PHARMACISTS UNITED FOR TRUTH AND TRANSPARENCY

COMPOUNDED PROBLEMS:

How Pharmacy Benefit Manager Practices Drive Up Drug Costs, Drive Out Pharmacy Providers and Decrease Patient Access to Care

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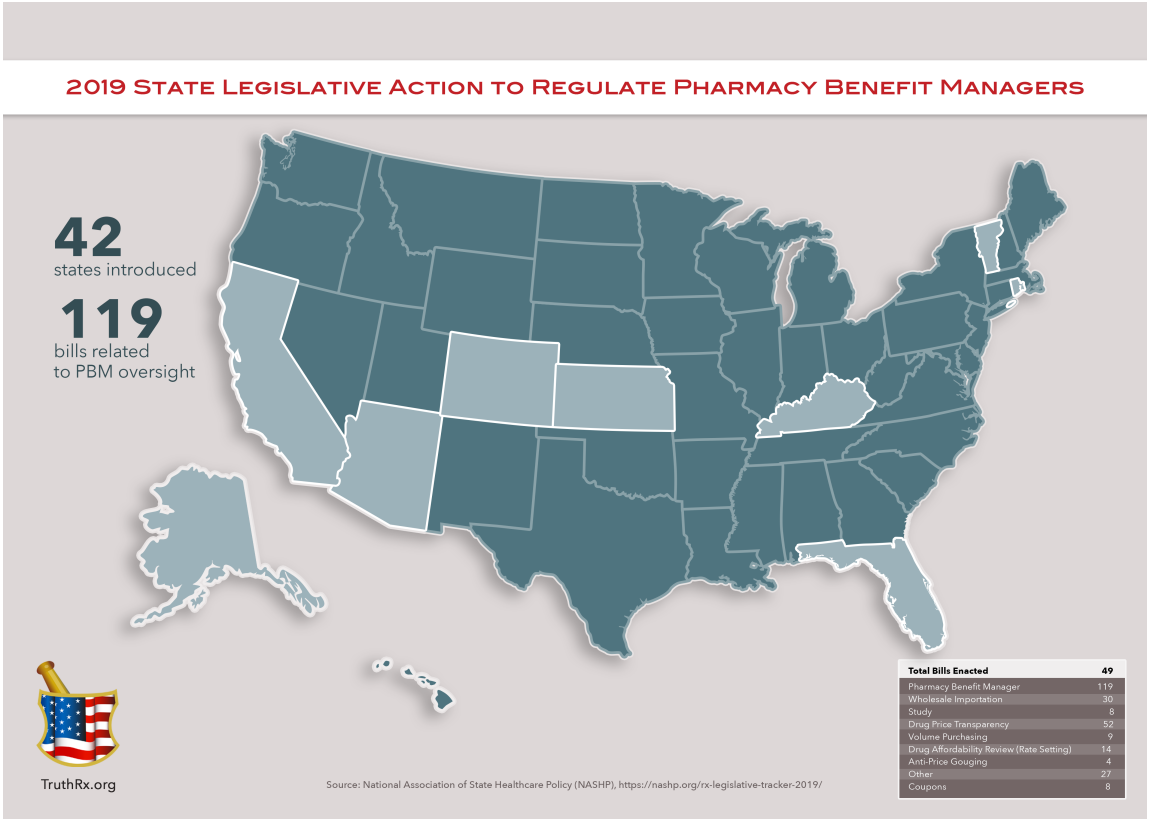


EXECUTIVE SUMMARY

They pose as the "good guys", promising to lower costs and increase savings at the pharmacy counter. They use slick, multi-million dollar branding campaigns and dubious statistics to position themselves as "community health hubs" and "on your side" but the reality of pharmacy benefit managers (PBMs) is they are neither good nor are they on anyone's side but their own.

From their humble beginnings as third-party prescription drug processors in the 1970s to their late self-appointed roles as "benefits plan designers" and drug manufacturer "negotiators", PBMs have turned a once straightforward aspect of the healthcare system into an opaque scheme so totally compounded with complexity that even the most gifted industry analysts can't seem to figure out what's happening.

