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Pharmacy Benefit Managers and the U.S. Pharmaceutical Market

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Abstract

What is the message? Critics of Pharmacy Benefit Managers (PBMs) claim that they contribute to rising spending on prescription drugs, while others argue that PBMs improve market efficiency. This controversy has stimulated new proposed legislation and investigations. The authors describe the PBM business model, clarify their impacts on the U.S. pharmaceutical market, and highlight areas where future research may help inform policymaking.

What is the evidence? An analysis of recent literature, studies and congressional investigations.

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Improving prescription drug affordability is high on the agenda of patients and policymakers in the United States. Drugs are generally covered by health plans and account for a small share of total annual health expenditures; however, they are ubiquitously consumed, and spending has grown over time.[1] Patients are commonly asked to pay some portion of the bill out-of-pocket at the pharmacy counter, and out-of-pocket costs associated with some needed prescription drugs may be quite high.[1] The Inflation Reduction Act of 2022, passed by the U.S. Congress in August 2023, aims to moderate public spending on prescription drugs covered by Medicare Part D and out-of-pocket spending by Medicare beneficiaries by improving the generosity of insurance provided by plans, reducing price increases, and negotiating the prices of some existing drugs.

Policymakers are now setting their sights on reforming the practices of other players in the pharmaceutical supply chain, notably pharmacy benefit managers (PBMs).[2-4] PBMs are central, yet enigmatic, market intermediaries that manage pharmacy benefits on behalf of health plans.[5] Critics claim PBMs contribute to rising spending on prescription drugs, while others argue that PBMs improve market efficiency. This controversy has stimulated new proposed legislation and investigations. The U.S. House of Representatives Committee on Oversight and Accountability produced a series of reports and held hearings which provided some details about PBM practices and their potential impacts on drug pricing and availability. The U.S. Senate has proposed bipartisan-supported reforms to PBM business practices such as the Modernizing and Ensuring PBM Accountability Act (MEPA) (S. 2973 118th Congress 2023-2024), but these proposals were not included in the recently passed 2024 appropriations bill. The Federal Trade Commission (FTC) is also pursuing an investigation into the practices of PBMs.[6]

In this essay we describe the business model of PBMs, clarify their potentially desirable and undesirable impacts on the U.S. pharmaceutical market, and highlight areas where future research may help inform policymaking.[7]

The Role of PBMs in the US Prescription Drug Market

Figure 1 sketches the central intermediary role PBMs play in drug markets. Drug makers bring new brand drugs to market and set the list price of their products. Patients contract with health plans (payors) to provide coverage for needed medical care, including pharmacy benefits. Plans can negotiate with brand drug makers for rebates based on their members' expected pharmacy use and the drug's formulary placement or, more commonly, hire a PBM to perform these responsibilities. In turn, PBMs act as a provider of these services to multiple health plans. It is in this sense, that PBMs act as intermediaries for payors. Patients pay premiums to their health plan and an out-of-pocket cost in the form of copays or coinsurance when a prescribed drug is dispensed at the pharmacy counter (for simplicity, we omit pharmacies from the Figure). The out-of-pocket cost patients incur for a dispensed brand drug is usually far less than the transaction price at which the drug is purchased by the pharmacy from the drug maker. The remainder of the cost of the dispensed drug is paid by the health plan to the pharmacy as reimbursement. Finally, the transaction, or 'net', price of a drug is the list price set by the drug maker minus any rebates offered to the PBM. Typically, drug makers only pay rebates to PBMs on brand drugs.

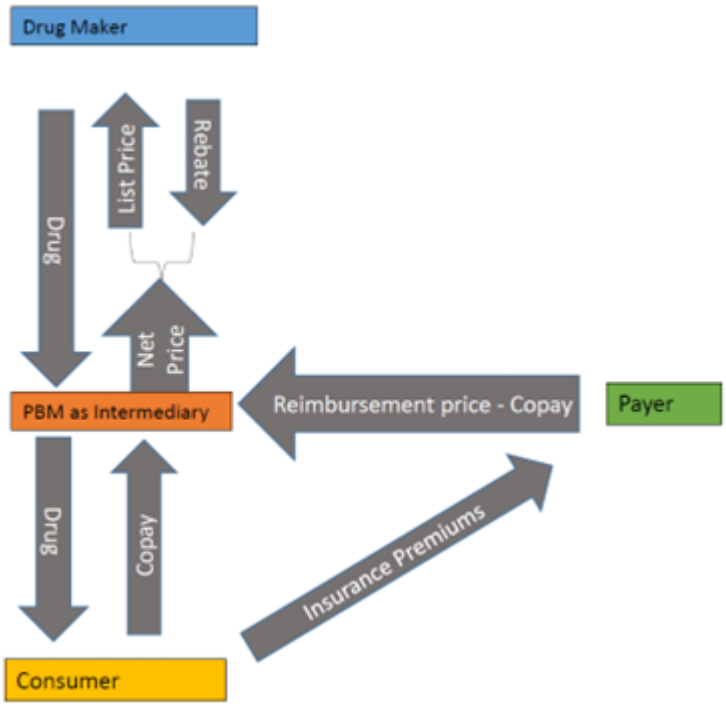


Figure. Pharmacy Benefit Managers as an Intermediary between Drug Makers, Health Plans, and Consumers

