



Understanding the Evolving Business Models and Revenue of Pharmacy Benefit Managers

2021



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The PBM Accountability Project gratefully acknowledges the research and analytics contributions of 3 Axis Advisors. To learn more about the organization, visit <https://www.3axisadvisors.com/>

Executive Summary

Pharmacy benefit managers (PBMs) are situated at the center of the U.S. pharmaceutical ecosystem, overseeing pharmacy benefits on behalf of payers, including employers, multi-employer and other health plan sponsors, and public and private insurers, for the vast majority of individuals with prescription drug coverage. While the primary role of PBMs is to provide administrative services to payers, revenue flows to PBMs from multiple stakeholders in the supply chain, not just their clients.

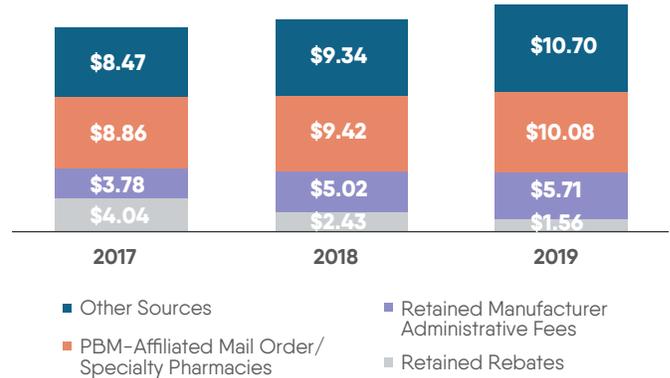
Given that PBMs claim to be the “only members of the prescription drug supply chain that are working to lower drug costs,”¹ discussions concerning PBMs’ impact on the market can be informed by a better understanding of the overall financial incentives driving PBM behavior, as well as possible sources of conflict with their assertion. This analysis reveals that PBMs utilize multiple avenues and business activities to exert influence over, and derive revenue from, others in the pharmaceutical supply chain.

While our analysis of publicly available data shows that total PBM gross profit increased over the study period, it also shows that the sources of PBM revenue have shifted due to changes in contracting practices, competitive pressures, and public scrutiny. Looking ahead, in accordance with trends based on observed data and our survey conducted for this study, we can expect that PBMs’ revenue sources will continue to evolve in response to changing market dynamics.

When considering future prescription drug policy options, it is vital to consider the implications of PBM incentive structures for patients and other stakeholders within the market:

- **PBM revenue is directly linked to list price growth, leading to misaligned incentives in the system.** Several sources of PBM revenue for medicines are linked directly to the list price of the medicine. When the list price of a medicine goes up, the PBM collects more revenue. These misaligned incentives can drive up costs for plans and patients.

PBM Gross Profit (\$B), 2017-2019



- **Excess complexity and information asymmetry in the market prevent payers and patients from properly evaluating PBM decisions or drug costs.** PBMs’ general lack of transparency is critical to their operations. It allows them to buy a product or service from one stakeholder in the system and sell that product or service to another stakeholder at a higher price without the payer understanding the true cost or inflationary nature of the services purchased.
- **Lack of meaningful PBM industry standards, limited transparency, and lack of regulatory oversight enable PBM revenue growth.** Many PBM contracting mechanisms and revenue sources lack agreed-upon definitions, providing PBMs with the broad flexibility to interpret the terms of a contract in their favor.

Financial incentives created by a variety of PBM revenue sources undoubtedly influence PBMs’ behavior within the U.S. pharmaceutical market and, thus, the prescription drug costs borne by patients and plan sponsors. Several new approaches and proposed policy reforms offer potential solutions to address misaligned incentives in the system, improve competition and transparency, and mitigate consequences to payers and patients.

SEE KEY FINDINGS ON NEXT PAGE

KEY FINDINGS

- Overall, gross profit (defined as revenue minus the cost of goods sold) increased by 12%, from \$25 billion in 2017 to \$28 billion in 2019.
- Between 2017 and 2019, PBMs adapted their business model to rely more on revenue collected through fees assessed on manufacturers and payers and gross profit on prescriptions filled through affiliated mail order and specialty pharmacies, while shifting away from a dependence on retained rebates.
- Gross profit from retained rebates paid by manufacturers decreased from \$4 billion in 2017 to \$1.6 billion in 2019.
- Gross profit from retained administrative fees paid by manufacturers increased by 51%, from \$3.8 billion to \$5.7 billion over the study period.
- Gross profit from PBM-owned mail order and specialty pharmacies increased from \$8.9 billion in 2017 to \$10.1 billion in 2019.

- Gross profit from other sources increased from \$8.5 billion in 2017 to \$10.7 billion in 2019.

It is notable that available financial data proved insufficient to fully describe the source of nearly 40% of PBMs' total gross profit. Exploration of all publicly available data, an extensive review of the literature and our survey of industry insiders cast little light onto specific gross profit derived from a variety of PBM business practices that include, but may not be limited to, spread pricing, pharmacy fees and clawbacks, fees collected from payers, and other non-administrative fees collected from manufacturers.

- In a limited survey with industry insiders conducted for this study:
 - » A majority disclosed that they expect revenue to increase from total fees PBMs collected from payers.
 - » Half disclosed that they expect revenue to increase from both effective rate arrangements with pharmacy networks and fees collected from manufacturers.

Introduction

Pharmacy benefit managers (PBMs) have gained increasing attention in recent years as the “middlemen” in the pharmaceutical market. However, PBMs’ influence over the pharmaceutical market is not well understood. This study looks to clarify the role that PBMs play and, through primary and secondary research, quantify the ways in which PBMs derive revenue from that role. Given that PBMs claim to be the “only members of the prescription drug supply chain that are working to lower drug costs,”² discussions concerning PBM impact on the market can be informed by a better understanding of the overall financial incentives driving PBM behavior, as well as possible sources of conflict with their

assertion. This understanding is critical when considering potential policy interventions to address medicine spending and pricing in the United States.

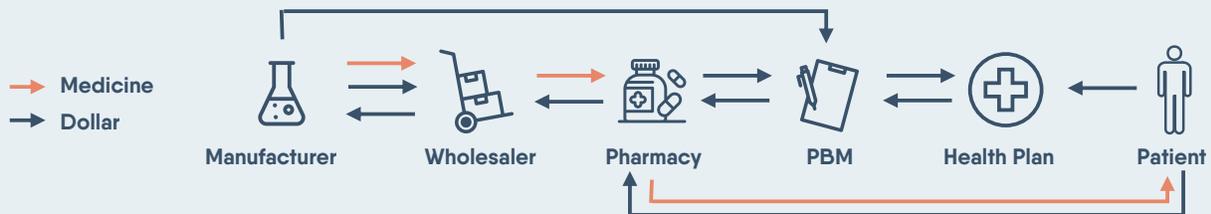
OVERVIEW OF THE PBM BUSINESS MODEL

PBMs, first formed in the 1960s, originally specialized in prescription claims processing, mail order pharmacy services, network design, and account management. As spending on prescription medications grew, PBMs became more involved in the management of pharmacy benefit spending on behalf of their plan sponsor clients.



Box 1: The Pharmaceutical Payment and Distribution Supply Chain

The U.S. pharmaceutical supply chain is complex and includes a variety of players. At the start of the chain are manufacturers, who develop medicines and bring them to market. At the end of the chain are patients, who benefit from those medicines. In between, other stakeholders play a role in the movement of, and payment for, pharmaceuticals.



* Simplified illustrative representation of the pharmaceutical supply chain; this graphic is not intended to represent every relationship and stakeholder in the marketplace

Since then, PBMs have evolved to take on more business activities and meet the changing needs of their clients. Today, PBMs manage and oversee pharmacy benefits for the vast majority of individuals with prescription drug coverage on behalf of employers and insurers, including Medicare, Medicaid, and private insurance.

PBMs leverage their size and influence to negotiate with pharmaceutical manufacturers on behalf of their clients to lower the net price of medicines through rebates, discounts, and other price concessions. Price concessions negotiated between pharmaceutical companies and PBMs could be passed through to PBMs' clients, reducing the payers' spending on drugs utilized by their beneficiaries.

On the other end of the transaction, PBMs also create pharmacy networks, which determine where beneficiaries may obtain medicines through prescription drug coverage administered by the PBM/health plan. The size and scale of PBMs also enable them to negotiate lower prices with network pharmacies, which may produce further savings that could be passed through to payers, as well.

