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Drug Companies' Patient-Assistance Programs — Helping Patients or Profits?

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Implementing patient cost sharing in the form of copayments, coinsurance, and deductibles is one of the more reliable methods for reducing health care costs. But imposing cost sharing reduces patients' demand for medical care, which sets the interests of insurers at odds with the interests of health care providers and drug and device manufacturers, who generally benefit when patients use more services.

Pharmaceutical manufacturers have attempted to blunt the impact of drug copayments and coinsurance on patients by funding patient-assistance programs. These programs offset patients' out-of-pocket drug costs, typically on generous terms. Biogen's program for its multiple sclerosis drug dimethyl fumarate, for example, caps patients' copayments at $10 per month, less than 1% of the total cost of the drug. Dendreon covers up to $6,000 of patients' copayments, coinsurance, and deductibles for its $93,000 prostate therapy sipuleucel-T (Provenge), boasting that "75% of patients receiving Provenge are expected to have minimal to no out-of-pocket costs."[1] It even provides assistance with the costs patients incur for travel to receive treatment.

According to industry sources, more than 300 drugs have associated patient-assistance programs, and manufacturers spend about $4 billion per year on these programs.[2] The table lists patient-assistance programs for some top-selling specialty drugs. None of these programs has an income limit, though trastuzumab's copay-card program imposes a $9,000 benefit cap for patients in households with incomes of more than $100,000.

Assistance programs are a triple boon for manufacturers. They increase demand, allow companies to charge higher prices, and provide public-relations benefits. Assistance programs are an especially attractive proposition for firms that sell particularly costly drugs. Faced with high out-of-pocket costs, some patients may decide against taking an expensive medication. Patient-assistance programs can convert such patients from nonusers to users. Programs must incur costs for patients who would have used the drug even in the absence of a program, but manufacturers can afford to pay a lot of $25 or $50 copayments in return for even a small increase in the sales of a $50,000 drug.

Although many patients and physicians view patient-assistance programs as a financial lifeline,

Patient-Assistance Programs for Selected Top-Selling Specialty Drugs.

Drug	Primary Indication	Program	Maximum Assistance Per Year	Patient's Cost
Rituximab	Rheumatoid arthritis	RACopay	$10,000	$5 per copay
Infliximab	Rheumatoid arthritis	RemiStart Patient Rebate Program	$8,000	$50 per infusion
Trastuzumab	Breast cancer	BioOncology Co-pay Card	$24,000	20%, up to a maximum of $100, per treatment
Efavirenz	HIV	Bristol-Myers Squibb Co-Pay Assist Program	$4,800	$0
Interferon beta-1a	Multiple sclerosis	ActiveAccess	Income-based limit	$10 per month

Medicare and other payers take a dim view of efforts to subsidize patients' out-of-pocket costs. They worry that patient-assistance programs discourage patients from using generic drugs and other less costly alternatives to new, patent-protected therapies.

Some programs provide assistance for the purchase of high-cost drugs that have no generic equivalents or close therapeutic substitutes. In such cases, assistance programs can expand access to therapies that represent the standard of care but can also promote use among patients who do not place a high value on the health benefits associated with these therapies.

Patient-assistance programs may lead to higher drug prices as a result of the interplay between patient demand and prices. Economic theory predicts that if patient demand becomes less sensitive to prices, manufacturers of on-patent drugs will respond by setting higher prices. There is evidence to support this theory. In 1989, Germany began requiring patients to pay higher out-of-pocket costs for drugs with prices that exceed those of similar drugs. After this policy was implemented, drug prices dropped by 10 to 26%.[3] The link between patients' out-of-pocket costs and drug prices presents a chicken-and-egg scenario: Do high prices make patient-assistance programs necessary, or do patient-assistance programs lead to higher prices? The answer is a bit of both.

The Office of Inspector General of the Department of Health and Human Services (DHHS) has warned that patient-assistance programs may violate the federal anti-kickback statute by providing a "remuneration" that illegally induces consumption of services.[4] The DHHS prohibits patient-assistance programs affiliated with a pharmaceutical manufacturer from subsidizing beneficiaries' costs for physician-administered drugs covered under Medicare's Part B benefit and prescription drugs covered under the Part D benefit. This prohibition mirrors the requirement that hospitals and physicians make a reasonable effort to collect coinsurance from Medicare beneficiaries.