PBMs influence the rebates offered by brand drug makers through the design of formularies. Formularies place drugs on different tiers, each with a different out-of-pocket cost to patients. Patients typically can acquire generic drugs for minimal out-of-pocket expenses because the PBM has placed them in the lowest tier. Preferred brand drugs are placed in a higher tier, and consumers pay higher, but still low, out-of-pocket costs for these drugs. To access non-preferred drugs, consumers will have to pay even higher out-of-pocket costs.

Potentially Desirable Effects of PBMs on the U.S. Pharmaceutical Market

PBM formularies provide convenience and create efficiencies for payors. Instead of each plan setting up and managing its own formulary, PBMs may operate the same formulary or similar formularies on behalf of multiple plans. Thus, PBMs consolidate health plans' negotiations with drug makers for formulary placement. PBMs also negotiate pharmacy fees on behalf of multiple health plans.

Formularies operated by a PBM encourage patients insured by plans to choose inexpensive generic drugs because the lowest tier gives patients access to generic drugs at a nominal out-of-pocket cost. The use of generic drugs, especially those commonly used to manage such chronic illnesses as diabetes, depression, and cardiovascular disease, creates significant cost savings for plans and patients.[1,4] Indeed, with the increasing prominence of PBMs in the U.S. market, we have seen a dramatic shift towards the use of generic drugs over the past two decades. More than 90% of prescriptions filled in the United States in 2022 were for generic drugs.[8]

Formularies also steer patients to use preferred brand drugs over non-preferred brands. This steering effect reduces the net price of drugs because brand drug makers offer higher rebates to PBMs to increase the chances that their drug will be placed on a preferred brand tier rather than a less desirable non-preferred brand tier.[9] In effect, formulary design heightens competition between the makers of brand drugs. From this perspective, it is perhaps not surprising that

rebates offered by drug makers grow with the extent of competition in a drug's therapeutic class and are concentrated in a relatively small number of products.[4] Weinstein and Schulman (2020) report evidence that PBM formulary exclusions of brand drugs grew between 2011 and 2020 and are associated with more extensive rebate payments by drug makers to PBMs.[10] In addition, recent work by Kakani, Chernew and Chandra (2020) and Feng and Maini (2024) suggest PBMs act to lower net prices and consequently spending on prescription drugs.[11, 12]

PBMs may also steer patients toward low-priced pharmacy services. Like managed care organizations, PBMs construct 'preferred' pharmacy networks on behalf of health plans. Researchers have found that beneficiaries of Medicare Part D plans with preferred pharmacy networks pay lower out-of-pocket prices for retail prescription drugs.[2,3] PBMs also operate their own mail order pharmacies. Patients may prefer mail order for the convenience of obtaining prescriptions at home rather than having to travel to a pharmacy. Prescriptions of drugs used chronically are commonly dispensed through mail order in higher quantities, such as a three-month supply, and mail order dispensing services may also be less costly than through retail pharmacies providing cost savings to patients and plans. PBM-owned pharmacies, such as CVS-Caremark, also compete with large standalone pharmacy chains, such as Walgreens, and the pharmacies of retail grocery store chains. Competition may increase service quality and decrease the prices paid for pharmacy dispensing fees.

Health plans compensate PBMs for delivering these various services. Generally, PBMs are paid using one of two models. In the first model, sometimes called the 'pass-through' model, the PBM bills the plan the exact cost of the dispensed drug and passes that amount to the pharmacy, and also passes 100% of the rebates it receives from the brand drug maker to the plan. In this model, compensation for the PBM's services takes the form of fees, so there is a transparent connection between the services provided and the fees paid. In the second model, sometimes called the 'spread-pricing' model, the PBM is paid through spread-pricing or rebate retention. Under spread-pricing, the contract permits the PBM to bill the plan a rate per dispensed prescription that is higher than the PBM pays to the pharmacy per dispensed prescription and to retain the difference. Under rebate retention, the PBM retains a specified percentage of the rebates it receives from brand drug makers and passes the remainder to the plan. These PBM payment models compete as alternatives in the marketplace, and plans often have a choice of

one or the other, or a hybrid of the two. PBMs may also receive fees from drug makers.

