COMMENTARY

Pharmacy Benefit Management: The Cost of Drug Price Rebates

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Abstract: Pharmacy Benefit Managers (PBM) induce drug manufacturers to offer rebates to insurers and employers by denying coverage through formulary exclusions, impeding physician prescription through prior authorization, and reducing patient drug use through cost sharing. As they tighten these access obstacles, PBMs reduce the net prices received by the manufacturers.

Many therapeutic categories served by the pharmaceutical industry have a high potential for competition, with multiple firms willing to reduce prices if they believe they can thereby increase sales. But potential competition translates into actual competition only if purchasers reward lower prices with higher volumes. In his broad-ranging Congressional testimony, Benjamin Rome spares no participants in the pharmaceutical sector but directs his strongest criticism at the manufacturers themselves, for posting high prices. This commentary will focus on the Pharmacy Benefit Managers (PBM), whose role it is to reduce those prices. PBMs induce drug manufacturers to offer rebates to insurers and employers by threatening to deny coverage through formulary exclusions, impede physician prescription through prior authorization, and reduce patient drug use through cost sharing. As they have tightened these access obstacles, PBMs have been able to squeeze larger rebates from manufacturers, reducing the net price received by the manufacturer. But in so doing they also impose ever-greater administrative burdens, transaction costs, and adverse health outcomes on the health care system.

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PBMs Reduce Net Prices

While list prices have continued to grow year over year, net prices have fallen significantly for generics and are drifting downwards for many categories of branded drugs. The success of the PBMs is due in part to the consolidation of their sector, which threatens pharmaceutical firms with significant losses in sales if they cannot come to terms. The three largest PBMs now account for 85% of the drugs that are distributed through mail order, retail, and chain pharmacies.[1] This excludes the approximately one-third of drugs that pass through the "buy and bill" distribution channel to hospitals and other provider entities and are not subject to price rebate negotiations by PBMs.

The rebates negotiated by PBMs are testimony to the highly competitive nature of the pharmaceutical market. Over 90% of prescriptions in the US are filled with generic drugs, where competition drives prices down to the marginal costs of manufacturing and distribution. Prices for generics are lower in the large US market than in Europe.

Similarly, biologic products that have lost their patent and regulatory exclusivity increasingly face competition from biosimilars, though with fewer entrants

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and smaller rebates than traditional small molecule drugs. The most recent generation of biosimilars is experiencing rates of volume growth and price declines more substantial than the earlier generations, though the US biosimilar market still lags behind the market shares and price savings achieved in Europe.[2] This pattern may flip as the FDA approves the interchangeability of biosimilars, which will allow pharmacists to substitute biosimilars in place of a branded biologic medication without requiring a new prescription, analogous to similar substitution that is commonplace for generic drugs.

Even drugs still enjoying patent and FDA protection face potential price competition from products with different mechanisms of action but similar therapeutic effects. The innovation race among pharmaceutical firms, all seeking to enter the most profitable markets, undermines profitability of drugs except where physicians or patients are unwilling to switch to lower-priced alternatives due to uncertainty about safety, efficacy, or convenience.

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PBMs Impose Social Costs

In wresting rebates from manufacturers, PBMs impose substantial administrative burdens and transaction costs on the pharmaceutical supply chain, leading to adverse health impacts on patients. These can best be understood by examining the instruments used by PBMs to negotiate rebates.

Formulary exclusions. PBMs develop formularies, defined as the list of drugs for which they will offer insurance coverage and reimbursement, and demand rebates from manufacturers under the threat of exclusion. Formulary exclusion imposes minimal burdens in therapeutic categories where there exist multiple generic offerings but can adversely affect patients and require expensive and time-consuming administration in categories with similar but not identical drugs. PBMs have become more aggressive in limiting their formularies in recent years. Between 2016 and 2022, the number of drugs excluded from formularies for the three major PBMs increased from less than 100 to over 400.[3] Single-payer health systems such as those in Europe also threaten non-coverage to leverage discounts, limiting access in favor of affordability. But the process is much more burdensome to physicians in the US multi-payer system with different policies for which drug is permitted for which patient by which PBM and under which conditions.

Utilization management. Even if a drug is included in a formulary, high-cost drugs are often subject to utilization management policies. Prescribers may be required to obtain prior authorization, providing attestation and documentation to the PBM or insurer that the patient has the correct indication, severity of illness, and history of treatment. The prescribers and patient may be required to "step" through various lower-cost alternatives before using an expensive drug, even if the patient has tried and failed on those alternatives in the past.[4] Manufacturers willing to offer large rebates are compensated with milder forms of utilization management.

Consumer cost sharing. Drugs that offer a rebate sufficiently large to merit formulary inclusion nevertheless can be subject to significant financial barriers to access. The patient's responsibility increasingly is comprised of an annual deductible and percentage coinsurance, both linked to the manufacturer's list price rather than the post-rebate net price. These list prices continue to rise in part due to the PBM rebates, because the manufacturer raises the list price in anticipation of having to pay rebates. One-third of patients with employer-sponsored insurance now have an annual deductible of $2000 or more and approximately one-fourth have an annual out-of-pocket maximum of $6000 or more.[5] Cost sharing is

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consistently associated with non-adherence and poor health outcomes, especially for patients with chronic conditions.[6]

The war of all against all. The transaction costs imposed by PBMs extend beyond prescribers and patients and encompass all participants in the pharmaceutical supply chain. Enacting utilization management tools requires trained administrative and clinician staff on the part of the PBMs and their employer and insurer clients. Physician practices must devote many hours to obtain prior authorization for their patients' prescriptions. Pharmaceutical firms fund programs to help doctors navigate prior authorization and to help patients cover their cost-sharing obligations. PBMs respond to these pharmaceutical industry programs by intensifying their own efforts, excluding more drugs from their formularies, tightening the documentation requirements for prior authorization, raising consumer cost-sharing levels, and refusing to credit manufacturer contributions against the patient's cost-sharing obligations. It has become a war of all against all. A conservative accounting estimated $100 billion as the annual direct cost of utilization management, even without the human costs of physician frustration and patient non-compliance.[7]

Conclusion: A Better Way?

The US appears to be stuck in a dysfunctional cycle of high drug prices and rebates, stringent utilization management, industry programs to counteract PBM initiatives, intensification of PBM initiatives, and further increases in prices and rebates. There must be a better way.

Some policy analysts argue for a compromise in which pharmaceutical manufacturers limit their prices to cost-effectiveness benchmarks and purchasers align their utilization management and cost-sharing requirements with evidence-based clinical criteria.[8] The nonprofit Institute for Clinical and Economic Review (ICER) publishes both sets of benchmarks. Such a compromise could take the form of transparent price discounts rather than confidential price rebates.

Unfortunately, examples of contractual agreements for value-based price and access are few and far between. In part, this reflects the power of the entities that profit from the status quo, including the PBMs. In part, however, it reflects the fragmentation of the private purchasers, no one of which has the scale to transform the market. If there is to be improvement in the efficiency of the pharmaceutical supply chain, it likely will require leadership from Medicare, the only entity with the size and sophistication to develop, test, and implement new pharmaceutical payment structures.

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