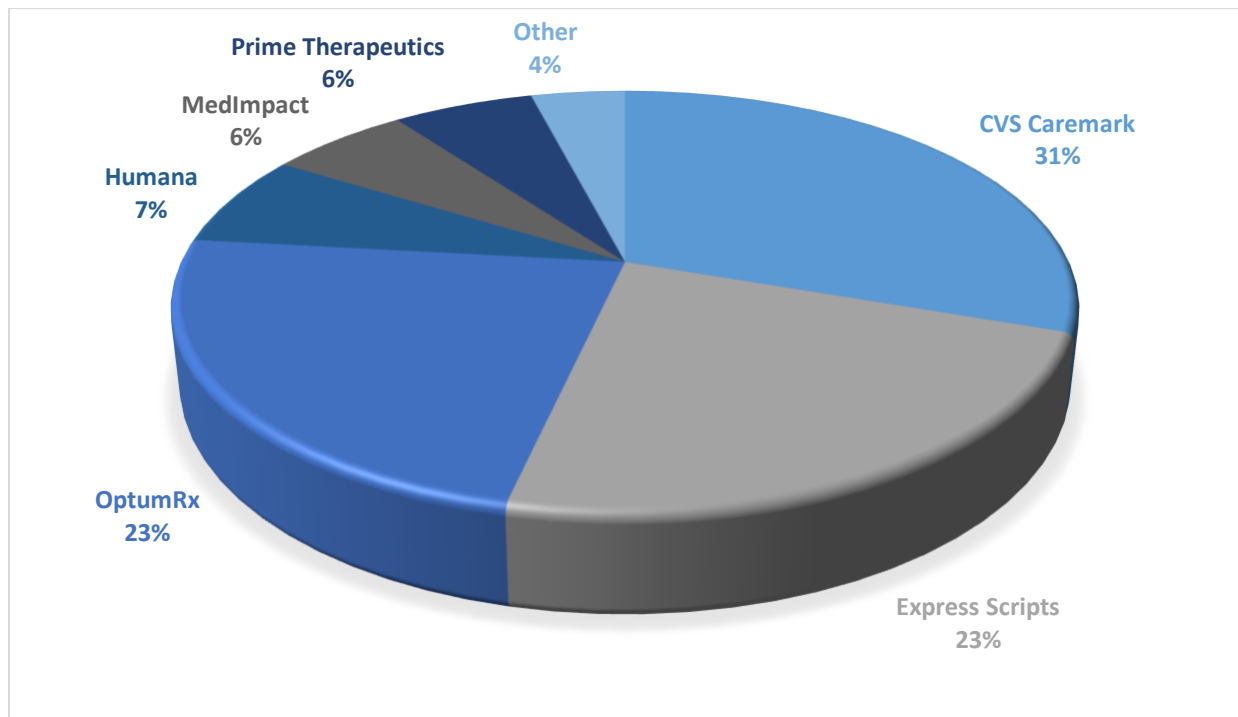
This rapid evolution of the PBM and health insurance industry shows how a limited number of corporations wield an outsized level of control and influence in the prescription drug coverage marketplace. Fewer payers spells harm to patients, especially cancer patients. These integrated companies have greater 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.

¹⁹ <https://www.primetherapeutics.com/en/news/pressreleases/2019/release-prime-express-scripts-collaboration.html>

Figure 4. Market Share by PBM in U.S. Prescription Benefits Market in 2018²⁰



As can be seen in the figure above, consolidation has created merged entities that have oppressive power. This creates a virtual chokehold not 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.

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-look-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/>

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

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>

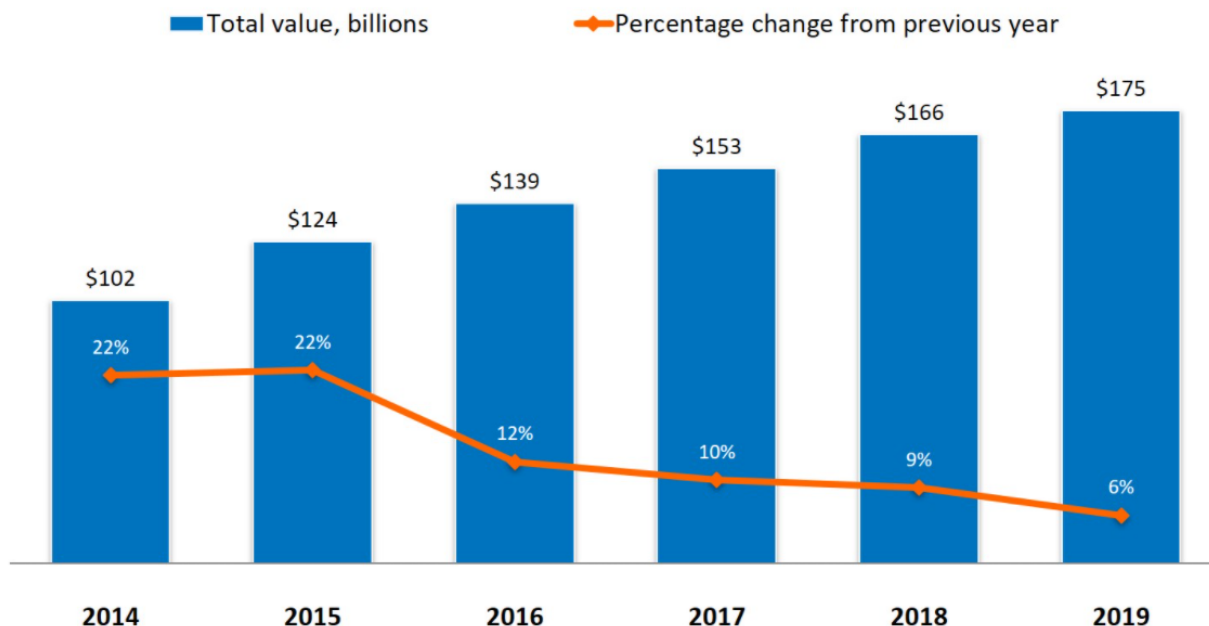
²⁴ See, Federal Trade Commission, “Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies,” August 2005, accessible online: https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitpt_0.pdf

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

Total Value of Pharmaceutical Manufacturers' Gross-to-Net Reductions for Brand-Name Drugs, 2014 to 2019



Source: Drug Channels Institute analysis of IQVIA Institute data; Drug Channels Institute estimates. Gross-to-Net Reductions include the total value of rebates, off-invoice discounts, copay assistance, price concessions, and such other reductions as distribution fees, product returns, the 340B Drug Pricing Program, and more.