PBMs are situated at the center of the pharmaceutical ecosystem and interact with manufacturers, payers, pharmacies, and patients (see: Box 1). They are able to use this gatekeeper role to exert influence over, and derive revenue from, others in the pharmaceutical supply chain. Key functions carried out by PBMs are:

- **Manage the electronic processing of pharmacy claims:** Pharmacy claims are adjudicated in real time through coordination between the PBM and the pharmacy. This allows patients to access their medicines quickly in most instances.¹ The streamlined nature of this process contrasts with that of medical claims (from hospitals or doctors' offices), which can take months to fully process.
- **Implement the pharmacy plan benefit:** PBMs conduct drug utilization reviews (DUR) and develop and manage the plan formulary, which determines whether a medicine is covered by a patient's insurer, the level of cost sharing patients are required to pay to access their medicines, and any utilization management requirements, including step therapy, prior authorization, and quantity limit restrictions.

i. The 1996 Health Insurance Portability and Accountability Act (HIPAA) led to the adoption of certain standard transactions for the electronic exchange of health care data. The standard pharmacy transactions, maintained by the National Council for Prescription Drug Programs (NCPDP), facilitate communication between a member's pharmacy and his or her PBM.

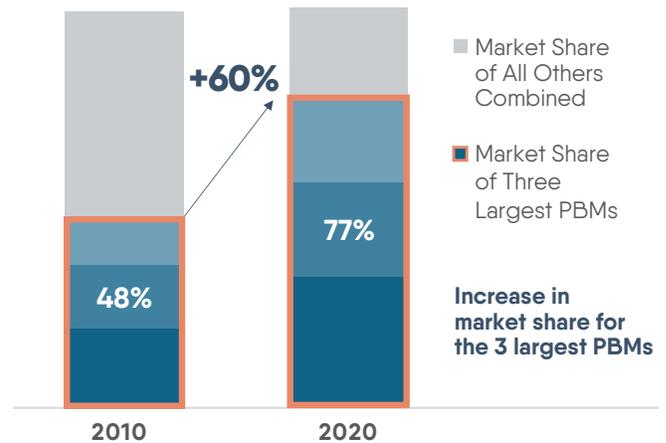
- Establish and/or operate pharmacy networks:** PBMs often use plan benefit design to incentivize members to use specific pharmacies by offering lower cost sharing for, or restricting coverage to, prescriptions filled at certain sites. Additionally, large PBMs operate their own mail order and specialty pharmacies and similarly incentivize clients to use their internal network over non-affiliated pharmacies.³
- Establish pharmacy payment rates:** PBMs establish the reimbursement rates paid to pharmacies that dispense drugs to the PBM's members. This reimbursement rate may be different from the rate negotiated with the PBM's health plan/employer client for the same drug.⁴

PBMs are able to use this gatekeeper role to exert influence over, and derive revenue from, others in the pharmaceutical supply chain.

PBM NEGOTIATING TOOLS

The PBM market is highly consolidated, with three main players—CVS Caremark, OptumRx, and Express Scripts—accounting for 77% of the market in 2020.⁵ This high level of industry consolidation was achieved in part through large-scale horizontal mergers – for example, UnitedHealth Group's (OptumRx division) \$12.8 billion acquisition of Catamaran in 2015.⁶ The remaining 23% of the market is comprised of smaller or specialized PBMs. However, the amount of market consolidation may be understated as these smaller businesses frequently contract or partner with the three largest PBMs to take advantage of their negotiating power and service offerings, further contributing to consolidation of the market. As an example, in late 2019, Prime Therapeutics announced a partnership with Express Scripts to provide retail pharmacy network and pharmaceutical manufacturer contracting.⁷ Other smaller PBMs (including Kroger Prescription Plans and Humana's commercial lines of business) also rely on Express Scripts for manufacturer contracting.⁸

Figure 1: PBM Market Share, 2010–2020



Note: In 2010, the three largest PBMs were Medco Health Solutions, Argus Health Systems and Express Scripts. In 2020, the three largest PBMs were CVS Caremark, OptumRx, and Express Scripts
Sources: Fein A. "The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute, March 2021.

In addition to the significant horizontal consolidation observed in the PBM market, vertical consolidation has become pervasive, with each of the top three PBMs now associated with one of the country's largest health insurance companies,ⁱⁱ a specialty pharmacy, a traditional mail-order pharmacy, and a group purchasing organization (GPO) entity.⁹ These relationships have blurred the lines between PBM and client, leading to an overall reduction in transparency and increasing barriers to competition. However, these partnerships may also create cost-saving efficiencies by leveraging economies of scale and improved information sharing between the entities.

Consequences of vertical consolidation may include reduced patient choice of provider, pharmacy, or medication. As an example, the combined CVS/Aetna entity has an incentive to steer patients toward CVS's retail clinics (HealthHUB, Minute Clinic). Because CVS/Aetna employs the providers that staff these clinics, it can exert greater control over their prescribing behavior and payment rates (e.g., formulary compliance, prescribing volume, and use of integrated specialty pharmacies).¹⁰ While retail clinics may enhance access to care for certain patients,

ii. The insurers are the first (Anthem), third (UnitedHealthcare) and fourth (Cigna) largest by membership in the U.S.

Table 1: Vertical Consolidation Among the Three Largest PBMs, 2021

	OptumRx	CVS Caremark	Express Scripts
Health Plan	UnitedHealthcare	Aetna	Cigna
Specialty and/or Retail Pharmacy	Optum Specialty, Diplomat, Genoa	CVS Pharmacy, CVS Specialty	Accredo
Generic Sourcing Entities	N/A	Red Oak	Econdisc
GPO Entity	Emisar	Zinc	Ascent

some have raised concerns around the expanded influence of these vertically integrated entities on the drug supply chain and patient care.¹¹ A similar dynamic exists for the other integrated PBMs, which also own or partner with provider groups.¹²

Brand Medicines

As brand medicines account for the majority of total prescription medicine spending, PBMs place a high priority on negotiating with brand manufacturers to lower the net costs of those medications. In addition to their highly concentrated market power, PBMs have several additional tools that can be leveraged when negotiating with manufacturers, including formulary design (tier placement and cost sharing), formulary exclusions, and utilization management.

Tier Placement and Cost-Sharing

PBMs, sometimes in consultation with health plans, classify drugs included on formulary into different cost-sharing tiers, with generic drugs and “preferred” brand drugs typically being less costly to patients than “specialty” and “non-preferred” brands. In 2021, 88% of people with employer-sponsored insurance were in plans with three or more cost-sharing tiers for prescription drugs. Cost sharing can vary substantially by tier. For example, among those in plans with four tiers, average cost-sharing ranged from a \$12 copayment or 20% coinsurance for first tier/preferred drugs to a \$124 copayment or 32% coinsurance for fourth tier drugs.¹³

These differing cost-sharing levels can have a significant impact on medication adherence and

patient access. As cost sharing increases, patients may face affordability challenges and may be more likely to abandon their medicine at the pharmacy counter.¹⁴ In 2020, more than half of commercially insured patients did not fill their new prescription when out-of-pocket costs exceeded \$250. In comparison, just 8% of patients abandoned their prescriptions when out-of-pocket costs were under \$20.¹⁵ Consequently, in competitive classes of medicines, manufacturers have an incentive to offer price concessions to PBMs in exchange for more favorable tier placement over their competitors, which allows for potentially broader patient access to their medicines.

Over recent years, certain patients taking high-cost drugs have faced increasing exposure to high out-of-pocket costs.¹⁶ This has occurred as both deductibles and coinsurance (rather than fixed dollar copayments) are more frequently applied to prescription drugs. Coinsurance and deductible amounts are often based on the undiscounted list price of a medicine, instead of the net cost to the PBM/health plan. Patients with coinsurance and deductibles often face higher out-of-pocket costs than those with fixed copayment cost sharing.¹⁷

In an attempt to defray the costs associated with filling a prescription and to encourage medication adherence, some manufacturers offer cost-sharing assistance programs that help pay for some or all of the patient’s out-of-pocket cost. Some argue these programs undermine PBMs’ ability to discourage utilization of unfavored medications and leverage tier placement when negotiating with manufacturers.¹⁸ In response, many PBMs have developed strategies to erode the direct patient benefits of cost-sharing assistance programs, including accumulator adjustment programs and copay maximizers (see: Box 2).¹⁹

Box 2: PBM Strategies for Mitigating the Impact of Manufacturer Cost-Sharing Assistance

Accumulator adjustment programs prevent manufacturer cost-sharing assistance from being applied to patient deductibles or out-of-pocket maximums, resulting in higher patient costs.

