Health Affairs

PRESCRIPTION DRUG PRICING

HEALTH POLICY BRIEF SERIES
SEPTEMBER 2017 | 12

PHARMACY BENEFIT MANAGERS

On behalf of payers, pharmacy benefit managers negotiate rebates from drug makers in exchange for preferred formulary placement.

Pharmacy benefit managers (PBMs) represent health insurers, self-insured employers, union health plans, and government purchasers in the selection, purchase, and distribution of pharmaceuticals. As brokers between payers (representing patients), drug manufacturers, and dispensers (pharmacies), PBMs play an important and contentious role: They decide which drug products are used most frequently and how much each participant in the drug delivery system is paid for its part in the process. PBMs are key participants in the administration of drug benefits for more than 266 million Americans with health insurance, using volume-buying leverage to negotiate discounts from manufacturers, generally delivered in the form of rebates. PBMs subsequently share these rebates with their customers—the payers. They also create networks of pharmacies (often supplemented with mail-order operations) and negotiate reduced dispensing fees. PBMs extract a piece of the overall purchase price for a drug at each of these points within the drug delivery system, and because they are opaque about the size of discounts obtained, they experience constant scrutiny.

Background

Pharmacy benefit managers became a major force in the late 1980s, expanding from pharmacy claims processing to a business model that forced drug manufacturers to engage in price competition in several drug categories. These categories, including angiotensin-converting enzyme inhibitors, statins, and nonsedating antihistamines, were dominated by multiple similar brand-name drugs that were not suitable for generic substitution. PBMs supported therapeutic interchange by selecting one brand among similar brands in a class as the preferred choice and negotiating discounts from that manufacturer in the form of rebates. That approach lowered the cost of that brand to payers and often lowered direct costs for the patient through placement of the brand on a preferred formulary tier. PBMs were so effective at product selection and earning discounts that three of the early PBMs were purchased by major pharmaceutical companies: Merck (Medco), Eli Lilly (PCS), and GlaxoSmithKline (DPS). That ownership raised concerns among payers that PBMs were favoring certain drugs to the benefit of their parent companies. Such concerns were assuaged when those pharmaceutical companies later sold their PBMs. Merck persevered the longest, owning its PBM Medco until 2003.

WITH SUPPORT FROM:

The Commonwealth Fund

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PBMs gained more prominence—and recognition from the federal government—in 2003 with passage of the Medicare Modernization Act (MMA). This law implemented the Medicare Part D outpatient drug benefit using private plans that competed for customers based on their ability to negotiate favorable drug prices, create formularies, and hold down premiums. PBMs generally represent the Part D plans in these negotiations, serving as surrogates for the government. MMA, in fact, includes a noninterference provision, section 1860D-11(i), which restricts direct government involvement in Part D price negotiations.

> "In 2014, the top three PBMs managed pharmacy benefits for over 180 million lives."

To be effective as negotiators with pharmaceutical marketers, PBMs need size. The more covered lives (insured customers) represented by a PBM, the more likely that manufacturers will offer rebates in return for potential market share. This reliance on large size has led to consolidation in the PBM industry during the past decade. In 2014 the top three PBMs managed pharmacy benefits for over 180 million lives—about 80 percent of the total number covered by PBMs. Evidencing recent consolidation, two years earlier, when the Federal Trade Commission approved the acquisition of Medco by Express Scripts, the agency found there were "at least ten significant competitors" in the PBM segment. The current top-three firms represent three different models: the standalone PBM (Express Scripts); the PBM aligned with a major retail drugstore (CVS Health); and a PBM associated with a major health insurer (OptumRx, UnitedHealth Group).

Payers tend to defer to PBMs to handle drug budgets because the latter have established retail networks, mail-order distribution centers, and experience building and managing continuously evolving drug formularies (Exhibit 1). Perhaps most important, from the payer perspective, PBMs have standing with the pharmaceutical industry in price negotiations.

PBMs' Impact On Drug Expenditures And Prices

PBMs derive revenues from the following sources:

(1) Fees from their clients (insurers, self-insured employers, union health plans, and government) for administration of claims and drug dispensing;

(2) A share of the savings from rebates negotiated from drug companies; and

(3) A combination of fees and shared savings from the maintenance of pharmacy networks.