PBMs sit at the center of the prescription drug supply chain, profiting at nearly every stage. To understand how the high drug pricing crisis can be resolved, we must first understand the role of PBM practices, and how these practices drive up drug prices while concurrently driving out pharmacies and limiting patient access to care and medication.

THE PRESCRIPTION DRUG MARKETPLACE AT A GLANCE

Most Americans think the prescription drug market is comprised of only a few players: the drug manufacturer, the pharmacy, the health plan, and the patient. In reality, there are several players in a system that has morphed into a tightly-controlled oligopoly. Among the key market players:

The drug manufacturers **-** Responsible for research and development of new medications and improvement of existing medications. Consumer demand for drugs that work faster/better/with fewer side effects and their expectation that manufacturers find cures for still-uncured life-threatening diseases like cancer and multiple sclerosis keeps the pressure on drugmakers to constantly innovate and find markets for newly-developed drugs..

The insurance payer/health plan sponsors - Employers who are self-insured and therefore subject to oversight under the Employee Retirement Income Securities Act (ERISA), state and federal governments who sponsor Medicaid and Medicare, large commercial plans offered by corporate insurers like Cigna and UnitedHealth. These are the entities who comprise health plan payers/sponsors and are likely being taken advantage of by PBM opacity and lack of regulation.

The pharmacy **-** the only access point for patients to fill prescriptions, pharmacies are responsible for dispensing medication, counseling patients and monitoring patient progress in partnership with the patient's physician. Pharmacies depend on health plan contracts in order to have patients to serve, but health plan contracts generally come with "take it or leave it" terms that are ultimately unfavorable to pharmacies and their patients.

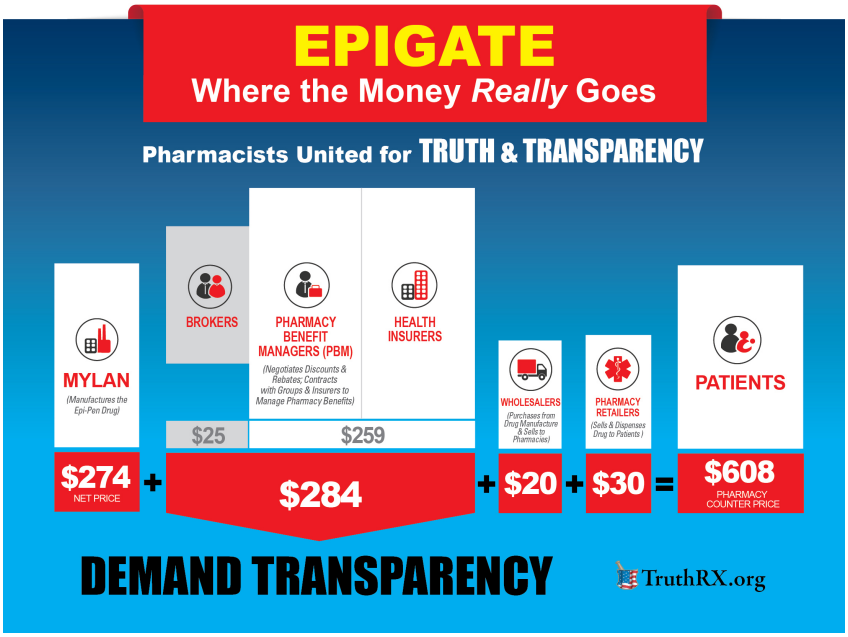
The PBM - the architect of the patient's benefits plan, the adjudicator of pharmacy claims and the pharmacy reimburser, the entity that bills the health plan for services rendered, the decision maker for what drugs are included on the formulary, the intermediary between the patient and the physician/hospital and often the decider of the patient's medications. PBMs wield enormous power and daily make decisions from their corporate offices that have long term implications on a patient's health or life. PBMs are not trained in medicine, and do not take the same oath of care as do doctors and pharmacists.

