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OVERVIEW

Pharmacy Benefit Managers (PBMs) exert outsize influence over patients and pharmacies, yet are largely unregulated. The following pages will illustrate some of the abusive behaviors PBMs engage in so these corporations can be better understood, along with the need for legislative, regulatory, and legal remedies.

PBMs, are largely unrecognized by most beneficiaries (patients) and misunderstood by many employers and payors (including governmental entities and taxpayers), but they profoundly influence U.S. health care decision-making and drug spend. PBMs use this influence to increase their outlandish profits at the expense of patient care, local pharmacy access, and pharmaceutical innovation.

How much influence do PBM's have? In 2021, the top three PBMs controlled approximately 80% of the market.[1] CVS Caremark, the PBM owned by CVS Health, is the largest PBM in the U.S., accounting for nearly 33% of covered lives.[2] This significant market share allows CVS Caremark (as well as the other largest PBMs) to exercise undue market leverage and generate outsized profits for themselves. Furthermore, CVS owns health insurer Aetna.

PBMs determine which pharmacies will be included in a prescription drug plan's network. These networks often limit patient choice by excluding pharmacies that may be willing to accept the contractual terms. This may be acceptable to the PBMs, but not to the patients who rely on meaningful access. They also decide how much pharmacies will be paid for their services. Some incentivize plan sponsors to require plan beneficiaries to use a mail order pharmacy – often one owned and operated by the PBM – and their own retail pharmacies for certain medications. They also determine which medications will be covered by the plan, or plan formulary, and drug manufacturers often pay "rebates" to PBMs to get their drugs onto those formularies. While their role goes largely unnoticed, the nontransparent nature of the traditional PBM business model can often lead to patients paying more out of their pockets for their prescription medications.

PBM mistreatment of patients, pharmacies and payors (including taxpayers) can be broken down into broad categories, including:

1. Network Issues
2. Patient Issues
3. Pharmacy Anti-competitiveness
4. Reimbursement Issues
5. Coercive Contracting
6. Fraud, Waste and Abuse
7. Recent and Pending Litigation

1. www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html?m=1
2. According to CVS, it has 90 million PBM plan members. See CVS, available at cvshealth.com/about/facts-and-company-information. The Pharmaceutical Care Management Association testified that PBMs administer drug plans for more than 266 million Americans; see also Testimony of Mark Merritt, PCMA.

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NETWORK ISSUES

PBM issues affecting pharmacies and patients include preferred/restrictive networks and mandated use of PBM affiliated retail, mail-order, or specialty pharmacies. The purpose is to increase their profits by driving patients, regardless of their choice, to PBM owned or affiliated pharmacies and away from their competitors.

Preferred/Restrictive Networks
Many PBMS require their beneficiaries to use the pharmacy of the PBM's choice, not the pharmacy the beneficiary feels the most comfortable using or is most convenient for them. Community pharmacies or other pharmacies that are willing to accept the same terms and conditions of other pharmacies in the network are prohibited from participating in the network.

For example: A pharmacy in Virginia reported that their health plan changed their policy for maintenance medications for small group plans in the 3rd quarter of 2019. Patients are now required to obtain their medications through mail order or at CVS retail. This change occurred after Anthem switched from ESI to IngenioRx, which is operated by CVS. Due to this change, the pharmacy saw the patient out of pocket costs for Insulin grow from $0 to over $500 for patients continuing to use their pharmacy.

Mandatory use of PBM owned or affiliated pharmacy
Mandatory use of a PBM affiliate pharmacy is similar to restrictive networks. Even if a PBM does not have a restrictive network, it may still require patients to fill certain prescriptions at their own retail, mail order, or specialty pharmacy.

For example: Aetna/Caremark forced a patient in Connecticut to fill a 90-day supply of Symbicort at CVS pharmacy or CVS Caremark Mail Service Pharmacy. The patient would have to pay the full cost if he/she filled the prescription at the independent pharmacy of his/her choice.

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PATIENT HARMS

PBMs harm patients both directly and indirectly. PBM practices, like inflexible prior authorization requirements, gag orders on pharmacies, and DIR/ retroactive claim adjustments all directly affect the patient's health and wallet. PBM practices which cause pharmacy closures affect the patient as well by limiting convenient access to local pharmacist providers.

PBM Direct Impact on Patients
Stringent step therapy protocols, prior authorizations, gag orders on pharmacies, and retroactive claims adjustments all directly affect the patient. What is more, most of the time the patient is unaware of these hurdles affecting their care.

For example: CMS estimated that its 2018 proposed Part D rule, which included all pharmacy price concessions, or DIR fees, at the point of sale would reduce patient out-of-pocket costs by $9.2 billion over ten years even when factoring in the potential for increased premiums.8 For example, PBMs had long included "gag clauses" in their contracts with pharmacies, which prohibited pharmacies from disclosing cheaper alternatives to patients cheaper if they paid cash. Additionally, patients are paying more at the pharmacy counter than they should because PBMs often "claw back" pharmacy reimbursements and since the patient pays a copay based on the pre-clawback reimbursement, their copay should be based on the lowest payment to the pharmacy.

