

The Prescription Drug Safety Net: Access to Pharmaceuticals for the Uninsured

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OVERVIEW — *This background paper provides an overview of organized programs that provide access to prescription drug products for uninsured persons, with an emphasis on manufacturer-sponsored pharmacy assistance programs (PAPs) and the federal 340B drug pricing program. It summarizes the chief characteristics of these programs and reviews concerns regarding the reach and efficiency of these efforts. The paper begins with a brief examination of the number of people who lack insurance coverage for prescription drugs and discusses the influence of this gap in coverage on health status. The paper also describes informal mechanisms providers frequently use to help uninsured patients fill their prescriptions, such as sample dispensing. The paper briefly explores the impact of Medicare Part D on both manufacturer-sponsored PAPs and state pharmacy assistance programs that have not traditionally focused on the under-65 uninsured population.*

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One of the most prominent health care headlines of 2006 concerned the implementation of the Part D prescription drug benefit, a voluntary prescription drug benefit available to Medicare beneficiaries. Although some gaps remain, Part D has certainly strengthened the prescription drug safety net for Medicare beneficiaries, particularly for the elderly and disabled individuals who are eligible for low-income subsidies. A significant number of beneficiaries who previously lacked insurance coverage for prescription drugs now get coverage through Part D. One result of these developments is the potential for policymakers to shift their focus to the non-Medicare population lacking prescription drug coverage and the safety net available to them.

When an uninsured person needs medical attention, he or she may go to a community health center, a clinic, or a hospital emergency room to receive care regardless of ability to pay. If an uninsured person needs a prescription, the facility might provide a few days' supply to get things started. But the local pharmacy will not fill an entire prescription for free. What are the alternatives for this person?

For individuals who lack public or private health insurance to cover their prescription drug needs, there are a number of resources available to help provide access to drugs. Two important components of this "safety net" are programs established by pharmaceutical manufacturers to make their drugs available to those with low incomes and the federal government's program to offer drugs at a discounted price for safety net institutions, such as community health centers and public hospitals. These two programs each make available about \$4 to \$5 billion in drugs annually; together they are equivalent to nearly 5 percent of total drug spending in the United States. Some individuals also may be provided free drugs by physicians who dispense the samples provided to them by manufacturers.

Individuals sometimes find these programs a vital lifeline that provides critical drugs not available by any other means. But others may find these programs cumbersome to use, either requiring extensive paperwork to establish eligibility or limiting their access to certain providers or certain drugs.

This background paper describes the various safety net programs for prescription drugs as well as some of the issues involved in using them. The primary focus is on programs designed to serve people without insurance coverage for drugs, including the working uninsured, those who are poor

but not eligible for coverage under Medicaid or other public programs, and those whose insurance plans do not provide drug coverage. The paper does not examine the role played by public programs in providing drug coverage or the resources available to uninsured Americans that are not focused specifically on prescription drugs.¹

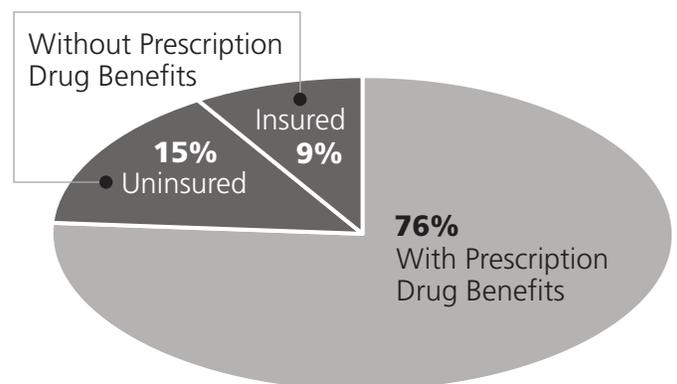
After a brief review of the target population for these safety net programs, the paper examines programs created by pharmaceutical manufacturers to provide their drugs to needy individuals, as well as the barriers to their use and various efforts to improve access to these programs. It also discusses briefly the changes that have occurred in these programs as a result of the implementation of Medicare Part D. The next section looks at the federal program that helps clinics, hospitals, and other safety net providers obtain drugs at discounted prices, thus strengthening their ability to get needed drugs for the patients they serve. Individual physicians play a role as well, and the next sections of the paper describe the use of drug samples by physicians as well as the potential for physicians to prescribe drugs more cost-effectively for those who lack coverage. Finally, the paper discusses some considerations for policymakers who might want to strengthen the safety net for drugs.

BACKGROUND: GAPS IN COVERAGE FOR PRESCRIPTION DRUGS

Nearly one-fourth (24 percent) of adults aged 19 to 64 lacked insurance coverage for prescription drugs at some point in 2001, the most recent year for which good data are available (Figure 1).² Nearly two-thirds of those without drug coverage did not have any kind of health insurance; the rest were insured but lacked coverage for prescription drugs. An earlier study found that a similar proportion (23 percent) of the non-Medicare population lacked insurance coverage for prescription drugs in 1996.³ According to the latter study, nearly all workers covered by employer health plans and all Medicaid beneficiaries had prescription drug coverage, whereas drug coverage was less universally included in other forms of coverage, such as policies purchased through the individual insurance market.

The 1996 survey data showed that near-poor individuals were the most likely to lack coverage for drugs [36.5 percent of those with incomes between 100 and 200 percent of the federal poverty level (FPL); for 2007 the FPL is \$10,210 for a single person, \$13,690 for a family of two], but there were significant numbers at different income levels. About 14 percent of those with incomes above 400 percent of the FPL lacked coverage for drugs.⁴ Similarly, the

FIGURE 1
Distribution of Prescription Drug Benefits
Among Adults Aged 19 to 64, 2001



Source: Claudia L. Schur, Michelle M. Doty, and Marc L. Berk, "Lack of Prescription Coverage Among the Under 65: A Symptom of Underinsurance," Issue Brief, Task Force on the Future of Health Insurance, The Commonwealth Fund, February 2004; available at www.cmwf.org/usr_doc/Schur_under65.pdf.

absence of coverage ranges across people with different health status. Those in poor health in the 1996 survey were more likely than those in better health to have drug coverage (84 percent versus the overall level of 77 percent), perhaps because they seek out private coverage sources or are more likely to be eligible for (and enroll in) public sector coverage.⁵

The absence of drug coverage has clear consequences. Based on the 2001 survey, nonelderly adults without drug coverage were almost twice as likely to report not filling a prescription due to cost (Figure 2). They are also less likely to see a doctor when sick or to skip recommended tests or follow-up care, possibly because they know that filling a recommended prescription will be difficult or impossible.⁶

Other studies provide additional evidence that people skip their drugs when costs are high. A 2001 Quebec study found that, after imposition of higher cost sharing, patients took fewer drugs identified by researchers as “essential” and experienced an increased use of emergency room visits and admissions to hospitals or nursing homes. There was also a decline in the use of “less essential” drugs, but this change was not associated with an increase in the use of other health services.⁷ Another study of increased cost sharing in two Medicare health maintenance organizations (HMOs) found lower drug utilization but no consistent changes in either medical care utilization (office visits, emergency room visits, home health visits, and hospitalizations) or total medical care expenses.⁸

