



The Economic Costs of Pharmacy Benefit Managers: A Review of the Literature

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Executive Summary

This literature review surveys studies that have examined the impact from PBMs on patients and the overall pharmaceutical market. In summary, these studies have found that, due to the current regulatory inefficiencies, PBMs:

- Create pricing uncertainty by incentivizing higher list prices for medicines that enable large rebates and discounts (which are particularly valuable for PBMs);
- The large discrepancy between list prices and transaction prices cause higher patient co-pays than necessary (co-pays typically depend on list prices);
- For Medicare Part D patients, the higher list prices and higher co-pays can push patients into the coverage gap (donut hole) faster;
- Impose large, and often unknown, fees that create substantial revenue uncertainty and volatility, which are particularly problematic for small, long-term care, and specialty pharmacies;
- Increase PBMs' share of the gross expenditures at the expense of pharmacies and manufacturers; and,
- Through control of the drug formularies, impose undue influence on the medicines patients can access.

Introduction

Only Lewis Carroll could appreciate how pharmaceuticals are currently priced in the U.S. Unfortunately, as the pricing process continues to grow *curiouser and curiouser*, the costs being imposed on patients and the health care system continues to worsen.

These large costs arise because the regulatory environment is plagued with adverse market incentives. The current adverse incentives for pharmacy benefit managers (PBMs) – the middlemen who process prescription transactions, negotiate drug discounts, and manage the drug formularies for health plans – exemplify these problems.

The role of PBMs is to “aggregate the buying power of health plans and employer groups by negotiating discounted purchase prices with retail pharmacies, purchasing drugs at discounted prices for delivery by mail, and separately securing rebates on brand pharmaceuticals from manufacturers.”¹ These negotiated discounts and rebates lower the actual transaction prices relative to the list prices.

In practice, the large gap between the list prices for drugs and the actual transaction prices creates an opaque and complicated pricing environment. From the PBMs' perspective, the greater market complexity created by the less transparent pricing environment makes it easier to earn higher profits. It also, however, makes PBMs' business operations more complicated. For instance, “according to an industry

auditor frequently hired by health plans to audit their PBMs' performance, in more than 400 audits 'we have never found a single situation where something wasn't wrong.'²

From a health system perspective, this dizzying pricing environment distorts the pharmaceutical market to the detriment of patients, pharmacies, manufacturers, and payers. Due to their government sponsored "near-monopoly" position, PBMs can charge fees that are high and retrospective. The retrospective fees, such as the direct and indirect remuneration fees (DIR), are particularly problematic as they "claw back" revenues from pharmacies based on sales that were made months earlier. Consequently, unlike a typical transaction, many pharmacies will not know how much revenue they earned from the sale of a drug until months after the transaction has been completed.

High fixed costs and large bureaucracies are typically more burdensome on smaller businesses.

High fixed costs and large bureaucracies are typically more burdensome on smaller businesses. This is the case with respect to the costs PBMs impose on small family-owned pharmacies, specialty pharmacies (pharmacies that provide comprehensive services, such as enhanced consultation services, for chronic patients), and long-term care pharmacies. Due to the bureaucracy, high fees, and retroactive claw back provisions that PBMs create, these pharmacies often lose the ability to effectively compete.

Perhaps worse, patient care suffers as smaller pharmacies, specialty pharmacies, and long-term care pharmacies find it more difficult to serve their customers, or even stay in business.³ For instance, according to a survey conducted by the National Community Pharmacists Association, "almost 87 percent of respondents reported that PBM auditing practices have a significant to very significant impact on respondents' ability to provide patient care and remain in business, which can lead to decreased access to care."⁴

Patients are also harmed because the current payment structure disenfranchises patients by removing their input from most of the major decisions regarding the drug's costs and availability. Patients have become passive spectators in a market where their interests should be the driving factor.

While many of the perverse outcomes in the health care market are due to the ineffectual regulatory environment, with respect to PBMs, a growing body of literature is emerging that illustrates PBMs are exploiting the regulatory environment and creating many adverse trends. Since the regulatory environment is the enabler of these adverse outcomes, effective reforms can eliminate them.

When the market is working efficiently, PBMs reduce operating costs in the pharmaceutical market by creating economies of scale and negotiating better pricing on drugs through bulk purchases. The goal of reforms should be to establish a regulatory environment that does not overly empower PBMs, but enables these organizations to perform the middleman functions that manufacturers, pharmacies, payers, and patients will value.