PBM Indirect Harm on Patients
Abusive PBM practices aimed at pharmacies also affect patients when pharmacies are forced to close.

For example: Between 2010 and 2018, the number of independent pharmacies decreased from 23,064 stores in 2010 to 21,767 stores in 2018. That's a decline of 1,297 stores, or roughly 6 percent. Low reimbursements and other practices that lead to pharmacy closures can have drastic negative effects on patients. A study by the Rural Policy Research Institute found that reimbursements under the cost of acquisition led to the closure of 1,231 independent pharmacies in rural areas between 2003 and 2018. As a result, 630 rural communities nationwide that had at least one retail pharmacy in 2003 had zero retail pharmacies in 2018.[3]

This also impacts patients in urban areas. Between 2009 and 2015, 1 in 8 pharmacies closed as a result of lower-than-cost reimbursements in the Medicaid and Medicare programs, disproportionately affecting independent pharmacies and low-income neighborhoods.[4]

3. Abiodun Salako, Fred Ullrich & Keith Mueller, Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018, RUPRI Center for Rural Health Policy Analysis, July 2018, Rural Policy Brief No. 2018-2, available at rupri.public-health.uiowa.edu/publications/policybriefs/2018/2018%20 Pharmacy%20Closures.pdf.
4. Jenny S. Guadamuz, G. Caleb Alexander, Shannon N. Zenk & Dima M. Qato, Assessment of Pharmacy Closures in the United States From 2009 Through 2015, JAMA Internal Medicine, Oct. 21, 2019, www.jamainternalmedicine.com.

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PHARMACY ANTI-COMPETITIVENESS

Pharmacy anti-competitiveness includes many issues. **PBMs are direct competitors of community pharmacies**, yet they get to determine how much the community pharmacy will get paid, which networks they can operate in, the types of medications and the duration of the supply that can be dispensed.

A system allowing dominant companies to dictate such terms to their smaller competitors is anti-competitive on its face. Unfortunately, the anti-competitiveness of the PBM pharmacy relationship has been exacerbated by the consolidation in the industry- due to vertical integration (i.e. Aetna, Caremark, CVS) and horizontal integration (i.e. merger of large PBMs such as the 2012 merger of Express Scripts and Medco).

Low reimbursements, retroactive claw backs, the use of patient information for steering, onerous audits, and mandating the use of their own pharmacies are just a few anti-competitive practices PBMs engage in every day.

It is clear that the ultimate purpose of these practices is to drive patients to their own pharmacies and enhance their profits at the expense of pharmacies and patients.

For example: A pharmacy shared a story of a PBM aggressively trying to recoup money for a prescription dispensed to a patient who goes by his middle name. The doctor wrote the prescription using only the middle name, but the PBM had him in their system with first and middle name. It was an onerous process for the pharmacy to prove that they dispensed the medication to the correct patient. While PBMs claim audits are used to detect fraud, waste, and abuse, examples show they recoup payments based on small clerical errors rather than focusing on whether the correct patient received the correct dosage of the correct medication on the correct date.

Additionally, NCPA received examples from pharmacists servicing military Tricare prescriptions. The PBM, Express Scripts, waited 5 years to recoup reimbursements for prescriptions dispensed in 2015 and for suspect reasons.

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REIMBURSEMENT ISSUES

Reimbursement issues remain the biggest threat to community pharmacy viability, thus one of the biggest threats to patient access.

Underwater reimbursement and non-transparent and outdated maximum allowable cost (MAC) lists, which reimbursements in most health plans and programs are based, remain two of the biggest problems.

Pharmacies are constantly reimbursed below drug acquisition cost and the cost to dispense regardless of the health plan or program.

Not only are pharmacies too often reimbursed below their cost at the time they fill a prescription, but they are also subject to retroactive claims reductions, or DIR fees, for prescriptions filled under Medicare. DIR fees are assessed weeks or even months after a prescription is filled. This practice further reduces reimbursements while providing little, if any, transparency, while straining pharmacy operations.

For example: One former pharmacy owner in Idaho reported that he served many patients in adult mental health homes who were on Invega Trinza. His reimbursement for that medication was reduced severely to where he was reimbursed $7,000 for a $7,500 medication. This bankrupted him and forced him out of pharmacy altogether.

Furthermore, a pharmacist in California provided an analysis of his DIR fees for the time periods of March-August 2019 as well as January-June 2020. The analysis demonstrated that while the pharmacy significantly improved their metrics to a rating of over 90% in all categories in 2020 compared to their raring in 2019, their DIR fees still increased.

Additionally, pushing pharmacists out of business seems to be a strategy for at least one PBM. Several pharmacies have indicated that they received solicitation letters from CVS Caremark offering to purchase their pharmacy after the PBM had slashed reimbursement rates

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COERCIVE CONTRACTING

Because pharmacies have essentially no competitive bargaining power when "negotiating" a contract with PBMs they are usually forced to accept all contract terms-even those terms that are unfair and arbitrary.

Considering three PBMs monopolize the marketplace and cover over 80% of insured lives, as a practical matter, a pharmacy cannot refuse a contract when potentially 30-50% of their patients would be covered by the contract (depending on the PBMs local market concentration).