Similarly, several studies have addressed the impact of drug costs by looking at the effect of capped drug benefits. Two studies of monthly limits on prescriptions by Medicaid programs showed that reduced drug use resulted in increased nursing home admissions and, for patients with schizophrenia, increased visits to community mental health centers, use of emergency mental health services, and partial hospitalization (although no increase in hospital admissions).⁹ About one-third of Medicare beneficiaries with chronic illnesses who enrolled in eight managed care plans with a capped drug benefit reported not filling a prescription or reducing the prescribed dosage because of their out-of-pocket costs. The result was under-use of needed medications, especially for those with lower incomes or poorer health.¹⁰

A further illustration of what happens to people without access to drug coverage comes from a study of Oregon residents who were enrolled in the state’s Medically Needy program as of January 2003 but lost access to those benefits because of shortfalls in the state budget. Although most were eligible for Medicare coverage for medical benefits, the state program had

FIGURE 2
Percentage of Adults Aged 19 to 64 Who Did Not Fill a Prescription Due to Cost, 2001, by Insurance Category

		Percent of adults who did not fill a prescription	
Without Prescription Drug Benefits	Uninsured		30%
	Insured		28%
With Prescription Drug Benefits	Insured	16%	

Source: Schur, Doty, and Berk, “Lack of Prescription Coverage Among the Under 65.”

been paying for their prescription drugs and fee-for-service Medicare was not yet offering such coverage. On average, the individuals studied used the same number of prescriptions as when they were in the Medically Needy program, but half reported that they were prescribed drugs they were not taking because of cost. One-third of those surveyed also indicated that they switched to a similar, but lower-cost drug; nearly half said they were paying out of pocket (46 percent); and some reported using drug company assistance programs (26 percent) or getting free samples from their doctors (7 percent). Respondents also reported cutting back their food budget, skipping or delaying bills, or borrowing money to pay for prescribed drugs.¹¹

MANUFACTURER-SPONSORED PRESCRIPTION ASSISTANCE PROGRAMS

When an uninsured person needs help filling prescriptions and cannot afford the cost of these drugs, he or she may seek to obtain drugs free of charge from pharmaceutical manufacturers. Many manufacturers have established prescription assistance programs (PAPs) to provide certain low-income people the ability to obtain drugs they might not be able to purchase without assistance. There are about 180 manufacturer-sponsored programs, according to the Partnership for Prescription Assistance, a program launched in 2005 by the Pharmaceutical Research and Manufacturers of America (PhRMA) to provide outreach and simplified access to these programs. Some programs have been around for as long as 50 years, but they have taken on different forms over the years. In 2005, manufacturer PAPs donated drugs with an estimated wholesale value of about \$5 billion.¹²

In general, these manufacturer-sponsored programs are designed as temporary programs to be used as a last resort for people who have exhausted all public program options, have no private insurance, and have low incomes. Most major manufacturers offer programs, although they may not make all their drugs available. Resource services that offer consolidated lists of the drugs available across plans suggest that at least 1,500 drugs are available through these programs.¹³ A November 2000 report by the U.S. Government Accountability Office (GAO; then known as the General Accounting Office) found that all but 2 from a list of 50 commonly prescribed brand-name drugs for elderly patients were available through manufacturer PAPs.¹⁴ As described below, two programs have been launched to make some commonly prescribed generic drugs available. A service that includes these generics in its list suggests that a total of about 3,000 drugs can be obtained through PAPs.

Eligibility and application requirements vary across the different programs, but typically they require that applicants be U.S. citizens and have incomes below 200 percent of the FPL.¹⁵ Generally, anyone with prescription drug coverage is not eligible (although exceptions for some Medicare beneficiaries with Part D coverage are discussed below), and some companies require that applicants have no health insurance of any kind.¹⁶

There appears to be no reliable count of how many people have obtained drugs through these programs. According to the Partnership, more than 3 million people have received help through the Partnership in nearly two years, but this number includes those who received advice but did not obtain drugs through the PAPs.¹⁷ And other patients obtain help from PAPs without going through the Partnership. PhRMA reports that in 2005 an estimated 36 million prescriptions (with a wholesale value of about \$5 billion) were filled through manufacturer programs.¹⁸

In some programs, the physician must apply on behalf of the patient. In others, a patient advocate or patient is allowed to apply, though even these typically require information about the prescribing physician and often the physician's signature.¹⁹ Some physicians' offices that prescribe high-cost drugs have a staff person who seeks out assistance programs for which a particular patient might be eligible. This approach is especially used by oncology practices and others who regularly prescribe expensive physician-administered drugs. In addition, PAPs are often used by certain safety net providers, such as free clinics that do not qualify for receiving low-cost drugs through the federal 340B program (described below).

Under the PAPs, medications are usually shipped to a clinic or doctor's office, rather than directly to the patient; under some plans, patients receive a voucher for the drugs to be redeemed at a pharmacy. In most cases, there is no charge to the patient. But some programs charge the patient co-payments, dispensing fees, or shipping and handling fees.

Issues Raised by Manufacturer Programs

Learning about manufacturer programs may be the first barrier to their use by uninsured patients. Indigent people are least likely to have access to a primary care physician or to know what medications they need. When they do have a prescription for a costly drug, they may not know that manufacturer PAPs exist. As a result, the people who need these programs the most may have the hardest time accessing them. Furthermore, they may discover that each of their expensive drugs is made by a different manufacturer and that each requires a separate application, often with different information required.

Manufacturer sales representatives typically inform physicians about PAPs, although sometimes physicians have to request the information.²⁰ PhRMA's Partnership (see "Points of Access," below) has raised the visibility of these programs in recent years with a national outreach program that includes celebrity spokespersons, toll-free telephone lines, television advertisements, partnerships with various organizations, and two "Help is Here Express" buses traveling around the country.²¹

One significant challenge faced by users of manufacturer PAPs is the complexity of the application process. The process often becomes a greater burden to staff at physicians' offices or clinics than to patients, because

There is no reliable count of how many people have obtained drugs through PAPs, but PhRMA estimates that about 36 million prescriptions, worth about \$5 billion, were donated in 2005.

staff are often responsible for completing the applications. Physicians' offices may choose to take on this task because their patients may have no other means of obtaining needed medications, but they report that it can be a drain on office resources. Physicians also point out that they are not reimbursed for doing paperwork, although there is a billing code for "special reports such as insurance forms, more than the information conveyed in the usual medical communications or standard reporting forms."²² According to one study that surveyed clinics in several states, clinic staff spent an average of 111 hours per month (12 hours for pharmacists, 20 hours for physicians, and 79 hours for other staff) in processing applications. In fact, two-thirds of clinics that did not use the manufacturer PAPs cited the fact that they are "too time-consuming and complex."²³

Although the time demands of processing applications represent a real cost for providers, software or other management resources are available to help the processing of applications. Several vendors offer the ability to process applications electronically, and two of the vendors indicate that they can offer electronic applications for nearly two-thirds of the programs.²⁴ Although the cost of these resources (as much as \$5,000 annually) can stress already tight budgets for safety net providers, well-designed management resources may be cost effective because they reduce staff time spent on such tasks.²⁵

The time demands are complicated by several factors: the requirement to submit new applications after a set period of time or dosage change, the need in many cases to submit separate applications for different medications, and the possibility that application requirements might change over time. The GAO study found, for example, that some programs required separate applications even when a patient sought to get more than one drug from the same program. In addition, while prescription refills could be obtained, programs sometimes required patients to reapply.²⁶ At the very least, patients requiring medications from more than one company needed to complete separate applications for each, though some new initiatives (see "Innovative Ways," below) allow a single application.