Pressure for legislative reforms that would address these flaws has been building. For instance, S.637 (the Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act of 2017) in the current Congress would promote greater pricing transparency of PBMs for the Medicare Part D program.⁵ Broader payment reforms are necessary, however, to further improve the cost environment and empower patients.

Impact from PBMs on costs and prices

Most of the reviewed studies examined found that PBMs are having an adverse impact on the overall costs and prices of pharmaceuticals, and encourage an overly-complicated pricing structure. In contrast to most markets, where the final consumer expenditures conclude the transaction, due to PBMs, the pharmaceutical market contains even more transactions. As summarized by the Berkeley Research Group (BRG), “the purchase price of a prescription drug can ultimately be distilled into three types of transactions: initial gross expenditures on prescription drugs made by patients and their health plans (both public and private), payments and discounts along the supply chain, and retrospective rebates.”⁶

As documented in several studies, due to the growth in the latter two transactions (payments and discounts along the supply chain, and retrospective rebates) PBMs have been able to grow their share of total pharmaceutical expenditures at the expense of pharmacies and manufacturers.

With respect to the profitability of PBMs, the rebates from manufacturers are particularly important. As noted by Meador (2011):

While exacting deep discounts from pharmacies helps PBMs to cut costs by sharing in the discounts with plan sponsors, the real money is made through rebates from drug manufacturers. Manufacturers will offer rebates to PBMs based on how much the PBM increases the manufacturer’s market share for a given drug. The catch is that the PBMs are not required to share information about these rebates with plan sponsors, and in the vast majority of cases do not. Instead, they pocket some or all of the money saved.⁷

This lack of pricing transparency has enabled the middlemen to significantly increase their share of the revenues relative to manufacturers and pharmacies. For instance, the aforementioned BRG study documented the total pharmaceutical expenditures in 2013 through 2015 by the type of transaction.

The expenditures devoted toward “the payments and discounts along the supply chain” and the “retrospective rebates” accounted for 30.5 percent of the \$349.1 billion in gross expenditures on branded pharmaceuticals, or \$106.4 billion.⁸ The total amount of revenues branded manufacturers received in 2015 was \$218.6 billion, or 62.6 percent of gross expenditures on branded pharmaceuticals. The difference was earned by wholesalers and retailers.⁹ Overall, nearly one-third of the total expenditures on branded pharmaceuticals were, in some way, rebated back to PBMs and payers in 2015.

Moreover, these expenditures on discounts and rebates are growing relative to all other expenditures. Between 2013 and 2015, the share of the gross branded drug expenditures from fees, retrospective rebates, and discounts grew 5.2 percentage points, more than offsetting the 4.4 percentage point decline in the manufacturers’ share.¹⁰ These numbers indicate that PBMs’ share of revenues rose at the expense of the manufacturers that produce the drugs for consumers, and the pharmacies that dispense the drugs to consumers.

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The growing share of expenditures received by PBMs is consistent with their consolidating market power as documented by Frier Levitt, LLC (2017).¹¹ Sustained market power is seldom durable without govern-

ment support. And, this is the case with PBMs. In the case of PBMs, by leveraging the complex health care regulations, PBMs have been able to establish undue market power over other industry participants. The increasing consolidation and integration of PBMs has enabled,

these companies [to use] their immense market share to design a variety of business tactics aimed at gaining additional profits, reducing amounts paid to pharmacy providers, and driving prescription volume to the PBMs' wholly-owned pharmacies. These include mandatory mail order for maintenance medications (in which patients are denied a choice of pharmacy and forced to receive drugs from the PBM's wholly-owned mail order pharmacy), arbitrary exclusion of specialty pharmacies from PBM networks, and below-acquisition cost reimbursement. Altogether, PBM business tactics make it nearly impossible for pharmacy providers to stay viable.¹²

These concerns were also substantiated in a January 2017 report from the Centers for Medicare & Medicaid Services (CMS).¹³ The CMS report found that the rebates that drug companies pay are growing, but it is the PBMs that are benefiting. Particularly troubling, the CMS noted that “beneficiaries’ cost-sharing is calculated based on the drug price at the point-of-sale, without regard to rebates and other price concessions received after the point-of-sale. Therefore, while DIR may hold down total program expenses (and beneficiary premiums), it does not reduce the cost of drugs for beneficiaries at the point-of-sale.”¹⁴