Copay maximizers modify patient cost sharing to be equivalent to the entire value of the manufacturer's assistance program spread evenly throughout the year to extract the maximum value from manufacturers.

Formulary Exclusions

When there are multiple medicines to treat a condition, PBMs can choose to include only some of the medicines on the formulary and exclude others from coverage entirely. When a drug is excluded from the formulary, a patient who is prescribed a particular drug may have to a) pay for it entirely out of pocket; b) undergo an appeals process to access coverage; or c) work with their physician to obtain a different prescription for an alternate medicine.²⁰ Even if certain drugs are on the formulary, their coverage may be less comprehensive. While rules vary by market, large and self-insured group health plans in the commercial market generally have the greatest flexibility when determining their drug benefit design.ⁱⁱⁱ

The threat of formulary exclusion has become an increasingly powerful negotiating tool for PBMs, allowing them to negotiate significant price concessions from brand manufacturers facing competition from other medicines and lower pharmacy plan costs. From 2014 to 2020, the number of medicines excluded from the standard formularies of at least one of the three largest PBMs increased by an average of 34% per year.²¹ Of the drugs that were excluded by the three largest PBMs in 2020, one in five

were single-source brand medicines with no generic or biosimilar equivalent on the market.²² In a report published in January 2021, the United States Senate Finance Committee (SFC) observed: "Pharmaceutical companies are sensitive to the sheer size of PBMs and the resulting product volumes they can affect, which allows the middlemen to extract higher rebates from manufacturers through the use of formulary exclusion tactics."²³

Utilization Management

Utilization management techniques—including step therapy, prior authorization, and quantity limits—are applied by PBMs to influence access to, and utilization of, specific medicines, regardless of the preferences of the prescriber, dispenser, and patient (see: Box 3).

Utilization management is widely used and particularly common for specialty drugs, which represent a large and growing share of drug spending.^{iv,24} In 2018, 95% of self-insured employers had plans with prior authorization requirements, and 86% had plans that required step therapy for specialty medicines covered on their formularies.²⁵

Box 3: Common Forms of Utilization Management

STEP THERAPY: Requires patients to try one or more treatments preferred by the PBM before the insurer will cover the originally prescribed drug

PRIOR AUTHORIZATION: Requires a patient's physician to provide documentation that the patient meets certain clinical requirements before the PBM will cover a drug

QUANTITY LIMITS: Establishes a maximum amount of a medicine that can be covered over a specified period

iii. Under current regulations, they are able to designate certain covered drugs as non-essential health benefits, which allows them to exclude those drugs from the annual limitation on cost sharing and to impose annual and lifetime dollar limits on them. In other words, even if a drug is "covered," a patient may end up paying above the plan's out-of-pocket limit, or a plan may stop covering the drug once it has paid a certain dollar amount for it.

iv. IQVIA defines specialty drugs as "those that treat chronic, complex or rare diseases, and possess additional distribution, care delivery and/or cost characteristics which require special management by stakeholders." As of 2020, specialty drugs reportedly account for more than half of U.S. net drug spending, compared to 27% in 2010.

There are conflicting bodies of research on the impact of utilization management on patients and the health care system as a whole.²⁶ Some research has found prior authorization and step therapy can have unintended consequences, including delays in patient treatment and higher direct and indirect health care costs.²⁷ Other research has found utilization management produces no negative impact on patients and results in overall cost savings.²⁸ Challenges with measuring the impact of utilization management make it difficult to determine whether these techniques offer an efficient way to lower health care spending. Importantly, oversight of PBM utilization management tactics is limited and can vary by state and plan.

Generic Medicines

While brand medications may represent the majority of prescription drug expenditures, generic medications represent most of the utilization. Today, generics represent 90% of dispensed prescriptions in the United States.²⁹ The use of generic medications in place of brands is one of the more effective mechanisms to control drug costs for both plans and patients. In 2020, the use of generic medicines saved the health care system an estimated \$313 billion.³⁰ On average, patients pay \$6.97 out of pocket for their generic medicines, with over 90% of generic prescriptions costing patients less than \$20 in 2020.³¹

While PBMs have access to the same tools to control generic drug costs as they do for brands, the approach to tiering, cost sharing and formulary exclusions can be different. For generic drugs, PBMs generally do not differentiate between manufacturers when it comes to formulary placement and utilization management. As a result, generic manufacturers are not incentivized to offer rebates or other price concessions directly to the PBM. Rather, generic manufacturers compete by offering discounts and price concessions to pharmacies, which traditionally have preferred to purchase the lowest-cost option among equivalent products (see: Box 4). However, as will be discussed, changes in the incentive structure PBMs create via reimbursement practices to pharmacies have started to recalibrate pharmacy purchasing behavior away from the lowest cost medications.

Because generic medications represent a majority of dispensed medications, additional tools that PBMs employ to manage generic drugs include drug utilization review (DUR) and the development of pharmacy networks to manage generic utilization and costs.

Drug Utilization Review (DUR)

DUR is an ongoing, systematic process designed to facilitate the appropriate and effective use of medications.³² PBMs use DUR protocols to provide information about the appropriateness of a drug for a specific patient by using automated predetermined criteria that generally take into consideration co-morbid conditions and other medicines a patient may be taking.

Certain DUR activities are required for participation in federal programs, like Medicare and Medicaid.³³ Managed health care systems and PBMs state that these programs play a key role in helping improve the prescribing, administration, and use of medications, including encouraging prescribers to use more generic drugs and comply with treatment guidelines.³⁴ These, in turn, may help control costs directly, through more appropriate use of generic medications, or indirectly, through preventing harm and avoidable health care costs that may result from inappropriate medication use.

Despite being a main function of a PBM's oversight of drug utilization, it is difficult to quantify the ultimate impact of DUR on patient outcomes and total cost. Additionally, provider groups have taken issue with the number of DUR alerts generated, which could lead to alert fatigue, undermining the intended purpose of the program.³⁵

The threat of formulary exclusion has become an increasingly powerful negotiating tool for PBMs, allowing them to negotiate significant price concessions from brand manufacturers facing competition from other medicines and lower pharmacy plan costs.

Pharmacy Network Contracting

A core component of PBMs' functionality is the establishment and maintenance of pharmacy networks. A network consists of pharmacies that have entered into an agreement with a PBM to dispense prescriptions to enrollees of the health plans that contract for PBM services. Pharmacy networks can be 'Open' (members can use any pharmacy with no difference in cost sharing), 'Preferred' (member can use any pharmacy, though patient cost sharing is lower at preferred pharmacies), or 'Closed' (patients are unable to use their benefits at out-of-network locations and may even be required to use a single mail order pharmacy for pre-specified medications).

PBM pharmacy networks enable patients with prescription drug coverage to get prescriptions filled at retail, mail, and/or specialty pharmacies.

- **Retail Pharmacy Networks:** These contracts ensure access to care when and where patients need it. These networks are used by PBMs to obtain greater discounts on drug expenditures by leveraging their covered lives against the access to other pharmacies in a particular geographic area.³⁶
- **Mail Order Pharmacy Networks:** The three largest PBMs all operate their own mail order pharmacies and can use plan benefit design to encourage, or in some

cases, require mail order use among members.^{v,37} PBM-owned mail order pharmacies are among the largest pharmacies in the U.S. and use their size as a negotiating tool with generic manufacturers.³⁸

- **Specialty Pharmacy Networks:** Similarly, the top three specialty pharmacies by revenue and market share are also owned by the largest PBMs, who utilize their size and scale to negotiate drug discounts and favorable dispensing fees and protocols, including those related to generic specialty medications.³⁹

Box 4: Biosimilars

Biosimilars are medicines that have been designated by the FDA as "highly similar" to existing biologic brands. Because most biosimilars have not been approved as "interchangeable" with their reference products to date, pharmacists cannot automatically substitute a biosimilar for the reference product without consultation with the prescriber. As such, for PBM negotiation purposes, biosimilars resemble brands more so than generics in that they compete for PBM formulary placement rather than pharmacy shelf space.