Published on *Drug Channels* (www.DrugChannels.net) on August 4, 2020. This chart appears as Exhibit 159 in *The 2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, which is available at <http://drugch.nl/pharmacy>



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 biologic²⁷ – 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

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/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm291128.pdf>. Accessed June 25, 2018.

²⁸ See What Are Biosimilars? available at: <https://www.biosimilarsresourcecenter.org/faq/what-are-biosimilars/>

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 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

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>

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:

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 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

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

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 Feb 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

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 subsidize 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-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

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%20HDP%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/>

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.

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 rebate 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

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-medicare-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>

⁵⁸ Complaint, *Ohio Highway Patrol Retirement System v. Express Scripts, Inc.*, Case No. AM-20CV004504, Court of Common Pleas, Franklin 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>

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

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”

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 & 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,” March 6, 2020, accessible online: <https://www.statnews.com/2020/03/06/biosimilars-in-us-turn-five/>

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:

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>

- 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
- 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.

⁷⁴ See, e.g., Social Security Act § 1860D-15, 42 U.S.C. [1395w-115].

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 & Accountability to Drug Pricing (Dec. 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>.

- Require PBMs to report claims-level data on rebates collected on claims paid by plan 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.

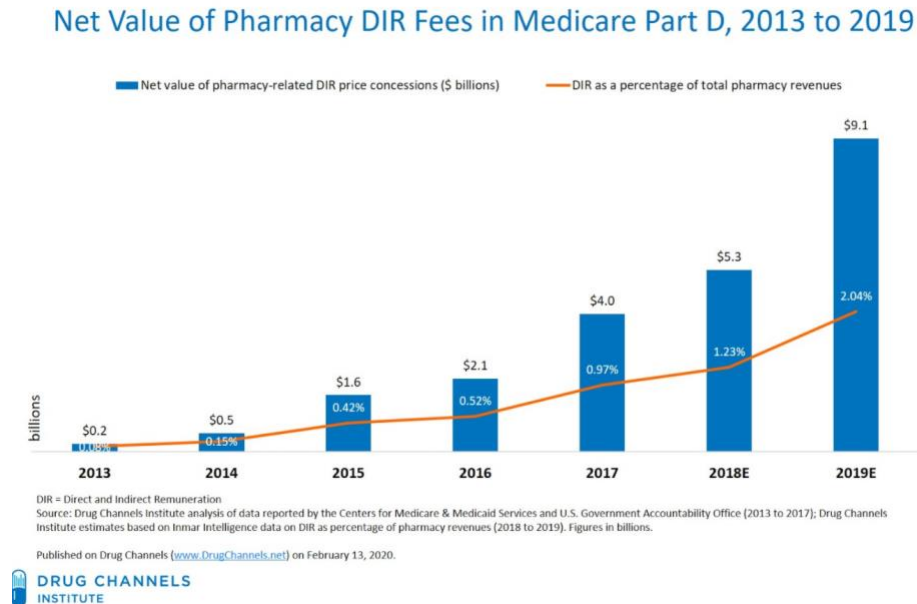
The concept of DIR fees arose out of Medicare Part D coverage for prescription drugs. Part D plan sponsors and Medicare Advantage plans offering drug coverage are paid by the government based on the actual cost for drug coverage. The actual cost is based on the Part D plan sponsor’s “negotiated price,” 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 lawmakers, 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

⁷⁷ Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62,175 (November 30, 2018).

⁷⁸ Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62,174 (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>.

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 number 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

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>.

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

⁸⁰ <https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/>

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. Studies 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 2018⁸⁵ (based on 2017 data), but saw its score drop to a 3.5 Star Rating in 2019⁸⁶ 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

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/>

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. 62,152, 62,176 (Nov. 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=pdffinder&utm_campaign=starimglink](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=pdffinder&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)*, (Jan. 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>

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

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

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

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.

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 reimbursement rates⁹⁹. 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.

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.

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 C.F.R. §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 C.F.R. §423.505(b)(18) Medicare Prescription Drug Benefit Manual, Chapter 6, Section 50.3.

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, statutes, 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.
 - 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

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>

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 twenty-four 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 have attempted to use their market size

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 Curiae Supporting Respondents, *Rutledge v. Pharm. Care Mgmt, Ass’n.*, 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>

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.

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/wpcontent/uploads/bpattachments/7218/ajmcpan032016inofficedispensingcontinuityofcarebynancyegerton.pdf>

These obstructionist policies harm patients, degrade the quality of prescribers and benefit only PBMs that are incentivized to continue to these illegitimate practices.

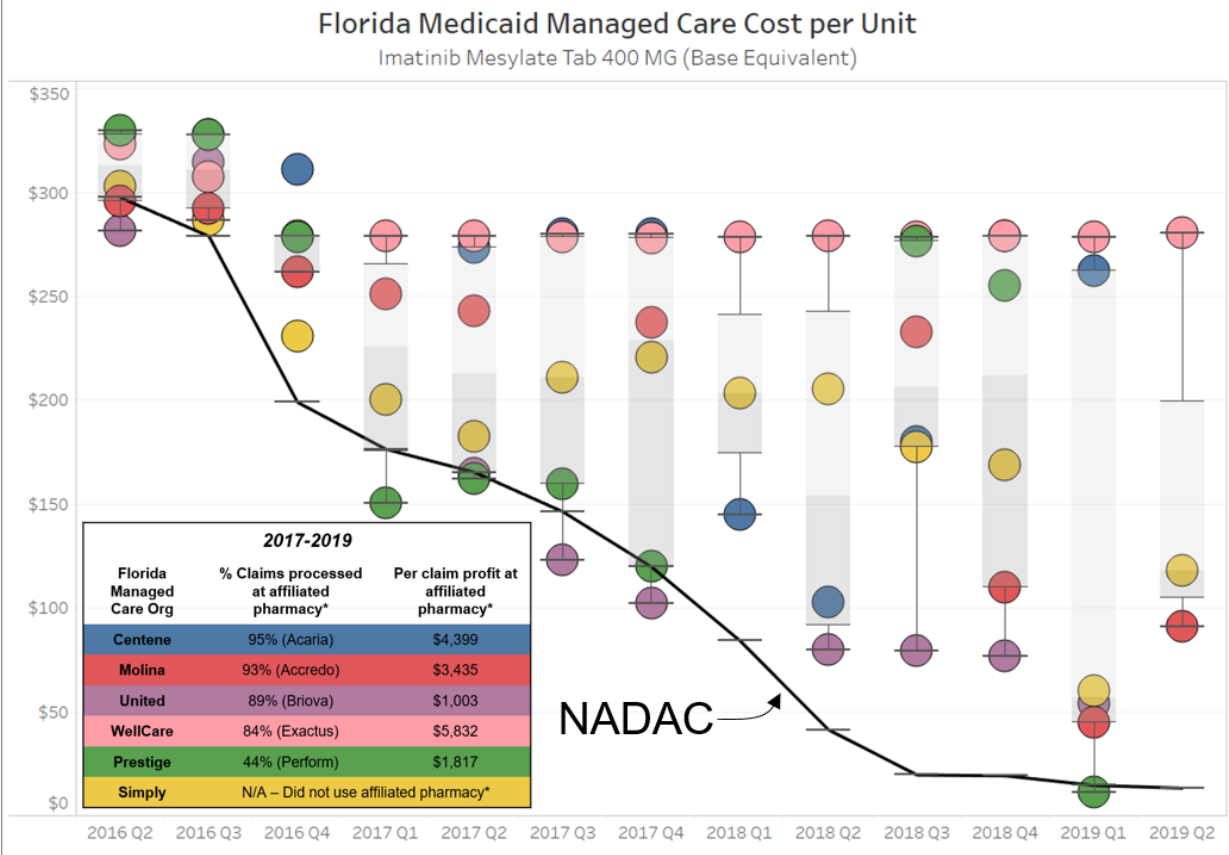
Finally, even when a community oncology practice has ultimately been admitted into a PBM's network, PBMs continue to utilize other tactics to drive patients away from community oncology practices, and towards PBM-owned or affiliated pharmacies. This includes tactics such as patient slamming and claim hijacking (*see*, Section 7, *infra*), misleading communications aimed at steering patients to PBM-owned 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.