PBMs, by encouraging high list prices, but large offsetting discounts, are, consequently, costing patients more money in higher than necessary co-pays every time they purchase their medications. This adverse impact on patients was also noted by Dr. Scott Gottlieb (who is the nominee to head the FDA as of this writing). According to Dr. Gottlieb, the rebates “don’t necessarily help offset the costs paid by those who need a particular drug. The rebates eventually make their way back to health plans to help offset the collective costs of premiums. But if a patient needs a particular drug, they will increasingly find that they are paying the full, negotiated price at the pharmacy counter. They never see the real “net” price, after the rebate is applied much later. The rebate is paid to the health plan, not the patient buying the drug.”¹⁵

Therefore, due to the opaque pricing structure for pharmaceuticals that PBMs enable, the costs paid by patients are based on prices that are significantly higher than the actual transactions prices. This unnecessarily increases out of pocket costs for all patients, and pushes Medicare beneficiaries into the coverage gap (also referred to as the donut hole) more quickly. In 2017, the coverage gap is \$3,700 of spending on covered drugs – indicating that once a patient breaches this gap they are responsible for all of their drug expenditures until they reach the out-of-pocket spending limit (\$4,950 as of 2017).¹⁶ A more transparent pricing structure would reduce these costs, saving patients money.

The fees and rebates also negatively impact pharmacies. Examining the impact on pharmacies from the DIR fees charged by PBMs, Frier Levitt, LLC (2017) found that with respect to Medicare Part D program,

while different iterations of DIR have existed in PBM contracts for some time, it was not until late-2015, early-2016, that PBMs began unilaterally modifying existing provider agreements with pharmacy providers to include their own version of DIR Fees. Medicare Part D provider agreements are often “contracts of adhesion,” where pharmacy providers are either forced to accept the PBM’s terms and conditions—which PBMs are free to modify at any time—or to discontinue participation in the PBM’s network....It is against this backdrop of consolidation and contract leverage that PBMs have begun retracting or

“clawing back” millions of dollars from pharmacy providers in a variety of fashions, all under the umbrella of DIR Fees. These PBM-imposed DIR Fees on pharmacy providers can include “pay-to-play” preferred pharmacy networks under Medicare Part D; payment reconciliations or “true ups” based on guaranteed contracted rates; payment adjustments based on fulfillment of performance or quality metrics; or a combination of the above.¹⁷

More broadly, the DIR fees are often flat fees that are imposed retroactively. This combination creates a large, and uncertain, burden on pharmacies (particularly smaller pharmacies that lack the cashflow and negotiation leverage), significantly disrupting their ability to operate.

Beyond raising prices, there is mounting evidence that PBMs price drugs arbitrarily. An analysis by Avalere Health found wide variation under Medicare Part D in generic drug prices sold on the same day, depending upon the payer (e.g. PBM).¹⁸

Impact from PBMs on service and competition

As opposed to focusing on the impact from PBMs on prices and expenditures, other studies have examined the impact from the current structure on quality of services. Here too, the studies have linked the incentives of PBMs to an adverse market outcome.

For example, long term care pharmacies are organizations that specialize in serving the estimated “two million seniors in America’s skilled nursing facilities...and assisted living facilities.”¹⁹ Long term care pharmacies will argue that they are better positioned to serve the unique needs of these patients, who require large numbers of medications, often with precise dosing requirements. Whether long term care pharmacies add value should depend upon their ability to serve this complicated population more effectively than other pharmacy options.

However, as Avalere Health documented, the pricing volatility, fees, and claw back provisions that PBMs impose are particularly burdensome on long term care pharmacies. The higher costs and revenue volatility cause long term care pharmacies to lose money on more than 60 percent of the generic medicines subject to the MAC pricing methodology they sell.²⁰ These competitive disadvantages create unnecessary obstacles for long term care pharmacies.

Studies have documented that most other industry participants face additional costs due to the current pricing environment, with the small pharmacies, arguably, being hurt the most.

Studies have documented that most other industry participants face additional costs due to the current pricing environment, with the small pharmacies, arguably, being hurt the most. For instance, a 2015 study by Applied Policy found that “the experiences of both CMS and large employers illustrate the difficulties that even large purchasers, including the federal government, can have in fully evaluating PBM contracts, even those contracts that are supposed to be transparent.”²¹ These extra difficulties manifest themselves in higher costs and reduced quality.

The bureaucratic fee structures create additional problems for specialty pharmacies, whose operations are often inconsistent with the rigid fee structures. As documented by the *Specialty Pharmacy Times*,

Typically, performance-based DIR fees are based on a pharmacy's performance in different quality metric categories established by the PBM. These categories are weighted, with some weighing as much as 25 percent and others as little as 5 percent. Some of the categories include ACE/ARB adherence, statin adherence, diabetes adherence, Comprehensive Medication Review completion rate, and formulary compliance.