Source: FDA, "Biosimilar and Interchangeable Products," <https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products#diffbiochange>

Methods

To better understand the sources and magnitude of PBM revenue, we conducted an analysis of financial records and public reporting documents, government reports, peer-reviewed and grey literature, and surveyed PBM and health plan representatives in coordination with 3 Axis Advisors (see Appendix for complete Methods). Overall, the analysis determined that between 2017 and

2019, PBM gross profit (defined as revenue minus the cost of goods sold) increased 12%, from \$25 billion to \$28 billion. Prior research has determined PBMs are able to convert an estimated 85% of gross profit into Earnings Before Interest, Taxes, Depreciation and Amortization (EBITDA), a significantly higher conversion rate than other stakeholders in the pharmaceutical supply chain.^{vi,40}

v. This dynamic has likely contributed to mail order pharmacies' increasing share of the market (accounting for 21% of retail pharmacy sales in 2007 to 37 percent in 2017).
vi. For comparison, health insurers and pharmacies convert about 30% of gross profit into EBITDA.

Results

While the primary role of PBMs is to provide administrative services to payers, much of PBM revenue is derived from service fees and charges to other entities, including pharmacies and manufacturers. PBMs generate gross profit through multiple avenues and business activities, including but not limited to retained rebates, retained manufacturer administrative service fees, and their own mail order/specialty pharmacies. Revenue flows to PBMs from multiple stakeholders in the supply chain, not just their payer clients.

While overall PBM gross profit increased over the study period, the sources of this gross profit have shifted due to changes in contracting practices, competitive

pressures, and public scrutiny. Looking ahead, in accordance with trends based on observed data and our survey conducted for this study, we can expect PBMs' revenue sources will continue to evolve in response to changing market dynamics.

RETAINED REBATES

PBMs negotiate rebates and discounts with pharmaceutical manufacturers to reduce the net cost of medications. The magnitude of these rebates and discounts has steadily increased in recent years. For example, manufacturer rebates in Medicare Part D are estimated to have increased from \$12.7 billion in 2013 to \$45.0 billion in 2020.⁴¹ Increasing rebates have been compounded by growing Medicaid statutory rebates, Part D coverage gap discounts, 340B discounts, and other mandatory price concessions and fees.⁴² This has led to a significant difference between the list price and the net amount manufacturers ultimately receive from the sale of medicine. In 2020, net prices for single-source brand medicines were, on average, 44% lower than their list prices.⁴³ The difference between total list price-based (gross) brand medicine spending and actual net spending received by manufacturers represented \$217 billion in 2020.⁴⁴ Of this total, rebates in the commercial and Part D markets accounted for the largest shares (23% and 21%, respectively).⁴⁵

Figure 2: PBM Gross Profit (\$B), 2017-2019

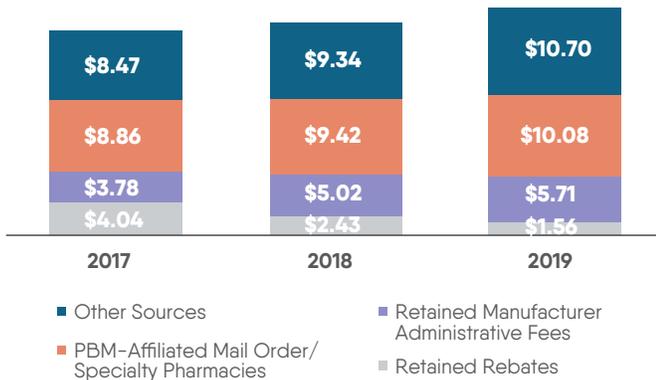
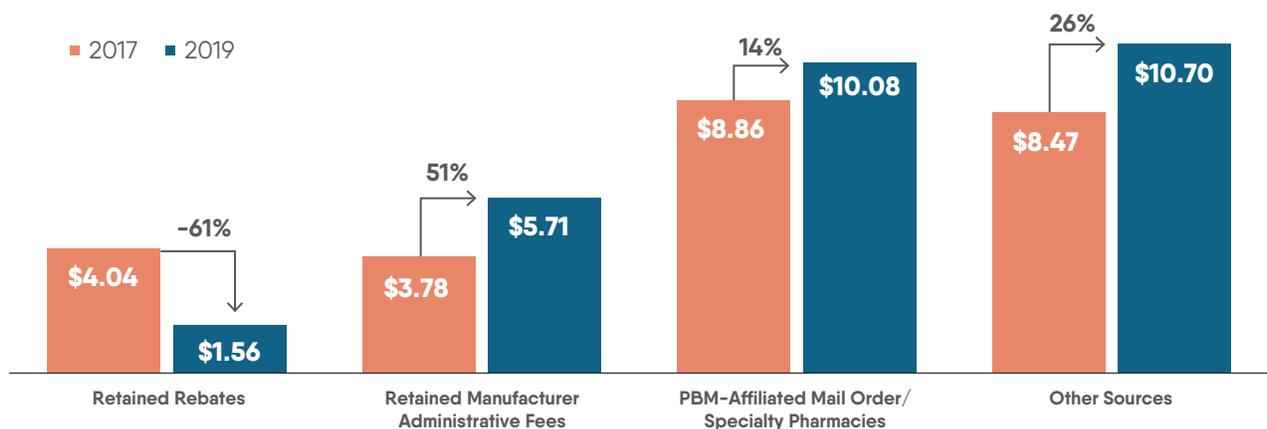


Figure 3: Changes in PBM Gross Profit (\$B) by Source, 2017 vs. 2019



While the primary role of PBMs is to provide administrative services to payers, much of PBM revenue is derived from service fees and charges to other entities, including pharmacies and manufacturers

Negotiated rebates can take many forms including, but certainly not limited to, formulary access/tier placement rebates, market share target rebates, and price protection rebates. Part D plans are required to report rebate collections to the Centers for Medicare & Medicaid Services (CMS) as part of direct and indirect remuneration (DIR) reporting. A recent analysis of these data by the Government Accountability Office (GAO) demonstrates that PBMs pass through to plan sponsors more than 99% of negotiated rebates in Part D.⁴⁶ However, historically, only a portion of negotiated rebates in the private market were typically shared with commercial plans, with the remainder retained by the PBM as compensation for their services.⁴⁷

As this practice came under scrutiny and the magnitude of rebates increased, large employers have increasingly negotiated contracts with full rebate pass-through to the plan sponsor. For example, in 2021, more than 75% of Express Scripts' commercial clients received all PBM negotiated rebates (full rebate pass-through to the plan), up from 50% in 2018. Prior to 2018, less than half of Express Scripts' clients had full rebate pass-through.⁴⁸ However, these funds are not typically passed through to the patient at the point of sale but instead are often used to lower premiums across the board or reduce cost sharing for other services.

While the share of total rebate dollars retained by PBMs has decreased, PBMs are still able to collect a modest amount of revenue due to the increasing size of total rebates, even as other sources of PBM revenue have also increased.

These dynamics have driven the observed decline of PBM revenue related to retained rebates. Between 2017 and 2019, retained rebates decreased from \$4 billion (17% of gross profit) to \$1.6 billion (6% of gross profit). Despite this decline in revenue from retained rebates, PBMs have managed to grow gross profit by relying on other sources, including fees and pharmacy margins.

RETAINED ADMINISTRATIVE FEES PAID BY MANUFACTURERS

In addition to rebates, PBMs obtain additional revenue through administrative service fees collected from pharmaceutical manufacturers for, among other things, administering, invoicing, allocating and collecting manufacturer rebates.⁴⁹

Most commonly, these fees are “calculated based on the price of the rebated drug or supplies along with the volume of utilization.”⁵⁰ In one instance, for example, this fee was capped at “the greater of (i) 4.58% of the average wholesale price [AWP], or (ii) 5.5% of the wholesale acquisition cost [WAC] of the products.”⁵¹

Fees may be directly negotiated between the PBM and the manufacturer or indirectly realized through the use of rebate aggregators. A rebate aggregator is an organization that either provides formulary management and rebate administrative services or aggregates purchasing volume and distributes rebates to PBMs.⁵²

Between 2017 and 2019, PBM gross profit from retained administrative fees paid by manufacturers increased 51%, from \$3.8 billion (15% of gross profit) to \$5.7 billion (20% of gross profit). Note that the earlier observed decline in PBM rebate revenue is almost entirely offset by the growth in observed manufacturer administrative fees alone.

INTERNAL MAIL/SPECIALTY PHARMACIES

The largest PBMs and specialty pharmacies have combined into vertically integrated organizations. Consequently, PBM-owned pharmacy operations have expanded beyond traditional mail order processing of routine maintenance drugs to the management of some of the most complex drug therapies currently on the market.