There are other entities in the prescription drug marketplace, including wholesale drug distributors, pharmacy services administrative organizations (PSAOs), the Food and Drug Administration and the Centers for Medicaid and Medicare (CMS) but for the purpose of brevity, the focus of this white paper will remain on the relationship between the above-listed players.

PBMS: HOW THEY WORK, WHY THEY ARE AT THE CENTER OF THE CONTROVERSY

Until 2016, when a group of mothers fed up with the high cost of the EpiPen took their case to social media, almost nothing was known about how drugs were priced and no one knew of the presence or roles of the shadowy PBM middlemen. In Congressional testimony, Heather Bresch, CEO of Epipen manufacturer Mylan, put PBMs front and center with her explanation of how the rebates her company was required to provide in order to be included on drug plan formularies was actually driving the cost of an EpiPen from $203 per two-pack to $603 per 2-pack. [1]

Figure 1



Most people only know PBMs by the prescription drug coverage card they carry in their wallet, and even then they mostly know the "Big 3" PBMs: CVS Caremark, OptumRx, and Express Scripts. Together these 3 PBMs hold more than 80% of the prescription drug coverage market - meaning of all the prescription drugs processed through insurance, more than 80% go through CVS Caremark, OptumRx or Express Scripts.

Further, OptumRx is owned by UnitedHealth Group, who at #6 on the Fortune 500 is the largest health insurer in the U.S, just barely outranking #8 CVS Health, who owns Caremark. Formerly ranked #23 on the Fortune 500, Express Scripts now ranks #65 - just below #61 Pfizer, the largest drug manufacturer in the U.S.

Like most PBMs, the "Big 3" position themselves as benefits plan designers and prescription cost containers but they are, in fact, buyers and resellers of prescription drugs who cut deals with prescription drug wholesalers like McKesson (#7 on the Fortune 500). Then, in the name of "cost savings" these PBMs steer patients to their own pharmacies using financial incentives and misleading "updates" - marketing tactics that they bar other pharmacies on the provider network from using. This results in the squeezing out of local pharmacies, by essentially cutting them off from their patients.

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[1] C-SPAN "EpiPen Price Increase" hearing 9.21.16 https://cs.pn/2cKiulj

FOX, MEET HENHOUSE:

PBM PRACTICES THAT DRIVE UP DRUG COSTS AND DRIVE OUT COMPETITION

A profound lack of oversight at the state and federal level has resulted in PBM self-governance and a plethora of practices that exploit nearly every aspect of the prescription drug market and turn even the most basic business processes into PBM revenue-generation streams. These practices include:

EXCESSIVE SPREAD PRICING

Defined as the difference between what the PBM reimburses the pharmacy for dispensing a particular drug and what it charges the health plan for that same drug, PBM spread pricing made national headlines late last year when the State of Ohio unhappily discovered it had paid its Medicaid-contracted PBM some $225 million over the cost of Medicaid-covered prescriptions. Investigations in Arkansas, Pennsylvania, New York, Michigan, and Illinois yielded similar results, with New York showing an eye-popping $300 million per year spent on just the spread. [2] According to the Congressional Budget Office, upon reviewing S. 1895 (Lower Healthcare Costs Act), U.S. taxpayers could save $5.2 billion per year if PBM spread were eliminated.[3]

NEGOTIATING AND KEEPING MANUFACTURER REBATES

In what can best be described as a reverse-bid "pay-to-play" system, PBMs negotiate manufacturer rebates for themselves and use those rebates to determine which drugs will be covered on formulary. Some rebates even guarantee a drug's exclusivity in a given category on formulary.[4]

Rebates may be passed in part or whole on to the Health Plan payer, who is usually the insurance company/corporate parent of the PBM, but could be passed on to the state or federal government where Medicaid or Medicare claims are concerned. In absolutely no case are rebates passed on to the patient, who buys and consumes the medication. The practice of negotiating and keeping rebates robs American patients of crucial cost savings at the pharmacy counter and keeps drug costs artificially inflated. Someone has to absorb the rebate cost, and that someone will either be the patient or the pharmacy.