Eligibility requirements reflect the efforts of sponsoring manufacturers to target a particular population for the drugs they are giving away. But one result is that documentation requirements to verify patient eligibility can be complex and difficult to achieve. Some programs have required that information on the patient's income be documented, for example, by a copy of a tax return. Others have required documentation stating that a patient is not eligible for assistance from public programs such as Medicaid.²⁷ These types of documents can be difficult for some patients to get or retain.

Because most programs distribute drugs to approved patients through health care providers, some providers report that this requires them to maintain proper storage and inventory management for the drugs. As a result, they often prefer programs that provide coupons or vouchers allowing the patients to obtain the drugs directly from a pharmacy. These

coupon or voucher systems also may avoid the time lag between establishing eligibility and actual delivery of the drug. Absent such a system, delays can be significant. The GAO found that while many programs could deliver drugs in less than seven days, one program reported that it could take up to 42 days between approval of the application and shipment of the drug. Because of this delivery lag, clinics typically preferred to use PAPs without voucher systems only for chronic, rather than acute, conditions.²⁸

Of course, many of the expensive drugs sought through the PAPs are administered by physicians via injection or infusion and so providers are accustomed to dealing with inventory and storage issues. For example, oncologists who offer chemotherapy in the office setting typically maintain an inventory of drugs so that they can make adjustments to the prescribed therapy on the day of treatment.

In the previously described survey of Oregon residents who lost drug coverage when a state program was cut back, 67 percent of respondents said they were aware of manufacturer PAPs, and 45 percent were using them (about half said these programs were their primary source for drugs). Most reported getting help with the paperwork, usually from a doctor's office or clinic. Despite the fact that a significant number of this group were getting help from PAPs, over half of these patients found the programs hard to use and were not confident of getting continued help from them. They also indicated that they were obtaining only some of their prescriptions filled through these programs, usually because not all were offered by a PAP. Of those who had never applied to a PAP, some were simply unaware of the programs or felt it was too much hassle, while others knew that the programs did not cover their particular drugs.²⁹

Innovative Ways to Streamline Access

The challenges faced in completing applications for manufacturer PAPs have led safety net providers to seek ways to streamline access to these programs. In some cases, this may simply mean devoting adequate resources to the task. One health center found that doing so had a payoff: dedicating one full-time staff member to handling program applications generated more than \$300,000 worth of free drugs in one year. In Cleveland, a county hospital put automated prompts into its electronic medical record system to assist physicians in obtaining donated drugs. And a county hospital in Indianapolis was able to arrange for a system of bulk replacement from drug manufacturers in cases where patients were deemed eligible for the program instead of applying individually for each patient. The result was \$3 million worth of free drugs, double the level of the two previous years.³⁰ In other cases, a physician's office may recruit a volunteer patient advocate who works with patients to identify programs that may help them, assists them with the applications, and helps track delivery of the drugs and the process for getting renewals.³¹ When volunteer resources are not available, some private physician practices have experimented with

Safety net providers have been seeking ways to streamline access to PAPs.

charging patients a modest fee (\$5 to \$10) for every application to defray the costs of assisting them in accessing free drugs.³²

Because of the complexities and challenges inherent to obtaining drugs through manufacturer PAPs, some innovative programs have emerged to simplify access for clinics and other safety net providers. Some programs are narrowly focused on making drugs available to existing clinics or other safety net providers, while others are more fully integrated with providing access to other health care services.

- The **Rx Partnership** was launched in 2003 with the help of the Virginia Health Care Foundation to make free prescription drugs available to participating free clinics and community health centers in Virginia. The program, using a combination of state funding and private grants, solicits free medications in bulk from manufacturers and arranges for their distribution directly to free clinics and community health centers. Participating clinics must operate a licensed pharmacy and pay a \$250 one-time fee to join the partnership. The advantage of this approach is that patients can fill their prescriptions immediately and avoid the wait that is common in PAPs; availability of medications, however, is limited to the drugs that participating manufacturers choose to make available. Nearly \$2 million in drugs was distributed in the first year of operation.³³
- **MEDBANK**, a nonprofit organization based in Maryland, has connected patients to manufacturer PAPs since 2001. In its first five years of operation, it helped nearly 35,000 patients fill more than 400,000 prescriptions with drugs worth over \$100 million. To be eligible, applicants must have a monthly income above \$926.01 for one person (\$1,070.01 for a household of two) and no source of drug coverage. Those with lower incomes are referred to state programs. Started with a foundation grant, MEDBANK now gets one-third of its funding from the state, with the rest coming from grants and donations. Some drugs are made available through a bulk-distribution pharmacy, which distributes drugs from four participating manufacturers to physicians. Other medications are arranged through manufacturer PAPs, with MEDBANK automating the application process and handling application renewals for physicians. The program has been replicated in New Mexico.³⁴
- South Carolina's **Communicare** program involves a network of physicians who see patients in their offices at no charge. In order to make sure patients could get the drugs they need, the physicians negotiated arrangements with some manufacturers to donate free drugs. Established in 1993, a network of 2,500 physicians serves about 15,000 patients across the state. Communicare now operates a central pharmacy that dispenses donated drugs by mail to patients' homes, physicians' offices, or a network of free clinics. To be eligible, patients must have incomes below 200 percent of the FPL and be uninsured.³⁵

These programs and others like them have the potential to simplify the process considerably, particularly when they can arrange with manufacturers

to provide bulk supplies of needed drugs instead of the labor-intensive process of applying separately for each patient. No systematic evaluation of these programs has been attempted, but one program that operated under a California litigation settlement from 1999 to 2003 reported to the court highly positive reviews from participating clinics. Over four years, this program distributed 2.6 million monthly supplies of drugs to indigent patients. The success of these programs, however, tends to rely on a source of funding and the energy and creativity of those creating and running the programs.

Points of Access for Multiple Programs

Some recent initiatives have attempted to simplify procedures and to avoid some of the problems associated with having separate procedures for each manufacturer's program.

The manufacturers, working through their trade association (PhRMA), have sponsored the Partnership for Prescription Assistance. Launched in April 2005, the Partnership reports having helped over 3 million patients since its inception.³⁶ As noted above, the program has promoted heavily through television advertising and other means. Patients can call a toll-free number or use the program's Web site (www.pparx.org), where they enter their income, drug needs, and other information relevant to determining their qualification for participating programs. They may receive referrals to any of 180 PAPs operated by manufacturers, as well as 300 other public and private patient assistance programs. The Partnership will send people applications that are partially completed (or they can print these off the Web site).³⁷ Manufacturer programs, however, maintain separate application forms and separate eligibility requirements. The Partnership was based on other PhRMA-supported state pilots in Wisconsin, New Mexico, and Georgia, and similar statewide efforts in several other states.