These "take it or leave it" contracts are full of provisions that seem more anti-competitive in nature than for patient safety or program integrity. Many PBMs are superseding state boards of pharmacy by placing more stringent accreditation or certification requirements on pharmacies. When PBMs make decisions regarding who can practice and how they can practice, these decisions encroach and undermine the domain of the state board of pharmacy and restrict patient access to otherwise qualified pharmacists. Other examples of these arbitrary provisions include prohibition of community pharmacy delivery services, arbitration clauses that leave no other legal recourse, and prohibition of 90-day fills.

To compound matters, some PBMs require pharmacies to opt-out. That is, they will consider a pharmacy has agreed to the contract terms unless the pharmacy specifically opts out of the contract.

For example: A pharmacy owner is Pennsylvania noted that a large PBM faxed their contract which included opt-out language during the height of the COVID-19 pandemic. Due to the volume of faxes he was receiving, he initially missed the contract come through on his fax machine. He was fortunate, however, that he had heard about the contract, was able to locate it, and opt-out prior to the deadline.

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FRAUD, WASTE AND ABUSE

Opaque PBM practices negatively impact patients and community pharmacies, but they also contribute to ever-increasing prescription drug costs for plan sponsors and taxpayers.

Fraud, waste, and abuse perpetrated by PBMS can mean many things. PBMs do not compensate patients for overpayment of copays after they have clawed back pharmacy reimbursements. PBMs engage in "spread pricing" by reimbursing pharmacies less on a claim than the payor/employer/government paid the PBM for a claim. The PBM pockets that "spread" as a source of revenue-in addition to administration fees, rebates, and pharmacy claw backs.

However, one of the worst examples of waste is PBM mail order. PBMs will mandate that patients use mail order, and the PBM will continue to send medications and other medical supplies that far exceed the patient's need.

For example: Pharmacists continue to share stories for patients bringing boxes and boxes of unused medication and other supplies to pharmacies asking for help with disposal. These include one pharmacy that shared **a photo documenting over $284,000 worth of mail order waste** for specialty medications.

Another pharmacist documented **$27,000 worth of wasted medications for a single patient**.

In many instances, the patient is on a government funded health plan, which means taxpayers are funding unused medicine.

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LEGAL CASES SURROUNDING PBMS

PBMs are largely unregulated, yet many states have passed laws attempting to impose reasonable regulation and oversight over these corporations. Far too often, however, the PBMs legislative advances up in the courts. They often rely on the Employee Retirement Income Security Act (ERISA) to argue the states are powerless to act.

The Supreme Court of the United States on Dec. 10, 2020, issued a unanimous decision in *Rutledge v. PCMA*, No. 18-540 (www.supremecourt.gov/opinions/20pdf/18-540_m64o.pdf), holding that a federal law, the Employee Retirement Income Security Act of 1974 (ERISA), does not prevent states from enacting laws regulating the abusive payment practices of pharmacy benefit managers, the controversial middlemen that manage prescription drug benefits for health insurers, Medicare Part D drug plans, and large employers. The 8-0 decision (Justice Barrett did not participate) was a resounding victory for patients and community pharmacies, which have been fighting for years to regulate PBMs.

The Pharmaceutical Care Management Association, the lobbying arm of the PBM industry, had argued that ERISA preempts Act 900, an Arkansas law that includes rate regulation and enforcement provisions to ensure that PBMs compensate pharmacists fairly for the medications they dispense to patients. The Court rejected PCMA's arguments and found there was no federal preemption when states are regulating pricing and rates.

It is not surprising that nearly every state — red and blue — has enacted laws regulating PBMs. It is also why the federal government and nearly every state — from Texas to California — argued in defense of Arkansas' law in the Supreme Court. PBMs are middlemen who have secretly put their own interests and record-breaking profits above the patients and plans that they are supposed to serve. The Supreme Court cleared the way for state laws like Arkansas to police PBMs' abusive behavior and protect patient access to affordable medications. This is a historic victory for pharmacists and their patients.

There are other cases making their way through the courts in which PBMs are making the same ERISA preemption argument. In *PCMA v. Wilke* (formerly *PCMA v. Tufte*), the Eighth Circuit court of appeals, the same court that invalidated the Arkansas PBM statute, ruled that a North Dakota PBM law was invalid due to ERISA. The Supreme Court has remanded the North Dakota case back to the Eight Circuit for reconsideration in light of their decision in the *Rutledge* case.

However, the case of *PCMA v. Mulready* that relates to a PBM regulation statute in Oklahoma is pending in the Tenth Circuit. A district court has ruled that the state of Oklahoma can enforce the law while it makes it is pending in court. PCMA has filed an appeal with the Tenth Circuit, which was denied.

ERISA is the crutch the PBMs lean on to try to invalidate state laws. The ruling by the Supreme Court in *Rutledge v. PCMA* has greatly chipped away at the PBM "ERISA excuse" and will create opportunities in the states to further regulate PBMs-both through enforcement of existing statutes and passage of new legislation.