Specialty pharmacy steering and drug mispricing in Florida Medicaid

In a study published in January 2020, 3 Axis Advisors found significant steering of high cost specialty drugs by Florida's Medicaid Managed Care Organizations (MCOs) to pharmacies affiliated with either themselves or their PBM. 3 Axis also found staggering drug overpricing by these same MCOs, especially on generic specialty medications.

This chart shows Florida's MCO pricing for blockbuster oral leukemia treatment, generic Gleevec (imatinib mesylate), since its release. While its true acquisition cost (i.e. the National Average Drug Acquisition Cost or "NADAC") declined precipitously, Florida's largest MCOs did not pass these savings onto the state. Rather, as shown in the table/legend, they disproportionately recognized egregious profits in their affiliated pharmacies.



* 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

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

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-documented¹¹⁴ 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,

¹¹¹ See CVS Health Corp., Letter to Congressman Ed Whitfield from Senior Vice President of Government and Public Affairs Melissa A. Schulman (Feb. 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_VolIII.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/>.

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 twenty years. The patient's PBM mandated that the patient 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 patients 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 requires 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

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/>.

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/ajax/the-advantage-of-independent-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/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>

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 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 lowering 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.

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>

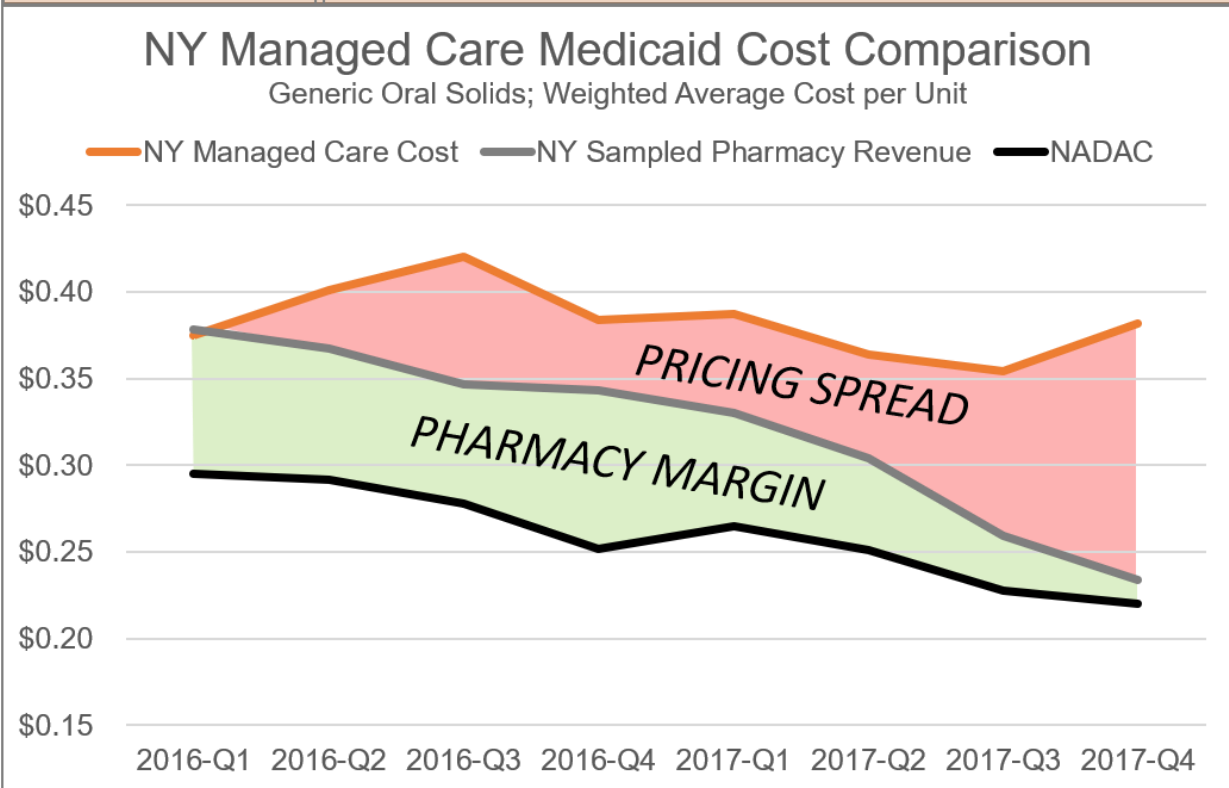
¹²² See Oncology Care Model (last updated May 15, 2020), <https://innovation.cms.gov/innovation-models/oncology-care>. See also Value-Based Care Leads the Way to Lower Costs and Better Quality (December 4, 2019), <https://www.ahip.org/value-based-care-leads-the-way-to-lower-costs-and-better-quality/>. 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).

PBMs are retaining more profit through hidden pricing spreads

In a study published in January 2019, 3 Axis Advisors compared the payments received on over 170,000 claims by a sample of 11 NY pharmacies to costs reported by CMS for generic oral solid drugs dispensed in New York's Medicaid managed care program.