Some nonprofit organizations question PhRMA's motives and argue that the same funds could be better spent, especially given the existing efforts by many such nonprofits to design innovative ways to streamline the process of obtaining drugs through manufacturer PAPs. A key question is whether the Partnership is designed in the best way to help clinics and other providers, who would benefit by a standardized and simplified application form and uniform eligibility requirements. Others have raised concerns that the industry might be "looking for success through marketing and exposure, more than at the drugs actually delivered to patients."³⁸

An alternative resource that is not tied to the manufacturers is RxAssist (www.rxassist.com), a pharmaceutical access information center funded by foundations, corporate sponsorships, and private donations. It is operated by Volunteers in Health Care (based in the Brown University Center for Primary Care and Prevention), a resource center for safety net health care providers. RxAssist maintains a database of patient assistance programs as well as other resources for both patients and providers. Like the Partnership, RxAssist maintains a Web site that helps simplify the

application process for those seeking to use manufacturer PAPs.³⁹ Another resource, NeedyMeds (www.needymeds.com) provides information on available programs. This nonprofit organization started when an Alabama social worker put together a database on PAPs. A family physician launched the Web site in 1997.⁴⁰

Manufacturer-Sponsored Discount Cards

Discount cards are available from a variety of sources, including retail pharmacies, states, and other organizations. About a dozen states have such programs, and several have shifted focus from seniors to a younger, uninsured population (see text box for description on state-sponsored discount card programs).

One private-sector discount card was introduced in 2005 by ten manufacturers as an alternative to their own PAPs. This joint card, known as the Together Rx Access card, allows qualifying individuals to pick up maintenance drugs at the pharmacy at a discounted price, whereas many PAPs

State-Sponsored Drug Discount Cards

About a dozen states currently operate discount card programs that provide a safety net for some residents, including populations under age 65. Several additional programs are available only for seniors or disabled Medicare beneficiaries, and several others have been enacted but are not yet operational. Typically, these programs are open to individuals below a given income threshold (often between 200 and 400 percent of the FPL) and without any other source of drug coverage. Discounts are made available at participating pharmacies. Maine's Rx Plus program, for example, is open to anyone who meets income guidelines and offers discounts from 15 to 60 percent off retail prices for drugs on its preferred drug list. After Medicare introduced its Part D program, some states that initially created discount cards for their Medicare-eligible residents have shifted their focus to under-65 uninsured residents. Although its program is not yet operational, California in 2006 enacted a law to provide discounts (leveraging the purchasing power it now uses for Medicaid) on drug purchases by uninsured low- and moderate-income residents (those below 300 percent of the FPL or qualifying based on high medical expenses).

Source: National Conference of State Legislatures, "State Pharmaceutical Assistance Programs," updated April 11, 2007, available at www.ncsl.org/programs/health/drugaid.htm; Maine Health and Human Services, Office of Elder Services, "A Guide to Prescription Drug Assistance in Maine – November 2005," available at www.maine.gov/dhhs/beas/medbook.htm; and Office of the Governor, "Governor Schwarzenegger Signs Legislation to Make Prescription Drugs More Affordable for Uninsured Californians," press release, September 29, 2006, available at <http://gov.ca.gov/index.php?/press-release/4159>.

focus on higher-cost drugs and require the person to get the drug at the physician's office. Coverage extends to over 300 drugs (mostly brand-name products) with typical discounts from 25 percent to 40 percent. But unlike many of the separate PAPs, drugs cannot be obtained free of charge (though referrals may be made to such programs).⁴¹ Individuals are eligible for the Together Rx Access card if they have incomes no more than about 300 percent of the FPL, as long as they have no prescription drug coverage, are not eligible for Medicare, and are U.S. citizens. Eligibility can be determined through an online application, which offers immediate determination of eligibility, or by a mail-in application. Once obtained, the card can be used at participating pharmacies, which include a majority of pharmacies across the country. By the end of 2006, nearly 800,000 people had obtained a card.⁴²

In general, however, discount cards provide only limited assistance to those with limited means. In particular, indigent patients may not be able to afford even the discounted price of an expensive drug. A 2002 study sponsored by the Kaiser Family Foundation highlighted other issues consumers confront when they try to shop for the discount card program that will generate the most cost savings for them. Obstacles include lack of standardization of drug cards' benefit descriptions, restriction of discounts to specific drugs only, use of undisclosed prices from which discounts are derived, inconsistency of prices, and availability of discounts only for mail-order purchases. In some cases, the discounted price can only be obtained from a pharmacy in the program's network, and the availability of that price varies from store to store and over time.⁴³

PAPs for Generic Drugs

Most manufacturer PAPs provide only brand-name drugs within the period of patent protection. On the one hand, this means they provide access to the most expensive drugs, while patients may be able to afford needed generic drugs without assistance. Many generic drugs are relatively inexpensive (often under \$5 for a one-month supply), so the need for help in obtaining them is less than for brand-name drugs. Recent initiatives by large pharmacy retailers such as Wal-Mart, Kmart, and Target have helped to guarantee low prices for at least some generic drugs. But some generic drugs can be quite expensive, including some specialty drugs and some newly approved generics (such as those in the six-month period when one manufacturer has exclusivity for its generic version after the originator drug has gone off patent).⁴⁴

Furthermore, in drug classes that include both generic and brand-name options, the availability of free brand-name drugs through PAPs may encourage their use when a generic alternative may be preferable for a particular patient. Also, if the patient loses eligibility for the free drug, there could be complications in switching at that time to the cheaper generic option.

Most manufacturer PAPs provide only brand-name drugs within the period of patent protection.

Two relatively new programs have improved access to generics at reduced prices. These programs represent limited attempts to provide the same help that manufacturers provide for brand-name drugs.

In the fall of 2004, Rx Outreach was launched by Express Scripts, one of the largest pharmacy benefit managers in the United States. The program's Web site reports that the program was inspired by an Express Scripts employee who witnessed a family member's struggle to pay for medications. This generic PAP offers about 120 generic drugs to individuals with household incomes below 250 percent of the FPL. There is no restriction based on either the patient's age or eligibility for other programs. Patients pay either \$20 or \$30 (depending on the drug) for a three-month prescription, and the drugs can be sent to patients' homes, clinics, or other providers.⁴⁵

Xubex Pharmaceutical Services offers a similar program that makes available about 250 generic drugs. For a 90-day supply, the patient is charged \$20 to \$30, plus a \$3.95 shipping and handling fee, for each order. Like Rx Outreach, eligibility requires an income below 250 percent of the FPL. With this program, however, those with insurance coverage (other than enrollment in Medicare Part D) are not eligible. Unlike Rx Outreach, proof of income (for example, a pay stub) is required.⁴⁶

Both programs offer many of the most commonly prescribed generic drugs. Because the drugs offered by these two programs are not free, it is unclear how much benefit they offer. The cost of obtaining some of these drugs may be little better than purchasing them from retail pharmacies, especially as the competition over generic drug pricing has become more intense. For example, a 90-supply through Wal-Mart's program would cost \$12 compared to \$20 for most drugs through these two programs. But Rx Outreach and Xubex include some drugs not available in Wal-Mart's new program, such as simvastatin (generic Zocor) and sertraline (generic Zoloft), both commonly prescribed drugs that went off patent in 2006. In addition, many of the safety net providers that help patients obtain drugs may have access to better prices through the 340B program (below).