Health care service providers, like mail and specialty pharmacies, may be appealing acquisitions for PBMs as they are not restricted by profitability regulations, such as Medical Loss Ratio (MLR), that insurance companies face. Because PBMs are responsible for determining payment rates for pharmacies within their network, the ownership

of pharmacies can allow PBMs to retain a greater share of revenue based upon the reimbursement rates these pharmacies can negotiate. These acquisitions may be contributing to the growth of programs like “white bagging,” which can require health care facilities to obtain provider-administered pharmaceuticals from the PBM’s owned- and- operated specialty pharmacy, shifting claims from the medical benefit to the pharmacy benefit, where PBMs are better able to manage utilization and shift medication margins from external providers to their own affiliated pharmacies.⁵³

Our results demonstrate that gross profit from PBM-owned mail order and specialty pharmacies has increased from \$8.9 billion (35% of gross profit) in 2017 to \$10.1 billion (36% of gross profit) in 2019.

OTHER SOURCES

Due to the pervasive lack of transparency in the PBM market, it was not possible to fully disaggregate study results for the PBM gross profit summarized, herein as “Other Sources.” In total, Other Sources summed to \$8.5 billion in 2017 and grew to \$10.7 billion in 2019.

It is notable that available financial data proved insufficient to fully describe the source of nearly 40% of PBMs’ total gross profit. Exploration of all publicly available data, an extensive review of the literature and our survey of industry insiders cast little light onto specific gross profit derived from a variety of PBM business practices that include, but may not be limited to, spread pricing, pharmacy fees and clawbacks, fees collected from payers, and other non-administrative fees collected from manufacturers. What is clear is that much of PBMs’ gross profit is collected from entities other than the payer clients served by PBMs.

Service Fees Paid by Plan Sponsors

Sponsors of prescription drug benefits, including Medicare, employers, and health insurers, generally pay PBMs service, administrative, or transaction fees, on a per-prescription or per-member basis. PBMs incur a cost to transact claims electronically and in real time based upon relationships with trading partners

such as clearinghouses or switching companies. In fully transparent PBM contracts, these service fees are the only source of PBM revenue from plan sponsors; they constitute full payment for administration of the pharmacy benefits. By contrast, traditional PBM contracts may reduce these service fees, because revenue are derived from other sources. Of note, in our survey of PBM representatives, more than 60% expected revenue from the total fees PBMs collect from payers to increase between 2021 and 2024. This increase in fees collected from plan sponsors is likely driven by the accelerating shift to pass-through models, where PBMs retain few, if any, rebate and spread dollars and instead transfer them to the plan sponsor, while depending on plan sponsor fees for compensation.

It is notable that available financial data proved insufficient to fully describe the source of nearly 40% of PBMs’ total gross profit.

Spread Pricing and Other Revenue Collected from Pharmacies

Through a practice known as “spread pricing,” PBM reimbursement to retail pharmacies may be significantly lower than the amount charged to the health plan for the same medicine. This dynamic is most commonly observed among generic drugs due to the significant discounts that generic manufacturers offer directly to pharmacies and wholesalers. A pharmacy’s acquisition cost for a generic drug is often completely disconnected from the list price, and plans have little data available to “anchor” generic prices. It is therefore challenging for payers to gauge reasonable reimbursement rates for generics. PBMs can benefit from this lack of transparency by charging their clients more than they pay to reimburse pharmacies for those generic products.

In traditional PBM contracts, spread pricing is observed directly as the difference between the amount paid on the claim to the pharmacy and the amount reported to the health plan. As contracts have evolved in payers’

attempts to reduce excessive charges on generic drugs and gain greater transparency into PBM pricing practices, such as with the passage of state maximum allowable cost (MAC) laws, PBM contracting with network pharmacies has increasingly relied upon use of effective rate guarantees. Three quarters of PBM representatives surveyed reported an increasing use of effective rate arrangements with pharmacy networks over the study period. Effective rate agreements enable the PBM to collect spread, while still appearing to operate a pass-through pricing model.⁵⁴

An effective rate is a target reimbursement rate that a PBM establishes across a network of pharmacies. The effective rate is expressed as a percentage discount from the Average Wholesale Price (AWP)⁵⁵ of the total brand and generic drugs dispensed through the pharmacy network over a set period of time. In an effective rate arrangement, the PBM can first pay the pharmacy the same rate on a claim that it charges a payer at the time of transaction. This claim is then grouped together with tens of thousands of other commercial PBM claims to form a “network.” The pharmacy then signs a contract with the PBM that dictates aggregate reimbursement terms on the overall network. Months later, the PBM determines if it has overpaid or underpaid the pharmacies based on the contracted terms for the network and “trues up” the pharmacies, as needed. As such, effective rate contracts provide the PBM with a very intricate mechanism to technically offer payers a pass-through pricing structure when examining claims at the point-of-sale, while still collecting hidden spread from pharmacies when accounting for net price paid after all fees and clawbacks.

Similarly, the contract may allow for a reduction in aggregate reimbursement to the pharmacy for failure to meet certain measures: clinical (e.g., requiring the use of a statin for patients with diabetes), formulary (e.g., requiring that 90% of all products dispensed be preferred on the PBM’s formulary), or adherence (e.g., requiring a medication possession ratio (MPR) of at least 85% for antiretroviral medications). Disclosures by CMS in 2018 revealed that retrospective pharmacy price concessions (i.e., DIR) grew from \$229 million in 2013 to \$4 billion in 2017, linked to the growing prevalence of performance-based payment arrangements between PBMs and pharmacies.⁵⁶

In our survey of PBM representatives, more than 60% expected revenue from the total fees PBMs collect from payers to increase between 2021 and 2024.

Other Fees Collected from Manufacturers

In addition to administrative fees, PBMs also collect other types of fees from manufacturers for business services and activities, including but not limited to “maintenance and operation of the systems” and “access to drug utilization data.”⁵⁷ These fees, which can be calculated as a percentage of a medicine’s list price, may also compensate PBMs for services related to, among other things, “medical education, medication monitoring, [and] data management.”⁵⁸

Discussion: Emerging Trends and Policy Implications

Financial incentives created by a variety of PBM revenue sources undoubtedly influence PBMs’ behavior within the U.S. pharmaceutical market, and thus, the prescription drug costs borne by patients and plan

sponsors. When considering future prescription drug policy options, it is vital to consider the implications of PBM incentive structures for patients and other stakeholders within the market.

PBMS BENEFIT DIRECTLY FROM PRESCRIPTION MEDICINE LIST PRICE GROWTH, LEADING TO MISALIGNED INCENTIVES IN THE SYSTEM

Several sources of PBM revenue for medicines are linked directly to the list price of the medicine. Contracts between PBMs and brand manufacturers often specify that the PBM will be paid fees and rebates equal to agreed-upon percentages of the brand's list price (i.e., wholesale acquisition cost, or WAC).⁵⁹ When the list price of a medicine goes up, the PBM collects more revenue. This conflict of interest may lead PBMs to favor brand medicines with high list prices and large rebates, which may contribute to a growing market-wide trend in which net prices are significantly lower than a medicine's list price.

Notably, when manufacturers have acted to make lower list price authorized generics of their brand medicines available, PBMs' uptake has been generally poor. For example, two of the three largest PBMs exclude lower cost authorized generic hepatitis C treatments and insulin from their standard commercial formularies, while instead covering the higher list price brand equivalent.⁶⁰ These dynamics have also resulted in some PBMs preferring high list price products over lower list price generics. A study of Part D formularies in 2016 found that 72% of Part D plans placed at least one generic product on a higher cost sharing tier than the equivalent brand medicine.⁶¹

The growing disconnect between the list and net prices of brand medicines also results, almost without exception, in higher pricing of generic medications immediately following a brand medicine's loss of exclusivity.⁶² This occurs for the following reason: When brand medicines initially face generic competition, generic prices are generally pegged to a 0-15% discount off of the brand's Average Wholesale Price (AWP). Although the acquisition price of generic drugs does decline over time as additional generics enter the market, the initial AWP pricing enables PBMs to capture revenue on generic drugs via differential payments between providers and payers.