As shown below, 3 Axis found a dramatic increase in the difference between the state's reported costs and the pharmacy's received revenue (i.e. spread), increasing from essentially nothing at the start of 2016, to \$0.15 per pill by the end of 2017. By the end of 2017, these PBM actions had squeezed the pharmacy's gross margin (before operating costs) to just one penny per pill.



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

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>.

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 established 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

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 (Jan. 20, 2016), <http://www.drugchannels.net/2016/01/medicare-part-d-2016-75-of-seniors-in.html>

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 improved 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 C.F.R. § 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

¹²⁸ See, e.g., *Kentucky Ass’n of Health Plans v. Miller*, 538 U.S. 329 (2003)

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 C.F.R. §431.51(a)

¹³¹ N.C. Gen. Stat. Ann. § 58-51-37(c)

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.
- 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

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).

- Plan sponsors should require PBMs to seek approval from plan sponsors prior to establishing a standard and/or qualification for a provider network.
- Plan sponsor 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 have 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 documented¹³⁴ some egregious instances where the PBM blatantly lied to the patient and pharmacy staff, saying the prescribing physician had 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-

¹³⁴ <https://communityoncology.org/the-real-life-patient-impact-of-pbms-volume-i/>

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-

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>

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 specialty 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. In 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

¹³⁹ See The Real-Life Patient Impact of PBMs: Volume I, May 27, 2020, available at <https://communityoncology.org/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>

obtained them through the PBM’s mail-order pharmacy.¹⁴⁴ After he waited nearly two 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 burden 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.

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>

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

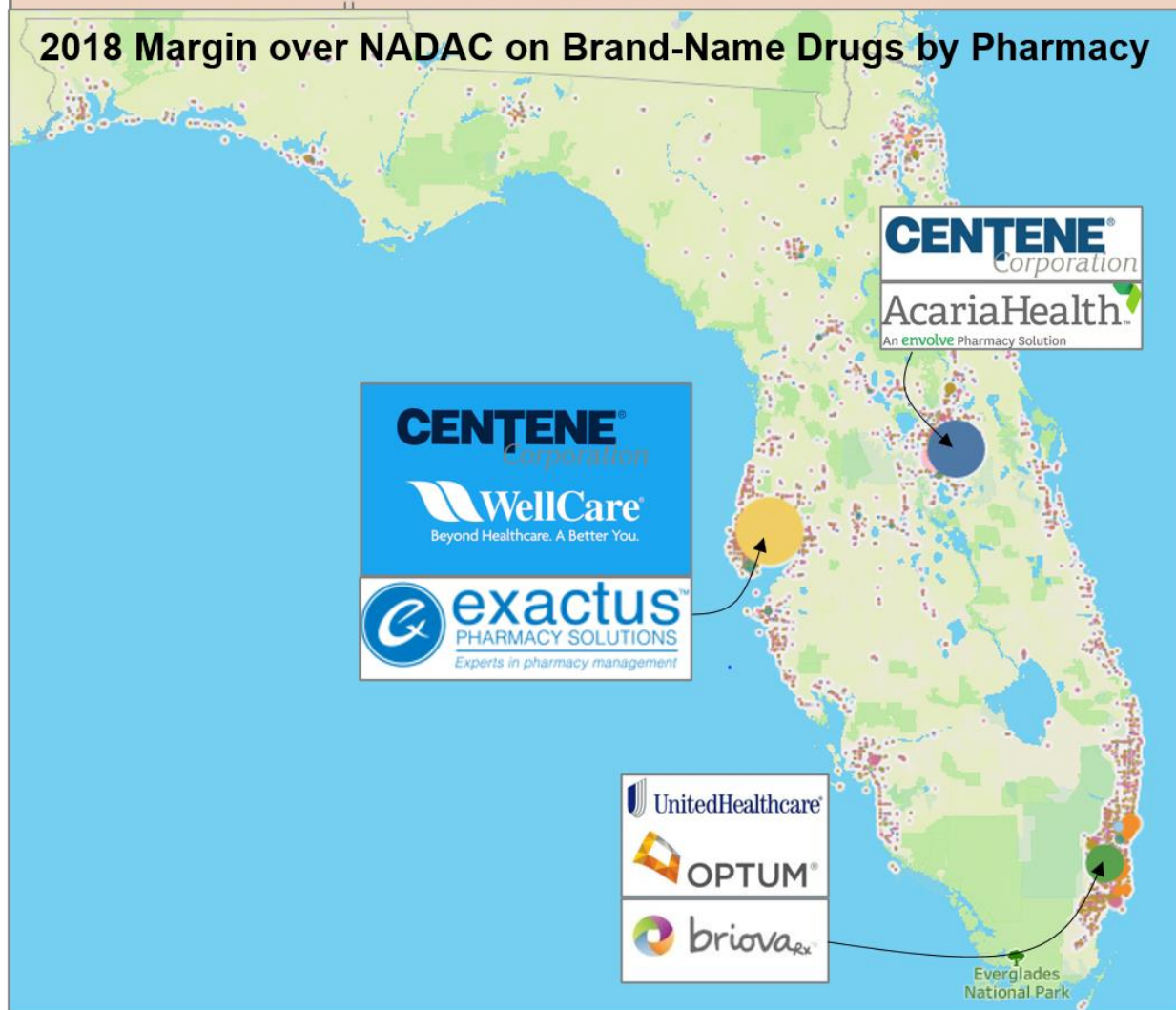
¹⁴⁹ <https://www.americanprogress.org/issues/healthcare/reports/2019/04/08/468302/excess-administrative-costs-burden-u-s-health-care-system/>

¹⁵⁰ <https://www.acpjournals.org/doi/10.7326/m16-2697>

Visualizing the disproportionate profitability of affiliated pharmacies in Florida Medicaid

3 Axis Advisors' study on the Florida Medicaid program also drilled into how profit (as measured by margin over NADAC) was distributed across Florida's pharmacies within the Medicaid managed care program.

On the below map, each pharmacy that dispensed a brand-name drug claim in Florida Medicaid managed care in 2018 is represented by a bubble. The size of the bubble indicates the amount of profit generated by the pharmacy in 2018 from Medicaid managed care brand-drug claims. As shown below, the three most profitable pharmacies in the state are the three specialty pharmacies directly owned by three of Florida's largest MCOs. Overall these three pharmacies collected 30% of all profit on brand-name drugs paid out to Florida pharmacies in 2018.