Rebates comprise such a significant percentage PBM revenue that the mere threat of losing rebates has resulted in contract updates two pharmacies stating any changes to the law will result in changes to pharmacy reimbursement models.[5]

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[2] 3AxisAdvisors.com https://bit.ly/2yr2tuQ

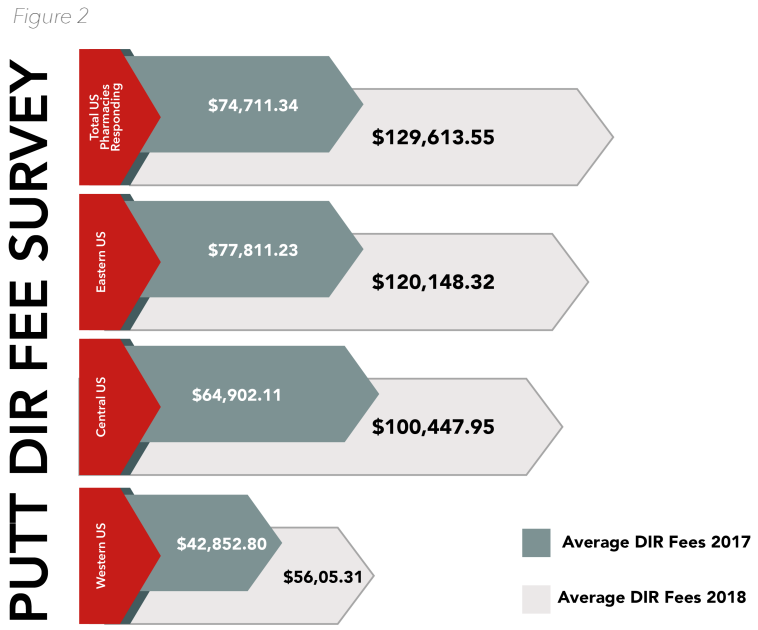
[3] Congressional Budget Office July 16, 2019 https://www.cbo.gov/system/files/2019-07/s1895_0.pdf

[4] House Energy and Commerce Hearing on Insulin, 4.10.19 https://bit.ly/2YQOkDt

[5] Aetna Pharmacy Contract update, January 2019

DIRECT AND INDIRECT REMUNERATION (DIR) AND OTHER FEES

Figure 2



PBMs collect fees from nearly every participant in the prescription drug supply chain: rebates from manufacturers; copayments from patients; administrative fees from health plan payers and fees collected from pharmacies for everything else.