Changes in Manufacturer PAPs as a Result of Medicare Part D

Before the implementation of Medicare Part D, many seniors used manufacturer PAPs to obtain drugs they could not afford to purchase. Under Part D, the poorest beneficiaries qualify for that program's low-income subsidy. Subsidy-eligible beneficiaries are relieved of most cost sharing, including the need to pay for the full cost of drugs if they reach the coverage gap (often referred to as the donut hole). But for those enrolling in Part D but not qualifying for the subsidy, out-of-pocket costs can remain substantial. Some individuals anticipated that they would be able to continue obtaining free or reduced-cost drugs through PAPs while in the coverage gap (or to avoid high cost sharing for some expensive drugs).

The Medicare Modernization Act of 2003 (MMA), however, does not count most purchases made by third parties toward the true out-of-pocket (TrOOP) spending threshold that qualifies beneficiaries for catastrophic coverage.⁴⁷ This policy was reiterated in 2005 when the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) ruled that the unpaid value of drugs provided by a manufacturer's PAP, such as when the beneficiary is in the coverage gap, does not count towards TrOOP. The OIG's ruling suggested that drug purchases subsidized by manufacturer PAPs present risks under the anti-kickback statute. The general idea is that providing costly drugs to the patient (for example, in the coverage gap) increases the likelihood of federal payments that benefit the manufacturer (for example, payment for the same drug once the beneficiary becomes eligible for catastrophic coverage). There is no legal penalty to the beneficiary, but the manufacturers must ensure that they are not providing drugs to Part D enrollees.⁴⁸

Not all beneficiaries are affected the same way by the ruling against these programs. For example, a beneficiary whose costs will exceed the catastrophic threshold as a result of purchasing drugs not available through these programs will still spend \$3,850 out of pocket before qualifying for catastrophic coverage (and then only about 5 percent cost sharing for additional drug purchases). By contrast, a beneficiary with only minimal costs beyond the drug previously obtained for free from a manufacturer program might have avoided ever reaching the gap with the PAP still in place, resulting in much lower overall out-of-pocket costs.

The OIG's ruling left manufacturers the option of continuing to make their PAPs available for beneficiaries not enrolled in Part D or those not eligible for Medicare. But most manufacturers realized that their PAPs would have to change. The OIG offered several alternatives:

- **Independent Charity PAPs** — A manufacturer can make donations to an independent charitable organization. But it cannot exercise control over the organization, nor base its donations on the amount of its drugs dispensed, and the charity must award assistance without regard to the manufacturer's interests.
- **PAPs Operating Outside Part D** — A manufacturer's PAP may provide drugs to beneficiaries enrolled in Part D as long as the drugs are provided completely outside the Part D benefit. Thus, for example, provision of the drugs cannot be contingent on a beneficiary's status relative to the coverage gap, and the value of purchases cannot count toward TrOOP. For example, a PAP could provide an expensive drug throughout the year. The beneficiary's Part D plan would provide all other drugs as if the expensive drug in question did not exist.
- **Coalition Model PAPs** — A group of manufacturers might create a PAP. To be allowed, such a PAP would have to involve a large number of manufacturers, include all drugs made by each participating manufacturer, and have a system by which no particular drug is favored.⁴⁹

According to a compilation by RxAssist in January 2007, manufacturers have responded in a number of ways. Some (24) closed their PAPs to all Medicare beneficiaries, while others (38 programs, including Bristol-Myers-Squibb, one of the largest manufacturers) restricted their programs to Medicare patients not enrolled in Part D. A few of these plans allow Medicare Part D enrollees to apply for selected medications only (for example, Enbrel, Zyprexa, or Prevacid), consistent with the second OIG alternative. Another set of manufacturers (19 programs, including most of the largest companies) allow all Medicare beneficiaries to apply—again consistent with the OIG rules—although they may be required to demonstrate financial hardship.⁵⁰

For example, Medicare beneficiaries who use Novartis transplant or oncology products (drugs that are normally covered under Medicare Part B rather than Part D) and who enroll in a Part D plan may continue to receive help through the Novartis PAP for those drugs as long as they continue to meet eligibility criteria for the PAP, do not qualify for the Part D low-income subsidy, and show financial hardship in affording their medications despite the Part D benefit coverage. Patients using other Novartis products are evaluated on the basis of individual circumstances, including their degree of financial hardship. In all cases, the value of the drugs received would not count toward TrOOP.⁵¹

Similarly, Pfizer expanded its program's eligibility policy so that people with insurance, including Medicare beneficiaries with Part D coverage, can get access if facing financial or medical hardship. After the Connection to Care program reviews the initial application to see if the patient meets the income requirement (household income at or below 200 percent of the FPL, with verification through a tax return) but has insurance coverage for their Pfizer drugs, they are sent a Hardship Exception Request Form. Once the patient and physician complete and sign that form, the program determines whether the patient is eligible to receive the requested drugs without charge. If approved, a three-month supply of the drug is typically shipped to the physician's office.⁵²

GlaxoSmithKline introduced a new program for 2007. GSK Access provides free medications to eligible Part D enrollees after they spend at least \$600 of their own money on outpatient drugs. The same people are also eligible for oncology medicines through an existing PAP. Eligibility requires an income below 250 percent of the FPL (or 350 percent for the oncology program). Medicare beneficiaries not enrolled in a Part D plan and not eligible for the Part D income-based subsidy would qualify for GlaxoSmithKline's existing PAP.

The short-term result of Part D implementation is that existing arrangements for some Medicare beneficiaries were disrupted. Some programs that supported patients' coinsurance for physician-administered drugs covered under Part B were, at least for a time, made unavailable to Medicare beneficiaries, and anecdotal evidence suggests an adverse effect for

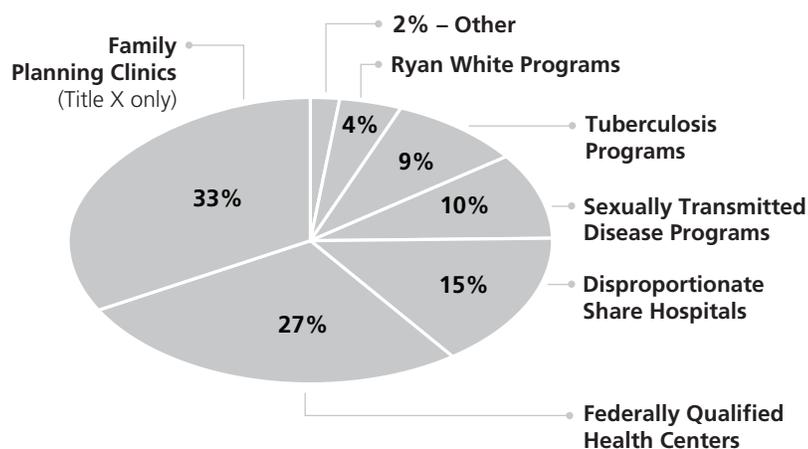
at least some beneficiaries and the physicians who administer these drugs. The situation continues to evolve as manufacturers revamp their program rules. For Part D drugs, beneficiaries eligible for the low-income subsidies generally no longer need the help of the PAPs as they enroll in a Part D plan. Beneficiaries not eligible for the subsidy but requiring help with cost sharing in the initial coverage period or with the cost of drugs in the coverage gap may be confused about their eligibility for PAPs. Many manufacturer programs invite applications from those with financial hardship, but at least two manufacturers were quoted in a recent trade newsletter as saying that enrollment from Part D enrollees was lower than expected.⁵³

THE FEDERAL 340B PROGRAM

Access to prescription drugs for uninsured individuals is always preceded by the need to see a physician or other provider who can write a prescription for the drug needed. Just as prescribers most often provide the point of access between the patient and manufacturer PAPs, many safety net providers also operate pharmacies that can obtain drugs and make them available to patients. The federal 340B program, established in the Veterans Health Care Act of 1992, offers a means by which these safety net providers can obtain drugs at a low price and stretch their resources. People without drug coverage may then be able to get their prescriptions filled either free of charge or at a reduced price, depending on the policies in force at the safety net clinic or hospital.