Private foundations are allowed to provide assistance subject to certain restrictions. For example, foundations cannot define their target patient population so narrowly that they effectively devote all their funds to one manufacturer's product. Manufacturers are permitted to contribute to and steer patients to foundations that provide assistance, and many do so. Manufacturers are also allowed to provide assistance to Part D beneficiaries "outside" the program; contributions cannot count toward beneficiaries' costs for purposes of reaching the Part D out-of-pocket threshold.

Like Medicare, private insurers have tried to discourage participation in patient-assistance programs, though with considerably less success. Judges have dismissed lawsuits brought by insurers against pharmaceutical manufacturers, rejecting the claim that assistance programs offer illegal bribes to patients.

The DHHS has sent mixed signals about whether patient-assistance programs can provide aid to patients enrolled in plans sold on the new health insurance exchanges. DHHS Secretary Kathleen Sebelius wrote in October 2013 that exchange plans are not federal health programs,[5] implying that pharmaceutical manufacturers can aid exchange enrollees without risking prosecution under the anti-kickback statute. However, the DHHS has discouraged hospitals and other providers from paying premiums or other cost-sharing liabilities for exchange enrollees. Pharmaceutical manufacturers and patient-advocacy groups are seeking clarification from the DHHS about the legality of patient-assistance programs' providing aid to exchange enrollees.

Given the high cost of many new drugs, the DHHS's approach to patient-assistance programs will strike many people as cold and insensitive, but I believe that the DHHS is absolutely right to limit the scope of these programs. Patient-assistance programs help individual patients but are associated with hidden costs for insurers and taxpayers. Cost sharing will accomplish nothing more than cost shifting if assistance programs shield patients from costs.

Drug companies could maximize the benefits and reduce the harms associated with patient-assistance programs by targeting their assistance to low-income patients; providing assistance for all medical expenses, not just expenses for a specific drug; and limiting assistance to patients whose out-of-pocket costs have exceeded a threshold, similar to what is done when an out-of-pocket maximum is used in an insurance plan. Programs constructed along these lines would expand patient access without undermining the beneficial aspects of cost sharing.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

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The Medicare Physician-Data Release — Context and Rationale

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On April 9, the Centers for Medicare and Medicaid Services (CMS) released detailed information on utilization by more than 880,000 physicians and other health care providers who care for Medicare beneficiaries. This data release was unprecedented in its size and scope: it included nearly 10 million records accounting for more than $77 billion in Medicare payments. The data have been downloaded or accessed more than 300,000 times from the CMS website since their release. But because the release has also come in for some criticism, it may be helpful to clarify its context and rationale.

In one of his first acts in office, President Barack Obama issued a memorandum calling for more open, participatory, and collaborative government, and in May 2013, he issued an executive order mandating implementation of an open-data policy in all federal departments. We at CMS have embraced this directive and worked to identify information and data that could be made publicly available even as we maintain safeguards to protect the privacy of our beneficiaries. We believe that greater transparency in the health care system can drive improvement in health and contribute to the delivery of higher-quality care at lower cost and that CMS can play an important role in stimulating a vibrant health-data ecosystem. By making data files available as "raw material," we aim to enable innovators and entrepreneurs to maximize the data's value for a wide array of users.

Examples of this commitment to open data include the Medicare Geographic Variation Public Use File and the Medicare Provider Utilization and Payment Data inpatient database — the former includes information on fee-for-service Medicare spending, utilization, and quality at the state, hospital referral region, and county levels, and the latter contains information on individual hospital utilization, submitted charges, and payments for the 100 most frequently occurring diagnosis-related groups in the Medicare program. The release of these data in 2013 sparked a national conversation about the appropriateness of hospital charges and about the large variation in charges for the same service, often in the same geographic area. These data sets are just two of the many that CMS and the Department of Health and Human Services have released over the past several years. Users can find these publicly available data sets and others by visiting the CMS Data Navigator (http://dnav.cms