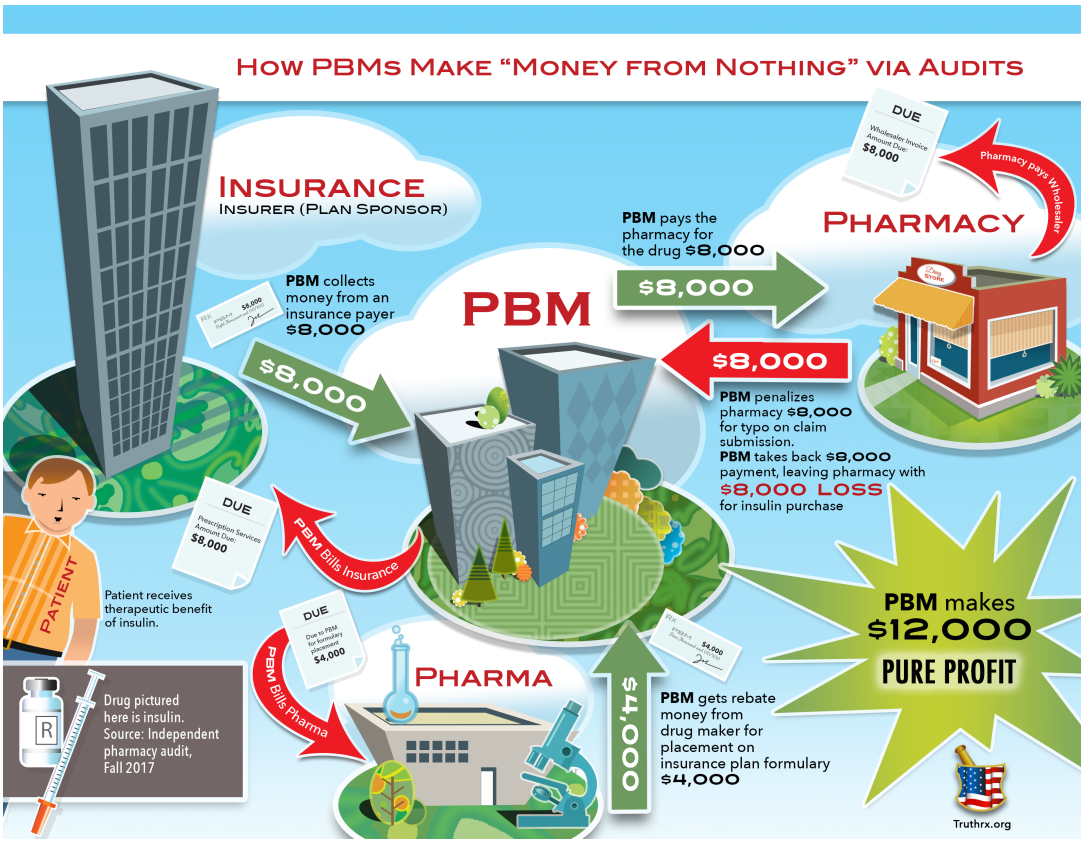
More than any other participant in the market, pharmacies are subject to every imaginable PBM fee in a kind of "company store" set up. Pharmacies must pay to submit claims for reimbursement; if the claim is rejected they must pay again to resubmit. There are PBM fees for claims appeals. Fees for network participation. Fees for PBM-required "certifications". And then there's Direct and Indirect Remuneration (DIR) fees - fees collected from pharmacies under Medicare Part D that are supposedly used to help lower healthcare costs for Medicare enrollees. In 2017, independent pharmacies paid average per-store DIR fees of $74,711. In 2018 independent pharmacies paid average per-store DIR fees of $129,614 - a 73% increase in one year. Because PBM transparency is not legally mandated, it is unclear what percentage of DIR fees collected are returned to CMS and what percentage is pocketed by PBMs for "services rendered."

ABUSIVE AUDIT PRACTICES

Excessive audits. Audits scheduled for the beginning or end of the month, typically the busiest time for pharmacies. Extreme fines and penalties for seemingly small errors including typos. Demands to prepare and submit to audits but no requirement for the auditor - the PBM - to report audit findings within a reasonable time frame back to the pharmacy. These are just a few of the practices pharmacies must endure as members of a PBM pharmacy network in order to have patients to serve. Often pharmacies are subject to stiff financial penalties for errors, without justification for why the fines are so steep. Figure 3 depicts the true story of a local pharmacy that was fined $8000 for a typo on a submission claim, and how the PBM netted a $12,000 gain as a result of the audit. This is but one example of how PBMs use fear and intimidation tactics to control pharmacies and generate additional revenue.

PATIENT STEERING & PHARMACY OWNERSHIP

Figure 3



The largest PBMs own pharmacies. CVS owns more than 9000 retail brick-and-mortar locations in the U.S. in addition to "specialty" and mail order pharmacies while Express Scripts owns specialty and mail order pharmacies. The obvious conflict of interest of a pharmacy benefits plan designer also owning pharmacies that compete with its network of pharmacy providers aside, PBMs engage in practices that are clear examples of patient steering and violation of the so-called "firewall" they claim exists between the patient management side of the firewall and the pharmacies who fill patient prescriptions.

