

Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead

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ABSTRACT

ISSUE: Pharmacy benefit managers (PBMs) are responsible for negotiating payment rates for a large share of prescription drugs distributed in the U.S. Recently, policymakers have expressed concern that certain PBMs' business practices may not be consistent with public policy goals to improve the value of pharmaceutical spending.

GOAL: We sought to explain key controversies related to PBM practices and their roles in driving value in the pharmaceutical market.

METHODS: Literature review and feedback from top experts on PBM business practices and potential policy solutions.

KEY FINDINGS AND CONCLUSION: In some cases, PBMs' use of rebates has contributed to high pharmaceutical prices, yet proposed solutions to the rebate controversy — including passing the rebate through to payers or patients — will not on their own reduce overall pharmaceutical spending without other policies that drive toward value. Policymakers seeking to reform pharmaceutical reimbursement beyond the practice of rebates will need to consider these changes in light of the recent mergers between PBMs and insurers and the entry of new market competitors.

TOPLINES

- ▶ Pharmacy benefit managers play a key role in the pharmaceutical distribution chain, but are subject to increasing scrutiny as policymakers have questioned their ability and incentives to lower prices and improve value.
- ▶ Reforming the use of rebates in pharmaceutical spending may achieve transparency and reduce out-of-pocket costs for patients in the short term but may not lower overall drug spending and must be paired with other changes to improve value.