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 pharmacy is a breach¹⁵⁴ 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 Servs., Inc. v. Express Scripts Holding Co.*, No. 4:18-CV-467 RLW, 2019 WL 1207866, (E.D. Mo. Mar. 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

¹⁵¹ 45 C.F.R. § 160.102

¹⁵² 45 C.F.R. § 164.508

¹⁵³ 45 C.F.R. § 164.506

¹⁵⁴ 45 C.F.R. § 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)

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 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.

¹⁵⁹ *Trone Health Services, Inc. v. Express Scripts Holding Co.*, No. 19-1774 (8th Cir. 2020)

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%20transparency%20in%20federal%20health%20programs.pdf>).

¹⁶¹ La. Stat. Ann. § 40:2870(A)(5)(a); Ga. Code Ann., § 26-4-119

- 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 plans¹⁶³ (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 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.

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>.

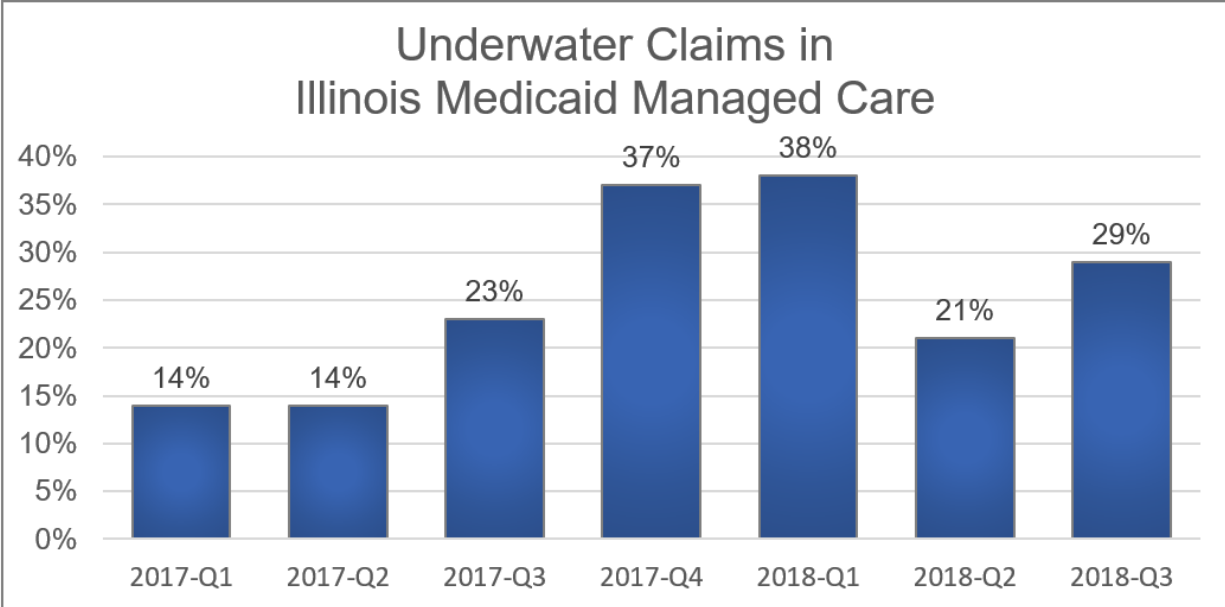
¹⁶⁴ <https://www.latimes.com/business/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html>

More than a third of claims reimbursed below cost in Illinois Medicaid Managed Care

In March 2019, 3 Axis Advisors published a study on pharmacy reimbursements and Medicaid program payments in the Illinois Medicaid program.

As part of the study, 3 Axis compared the reimbursements received by 21 pharmacies in Illinois Medicaid managed care, to the NADAC (i.e. average pharmacy acquisition cost) on the same set of claims. 3 Axis found that the percentage of “underwater” claims – meaning those paid out below the drug’s NADAC – rose from 14% in early 2017 to 38% in Q1 2018. Underwater reimbursements improved slightly in Q2 2018, before regressing again to nearly 30% in Q3 2018.

The study also found Medicaid managed care reimbursements to be the worst in Cook County (Chicago), a potentially devastating finding for inner-city Chicago pharmacies that must both serve a larger Medicaid patient base and pay higher labor costs.



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

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 & Accountability to Drug Pricing* (Dec. 11, 2018), at 6, 10-16.

to use one of 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.

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, (Feb. 27, 2018), available at <http://www.ncpa.co/pdf/judiciary-statement-on-cvs-aetna-merger.pdf>.

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 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

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*, ay 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 1*, 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).

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 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

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 C.F.R. § 423.505(b)(18).

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 Commc’n, 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.”)

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 law¹⁸⁰, 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.

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

¹⁸⁰ N.J.S.A. § 17b:27f-1 to -10

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 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

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>

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

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 Newwork.2010;8(Supp 4):S1-S12.

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 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

¹⁸⁶ 42 C.F.R. § 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

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 concerning, 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 insanitary 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 (including 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

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."

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 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

¹⁹² N.J.A.C. § 13:39-3.10.

¹⁹³ Ga. Code Ann. § 26-4-119.

¹⁹⁴ See, e.g., *In re Express Scripts, Inc., PBM Litigation*, 2008 WL 2952787 *5 (E.D. Mo. July 30, 2008).