Potentially Undesirable Effects of PBMs on the U.S. Pharmaceutical Market

One concern raised about the impact of PBMs is patient access to prescription drugs. Some empirical evidence suggests patient out-of-pocket costs on brand drugs have grown, even as rebates extracted from drug makers have also increased.[13] Others suggest rebates have increased without a measurable impact on access.[12]

Drug makers may react to PBM formularies in ways that undermine competition and increase costs. For example, brand drug makers may offer copay coupons or other types of patient assistance that shields patients from out-of-pocket expenses when using high-priced drugs placed in less desirable formulary tiers.[14] These activities may undermine the incentives to use generics when available. Brand drug makers may also undermine formulary competition by offering expanded rebates to PBMs in exchange for favorable formulary placement for a bundle of drugs they sell.[4,5] While this pricing strategy reduces net prices paid for drugs in the bundle, it may also reduce competition from drugs not in the bundle. It is possible that this strategy may contribute to the surprisingly limited uptake of available biosimilars (generic versions of biologic drugs).[15]

The economics of drug rebates may also cause PBMs to favor brand drugs with higher list prices. To see why, consider that a high list price brand drug with large rebates allows the PBM to offer a larger discount to health plan beneficiaries even if the transaction price of the drug (that is, the list price net of rebates) is unchanged. This can create a race to the top in list prices, a practice sometimes termed ‘shadow pricing’. The House Oversight and Accountability Committee reported numerous examples of shadow-pricing behavior by brand drugs facing brand competition, including that of Humira and Embrel and various brand insulin pens. This behavior causes patient harm. Contrary to the conventional wisdom that ‘nobody pays list price’, uninsured patients do. Also, high list prices can increase costs for patients paying deductibles and coinsurance because list prices are used in calculating these payments.

Finally, the growing market power of PBMs may distort the operation of markets. PBMs have

grown to become huge entities.[2-5] One PBM, Express Scripts, was more profitable than the health plans Anthem, Cigna, Aetna, or Humana in 2016.[7,16] Their concentrated buying power may allow PBMs to capture too much of the value they create through formulary design and the other services they provide to health plans. This value capture may involve charging high fees or retaining significant rebates for their services. Indeed, some House Oversight reports and recent work by Van Nuys et al (2021) suggest PBMs may be capturing an increasing amount of the value they create.[13] PBMs are also known to sign most-favored-nation (MFN) contracts with drug makers.[5,7] These contracts, which guarantee that a drug maker supplies drugs to a single PBM at the lowest price available in the market, make it more difficult for new entities to enter the market for PBM services and disrupt incumbents. They also may inhibit the generation of horizontal or vertical merger-related efficiencies. Information about MFNs and other potentially anticompetitive practices is not generally available. Analysts are learning more about these practices and potential harms through government investigations and documents obtained as part of lawsuits.[17]

Targets for Reforming PBMs and a Research Agenda

Our analysis of PBMs points to ways that they potentially enhance the efficiency of drug markets. Realizing this potential, however, requires that regulators and market participants pay attention to important threats. Some of these threats are the subject of proposed reforms or ongoing investigations into industry practices. Others, we believe, deserve additional investigation.

Antitrust regulators have well-established tools to assess and limit PBM mergers or MFN contracts that harm consumers. In contrast, the effects of the substantial vertical integration between PBMs, insurers, and pharmacies observed in the pharmaceutical market, are not well understood. We are particularly interested in the results of the ongoing FTC investigation into PBMs that are vertically integrated with large, national health insurers. Specifically, the FTC has announced an investigation into the business practices of three companies, Caremark, Express Scripts, and Optum Rx, that are vertically integrated with health insurers Aetna, Cigna, and UnitedHealthcare, respectively. Proposed legislative reforms also require the HHS Office of Inspector General (OIG) to investigate the impact of vertical integration between Part D plans,

PBMs, and pharmacies, including effects on firm profits, premiums, beneficiary out-of-pocket costs, and Medicare spending under the Part D program.

Our analysis also points to other aspects to drug makers and PBM practices that deserve deeper investigation. These include the potential anticompetitive effects of brand copay coupons, the bundling of brand drug rebates paid to PBMs, and the strategic manipulation of brand drug list prices.

Given the size, impact, and importance of the U.S. pharmaceutical industry, it is remarkable that we still know so little about the organization, financing, and impacts of PBMs. For example, while list price data is easily available, data on the rebates PBMs negotiate with drug makers are closely held secrets. One rationale for such secrecy is that firms believe that keeping rebates secret helps them retain a competitive advantage. However, this interest ought to be weighed against the potential benefits greater transparency would bring to policymaking, regulation, and analysis.

Given the complexity and centrality of PBMs to modern drug markets, economists, regulators, and legislators should devote substantial efforts to learning more about PBM operations, finances, and effects on patients and payors.

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