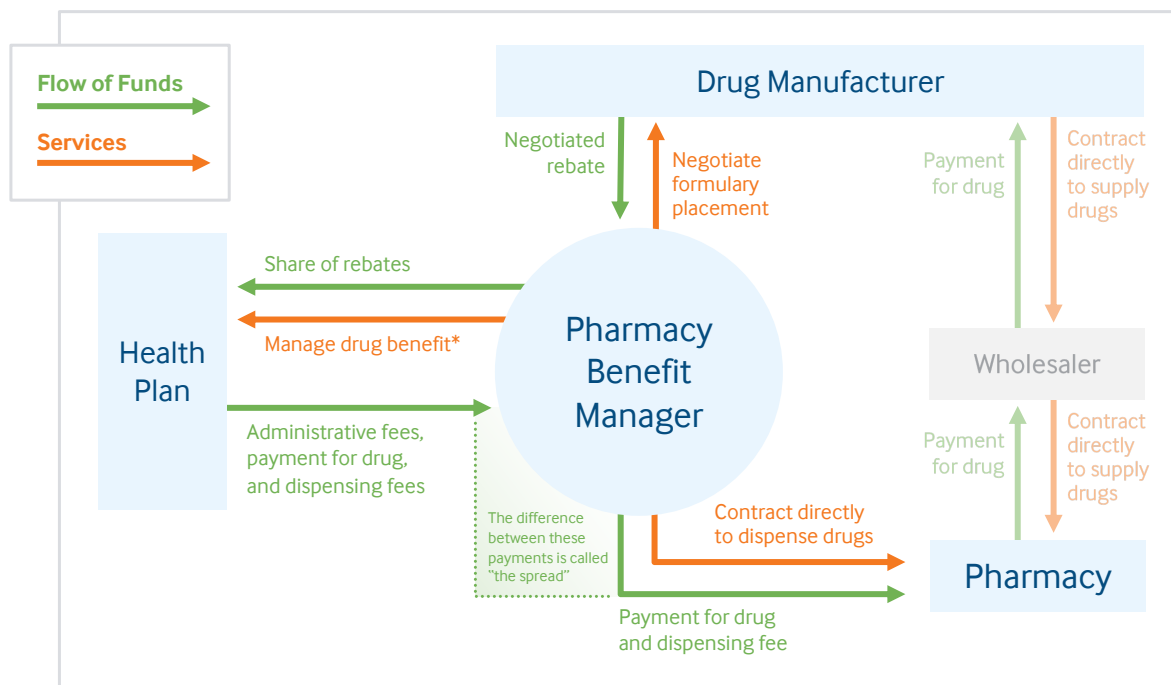
INTRODUCTION

Pharmaceutical expenditures have risen faster than other aspects of health care delivery; one review found the prices of widely used brand-name drugs have increased more than 120 percent since 2008.¹ While pharmaceutical manufacturers set prices in the U.S. market and therefore determine pricing increases, how the pharmaceutical distribution chain impacts prices and spending is not clear or transparent. To help manage their pharmaceutical costs, health insurers frequently contract with pharmacy benefit managers (PBMs), third-party administrators that manage the prescription drug benefit on behalf of the insurer. PBMs help health plans negotiate payment rates with manufacturers through the use of formularies and utilization management tools. In addition to contracting with commercial health plans, PBMs contract with state Medicaid departments and with commercial health plans to provide drug coverage for employer-sponsored plans, exchange plans, and Medicare Part D enrollees. As a result, there is a complicated web of dollars flowing between each of these actors. Drugs pass from manufacturers to

wholesalers to retail pharmacies and finally to patients. Payment runs in the opposite direction, with portions of the reimbursement in the form of rebates and discounts (Exhibit 1).

The Centers for Medicare and Medicaid Services (CMS) recently reported that PBMs have been able to extract larger rebates from manufacturers, which has contributed to lower net prices and dampened rates of growth in prescription drug spending over the past three years.² At the same time, policymakers have raised questions about the practices of PBMs and the extent to which they improve the value of pharmaceutical care in the U.S. To understand the most salient issues, we reached out to a sample of five experts from academia and the federal government³ and conducted a literature review, which included articles in peer-reviewed journals and newspapers, as well as relevant reports. We excluded articles directly connected to the pharmaceutical industry or its proxies.⁴ Two main topics consistently emerged: the practice of rebating⁵ and the prospect of future changes to the industry. In this issue brief, we define each topic and discuss potential solutions.

Exhibit 1. Role of a Pharmacy Benefit Manager in Providing Services and Flow of Funds for Prescription Drugs



* Includes establishing formulary and patient adherence programs and implementing utilization management tools – such as prior authorization, step therapy, and tiering – to steer patients toward certain drugs on formulary.

Data: Adapted from Congressional Budget Office, "Prescription Drug Pricing in the Private Sector" (CBO, Jan. 2007).

REBATES AND THEIR ROLE IN DRUG PRICING

Prescription drug rebates are paid to PBMs by manufacturers after the point of sale and can make up 40 percent or more of the drug's list price. They vary in size depending on a number of factors, such as the degree of competition the drug faces and the placement of drugs on the formulary.⁶ The process of negotiating rebates is a key tool that PBMs use to try to address high drug prices set by brand-name pharmaceutical manufacturers.

It is difficult to assess average rebate levels in the commercial market.⁷ Manufacturer rebates in Massachusetts were reported to be 12.4 percent of total pharmaceutical spending in the commercial market.⁸ PBMs report that in many of their contracts, 90 percent of rebates are passed on to health plans and payers. However, small payers and employers have reported that they did not receive this share (i.e., 90%) of savings.⁹ With drug-specific rebates kept confidential in contracts between manufacturers and PBMs, commercial plans have limited ability to assess the degree of cost-savings for their members, if their contract with the PBM does not guarantee them a certain level of savings.¹⁰

PBMs are reimbursed partially on the rebates they obtain, which are calculated as a percentage of a drug's list price. As a result, critics have made the contention that PBMs may have an incentive to prioritize high-priced drugs over drugs that are more cost-effective.¹¹ This has been cited to explain reports of cases in which tiering or other utilization management strategies were used to favor on-patent brand-name drugs over less expensive (i.e., potentially generic) drugs that are just as clinically useful.¹² Patients may bear these high prices if their cost-sharing is based on a percentage of the list price or if they are among the 25 percent of Americans who have high-deductible health plans.¹³ In the commercial market, 39 percent of employers reported plans having a deductible that includes the pharmacy benefit.¹⁴

POLICY RECOMMENDATIONS

Rebate pass-through to payers. Congress and the Trump administration have been grappling with whether to reform or eliminate the practice of rebates.¹⁵ Most of the rebate is purportedly passed on to the payer in a lump sum, which the payer then uses to offset health care costs and hold down premiums.¹⁶ One suggested reform that may be growing in popularity is requiring that the rebate be completely passed through to payers, thereby not allowing the PBM to retain any of the savings. This would make PBMs more dependent on generating revenue in other ways, such as administrative fees for managing pharmacy benefits and margins made from their mail order and specialty-drug businesses. However, such moves could also reduce the incentives PBMs have to negotiate high rebates, as they will not directly reap the benefits.