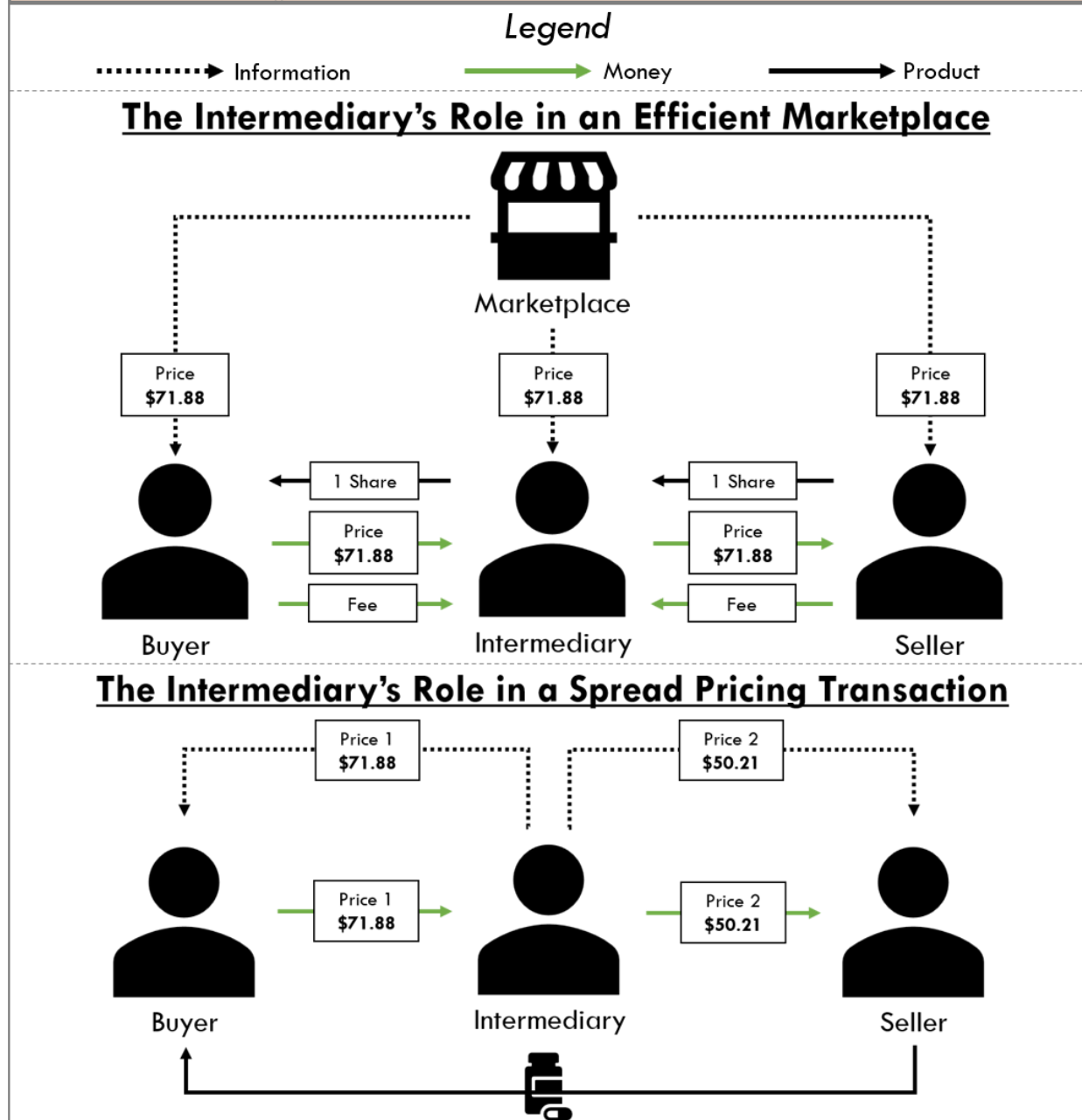
recently come to light in the Medicaid context, where PBMs manage benefits for state Medicaid MCOs, and where state governments have uncovered immense spreads in drug claims for Medicaid beneficiaries.¹⁹⁵ Ultimately, spread pricing practices reveal how PBMs are vertically integrated enterprises that 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.

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>

Comparing an efficient market transaction with a spread pricing drug transaction

To better understand how a spread pricing transaction works, it's helpful to first compare it to an efficient market transaction, such as would occur in buying or selling publicly traded stocks. The first illustration shows an intermediary's role in a stock transaction. First, all parties know the transaction price, as it is published in a transparent manner. In this case it is \$71.88. Both the buyer and seller transact based on this price, with the intermediary facilitating the transaction. For its services, the intermediary receives a small (highly competitive) fee.

When it comes to drugs, the intermediary's role is much more powerful. The intermediary (i.e. PBM) enters into separate contracts with the buyer and seller that allow it to set different prices for the same drug. Without a transparent marketplace to obtain pricing information, the buyer and seller both receive the price from the PBM, not from the marketplace. The PBM then has the latitude to charge one price to the buyer and pass through a lower price to the seller, pocketing the difference.



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 pharmacy 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

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/SchaefferCenter_RebatesListPrices_WhitePaper.pdf

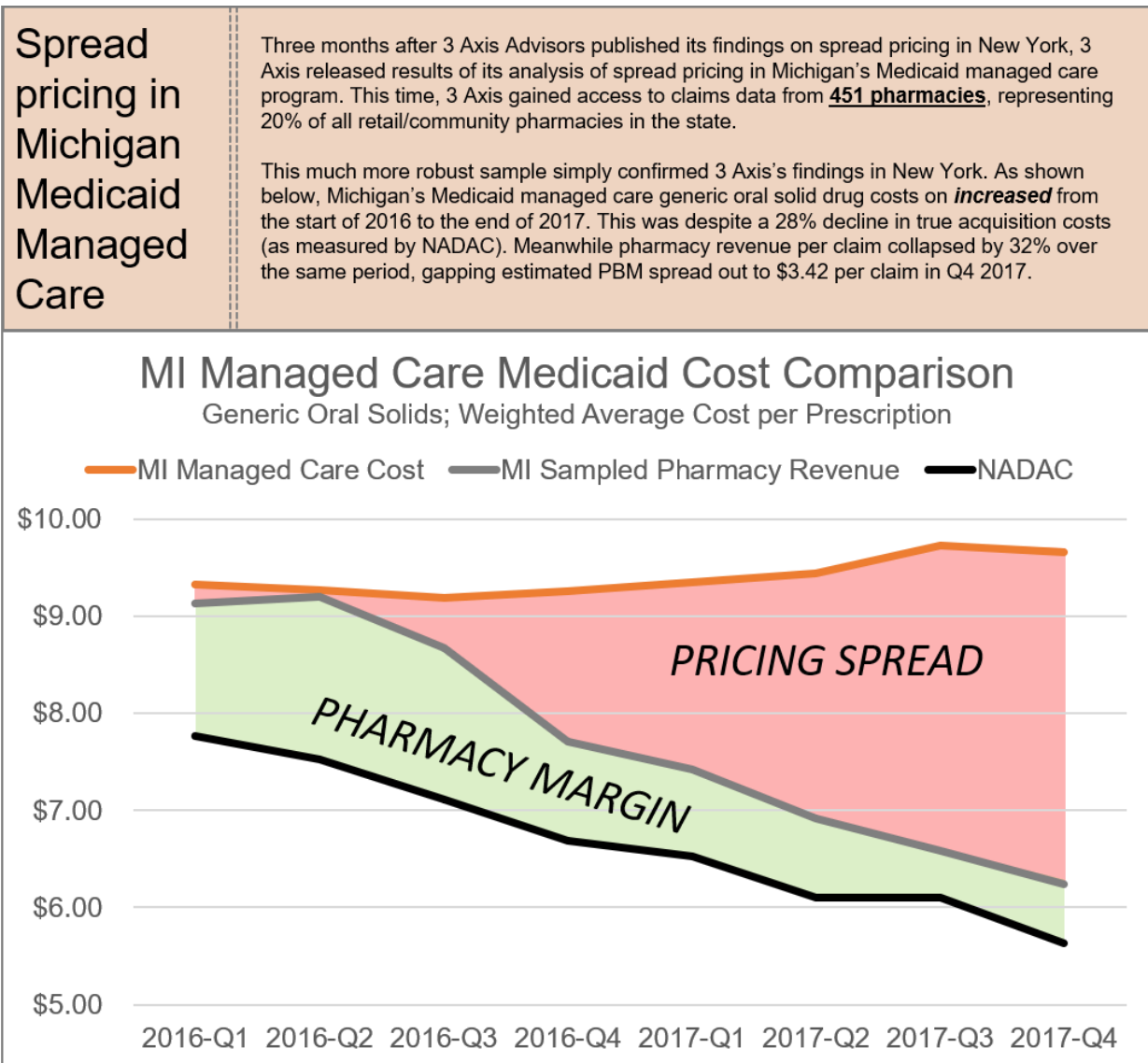
¹⁹⁷ 3Axis Advisors, *Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis*, 1, 3-4, January 30, 2020 <https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/5e384f26fc490b221da7ced1/1580748598035/FL+Master+Final+Download.pdf>. See also, Community 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/>