The 340B program places a ceiling on the price paid to manufacturers for prescription drugs when sold to certain safety net providers (see next section for how prices are established). The 12,000 entities that participate in the program include federally qualified health centers (FQHCs),⁵⁴ hemophilia treatment centers, Ryan White programs, sexually transmitted disease and tuberculosis programs, Title X family planning clinics, urban/638 tribal programs, and certain disproportionate share hospitals. About one-third of eligible providers are family planning clinics and one-fourth are FQHCs (Figure 3). The Ryan White AIDS Drug Assistance Programs (ADAPs), created to help improve access to drugs for those with HIV or AIDS, also benefit from the discounted prices made available under the 340B program (see text box, next page).

FIGURE 3
Distribution of Covered Sites in the 340B Program, by Type of Entity, Quarter 2, 2007



Source: 2007 Quarter 2 Statistics for 340B Covered Entities Number of Registered Covered Entity Sites by Entity Type, April 2, 2007, p. 2; available at ftp://ftp.hrsa.gov/bphc/pdf/jopa/Stats_2007_QTR_2.pdf.

The 340B program is administered by the Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services. Eligible entities must enroll with HRSA, after which they are added to a list of eligible entities. Manufacturers and wholesalers are supposed to make the 340B prices available to the all entities on HRSA's list.⁵⁵ HRSA estimates that annual purchasing volume for the program as a whole was about \$4 billion,⁵⁶ an amount similar to that provided through manufacturer PAPs.⁵⁷

For those without drug coverage, these safety net institutions tend to be key sources for obtaining drugs. In particular, FQHCs and other federally funded clinics are a major source of primary care services for many uninsured

AIDS Drug Assistance Programs

AIDS Drug Assistance Programs (ADAPs) are authorized by the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, which was enacted in 1990 to provide medical and support services to persons with HIV and AIDS who lacked adequate health insurance. ADAPs provide medications for HIV treatment and may also provide assistance toward other health care services, including health insurance for eligible clients. When ADAP was reauthorized in 2000, Congress included a supplemental program to help states expand HIV treatment to persons with incomes below 200 percent of the FPL. States must contribute one out of every four federal dollars in this supplemental program, and an ADAP's funds may only be used towards the purchase of HIV medications. Overall, ADAPs have approximately 142,000 participants (about one-fourth of those with HIV/AIDS); more than 80 percent of participants have incomes at or below 200 percent of the FPL, and two-thirds are African American or Hispanic. The program was reauthorized again in 2006 and changes include a new formula for state awards and a new minimum drug formulary. In 2006, estimated spending on drugs and insurance benefits by ADAPs was \$1.2 billion, and the average client was estimated to receive support of about \$12,000 in drug costs.

All 50 States, the District of Columbia, and the territories receive ADAP grants, which are calculated based on their proportion of the nation's living AIDS cases. Some programs also receive funds from state general revenues, other parts of the Ryan White CARE Act, or drug manufacturer rebates. Each state and territory determines its own eligibility criteria, although participants must be medically diagnosed with HIV and considered "low income." Some states require a specific CD4⁺ count (a test measuring the strength of a patient's immune system) for participation. Each state also determines the drugs included in its ADAP formulary, within the limits of the federal minimum, and how those medications are distributed. Some use a pharmacy reimbursement model like that of Medicaid, in which participating pharmacies bill ADAP for drugs dispensed to ADAP clients and then receive a rebate from the manufacturer to achieve the guaranteed 340B discount. Others purchase drugs themselves at the discounted price and mail them directly to clients, or distribute medications through public health clinic pharmacies. The high cost of the most effective HIV medications, the decline in AIDS mortality, and the steady rate of new HIV infections suggest that demand for ADAP services is likely to increase.

Source: Health Resources and Services Administration, "Title II: AIDS Drug Assistance Program," available at <http://hab.hrsa.gov/programs/adap>; Jessamy Taylor, "The Basics: The Ryan White CARE Act," National Health Policy Forum, September 14, 2005, available at www.nhpf.org/pdfs_basics/Basics_RyanWhite.pdf; and Jennifer Kates et al., "National ADAP Monitoring Project Annual Report: Summary and Detailed Findings," National Alliance of State and Territorial AIDS Directors and the Henry J. Kaiser Family Foundation, April 2007, available at www.kff.org/hivaids/7619.cfm.

Americans. Community health centers serve one in eight of those lacking insurance and one in five of low-income Americans without insurance.⁵⁸

The 340B program is also important for many safety net hospitals—specifically those qualifying as a disproportionate share hospital (DSH). These include government-owned or government-operated facilities as well as other nonprofit hospitals that have relationships with state or local governments to serve low-income patients. These hospitals must also have a Medicare disproportionate-share adjustment percentage over 11.75 percent, thus qualifying under Medicare’s rules as serving a higher-than-average number of uninsured or under-insured patients in comparison to other hospitals. The MMA made further changes to these rules so that about 800 more hospitals—mostly rural and small urban hospitals—now meet the DSH requirements for 340B eligibility.⁵⁹ In addition, more private nonprofit hospitals with local or state government contracts have started to participate in recent years.

Eligibility can be important for these qualifying hospitals in terms of purchases of outpatient drugs. They are particularly important for services provided in emergency departments, outpatient oncology and surgery departments, cardiac clinics, and other outpatient clinics. The lower prices for drugs in many of these settings benefit uninsured patients indirectly in that they reduce the cost to the hospital of treating these patients and, presumably, increase their willingness to take patients who are unable to pay. They may also reduce the charges made to these patients, some of whom attempt to pay. In addition, some hospitals operate outpatient clinics that make prescriptions available to patients for free or at reduced prices.