An alternative approach would be to require PBMs to pass through at least 90 percent of their rebate savings to all payers, including small health plans and employers. This would be consistent with what the PBM industry claims is current practice. Enforcing a pass-through law could be challenging. Federal legislation mandating minimum rebate levels be passed through could require public disclosure of rebate levels. This could result in manufacturers offering lower rebates or could discourage manufacturers from granting rebates in the first place.¹⁷ The government could avoid public disclosure of data by requiring PBMs to submit confidential data to a central oversight body, similar to the Medicaid Best Pricing Rule that requires manufacturers to submit their best price data to CMS.

Rebate pass-through to patients. Rebate reform could also be linked directly to patients' out-of-pocket costs. UnitedHealthcare announced in 2018 a plan to pass rebates along to 14 percent of its customers (in certain employer-sponsored health plans) at the point of sale, saving patients anywhere from a few dollars to hundreds per month.¹⁸

The federal government has also expressed interest in this idea, proposing to tie Medicare Part D beneficiary cost-sharing to rebate levels. Early in 2018, the Trump administration proposed to require Part D plans to pass on at least one-third of the total rebates and price concessions to patients at the point of sale.¹⁹ While tying patients' cost-sharing to rebates may improve transparency and in the short-term reduce out-of-pocket costs, the change would also result in higher overall drug spending from reduced savings passed-on from PBMs to health plans and ultimately higher health plan premiums. The Congressional Budget Office has estimated a budget increase of \$43.4 billion over 10 years to cover the additional premium increases for Part D plans as a result of this reform.²⁰

Under the Trump administration's most recent proposal, the Department of Health and Human Services (HHS) would only allow manufacturers and PBMs to negotiate rebates on behalf of Medicare beneficiaries if the rebates are fully passed through to Medicare patients at the point of sale.²¹ If passed, this regulatory change could completely alter the current pharmaceutical reimbursement methodology in the U.S. without a clear understanding of the impact.

Understanding rebates. When grappling with the question of how to reform the rebate system, it is important to think about what alternative pricing system might exist if policies were to eliminate or discourage the current practice of rebates. If manufacturers no longer offered rebates, would they instead offer lower list prices? It is more likely that manufacturers would maintain prices at close to the same levels by offering different prices to PBMs in the form of upfront discounts.²² These discounts would reflect the differing degrees of market power between the manufacturer and the PBM for each drug, as well as the negotiated formulary placement. While it is possible that discounts could be more transparent than rebates, these prices could also be kept confidential from health plans, resulting in a new type of "spread" problem, as already seen with PBMs and pharmacy reimbursement.

(See [text box on PBM–pharmacy contracts](#).) Health plans would need to try to estimate the actual price PBMs pay manufacturers, net of discount. Contracts could address this by stipulating the percent of discounts PBMs must pass on to health plans. Thus, a discounted system would not necessarily benefit health plans more than a rebate system.

It is critical that federal and state policymakers study data on drug rebates to better understand pharmaceutical spending in the U.S. In one state initiative, the attorney general in Massachusetts obtained rebate information from the commercial market to study the actual cost of pharmaceuticals to health plans and their members.²³ In addition to obtaining drug-specific rebate data, state and federal policymakers also need to study the contract terms between PBMs and their clients to understand the share of rebates that are passed on to payers. This would allow policymakers to analyze pharmaceutical prices net of rebates in the U.S. and internationally. These insights could help policymakers determine whether a rebate system offers the best opportunity for sustained pharmaceutical spending control or if a new methodology for pharmaceutical reimbursement would better improve value.²⁴

Pricing based on comparative clinical effectiveness. It may be possible to achieve some degree of transparency and short-term reduced out-of-pocket costs for patients, but such an approach to reform the rebate system on its own will not likely lower pharmaceutical spending and improve value overall. Any attempt to replace or diminish the practice of rebates must include a new system of competition among brand-name drug manufacturers. The new system could involve price negotiation, for example, or reimbursement that relies on a comparison of clinical value.

Recently, both CVS and Express Scripts have introduced new reimbursement models for PBM formulary management. (See [text box on CVS Caremark and Express Scripts](#).) This may signify the industry's awareness that the current practice of rebates is poised for change. However, questions remain about the degree to which price and rebate data must be accessible to the public and whether the models improve the value of drugs purchased.