New York, Illinois, Michigan and, notably, a 200-page report on spread pricing in the Florida Medicaid program.²⁰¹



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 losses on Medicaid prescriptions that it made it virtually impossible to continue to participate in the program.²⁰² The exposure of these abuses led

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>

²⁰² See, <https://www.dispatch.com/news/20180312/cvs-accused-of-using-medicare-rolls-in-ohio-to-push-out-competition>;

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 rule²⁰⁴ adopted standards for the calculation of Medical Loss Ratios (MLRs).²⁰⁵ More specifically, the final rule clarified that spread pricing must be reported 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).

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>

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 See 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

- 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.
- State 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.

11 Copay Accumulators and Maximizers

The increased prevalence of high deductible health plans or plans involving patient coinsurance²⁰⁹ 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

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

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 four 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 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,

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>

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>

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 months 3 and month 4 of a plan year (coinciding with when they

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>

reach the annual cap for manufacturer-sponsored copay 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

²²² <https://www.drugchannels.net/2019/04/addressing-rising-impact-of-copay.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 BW, Epstein AJ, 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>

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. 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%

²³⁴ <https://pharmaceuticalcommerce.com/brand-marketing-communications/copay-maximizers-have-murky-financial-implications-says-drug-channels/>

²³⁵ Cutler, R. L., Fernandez-Llimos, F., Frommer, M., Benrimoj, C., & 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>

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 "difficulty 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 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

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>

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.>

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
 - State 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.
- 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

²⁴⁶ See, 45 C.F.R. § 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>

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 has resulted in substantial challenges for independent pharmacy providers over the past several years.

²⁴⁷ See, e.g., NY PUB HEALTH § 280-a(1)(b).

²⁴⁸ Assoc. for Accessible Medicines, Generic Drug Access & 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 & Accountability to Drug Pricing (Dec. 11, 2018), https://www.paauditor.gov/Media/Default/Reports/RPT_PBM_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 & Accountability to Drug Pricing (Dec. 11, 2018), https://www.paauditor.gov/Media/Default/Reports/RPT_PBM_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.*

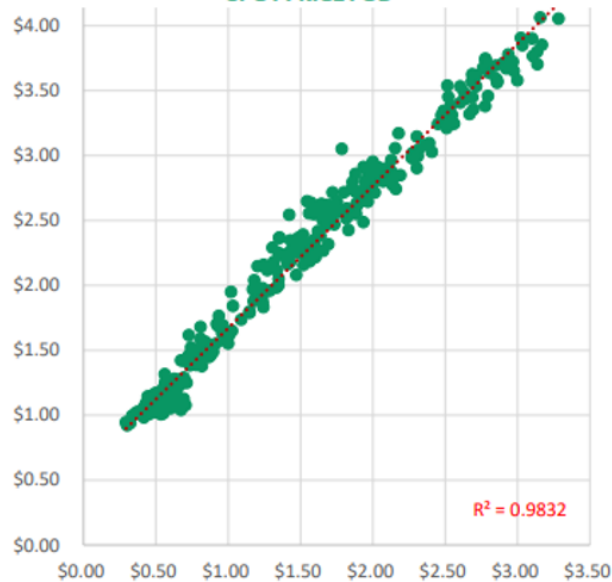
²⁵⁴ See, e.g., Eugene A. DePasquale, Bringing Transparency & Accountability to Drug Pricing (Dec. 11, 2018), https://www.paauditor.gov/Media/Default/Reports/RPT_PBM_FINAL.pdf.

Generic drug MAC rates are poorly correlated to acquisition costs

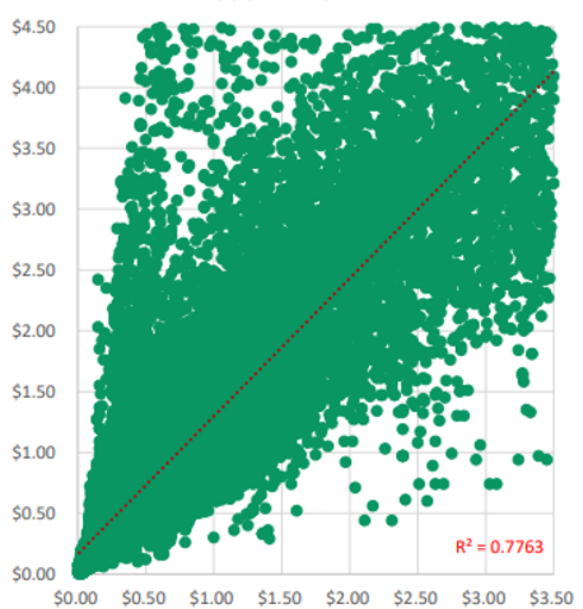
In April 2020, 3 Axis Advisors published a study evaluating the responsiveness of PBM MAC rate changes to increases in drug acquisition cost. At the time, there was palpable fear about the impact that COVID-19 could have on the generic drug supply chain, and whether PBMs would increase payment rates in line with increasing acquisition costs due to supply chain bottlenecks.