PBM price negotiations are opaque by design. PBM leaders and their payer clients believe that full transparency on rebate levels could quickly lead to a floor on bid prices, preventing further discounts.

MEDICARE PART D

The first eight years of drug spending under the Medicare Part D program (from 2006 to 2013) came in well below initial projections: a cumulative $353 billion spent by Medicare, compared to $550 billion originally estimated by the Congressional Budget Office (CBO). That performance is cited by advocates of private-sector negotiations in Part D as evidence that PBM competition and price management are successful tools in a major public program. However, some analyses suggest that lower-than-expected gross Part D spending might not be related directly to PBMs' negotiating skills; instead, the lower expenditures may derive more from an influx of generic versions of top-selling drugs, lower-than-anticipated Part D enrollment, and a trough period for new drug approvals.

It is difficult to estimate rebate levels obtained by PBMs serving Part D, because of the lack of transparency noted above. The PBM industry commissioned a 2016 study that projected $257 billion in savings to Part D plans from the continued use of PBMs from 2016 to 2025. A recent drug industry–commissioned study found that PBM plan rebates and negotiated discounts in Part D exceed discounts in the commercial/private markets by 10 percentage points. Using early data from the second year (2007) of Part D experience, the CBO estimated rebates on single-source brand-name products at 14 percent.

COMMERCIAL MARKET

It is similarly difficult to estimate rebate levels in the commercial market. However, a frequently used industry estimate is that PBMs achieve rebates of 30 percent off list price, accounting for all discounts and fees.

The most meaningful attempts to calculate the size of commercial rebates derive from the difference between invoice prices from manufacturers compared to net receipts to the manufacturer after all discounts and rebates have been deducted. Manufacturers have been more forthcoming with these figures in recent years to explain to the financial community the difference between published prices and subsequent revenues and, on a policy level, to try to deflect attention from high introductory list prices and annual price increases.

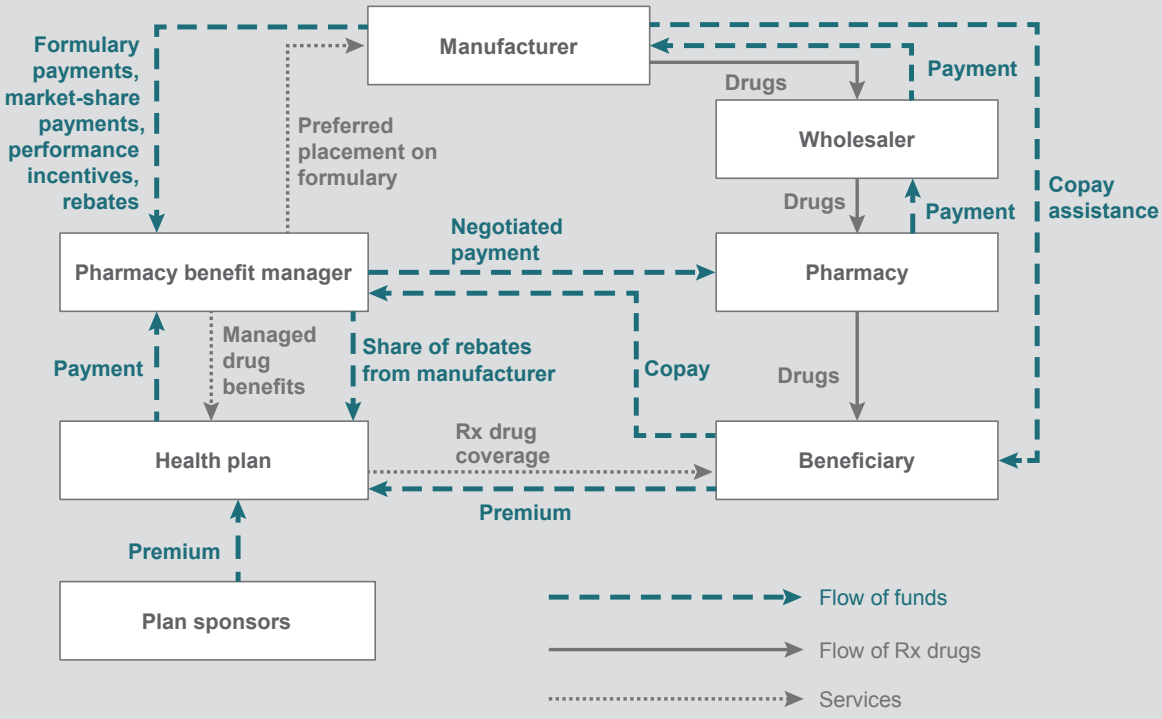
One recent analysis puts the total off-invoice concessions in the commercial market in 2016 at $127 billion—a 39 percent rebate level that includes a broad range of discount programs.