Patients with coinsurance or deductibles typically pay cost sharing tied to the list price of the medicine, not the lower net price ultimately paid by their insurer. Therefore, these patients do not directly benefit from rebates and

discounts manufacturers provide on their medicines. For such patients, cost sharing often increases when list prices increase, even absent a net price increase or increased revenue to the manufacturer.⁶³ In 2019, 49% of commercially insured patient out-of-pocket spending and 92% of Part D out-of-pocket spending on brand medicines was based on the undiscounted list price.⁶⁴

Ultimately, misalignment of PBM incentives may influence the behavior of all stakeholders in the supply chain. Some experts have argued this relationship between PBMs' compensation and the list price of medicines creates perverse incentives that may even result in PBMs dissuading or penalizing manufacturers from lowering list prices.⁶⁵ As noted by the Senate Finance Committee in January 2021, "PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price—and PBMs retain at least a portion of what they negotiate."⁶⁶

Despite the fact that the percentage share of total manufacturer rebates and fees retained by PBMs has decreased over time, evidence demonstrates that the absolute amount of PBM-retained manufacturer price concession dollars has increased, maintaining list-price based incentives. For example, in 2011, manufacturer price concessions from CVS Caremark's commercial and Part D clients totaled \$78 per covered life. Of this amount, CVS retained 27% and passed the remaining through to the plan sponsor. By contrast, in 2020, CVS retained just 3% of manufacturer price concessions, however, the total value increased to \$294 per covered life.⁶⁷

Several policy options have been suggested to correct these misaligned incentives, including requiring PBMs and plans to reflect rebates and discounts in patient out-of-pocket costs at the point of sale and shifting PBM compensation to a fixed fee, rather than a percentage of the medicine's list price. In a letter submitted to the Department of Health and Human Services (HHS), a coalition of consumer-focused groups, including Consumer Action, Consumer Federation of America, and Consumer Reports, argued that "prohibiting PBMs from being compensated based off the list price and ensuring that the savings from PBM negotiations are passed through to consumers, will change the drug manufacturers', PBMs', and payors' incentives."⁶⁸

EXCESS COMPLEXITY AND INFORMATION ASYMMETRY IN THE MARKET PREVENT PAYERS AND PATIENTS FROM PROPERLY EVALUATING PBM DECISIONS OR DRUG COSTS

Payers and patients cannot properly evaluate the cost and quality of the pharmacy benefits they receive due to PBMs' multi-layered, proprietary business models, which have been frequently characterized as packaged in a "black box."⁶⁹ PBMs' general lack of transparency is critical to their operations and allows them to buy a product or service from one stakeholder in the system and sell that product or service to another stakeholder at a higher price, without the payer understanding the true cost or inflationary nature of the services purchased – a practice known as "arbitrage." In other words, PBMs are able to "bury" the fees, a common practice within insurance models.⁷⁰ While this can lead a plan sponsor to underestimate the scope and size of PBM compensation under a benefits plan, it can also insulate the PBM from disruptive forms of competition due to the difficulty in assessing true "apples to apples" pricing comparisons among market alternatives. Several examples of this arbitrage dynamic include price protection rebates (see: Box 5) and, most notably, spread pricing.

Attempts to increase visibility into PBM practices and the magnitude of spread pricing in Medicaid have uncovered significant differences in the amounts billed to health plans and the amounts paid to pharmacies on prescription drug claims. As state Medicaid programs have increasingly relied on managed care organizations (MCOs) to administer the pharmacy benefit, the role of PBMs in Medicaid has also grown.⁷¹ Of note, medicines paid for by Medicaid MCOs are not subject to the same acquisition cost rules as Medicaid fee-for-service.⁷² Historically, PBMs have benefited from the lack of transparency in payments from MCOs and to pharmacies, which has allowed them to generate "spread." States are increasingly examining the budgetary impacts of their PBM contracts and spread pricing. Once identified, some states have moved to eliminate spread pricing via policy changes.⁷³

Multiple state attorneys general, auditors, and other offices have recently audited PBM practices among their Medicaid MCOs in Kentucky, Florida, Maryland, Ohio, and

Box 5: Price Protection Rebates

Price protection rebates prevent PBMs from experiencing the list price increases some argue they incentivize. Contracts between manufacturers and PBMs may establish a maximum percentage by which the manufacturer can increase its list prices, often ranging between 0 and 12%. If a drug's list price increases more than is allowed in the contract, the PBM receives a "price protection" rebate equal to the difference between the actual price and the maximum allowed price. While these rebates prevent PBMs from experiencing price increases, patients do not get the same protection to the extent that their cost sharing liability is linked to the list price.

Source: Senate Finance Committee. "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug," 2021. [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf)

Virginia.⁷⁴ These state government offices have greater visibility into PBM data related to their Medicaid MCOs compared to a typical employer, who generally has only modest audit rights and limited access to their own plan data. Expanded visibility of government offices compared to non-government plan sponsors provides them a unique ability to identify PBM spread pricing behaviors for drugs covered under the Medicaid managed care plans.

State investigations revealed that the average difference, or spread, between the amount PBMs charged state Medicaid programs and the amount PBMs reimbursed pharmacies per prescription for the medicine on behalf of Medicaid beneficiaries ranged from \$5.71 in Ohio to \$17.58 in Virginia in 2018 and 2019. This retained spread represented 8.9% to 12.9% of the prescription cost to the state Medicaid program.⁷⁵ Additionally, Maryland found that the spread retained by PBMs on generic, non-specialty claims in 2018 amounted to a third (33.1%) of total payments from the MCO to the PBM.⁷⁶

Apart from traditional "spread," PBMs can also benefit from directing high-margin prescriptions (those with a significant difference between the amount paid by the plan and the cost to acquire the drug) to their own specialty or mail order pharmacies.⁷⁷

To further complicate matters, the price paid to a pharmacy at the point of sale may not even reflect the final pharmacy reimbursement amount due to the increasing use of brand effective rates (BERs), generic effective rates (GERs), and dispensing fee effective rates (DFERs) in pharmacy contracts discussed previously.⁷⁸ If the overall effective rate guarantee was not met over the course of the year, the PBM implements a reconciliation or ‘true up’ process to reach the GER, BER, or DFER.⁷⁹ This reconciliation process may result in the ‘clawback’ of funds previously paid to a pharmacy. These clawback amounts may or may not be passed through or even disclosed to the payer.

Regardless of the contractual set-up, the ability for the PBM to pay one net rate for prescription drugs to pharmacies and bill a different rate (using perhaps an entirely different methodology) to plan sponsors for the same claims provides important real estate for PBMs to inflate the costs of medicines for the purposes of revenue generation. Further, since these effective rate guarantees are specifically linked to the list prices of the medications, any PBM revenue-generation obtained in this scheme would benefit from rising list prices over time. PBMs

clearly view these effective rate arrangements as integral to future revenue generation; 60% of PBM representatives surveyed for this report stated they believed the prevalence of effective rate arrangements with pharmacy networks would increase between 2021 and 2024.

Lastly, PBMs’ ability to optimize their revenue model on an ongoing basis through formulary management, specialty designations, brand/generic designations, and other means creates complexity in understanding PBM contracting costs and monitoring contract performance. Such flexibility, protected in provisions of PBM contracts with public sector and commercial plans, prevents market forces from acting efficiently to drive down costs for all stakeholders. It also allows PBMs to continuously make adjustments in real time to maximize the revenue they collect, a benefit that can be to the detriment of prescription drug payers. These practices can prevent both payers and patients from realizing the full benefits of cost reductions. As a result, some health plans are using new mechanisms to increase PBM competition when selecting pharmacy benefit contracts and conducting real-time adjudication of PBM compliance with contracts after they are awarded (see: Box 6).

Box 6: PBM Reverse Auctions

Public and private sector health plan sponsors looking to select a PBM to administer pharmacy benefits are increasingly relying upon “reverse auctions” to address poor visibility into PBM contracts. Reverse auctions are meant to create a more apples-to-apples comparison of the actual cost under competing PBM proposals. In order to compare complex and frequently opaque PBM pricing proposals on the basis of cost and value, plan sponsors in a reverse auction first determine their own pricing conventions and contract terms. PBM bidders are then required to accept these terms as a precondition for competing in a reverse auction to win the health plan’s business.

PBM reverse auctions often utilize a big-data technology platform containing pharmacy pricing data from multiple, nationally recognized sources and the plan sponsor’s preferred contract terms and drug

utilization patterns. The technology platform uses this information to project the costs of each PBM’s bid, which is then available for viewing by the plan sponsor and other competing PBMs. This visibility into competing offers incentivizes PBMs to underbid one another over multiple bidding rounds to win a contract with the plan sponsor.