As part of the study, 3 Axis performed a regression analysis of PBM MAC rates versus acquisition costs (i.e. NADAC). To add context, 3 Axis also performed a regression analysis of the input and output prices within a different retail marketplace – retail gasoline stations. As shown in the chart on the left, retail gasoline prices (the “output” price) are strongly and tightly correlated to spot gasoline prices (the “input” price). Conversely, as shown in the chart on the right, retail pharmacies do not operate in a market with such certainty and predictability, instead having to contend with a highly scattered relationship between their input costs (i.e. acquisition costs) and their output revenue (i.e. PBM MAC rates).

US REGULAR ALL FORMULATIONS RETAIL GASOLINE PRICES
VS. US GULF COAST CONVENTIONAL GASOLINE REGULAR
SPOT PRICE FOB



GENERIC DRUG REVENUE PER UNIT VS. ACQUISITION
COST PER UNIT



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

²⁵⁵ See, e.g., *PCMA v. Rutledge*, 240 F.Supp.3d 951, 960-61 (E.D. Ark. 2017).

²⁵⁶ *Id.*

²⁵⁷ *Id.* at 960.

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’ 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

²⁵⁸ *Id.*

²⁵⁹ Eugene A. DePasquale, Bringing Transparency & Accountability to Drug Pricing (Dec. 11, 2018), https://www.paauditor.gov/Media/Default/Reports/RPT_PBMs_FINAL.pdf.

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 & Accountability to Drug Pricing (Dec. 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 & Accountability to Drug Pricing (Dec. 11, 2018), https://www.paauditor.gov/Media/Default/Reports/RPT_PBMs_FINAL.pdf.

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 five to ten 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

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

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.

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.*

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 transparency 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

²⁷⁶ *Id.*

²⁷⁷ *Id.*

²⁷⁸ *Id.*

²⁷⁹ Texas HHSC Report on PBMs in Medicaid, Revised September 30, 2019.

²⁸⁰ *Id.*

²⁸¹ *Id.*

²⁸² See, e.g., Eugene A. DePasquale, Bringing Transparency & Accountability to Drug Pricing (Dec. 11, 2018), https://www.paauditor.gov/Media/Default/Reports/RPT_PBMs_FINAL.pdf.

²⁸³ See, e.g., AR ST § 17-92-507(g).

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 (AWP) 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 pharmacy providers retroactively without their knowledge or consent (for example via retroactive contracts with the pharmacy providers’ PSAOs), but in

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, 3 Axis 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>

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 Dispensing 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

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 US 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 US Department of Justice Antitrust Division," December 12, 2018, accessible online: <https://www.justice.gov/atr/page/file/1142771/download>.

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) 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 AWP diverge from true generic acquisition costs.

²⁹³ See generally, 3 Axis 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>

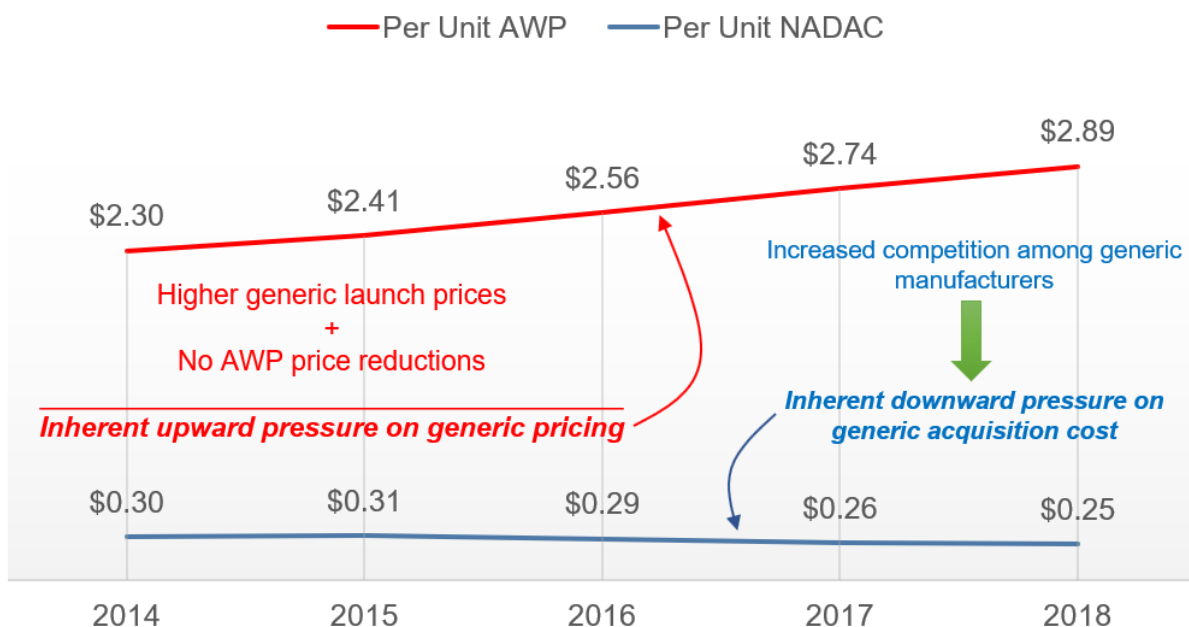
AWP is designed to *increase* over time, fooling payers in AWP discount contracts

Ultimately all GER/BER contracts are predicated on a discount to **Average Wholesale Price ("AWP")**. With so many payers believing that they are "protected" by guaranteed discounts off AWP, 3 Axis Advisors decided to evaluate AWP to see how valuable such guarantees really are.

To do so, 3 Axis calculated both the weighted average AWP and NADAC for Medicaid's mix of generic oral solid drugs. 3 Axis found that not only was AWP priced at a substantial premium to NADAC (11.6x higher in 2018), but AWP behaves the exact opposite of what one would expect for generic drugs. Generic drug prices are believed to **decrease** over time as manufacturer competition heats up and drives prices down. The blue line shows that this is happening for market-based acquisition costs (i.e. NADAC). Conversely, AWP's are designed to **increase** over time, driven by higher generic launch prices and the fact that generic manufacturers rarely ever bring down their unilaterally-set AWP's.

PBMs use this warped design of AWP to their benefit, luring clients into long-term contracts with steep AWP discounts and then collecting more money as aggregate AWP increases over time for generic drugs.

Medicaid Annual Weighted Average AWP vs. NADAC per Unit (Generic Oral Solids)



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 community 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’s²⁹⁹ and Indiana’s³⁰⁰ 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 law³⁰¹, requiring PBM pricing transparency and prohibiting below-cost reimbursement to pharmacies.

²⁹⁴ *See e.g.*, New York Cancer & Blood Specialists, “PBM Delays for Cancer Drugs May Risk Lives, Warn Oncologist,” 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

- 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.
 - 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 horizontal 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.