LAUNCH PRICES

PBMs have less influence with drug manufacturers at the time that initial prices are set, especially when a novel product has no close existing or new competition. However, PBMs can attempt to restrict the impact of new product prices on their clients by limiting early usage. Two recent examples include active efforts to restrain use of hepatitis C and PCSK9-inhibiting cholesterol drugs. PBMs, with Express Scripts as the most visible advocate, used public campaigns to highlight the price of the hepatitis C drug Sovaldi and called for tight restrictions to match the limited initial Food and Drug Administration

EXHIBIT 1

The Flow Of Products, Services, And Funds For Nonspecialty Drugs Covered Under Private Insurance And Purchased In A Retail Setting



SOURCE Neeraj Sood, Tiffany Shih, Karen Van Nuys, and Dana Goldman, "Follow the Money: The Flow of Funds in the Pharmaceutical Distribution System," Health Affairs Blog, June 13, 2017.

(FDA) labeling of the PCSK9 inhibitors Repatha and Praluent. PBMs inherently stand to benefit from higher-price products, as high prices create room for high rebates. However, because the primary customers for PBMs are payers, there is a strong countervailing obligation on PBMs to address high launch prices.

Recent Scrutiny Of PBMs

As intermediaries that extract savings for payers from the drug delivery system, PBMs are highly scrutinized by manufacturers and pharmacies. They have also recently drawn attention from public policy makers.

TRANSPARENCY AND SHARING OF REBATES

Recent public interest in deconstructing the components behind high drug launch prices has led to a renewed focus on PBM rebates. The brand-name drug sector has highlighted the share of invoice prices that go to rebates (26 percent) and the net revenues to the drug manufacturer (63 percent), taking the position that PBMs and insurers should return more savings directly to patients through clear reductions in cost sharing or reduced premiums.

The Centers for Medicare and Medicaid Services (CMS) has expressed recent interest in more transparency from PBMs and Part D plans on price concessions and pharmacy fees (paid to the PBM, plans, or both) at the point of sale. CMS cites a recent dramatic increase in post point-of-sale compensation to PBMs, called "direct and indirect remuneration," with those expenses growing to over 16 percent of Part D gross drug costs in 2015 (or $22.6 billion in direct and indirect remuneration out of total Part D gross drug costs of $137.4 billion). CMS states that one impact of the late point-of-sale adjustments is to increase cost sharing by beneficiaries, with the patient's cost sharing based on the gross price before these adjustments.

According to PBMs, payers receive an estimated 90 percent of rebate dollars and factor that income stream into various decisions, including plan premiums and deductibles. Payers don't necessarily use drug rebate savings on their drug budgets. To the extent that current public interest in understanding the source of high drug prices turns to the amount and handling of rebates, that discussion is likely to identify PBM activities as a target for policy makers looking for areas to reduce costs.

DRUG LIST PRICES

There is an implied argument from the brand-name drug sector that part of the reason for increases in existing product prices and high launch prices is the growth in rebates paid to the supply chain. A declining share of invoice prices being captured by manufacturers (from 67 percent in 2013 to 63 percent in 2015) puts pressure on manufacturers to increase the list sales price to maintain profit levels. The PBM industry refutes that contention with a study claiming that there is no correlation between price increase levels and average rebates.

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Health Policy Briefs are produced under a partnership of *Health Affairs* with the generous support of the Commonwealth Fund and Memorial Sloan Kettering Cancer Center. Text highlighted in blue is hyperlinked to outside sources in the online version of this brief.

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Cite as: "Health Policy Brief: Pharmacy Benefit Managers," *Health Affairs*, September 14, 2017. DOI: 10.1377/hpb2017.13

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