New Jersey was the first state to implement a PBM reverse auction. In two successive PBM reverse auctions for selecting a PBM vendor for the state’s public employee health plans covering 750,000 beneficiaries conducted in 2017 and 2019, the State of New Jersey reduced their pharmacy spending by \$2.53 billion. Several states subsequently enacted PBM reverse auction legislation, with Maryland (2020), Missouri (2021), and Colorado (2021) requiring PBM reverse auctions for all state employee health plans.

Source: Attiya A. “States Save on Rx Spending by Using Reverse Auctions for Pharmacy Benefit Manager Service Procurement,” National Academy for State Policy, August 2020. <https://www.nashp.org/states-save-on-rx-spending-by-using-reverse-auctions-for-pharmacy-benefit-manager-service-procurement>

LACK OF MEANINGFUL PBM INDUSTRY STANDARDS, LIMITED TRANSPARENCY, AND LACK OF REGULATORY OVERSIGHT ENABLE PBM REVENUE GROWTH

Many PBM contracting mechanisms and revenue sources lack agreed-upon definitions, providing PBMs with the broad flexibility to interpret the terms of a contract in their favor. As an example, PBMs have come under pressure for collecting manufacturer rebates that they do not pass through to their clients. In response, PBMs have shifted away from retained rebates and toward other sources of compensation (e.g., retained fees on brand medicines and pharmacy margins/spreads for generic medicines). In some instances, this shift is as easy as restructuring sources of revenue collected from manufacturers.⁸⁰ In other instances, it's through retail pharmacy sales channels. For example, PBMs have leveraged their lack of transparency in the pricing of prescription drugs to capture increased revenue per prescription on medications that they sell in higher volume through a practice generally referred to as "specialty pharmacy steering."⁸¹

As the PBM industry becomes increasingly consolidated and vertically integrated, it is more difficult to regulate and monitor; and PBMs are continuing to take steps to further consolidate. Between 2019 and 2021, all three of the largest PBMs formed their own rebate aggregators or group purchasing organizations (GPOs) as consolidated contracting entities to handle rebate negotiations on behalf of themselves and other PBMs.⁸² Industry experts believe these GPO entities, Ascent, Zinc, and Emisar,^{vii} are an attempt to introduce an additional non-transparent layer to the pharmaceutical supply chain and will be used to extract increasing and new fees that are more difficult for customers to track and audit. This increased complexity and reduced visibility may allow these supply chain entities to retain a larger share of rebates, fees, and/or other price concessions.⁸³ These GPO entities (and other vertical consolidation actions) face little regulatory scrutiny and ultimately increase PBM leverage, reduce transparency, distort market competition amongst PBMs, and further limit oversight capabilities, especially since two of the largest three GPOs are based outside of the U.S.⁸⁴

As the PBM industry becomes increasingly consolidated and vertically integrated, it is more difficult to regulate and monitor; and PBMs are continuing to take steps to further consolidate.

Employers are becoming increasingly frustrated with the lack of transparency in the system and the inability to ensure PBMs are acting in their best interest. As a result of this frustration, 67% of large employers report they would favor an alternative supply chain model based on medicines' net prices rather than the current rebate-based model.⁸⁵ According to Johns Hopkins Professors Ge Bai and Gerard Anderson, "While employers prefer low net prices to contain spending on drug benefits, PBMs prefer a widening gap between drugs' list prices and net prices... A wider gap brings PBMs more retained rebates and fees."⁸⁶

Some PBM contracts limit payer ability to hold the PBM accountable for compliance with contract terms by including provisions that allow only auditors approved by the PBM, limit on auditor access to documents, or preclude payor auditing of PBM contract compliance altogether.⁸⁷ These actions deprive employers of the ability to completely understand the drug benefit design, evaluate the efficiency of their drug utilization, and assess the PBM's overall performance.⁸⁸ Nevertheless, some have questioned why employers do not leverage existing contract negotiations with PBMs to require more transparent relationships and point-of-sale application of rebates.⁸⁹

From the patient's perspective, PBM reimbursement and cost-sharing structures can lead to instances where it is cheaper for patients to pay for some medicines completely out of pocket, rather than using their insurance.⁹⁰ Historically, PBMs had imposed "gag clauses" that prevented pharmacies from disclosing to customers that a drug might cost less if paid for out of pocket, without their insurance, than if processed through insurance. In 2018, these gag clauses were outlawed by Congress.⁹¹

vii. Ascent is associated with Express Scripts and was formed in 2019, Zinc is associated with CVS Health and was formed in 2020, and Emisar is associated with OptumRx and formed in 2021.

Federal lawmakers and regulators are continuing to pursue policies that would increase PBM transparency. Legislation under discussion includes limitations on spread pricing within Medicaid, disclosure requirements for plans in the commercial market, as well as requirements to restrict directing patients to access select medications at specialty pharmacies.⁹² The Congressional Budget Office expects those requirements could lead to more efficient competition among PBMs⁹³

Another policy solution gaining attention is imposing fiduciary or similar duties on PBMs. Under the Employee Retirement Income Security Act (ERISA), employer health and pension plan fiduciaries are subject to minimum standards, including the responsibility to “run the plan solely in the interest of participants and beneficiaries.”⁹⁴ Courts have repeatedly found that the PBMs in question have not functioned as ERISA fiduciaries. Some argue for legislation to change this, asserting that assumption of fiduciary responsibility could prevent or make it more difficult for PBMs to keep manufacturer retained rebates and impose spread pricing.⁹⁵

These GPO entities (and other vertical consolidation actions) face little regulatory scrutiny and ultimately increase PBM leverage, reduce transparency, distort market competition amongst PBMs, and further limit oversight capabilities

Historically, states had been largely unsuccessful in regulating PBM activities. However, in *Rutledge v. Pharmaceutical Care Management Association*, a unanimous Supreme Court upheld an Arkansas law that set standards for how PBMs reimburse their pharmacy networks, including reimbursement for plans subject to ERISA. This decision marked a turning point, allowing for more state oversight of PBMs. While the implications of the ruling are still to be seen, the decision may impact net health care expenditures very little due to the retrospective nature of pricing true-ups. Continued regulatory and legislative attention by policymakers suggests continuing dissatisfaction with outcomes of the current PBM marketplace.

Conclusion

Against a backdrop of changing contracting practices, competitive pressures, and public scrutiny, PBMs have succeeded in evolving and adjusting their business practices to grow revenue collected from their payer clients, patients, and other stakeholders within the supply chain, including pharmacies and manufacturers. Financial incentives created by multiple PBM revenue sources undoubtedly influence the behavior of PBMs in the prescription drug market.

While their role is central to the broader pharmaceutical supply chain ecosystem, misalignment of incentives, excess pricing complexity, and a lack of transparency and oversight contribute to the continued increase in prescription drug costs borne by payers and patients. Looking forward, new approaches and policy reforms that seek to mitigate these challenges may offer potential solutions to address the adverse cost consequences for patients, payers, and the health care system as a whole.

Appendix

Appendix A. Methodology & Data Sources

Component	Sources	Methodology Description	Limitations
Gross Profit (PBM Total Revenue Net of Cost of Goods Sold (COGS))	<ol style="list-style-type: none"> 1. CVS Health Annual Report for Fiscal Year Ended December 31, 2019 (Pharmacy Services segment). 2. CVS Health Annual Report for Fiscal Year Ended December 31, 2020 (Pharmacy Services segment). 3. Express Scripts Holding Company Annual Report for Fiscal Year Ended December 31, 2017. 4. Express Scripts Holding Company Quarterly Report for the Quarterly Period Ended September 30, 2018. 5. Cigna Annual Report for Fiscal Year Ended December 31, 2020 (Evernorth segment). 6. UnitedHealth Group Annual Report for Fiscal Year Ended December 31, 2018 (OptumRx segment). 7. UnitedHealth Group Annual Report for Fiscal Year Ended December 31, 2020 (OptumRx segment). 8. BofA Global Research, "UnitedHealth Group OptumRx Primer: Deep dive into UNH's drug management business," April 26, 2021. 	<ul style="list-style-type: none"> • Collect data on gross revenue and cost of goods sold from the three largest PBMs' financial reporting (CVS, ESI, Optum). • Note: ESI 2018 data extrapolated based on first three quarters of the year. • Note: Optum financial reporting excludes COGS. Optum's revenue net of COGS is estimated by assuming a similar ratio between revenue net of COGS and operating income as is observed for ESI and CVS. • Use market share data for the three largest PBMs to estimate the size of the full PBM market. 	<p>Estimating the full market based on an extrapolation of the largest 3 PBMs implicitly assumes that smaller PBMs are equally as profitable as the three largest PBMs. This may be an oversimplification to the extent that smaller PBMs achieve less advantageous contracting arrangements with manufacturers, pharmacies, and/or client health plans.</p>
Retained Rebates (Part D)	<ol style="list-style-type: none"> 1. CMS Part D Drug Spending Dashboard (2017-2019). 2. 2020 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplemental Medicaid Insurance Trust Funds. 3. CMS Final Rule, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses," May 23, 2019. 4. Drug Channels, "Pharmacy DIR Fees Hit a Record \$9 Billion in 2019 – That's 18% of Total Medicare Part D Rebates," February 13, 2020. 5. Government Accountability Office, "Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization," July 2019. 	<ul style="list-style-type: none"> • Collect data on total drug spending in Medicare Part D from drug spending dashboard. • Apply Direct and Indirect Remuneration (DIR) percentage from Trustee's Report to total drug spending. • Subtract DIR collected from pharmacies. • Exclude portion of rebates negotiated by the plan sponsor (not a PBM) per GAO reporting. • Reference GAO reporting for share of rebates retained by PBMs (not passed through to plan sponsor). 	