Although it is common for hospitals to get these discounts for drugs dispensed through their outpatient clinics, manufacturers are not required to participate for inpatient drug purchases. The MMA attempted to encourage more participation for inpatient drug purchases by removing one potential disincentive for manufacturers to extend deals in this setting.⁶⁰ Still, according to the organization Safety Net Hospitals for Pharmaceutical Access, hospitals are obtaining discounts on only about 12 percent of commonly used brand-name drugs for their inpatient services. Legislation [The Safety Net Inpatient Drug Affordability Act, introduced by Senators Thune (R-SD) and Bingaman (D-NM) and Representatives Emerson (R-MO) and Rush (D-IL)] was considered, but not passed, by the 109th Congress to extend the 340B program to inpatient settings. A potential effect of this legislation would be to reduce the costs to qualifying hospitals of caring for uninsured and under-insured patients.⁶¹

Prices Available Through the 340B Program

The advantage for safety net providers that participate in the 340B program is that they get access to drugs at far more favorable prices than are otherwise available to them in the marketplace. Under the terms of the

Veterans Health Care Act of 1992, manufacturers must make these drugs available at a discounted price as a condition of eligibility for Medicaid reimbursement. The amount of the discount follows the same formula used in the Medicaid program, and covered entities may negotiate discounts that are even greater than those obtained by Medicaid programs. Prices obtained through the 340B program are estimated to be about half of the “list price” paid by retail customers without access to any discounts. These prices are between 50 and 80 percent of the typical post-rebate price paid by private insurers.⁶²

Drug sales through the 340B program are subject to two key restrictions. One prevents resale of discounted drugs to anyone other than a patient of the participating entity. This anti-diversion rule protects manufacturers from situations where clinics, hospitals, or other participating facilities would make discounted drugs available to a broader array of patients. The second restriction ensures that manufacturers do not pay a Medicaid rebate for the same drug purchases that are made at 340B-discounted prices, that is, purchasers do not get more than one discount.

Further discounts below those available to all 340B entities can be obtained through the Prime Vendor Program, which operates under contract to the federal government. HealthCare Purchasing Partners International (HPPI), a group purchasing organization based in Texas, holds the current contract. HPPI has the ability to negotiate prices below the statutorily required prices as well as offer more favorable distribution arrangements for those entities that choose to participate in this program. The Prime Vendor Program also makes some other health care products available, including vaccines, diabetic meters, and test strips. At present, HPPI represents about one-third of the 340B-covered entities purchasing \$2.2 billion in drugs each year, and it uses this volume as leverage to negotiate discounts.⁶³ The program achieves an added discount of 11.6 percent on about 2,700 items.

Despite the general success of the 340B program in providing access to low drug prices, there are some concerns that participating providers do not always get the low prices to which they are entitled. The HHS OIG has reported several times recently on this program. An October 2005 study suggested that HRSA fails to oversee the program adequately by not always verifying that entities receive the low prices to which they are entitled. Specifically, it found that the government’s price files lack over one-fourth of the prices needed to verify that participating entities can obtain the discounts they are supposed to receive. It also found that neither HRSA nor the participating entities had the ability to verify that they received the appropriate discounts.⁶⁴ A subsequent OIG study, released in July 2006, compared actual prices paid by 340B entities to the ceiling prices. About 14 percent of total purchases exceeded the ceiling prices, resulting in overpayments. These overpayments were most likely to occur for low-volume entities and for low-cost drugs.⁶⁵

Prices obtained through the 340B program are estimated to be about half of the “list price” paid by retail customers without access to any discounts.

Problems Affecting the 340B Program and Potential Improvements

Despite the value of the 340B program, not all eligible entities actually participate in it. According to a survey of eligible entities conducted for HRSA, only 63.5 percent of 588 surveyed entities reported that they were participating.⁶⁶ The study also found significant discrepancies between those listed as participants on the government's Web site and those actually saying that they participated. Among the nonparticipating entities, about 40 percent indicated that they did not understand the 340B program "at all" while another 30 percent understood it "only slightly."

Among the barriers cited by eligible entities that might consider using the 340B program are high startup costs, the complexity of the required recordkeeping, the confusing nature of the program, and the perceived absence of adequate information about the program.⁶⁷ Some eligible entities even indicated that they had not heard of the program at all.

There have been several efforts to encourage more eligible entities to join the 340B program and to make its use easier. Extensive guidance is available through *The Bridge to 340B Comprehensive Pharmacy Solutions in Underserved Populations*, a guidebook prepared by Medicine for People in Need (Medpin) with support from HRSA's Pharmacy Services Support Center. Medpin, a program of the nonprofit California-based Public Health Institute and supported by several foundations in that state, works with safety net providers to improve access to medications. It makes this step-by-step guide available at no charge to safety net providers, especially community health centers and other clinics. It provides descriptions of various models for participating in the 340B program and offers key points of advice designed to encourage participation.⁶⁸

Another barrier cited by some health center administrators is the absence of a pharmacy. In general, eligible organizations must have some means of dispensing the drugs they purchase through the 340B program. Typically, they operate under one of three models: owning and operating an in-house pharmacy, contracting with a retail or mail-order pharmacy where the entity purchases the drugs but uses a contractor to provide the pharmacy services, or employing physicians or other providers who are licensed to dispense the drugs but do not operate an actual pharmacy. In the latter model, which may vary based on state law, the health center or other entity would own the drugs and assume fiscal responsibility for operating and dispensing costs.

Since 2001, HRSA has encouraged innovation by allowing several efforts on a demonstration basis to build on the 340B program to expand its reach to more people. There are about 20 such projects in operation, most of which involve getting more community health centers linked to the program. These demonstrations are important because many small clinics, especially in rural areas, lack the resources to operate a pharmacy. HRSA

is currently developing a regulatory notice that would allow some arrangements that have been used through demonstrations.

There are at least three different arrangements being used, many of which offer solutions to the current rules requiring that each site have some type of pharmacy setup on location. Perhaps the most common is to develop a network of covered entities that can share a common pharmacy. For example, a program in Spokane, Washington, uses “remote dispensing technology” to allow pharmacists at one health center to dispense drugs at remote health clinics. When necessary, patients receive counseling through video-conferencing. Similarly, Georgia’s Columbus Regional Community Healthcare Network links a local safety net hospital to two local health centers. The hospital provides the pharmacy services, including pharmacists to work with the physicians and nurses at the clinics.⁶⁹

Several of the demonstration projects focused on the delivery of care for diabetes. The goal was to show positive results in terms of management of the disease, getting patients access to pharmacists, and retaining their patients for at least 12 months. One health center in Tucson focused on services to Spanish-speaking and Native American people. Arizona state law was modified to allow pharmacists to initiate and modify medications consistent with written protocols approved by physicians. This use of collaborative drug therapy management allowed the pharmacist to monitor the patients, provide diabetes education, and make sure they received the needed drugs. Participating patients were able to lower their blood glucose, blood pressure, and cholesterol levels. Similar results were attained in other communities that also relied extensively on pharmacists or nurses.⁷⁰

Other resources available to eligible clinics include groups that work with pharmaceutical wholesalers to negotiate better prices for safety net providers, in addition to the Prime Vendor program described above. Soon after the 340B program was created, the Texas Association of Community Health Centers created the “340Better” program. Its purpose was to use the combined purchasing leverage of participating community health centers to improve the distribution of drugs obtained through the 340B program and to obtain even deeper discounts. The participating clinics have representatives serve on a collective Pharmaceuticals and Therapeutics (P&T) Committee to determine which high-cost drugs are dispensed most frequently. On the basis of this determination, the program has been able to negotiate discounts that average at least 15 percent below the 340B ceiling price. The program was expanded nationwide in 1997 and now works with a wholesaler (Cardinal Health) to serve nearly 400 community health centers from 37 states.⁷¹

Although many of the ideas described here have the potential to enroll a higher percentage of the eligible entities into the 340B program, the ultimate limitation of this approach is the uneven distribution of safety net

HRSA has encouraged innovation through demonstration projects to expand the reach of the 340B program.

providers in the United States.⁷² Some communities (for example, Boston, Massachusetts) have a wide array of community health centers—both federal qualified health centers and other comprehensive primary care providers that do not meet FQHC qualifications. But other communities (such as Little Rock, Arkansas) have few organized health centers of any type. In some cases, these communities may have free clinics that operate on a limited schedule and with volunteer physicians and nurses. The latter, however, are unlikely to qualify for participation in the 340B program even in partnership arrangements.