PBM–Pharmacy Contracts: The Spread and the Gag Clause

There have been controversies around how PBMs derive revenue from reimbursement to pharmacies. PBMs' reimbursement to pharmacies for generic drugs has been based on a maximum allowable cost (MAC) schedule, a PBM-generated list of off-patent drugs that includes the maximum price the PBM will pay for each. The MAC schedule can be kept confidential from health plans, allowing PBMs to charge health plans and employers a higher price. The PBM then retains the difference between the MAC price they pay the pharmacy and the price the health plan pays, which is termed "the spread." In a recent example of the pharmacy spread problem, two PBMs in Ohio reimbursed pharmacies \$2.3 billion and billed Medicaid \$2.5 billion for their generic and branded drugs, resulting in a spread of \$200 million.^a

Federal legislation proposed in 2017 and 2018 would mandate that PBMs update their MAC schedule to reflect generic drug price increases. This would likely protect pharmacies' margins (especially for nonchain pharmacies that may not have large bargaining power), but would not address the problem of not knowing what share of the overall pharmacy spread is being passed on to payers, and ultimately patients. These reforms are also limited in that most of them only affect generic drug prices. To impact a larger share of overall drug spending, payers would need to calculate and recoup the spread made on both generic and brand-name drugs.

Another controversial issue is the gag clause, a requirement PBMs wrote into pharmacy contracts that prohibits pharmacists from disclosing to patients that a drug may be less expensive if paid for directly without using insurance. This allows PBMs to profit from patients' copays. A recent *JAMA* study showed that copayments were higher than the cash price for one of four drugs purchased by patients with Medicare Part D insurance in 2013. For 12 of the 20 most commonly prescribed drugs, patients overpaid by more than 33 percent.^b The gag clauses in the contract may directly stipulate that patients cannot be informed of the cheaper alternative unless they ask. In some cases, the contractual language may be more nebulous, with broad language requiring that pharmaceutical reimbursement rates and prices be kept confidential. States and Congress have taken swift action on gag clauses. Between 2016 and September 2018, 27 states enacted laws that sought to prevent gag clauses. In September 2018, Congress passed a federal law prohibiting gag clauses.

^a Ohio Department of Medicaid, Report on MCP Pharmacy Benefit Manager Performance (State of Ohio, June 15, 2018).

^b Susan Jaffe, "No More Secrets: Congress Bans Pharmacist 'Gag Orders' on Drug Prices," *Kaiser Health News*, Oct. 10, 2018; and Karen Van Nuys et al., "Frequency and Magnitude of Co-payments Exceeding Prescription Drug Costs," *Journal of the American Medical Association* 319, no. 10 (2018): 1045–47.

POTENTIAL FOR PBM MARKET DISRUPTION

There are two other large potential shocks that could impact the industry — another round of PBM consolidation and competition from potential market disruptors such as Amazon.

Recent vertical integration between insurers and PBMs (Exhibit 2) raises questions about the degree to which integration will occur and what it would mean for pharmaceutical spending. A new wave of integration could improve the value of pharmaceutical purchasing by:

- allowing PBMs to diversify business lines away from the traditional rebate approach
- promoting physicians' use of cost-effective medicines
- consolidating pharmaceutical and clinical data to improve population health
- working with physicians, pharmacists, and patients to better manage care.²⁵

Under the current rebate system, reimbursement for prescription drugs is primarily based on volume, which may not be aligned with the finances of health plans or consumers. By aligning financial incentives with health plans, PBMs could begin to take on additional risk in pharmaceutical costs by basing reimbursement on the health benefits of the drugs as well as reductions in total cost of care, including inpatient and outpatient medical costs.

CVS Caremark and Express Scripts Make Changes to Formulary Models

In August 2018, CVS Caremark announced that it will use estimates of cost-effective pricing set by the independent Institute for Clinical and Economic Review (ICER) to determine whether a drug will be included in the formulary. Specifically, clients can exclude drugs that have therapeutic alternatives and do not meet the benchmark of \$100,000 per quality-adjusted life year. CVS Caremark's willingness to use ICER estimates may represent a significant move toward a more transparent, systematic approach to pharmaceutical coverage decisions. However, there is not yet public information on how this model affects rebates for these drugs and the extent to which they are passed on to insurers and employers. All these factors will need to be carefully considered when testing new reimbursement and coverage models in place of a traditional rebate approach.

