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PATIENT FINANCIAL SUPPORT

Manufacturer-sponsored financial support helps patients afford medicines but may thwart payers' efforts to use preferred drugs.

Patient financial support is among the most controversial issues in the public debate over high prescription drug prices and has become even more so as prices have risen exponentially in recent years. To manage escalating drug costs, payers have accelerated the use of tools such as formularies (list of preferred and nonpreferred drugs), with access limits enforced by varying rates of out-of-pocket cost sharing for patients. Drug manufacturers, in turn, often offer or fund patient financial support as a counter-strategy against payers' efforts to restrict access to certain drugs through high cost sharing. Such programs can alleviate some out-of-pocket cost burdens for patients and address financially driven nonadherence to medications. However, payers view manufacturers' financial support as an undercutting strategy to shield patients from drug costs, thereby driving use of higher-priced therapies when lower-cost generics or preferred brand therapies are available.

Background

Patients' out-of-pocket drug cost sharing is determined by their health plan's or pharmacy benefit manager's (PBM's) formulary—a list of preferred and nonpreferred prescription drugs. Preferred status is based on a drug's effectiveness, price, and the level of rebate the payer receives from the manufacturer for giving the drug preference over its competitors. Generics and preferred brand drugs are generally assigned lower patient cost sharing than nonpreferred brand drugs. As drug prices have increased, so has patient cost sharing, causing some patients to stretch, forgo, or discontinue medication that is too expensive. Drug manufacturers often seek to mitigate these effects by providing or funding various forms of patient financial support.

The aim of drug manufacturers' patient financial support is to minimize or remove out-of-pocket cost sharing as an obstacle when patients choose medications, thereby keeping them on brand-name drugs for longer. However, while patients might not feel the high costs of some drugs, the health system does absorb them. As a result, these programs play an increasing role in criticism of high drug spending.

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Patient Financial Support: What You Need To Know

Several issues are important in understanding the relationship of manufacturer-sponsored patient financial support to drug prices in the public and private sectors.

> "Manufacturers cannot provide coupons to beneficiaries of government programs."

TYPES OF SUPPORT

Manufacturers' patient financial support may take the form of copay coupons or patient assistance programs (PAPs), which differ in important ways. The Government Accountability Office (GAO) defines drug coupon programs as "those through which a drug manufacturer provides financial support directly to patients to reduce their out-of-pocket costs for drugs that the manufacturer sells." The Health and Human Services (HHS) Office of Inspector General extends the definition to include print and electronic coupons, debit cards, and direct reimbursements. Coupons, which generally do not carry income-related eligibility restrictions, have maximum annual discounts ranging from hundreds of dollars to tens of thousands of dollars.

In contrast to coupons, PAPs "provide free or discounted drugs to patients of low income," according to the GAO. Manufacturers may either sponsor their own PAPs, which distribute free medicines to qualified patients, or donate to independent foundations that then provide patients with financial assistance. Patients qualify for these programs on the basis of financial or medical need, or both.

A critical distinction between copay coupons and PAPs is manufacturers' ability to influence patients' choice of a specific drug. With copay coupons, manufacturers have direct control over the drug for which the coupon can be used. Their control over PAPs is more limited: They influence patients' drug choices through their own PAPs by giving away specific drugs. However, when manufacturers donate to independent charitable PAPs, they are prohibited from tying the use of those funds to any specific drug.

These dynamics relate to another important distinction between copays and PAPs: Manufacturers cannot provide coupons to beneficiaries of government programs—such as Medicare and Medicaid—while such beneficiaries can be eligible for some PAPs. Coupons are considered a direct inducement to buy a specific product, in violation of the federal anti-kickback statute in the Social Security Act. This law makes it a criminal offense to "knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward the referral or generation of business reimbursable by any federal health care program."

However, because manufacturers' donations to independent charitable PAPs may not be tied to the use of a specific drug, those programs are not seen as a direct inducement. According to the Centers for Medicare and Medicaid Services (CMS), "PAPs can provide assistance to [Medicare] Part D enrollees and interface with Part D plans by operating 'outside the Part D benefit' to ensure separateness of Part D benefits and PAP assistance." One important caveat is that aid on behalf of a PAP enrollee does not count toward that enrollee's Medicare Part D true-out-of-pocket expenditure, which determines when a beneficiary reaches the catastrophic coverage threshold at which Medicare covers the vast majority of drug costs.

Exhibit 1 lists the types of patient financial support and indicates both the level of manufacturer control and the availability of the support to public program beneficiaries.

APPROPRIATE PAP USE

Manufacturer donations to PAPs have grown significantly over the past twenty years. A 2000 GAO report found that PAPs sponsored by members of the brand pharmaceutical industry group Pharmaceutical Research and Manufacturers of America (PhRMA) provided $500 million worth of products to 1.5 million people in 1998. By 2014, donations through

PAPs increased to $7 billion annually, 93 percent of which was attributable to manufacturer PAPs that gave away drugs, for which they received a tax write-off. In 2017, ten of the fifteen largest US charitable foundations administer some form of PAP.