Performance within these categories determines the amount of DIR fees against a pharmacy, with lower performing pharmacies assessed a higher percentage-based DIR fee, whereas better performing pharmacies receive lower DIR fees. Performance-based DIR fees can be flat-fee-based or percentage-based.

Generally, each pharmacy will be assessed for DIR fees based on these fixed quality metric categories, regardless of whether the pharmacies have a claim subject to the reporting and measurement criteria, according to the authors. This means *specialty pharmacies will be judged by select PBMs using the same set of quality metric categories, even if the business model of specialty pharmacies renders the categories virtually inapplicable.*²²

Other studies have focused on the PBM constructed formularies, or the list of drugs that are covered, finding that the resulting co-pays on those drugs can incent anti-competitive and anti-patient outcomes. For example, Meador (2011) described,

the most common type of formulary [as] a three-tier plan, used by 67.2 percent of employers that hire PBMs. The first tier is for generic drugs and has the lowest co-pay, while the second and third tiers are for preferred and non-preferred brand-name drugs, respectively. The second tier, preferred brand-name drugs, is largely comprised of drugs for which PBMs receive the deepest rebates from drug manufacturers for increasing their market share. The third tier, non-preferred brand-name drugs, has the highest co-pays.²³

Since the drugs with the deepest rebates are not necessarily the most appropriate drug, nor the more cost-effective drug, the formulary tiers introduce a large potential for inefficiencies and excessive costs into the pharmaceutical market. The restrictive formularies can also lead to other perverse outcomes. For instance, Pociask (2017) noted that,

there are many cases where generic drug prices are lower than plan deductibles. Because some plan beneficiaries do not know this and pharmacists are not permitted to disclose this information under their agreements with PBMs, consumers are paying more than they should under their plans. The practice is called claw backs, and it's just one of several ways that some PBMs are increasing drug costs...²⁴

The purpose of a competitive marketplace is to reduce informational obstructions, and eliminate these types of perverse outcomes. However, the current market structure prevents pharmacists and other medical professionals from communicating this type of information to patients.

PBM policies have also been linked to limitations on patient services that can lead to reductions in the quality of medical care. Specifically, Frier Levitt (2016) documented that,

physician dispensing has been a critical part of the American healthcare system for decades, and dispensing physician practices have participated as in-network providers for various Medicare Part D pharmacy networks since the implementation of the Medicare

Part D program in 2006. There is good reason for this. Receiving medication directly from a patient's treating physician has been routinely proven to increase adherence, ensure timely receipt of medication, and improve patient health outcomes . . .

Despite the many positive benefits of physician dispensing, and the proven outcomes data highlighting the importance of the practice within the American healthcare system, pharmacy benefits managers ("PBMs") have begun a disturbing trend of systematically and surgically limiting access by patients to continue to obtain their outpatient medications from their dispensing physicians. Through a variety of mechanisms, PBMs have embarked on an increasing trend of limiting patient access to specialty drugs, by shifting the dispensing of these drugs to mail order pharmacies owned or associated with PBMs, despite the deleterious effects this has on patient care and access.²⁵

By causing limitations on medical services, such as the availability of oncology medications through a physician's practice, PBMs not only reduce the value added from current medical services as documented by Frier Levitt (2016), they also discourage potential innovations from being introduced.

Conclusion: Proposals needed to create greater market transparency

The studies reviewed above have connected the opaque and complicated pharmaceutical pricing structure to several adverse outcomes that are evident in the market. The best way to address these problems is to create greater transparency, and to simplify the pricing structure, with the goal of empowering greater competition.

Pociask (2017) suggested several reforms that centered on reducing the informational constraints; connecting patient co-pays to the transaction prices, not the artificially inflated list prices; and empowering pharmacists and medical professionals to communicate with patients regarding all drug and payment options.²⁶ As with many economic problems, reducing informational barriers and improving market efficiencies can reduce many of the costs currently being imposed on the pharmaceutical market, while also enabling PBMs to provide value-added services.

Toward this end, there are proposals currently under consideration that, if implemented, would begin to improve this transparency problem. For example, the Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act, if it became law, would require the Centers for Medicare and Medicaid Services to post the rebates that PBMs receive, and the proportion of those rebates that go to Medicare Part D beneficiaries.