In November 2018, Express Scripts announced its response to critiques about the practice of rebates. A new framework, called Flex, will create a two-tier formulary system. Health plans and employers can choose between: 1) the current, standard formulary with high list prices and rebates or 2) a new formulary with lower list prices and no rebates. Payers that have negotiated good rebate pass-throughs in their current PBM contracts may choose to stick with the status quo to ensure guaranteed rebates in their budgets. Other payers who are unhappy with the current practice of rebates may elect to use this Flex plan, where their PBM relies less on rebate revenue. However, in making their decision, payers will not be able to compare the net-of-rebate price of drugs in the standard formulary with the lower list price of drugs in the Flex formulary, making it difficult to determine which model is optimal. There are also questions around which drugs will be included in the Flex plan.

In addition to another round of vertical integration, the PBM industry could face new market entrants that disrupt current business practices. For example, Amazon purchased PillPack, a company that packages, sorts, and ships a month's supply of medicines to patients with chronic diseases. Through this acquisition, Amazon could become a competitor to pharmacies' and PBMs' mail-order lines of business²⁶ and could improve pricing transparency.²⁷ New entrants like Amazon could also partner with one or more PBMs to leverage their relationships with pharmacies, physicians, and manufacturers and to access their large patient base.²⁸

CONCLUSION

Pharmacy benefit managers are a consolidated and increasingly vertically integrated industry that currently plays an important role in pharmaceutical distribution. However, controversies surrounding the potential misalignment of their financial incentives with health plans, pharmacies, and patients have attracted public scrutiny. Although policymakers are considering reforming the rebate system by increasing transparency or requiring PBMs to pass through more rebate savings, this will not reduce overall pharmaceutical spending without other accompanying changes though it may reduce some out-of-pocket costs in the short-term. Policymakers need to consider which reforms, along with changes to PBM reimbursement, will bring value to the broader health care system. They should also consider the impact of reforms in light of recent mergers in the industry and the entry of new market competitors.²⁹

Exhibit 2. Pharmacy Benefit Managers: Market Overview

Example	History and Market Position	Proposed/Recently Completed Mergers
Express Scripts	<p>Not currently owned by a larger health care company.</p> <p>Increased its market share in 2012 by acquiring rival Medco Health Solutions (Merck's PBM spin-off) for \$29.1 billion.</p> <p>In 2016 and 2017, the legal battle between Anthem and Express Scripts over rebate savings resulted in Anthem announcing it will terminate its business with Express Scripts in 2019 when its current contract expires.</p>	<p>Express Scripts announced in December 2017 that it would merge with health insurer, Cigna. This deal was completed in December 2018.</p>
CVS Caremark	<p>A subsidiary of CVS Health, which owns the CVS chain of retail drug stores.</p> <p>In 2007, CVS Health acquired PBM Caremark Rx for \$21 billion, resulting in PBM CVS Caremark.</p>	<p>Anthem will contract with CVS Caremark in 2019 to pay its pharmacy claims but will negotiate rebates directly and manage its own formulary with manufacturers through the creation of its own PBM in partnership with CVS Health, Ingenio RX.</p> <p>CVS Health announced in December 2017 that it would acquire Aetna and completed the transaction in November 2018.</p>
Optum Rx	<p>A subsidiary of health insurer, UnitedHealth Group.</p> <p>In 2015 UnitedHealth Group acquired PBM Catamaran Corp for \$12.8 billion.</p>	<p>Already vertically integrated with UnitedHealth Group.</p>
Humana Pharmacy Solutions	<p>A subsidiary of health insurer Humana Inc.</p>	<p>N/A</p>
Prime Therapeutics	<p>Is owned by 18 Blue Cross and Blue Shield not-for-profit plans.</p> <p>In 2017, Prime Therapeutics and Walgreens formed a combined central specialty pharmacy and mail services company, as part of a strategic alliance. This jointly owned, new pharmacy company is called AllianceRx Walgreens Prime.</p>	<p>N/A</p>
Medimpact Healthcare Systems	<p>Privately held PBM.</p>	<p>N/A</p>

NOTES

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