Component	Sources	Methodology Description	Limitations
Retained Rebates (Commercial)	<ol style="list-style-type: none"> 1. IQVIA Institute for Human Data Science, “The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025,” May 2021. 2. IQVIA Institute for Human Data Science, “Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023,” May 2019. 3. Payer/PBM Survey (See Appendix B). 4. CVS 2016 Analyst Day presentation, “Driving More Affordable, Accessible and Effective Care.” 5. CVS, “CVS Health Responds to Request for Information on Trump Administration’s Blueprint to Lower Drug Prices,” July 16, 2018. 6. CVS, “Second Quarter 2018 Earnings Conference Call,” August 8, 2018. 7. Fierce Healthcare, “CVS Caremark shifts PBM model to 100% pass-through pricing and focus on net cost,” December 5, 2018. 8. Express Scripts, “The Rebate Debate,” June 29, 2017. 9. Cigna, “Cigna Reiterates Support for Proposed Merger with Express Scripts,” August 2018. 10. Fierce Healthcare, “CVS, Express Scripts provide a rare moment of transparency on rebate profits,” August 10, 2018. 	<ul style="list-style-type: none"> • Collect IQVIA data on total retail/mail drug spending at the WAC price for brand drugs. • Consistent with findings from Payer/PBM survey, assume a brand rebate percentage that aligns with Part D. • Estimate pass-through of commercial rebates based on ESI/CVS disclosures. 	<ul style="list-style-type: none"> • Analysis assumes that all rebates on commercial utilization are negotiated by a PBM. • Payer/PBM survey reflects the experience of individual respondents and may not be representative of the entire industry. • ESI/CVS disclosures on rebate pass-through may not be representative of the entire industry.
Retained Manufacturer Administrative Fees (Commercial)	<ol style="list-style-type: none"> 1. IQVIA Institute for Human Data Science, “The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025,” May 2021. 2. IQVIA Institute for Human Data Science, “Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023,” May 2019. 3. Payer/PBM Survey (See Appendix B). 	<ul style="list-style-type: none"> • Collect IQVIA data on total retail/mail drug spending at the WAC price for brand drugs in the commercial and Part D channels. • Collect data from Payer/PBM survey on typical administrative fee as a percentage of brand WAC spend and share of administrative fee passed through to plan sponsors. 	<p>Payer/PBM survey reflects the experience of individual respondents and may not be representative of the entire industry.</p>
Margin from Mail Order/Specialty Pharmacies	<ol style="list-style-type: none"> 1. IQVIA Institute for Human Data Science, “The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025,” May 2021. 2. IQVIA Institute for Human Data Science, “Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023,” May 2019. 3. Medicare Part D Prescription Drug Event Data (PDE), 2017–2019. 4. USC Shaeffer White Paper, “Flow of Money Through the Pharmaceutical Distribution System,” June 6, 2017. 	<ul style="list-style-type: none"> • Collect IQVIA data on total drug spending at the invoice price level for generic, traditional brand, and specialty brand drugs in the commercial and Part D channels. • Estimate the share of drug spend associated with dispenses by PBM-affiliated mail and specialty pharmacies based on Part D PDE Data. • Estimate the amounts reimbursed to PBM-affiliated mail and specialty pharmacies based on typical pharmacy margins for brand and generic drugs. • Subtract spending at the invoice price from reimbursement. 	<p>The use of PBM-affiliated mail and specialty pharmacies within Medicare Part D may differ from other lines of business. Analysis assumes that PBM-affiliated mail and specialty pharmacies earn margins that are (in percentage terms) consistent with retail community pharmacies studied by USC Shaeffer.</p>

Component	Sources	Methodology Description	Limitations
Other Sources		Subtract mail order/specialty pharmacy margin, retained rebates, and retained manufacturer administrative fees from PBM total revenue net of COGS.	To the extent that the limitations noted previously result in an under- or over-estimation of a particular revenue component, the amounts attributable to “other revenue sources” would also be under- or over-estimates.

Appendix B. Health Plan/PBM Survey

Our limited survey of health plan and PBM industry personnel for this study was conducted during August and September of 2021. Respondents included 16 health plan employees and eight PBM insiders (all of whom indicated having insight into the design or implementation of the drug benefit offered to their plan’s members).

The 24 total respondents are summarized below by organization type and number of covered lives:

Organization Type	# Covered Lives	Survey Repondents
Health plan that does not own a PBM (6 respondents)	3-5m	3
	1-3m	1
	250-500k	1
	<250K	1
Health plan that owns a PBM (10 respondents)	10m+	4
	3-5m	1
	1-3m	1
	500k-1m	2
	250k-500k	1
Independent PBM (6 respondents)	<250k	1
	10m+	2
	5-10m	1
Plan-owned PBM (2 respondents)	1-3m	3
	3-5m	1
	1-3m	1

The following tables present responses to questions from the survey respondents working as insiders at independent or plan-owned PBMs concerning recent historical PBM industry trends (2017-19) and industry trends in the near future (2021-24).

PBM RECENT HISTORICAL TRENDS

In the past few years (2017-2019), how have the following trended?

	Amount of rebate PBM passes through to commercial health plan or employer	Amount of revenue from spread pricing	Amount of admin fee PBM collects from health plan or employer	Amount of revenue derived from pharmacy networks (transaction fees, effective rate clawbacks, DIR fees)	Prevalence of PBM effective rate arrangements with pharmacy networks	Amount of clawback from effective rate arrangements	Amount of manufacturer price concessions retained by rebate aggregators or group purchasing organizations (e.g., Ascent/Zinc)
Do not know	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	12.5%
Decrease	0.0%	37.5%	12.5%	12.5%	0.0%	0.0%	0.0%
Neutral	12.5%	0.0%	50.0%	12.5%	25.0%	50.0%	37.5%
Increase	62.5%	62.5%	25.0%	75.0%	75.0%	50.0%	37.5%
Significant Increase (e.g., 5%+)	25.0%	0.0%	12.5%	0.0%	0.0%	0.0%	12.5%

Note: Results limited to PBM respondents (n=8)

PBM FUTURE TRENDS

How about over the next few years (2021-2024), what would you expect?

	Amount revenue from spread pricing	Amount of admin fee PBM collects from health plan or employer	Amount of fees collected from manufacturer	Amount of revenue derived from pharmacy networks (transaction fees, effective rate clawbacks, DIR fees)	Prevalence of PBM effective rate arrangements with pharmacy networks	Amount of clawback from effective rate arrangements	Amount of manufacturer price concessions retained by rebate aggregators or group purchasing organizations (e.g., Ascent/Zinc)
Do not know	0.0%	0.0%	12.5%	0.0%	0.0%	0.0%	12.5%
Decrease	37.5%	25.0%	0.0%	12.5%	0.0%	0.0%	0.0%
Neutral	25.0%	12.5%	12.5%	25.0%	37.5%	50.0%	37.5%
Increase	37.5%	62.5%	50.0%	50.0%	50.0%	50.0%	37.5%
Significant Increase (e.g., 5%+)	0.0%	0.0%	25.0%	12.5%	12.5%	0.0%	12.5%

Note: Results limited to PBM respondents (n=8)

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