As PAPs have grown in size, relationships between the organizations and drug manufacturers have come under intensified scrutiny. Some PAPs' independence has been called into question, and there have been investigations (for example, by the Internal Revenue Service) into whether manufacturers have wrongly received tax breaks as a part of the arrangements.

IMPACT ON PATIENTS' CHOICES

From the patient's perspective, financial assistance through any avenue may come as welcome relief when a physician recommends or prescribes a specific brand-name drug with a high price tag. Drug manufacturers contend that their financial support allows doctors and patients to make the most appropriate prescribing decisions, irrespective of cost. They also argue that the support improves adherence to therapy by keeping patients on their existing medicines.

On the other hand, some stakeholders have noted that the impact of coupons on consumers' out-of-pocket expenditures is time limited (most can be used for no more than a year) and that when coupons expire, patients may be reluctant to switch to an available lower-cost generic or preferred brand with which they might not be familiar.

IMPACT ON PRICE INCREASES

Express Scripts, a large pharmacy benefit manager strongly opposed to manufacturer-sponsored financial support, cites a report that found that during the five years following generic entry, coupons increase total drug spending by $30–$120 million per drug, or $700 million to $2.7 billion for all drugs studied, between 2007 and 2010. The study concluded that coupons "are associated with faster branded price growth," with roughly a 5 percent increase in price growth per year when the manufacturer makes coupons available. (Additional published perspective pieces and studies have been similarly critical of cost increases related to PAPs.)

Coupons have also been cited as a factor in Medicare Part B drug costs. While coupons are not permitted for Part B cost sharing, manufacturers can potentially maintain high list prices for purposes of Medicare reimbursement while offering copay coupons to privately insured patients to ensure their access. A recent GAO study estimated that for eighteen of the fifty drugs with the biggest Medicare Part B expenditures in 2013, $205 million in copay coupons were extended to privately insured patients.

EXHIBIT 1

Types Of Drug Manufacturer Financial Support And Their Uses

	Type of assistance	Can encourage/require use of a specific drug?	Can be provided to beneficiaries of government health care programs?
Copay coupons	Print or electronic copay coupons, debit cards, and direct reimbursements to offset cost sharing	Yes	No
Manufacturer-provided patient assistance programs	Free drugs	Yes	Yes
Manufacturer donations to independent charitable patient assistance programs	Direct cash grants	No	Yes

SOURCE Prevision Policy LLC.

Open Questions For The Future Of Patient Financial Support

The landscape of manufacturer-provided patient financial support is changing rapidly. Several recent developments bear watching to see how they will affect the continued use of both coupons and PAPs.

ASSISTANCE BANNED IF GENERIC AVAILABLE

Massachusetts is the only state to ban copay assistance for brand drugs when there is a generic equivalent. In fact, until 2012 the state prohibited all copay assistance, but under pressure from drug makers, the legislature lifted the prohibition with a sunset clause: The ban would take effect again in July 2017, along with the requirement that a study be conducted to determine the impact of copay assistance. The sunset clause and the study requirement were extended to July 2019, a delay again supported by the drug industry. As a result, there are as yet no real-world data to show an impact on overall health costs in the state. The distinction between banning all patient support (as in Medicare) versus only banning coupons when there is a generic available (as in Massachusetts) makes Massachusetts a unique case.

COPAY ASSISTANCE IN THE EXCHANGES

In 2013, ahead of the kickoff of the insurance exchanges (Marketplaces) created under the Affordable Care Act, there was some controversy about whether or not manufacturers could use copay coupons in the new Marketplaces. The administration concluded that the exchange markets are governed by the rules of commercial insurance, not by those of federal health programs. As a result, HHS determined that companies could use coupon programs for people enrolled in Marketplaces, as long as health plans accepted them. It is still unclear how coupons have played out in the exchanges. The biggest complaint from manufacturers has been reduced access to their more expensive innovative therapies—one anecdotal indicator either that there are relatively few manufacturers offering copay assistance in the exchanges or that financial support is having little impact against plans' tools to drive down costs.

NEW ANTI-KICKBACK STATUTE PROSECUTION

Federal prosecutors are increasingly looking at PAPs as relative unexplored territory in relation to the anti-kickback statute. Prosecutors have disclosed a number of investigations but have made no concrete allegations. The growth of the programs and proportional acceleration in drug sales in some cases have made PAPs a visible target for further investigation. Like False Claims Act prosecutions centered on off-label marketing or Medicaid "best price" violations, for example, the PAPs may be viewed as an attractive revenue line for prosecutors to pursue settlements under the HHS initiative to stop waste, fraud, and abuse.

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