WHAT PBMS SAY ABOUT THEIR BUSINESS

"How does $941 per person per year sound?" This was a tagline in a recent campaign initiated by the PBM lobbying organization Pharmaceutical Care Management Association (PCMA).[6] And while an average $941 per person per year sounds like "good" savings, the question most health plan payers fail to ask is "$941 per person per year as compared to what?"

Pharmacists United for Truth and Transparency, a national advocacy organization and PBM "watchdog" conducted a study of patient copayments for a 30-day supply of commonly prescribed drugs in 26 states of a federal employee benefits plan by CVS Caremark.[7] Results consistently showed the following:

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[6] PCMA.net "On Your Rx Side" campaign

[7] Pharmacists United for Truth and Transparency (PUTT), federal employee health plan study, Fall 2018.

Patient cost share was often 8-9 times less at an independent or community pharmacy than a PBM-owned retail pharmacy like CVS or a "big box" chain store like Walmart.

PBM mail-order pharmacy charged patients $10/month for a 30-day supply when the same medication was available at an independent pharmacy for less than $2 for the same prescription.

PBM "specialty" pharmacy often charged patients and their health plans several hundred, if not thousands, more for a so-called "specialty" medication than the same medicine would have cost if purchased at their neighborhood pharmacy.

How does an average $941 per person per year sound? Not as good when patients and their health plans realize they are paying PBMs $6,600 on Imatinib (a cancer medication) that could be purchased for $450 at their local pharmacy or paying their PBM $1,200 for Atazanavir (HIV medication) that could be purchased for $560 at their local pharmacy. This is PBM spread pricing in action, every day, on hundreds of life-saving drugs patients need.[8]

STATE-LEVEL ATTEMPTS TO REGULATE PBMS

In 2019, 42 states introduced 119 bills related to PBM oversight[9] in response to concerns from pharmacists and pharmacy owners over PBM practices. Bills of note in 2019 include:

New Jersey, A3717/S728 - outlaws the PBM practice of "clawing back" from pharmacies any retroactive fees that were previously undisclosed at the time of claim submission.

New York S6531/A8938a - requires greater transparency between PBMs and the patients and health plan clients, including disclosure of spread pricing and any rebates, discounts, clawbacks or other fees PBMs receive; also allows patients and pharmacies to directly sue PBMs in the event of harm as a result of PBM policy.

Louisiana SB41 - defines scope of PBM authority and fair trade practices; establishes the Attorney General, state Board of Pharmacy and Department of Insurance as regulatory bodies over PBMs; provides patients and pharmacies with a defined channel for complaints and assurance of action and oversight by the regulating body.

Georgia HB233 - pharmacy anti-steering and transparency act prohibiting the trade practice by PBMs of steering patients to their own pharmacies by outlawing the

[8] PUTT, from local school board study April 2019.

[9] National Association of State Healthcare Policy, 2019 Legislative Tracker https://bit.ly/2McLRNz

sharing of patient information between PBMs and their own pharmacies, among other practices.

New Mexico SB415 - prohibits PBMs from charging transaction fees including fees for submitting claims, fees for receipt and processing of a claim, fees for participation in PBM network or any other fees for service unless otherwise specified in the PBM-pharmacy contract.

In short, there is precedent for states to demand and receive greater accountability and transparency from PBMs in the matter of how drug benefits plans are designed, administered and paid for, and for practices related to how and from whom PBMs generate their greatest revenue streams.

CONCLUSION

The current "state of the union" with regard to healthcare is this: medication costs are skyrocketing, local pharmacies are closing at a rate of nearly 200 per year, and "pharmacy deserts" are developing in small and rural communities leaving patients with fewer options and less access to care.[10]

Regulatory oversight, transparency and laws that create a fair and equitable working environment for all players in the prescription drug marketplace will go a long way toward restoring sanity to the currently insane system. It is for this reason we call on state and the federal government to pass laws that protect patient access to their pharmacies and healthcare providers by demanding oversight and accountability of PBMs.

[10] National Community Pharmacists Association, 2015 survey. NCPAnet.org