Based on much of the literature reviewed, the goal of the C-THRU Act is generally beneficial. By ensuring better information, and improving the current opaque pricing environment, legislators can improve both the cost growth trends for pharmaceuticals and the quality of care for patients.

Endnotes

- 1 Vandervelde, A. and Blalock, E. (2017) “The pharmaceutical supply chain: gross expenditures realized by stakeholders” Berkeley Research Group.
- 2 Garrett, A.D., and Garis, R. (2007) “Leveling the Playing Field in the Pharmacy Benefit Management Industry” *Valparaiso University Law Review*, Volume 42, Number 1, pp.33-80, Fall.
- 3 Santye, L. (2017) “DIR Fees Have Wide-Ranging Impact on Specialty Pharmacy” *Specialty Pharmacy Times*, March 22.
- 4 Coster, J.M. (2013) “Letter to Director Jonathan Blum, Center for Medicare, Centers for Medicare & Medicaid Services” National Community Pharmacists Association, March 1.
- 5 <https://www.congress.gov/bill/115th-congress/senate-bill/637>.
- 6 Vandervelde, A. and Blalock, E. (2017) “The pharmaceutical supply chain: gross expenditures realized by stakeholders” Berkeley Research Group.
- 7 Meador, M. (2011) “Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry Through Regulation” *Annals of Health Law*, Vol. 20.
- 8 Vandervelde, A. and Blalock, E. (2017) “The pharmaceutical supply chain: gross expenditures realized by stakeholders” Berkeley Research Group.
- 9 Vandervelde, A. and Blalock, E. (2017) “The pharmaceutical supply chain: gross expenditures realized by stakeholders” Berkeley Research Group.
- 10 Vandervelde, A. and Blalock, E. (2017) “The pharmaceutical supply chain: gross expenditures realized by stakeholders” Berkeley Research Group.
- 11 (2017) “PBM DIR Fees Costing Medicare and Beneficiaries: Investigative White Paper on Background, Cost Impact, and Legal Issues” Frier Levitt, LLC, January.
- 12 (2017) “PBM DIR Fees Costing Medicare and Beneficiaries: Investigative White Paper on Background, Cost Impact, and Legal Issues” Frier Levitt, LLC, January.
- 13 (2017) “Medicare Part D – Direct and Indirect Remuneration (DIR)” Centers for Medicare and Medicaid Services, January 19.
- 14 (2017) “Medicare Part D – Direct and Indirect Remuneration (DIR)” Centers for Medicare and Medicaid Services, January 19.
- 15 Gottlieb, S. (2016) “Statement before the Senate Committee on Health, Education Labor and Pensions; Subcommittee on Children and Families: EpiPen Price Increases, How Regulatory Barriers Inhibit Pharmaceutical Competition” American Enterprise Institute, October 7.
- 16 2017 Medicare Part D Outlook; <https://q1medicare.com/PartD-The-2017-Medicare-Part-D-Outlook.php>.
- 17 (2017) “PBM DIR Fees Costing Medicare and Beneficiaries: Investigative White Paper on Background, Cost Impact, and Legal Issues” Frier Levitt, LLC, January.
- 18 (2015) “MAC Pricing Analysis: Prepared for the Senior Care Pharmacy Coalition” Avalere Health, Novem-

ber.

- 19 (2015) “Long-Term Care Pharmacy: the Evolving Marketplace and Emerging Policy Issues” Avalere Health, October.
- 20 (2015) “Long-Term Care Pharmacy: the Evolving Marketplace and Emerging Policy Issues” Avalere Health, October; (2015) “MAC Pricing Analysis: Prepared for the Senior Care Pharmacy Coalition” Avalere Health, November; and, Gilchrist, A. (2015) “PBMs Scrutinized for LTC Pharmacy Payment Practices” *Pharmacy Times*, November 22.
- 21 (2015) “Concerns regarding the pharmacy benefit management industry” *Applied Policy*, November.
- 22 Santye, L. (2017) “DIR Fees Have Wide-Ranging Impact on Specialty Pharmacy” *Specialty Pharmacy Times*, March 22; (emphasis added).
- 23 Meador, M. (2011) “Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry Through Regulation” *Annals of Health Law*, Vol. 20.
- 24 Pociask, S. (2017) “You Can Blame Pharmacy Benefit Managers for Higher Drug Prices” *Real Clear Health*, March 28.
- 25 (2016) “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” Frier Levitt, LLC, August.
- 26 Pociask, S. (2017) “You Can Blame Pharmacy Benefit Managers for Higher Drug Prices” *Real Clear Health*, March 28.