PHYSICIANS' ROLE IN HELPING PATIENTS WITHOUT DRUG COVERAGE

Physicians are not always aware of the challenges that drug costs impose on their patients' ability to comply with their prescription orders. But when they are aware, physicians have some ability to help their patients beyond connecting them to manufacturer PAPs or other safety net programs. Physicians may be able to make sample drugs available to their uninsured patients or to prescribe less expensive drugs.

Drug Samples as a Source of Medications

When a patient without drug coverage is fortunate enough to have a regular physician, that physician may use manufacturer-supplied samples as a way to help by provide a supply of drugs. The patient may receive enough drugs for the entire course of treatment, or at least enough to get started. In some cases, a small supply may provide the patient time to get enrolled with a manufacturer PAP or some other means of receiving needed drugs.

Most pharmaceutical manufacturers provide samples, especially for their newer brand-name drugs. Physicians may use samples for a variety of reasons, including making them available to patients who cannot afford to pay for the particular drug. Samples may also be used for patients who do not qualify for any appropriate manufacturer PAPs or public programs or for patients who are waiting for their medications to arrive from the PAP.

Estimates of the volume and frequency with which samples are used for uninsured or other low-income patients are difficult to obtain. Manufacturers made available to doctors about \$16 billion worth of sample drugs in 2004, more than the estimated total value of drugs distributed by PAPs and through the 340B program.⁷³ But this total represents the retail value of all drugs received by doctors and thus includes those given to insured patients for convenience and those never distributed to patients. According to a 2001 national survey of physicians, 92 percent of physicians said they had accepted free samples from a drug industry representative, and a 2003–2004 survey of physicians in six specialties found that 78 percent reporting receiving samples.⁷⁴ One study of 18 practices in Nebraska found that samples were used in about 20 percent of all patient encounters.

Samples were used for different circumstances, ranging from starter dosages to complete courses of antibiotics, to several months' supply of some drugs, and physicians attributed use to a variety of motives that included temporary relief or convenience, testing for efficacy or tolerability, as well as cost concerns.⁷⁵

In one recent study of obstetrician-gynecologists, physicians were asked about the ethics of various scenarios. Nearly all (92 percent) agreed that it was ethically proper to accept free samples of a new drug from a pharmaceutical manufacturer's representative, and most in fact had such samples and said that they distributed them to patients. The most common reason cited for distributing such samples was the patient's financial need (cited by over 90 percent of surveyed physicians as one of multiple reasons). One-third said that accepting samples would influence their decision to prescribe drugs they received as samples.⁷⁶ In two other studies, just over one-half of physicians thought that samples influenced their prescribing.⁷⁷

The use of samples raises both practical and ethical issues. Federal law requires providers to document in the chart when patients receive sample medications.⁷⁸ But it may be difficult to inventory all samples and report overall usage. Some medications require temperature-controlled storage, but finding such storage can be a problem for some physician offices. Furthermore, sample medications may not be adequately labeled when dispensed or may not contain dosing instructions and warnings of possible side effects. Typically, they are not available in childproof packaging. Although some providers may provide warnings or appropriate packaging for patients, as well as check for drug-drug and drug-disease interactions, this practice is not universal. Because of the difficulty in conducting inventory on and storing samples properly, such medications are at risk of expiring without notice or losing potency. In some states (for example, Florida), samples cannot simply be discarded when expired; thus, clinics must incur the cost of contracting with a disposal company to handle expired drugs.⁷⁹

The use of samples for uninsured patients also raises some ethical concerns. In their ethical codes, some physician groups address personal use and the effect of samples on drug selection but do not ban the use of samples.⁸⁰ Recently, however, some institutions, including the University of Michigan, the University of Pennsylvania, and Stanford University, have adopted complete or partial bans on drug samples. Because some physicians were concerned about the effect on indigent patients, the University of Pennsylvania's hospital instituted a program where patients get vouchers for medications instead of samples, and the hospital planned to make available free generic samples at primary care offices. Through this approach, the use of detailing (marketing to doctors by manufacturer representatives) might be reduced, and thus so might the influence on doctors' prescription choices.⁸¹ Instead of a ban on the use of samples, one California clinic systematized its process for receiving and storing samples by instituting a drug sample formulary and an electronic coding system. Emphasis was placed on using samples

The use of samples raises both practical and ethical issues.

for acute drug needs (for example, antibiotics) rather than medications for chronic illnesses. Storage was based on an electronic system, and samples were dispensed with labels and patient instructions similar to regular pharmacy dispensing.⁸²

Concerns about the use of samples have also been addressed in a report for the California Healthcare Foundation by John Piette, who argues that samples, while useful in the short term, may increase costs in the long run. His logic is that samples encourage both the prescribing of brand-name drugs instead of cheaper generic alternatives and the use of treatments of limited clinical value. He also argues that the use of free samples tends to increase the cost of promotion of products by manufacturer representatives and thus inflates the overall cost of health care.⁸³ The approach of providing vouchers to uninsured patients would not necessarily address these concerns unless there was a mechanism for including generic drugs.

Changes in Prescribing Behavior

Physicians may also consider reducing drug costs for their patients without drug coverage by shifting their thinking about which drugs to prescribe or by offering other alternatives. That is, if the goal is for doctors to find less costly treatment alternatives that their patients can afford, part of the solution might be to change the awareness of providers about less costly approaches to drug treatments. First, physicians and other providers would need to identify that their patients in fact require assistance to obtain prescribed drugs. Studies have shown that clinicians typically do not discuss cost-related issues with their patients.⁸⁴ According to two studies, between 30 and 40 percent of patients who reported cutting back on the use of drugs for reasons of cost informed their doctor or nurse in advance of doing so.⁸⁵ While there are legitimate barriers for both the clinician and the patient that make it a challenge to have these conversations, they must occur if physicians are to offer help.⁸⁶ Physicians also tend to be unaware of the cost of drugs—both the absolute cost of the medications for those without insurance coverage and the typical cost-sharing amounts for those with coverage.⁸⁷

Some available steps for a clinician to suggest, apart from offering access to relevant safety net programs, include minimizing prescriptions for drugs that are not truly necessary (especially for patients with multiple health conditions), increasing the effective use of generic drugs, considering less costly therapeutic alternatives, and physically splitting pills in cases where a pill's full dose is not necessary.⁸⁸ One might argue that some of these steps should always be part of good patient care, but they take on added importance for patients who may skip taking medications they cannot afford to purchase.

Generic substitution and therapeutic substitution may be required by health plans for their insured patients, but such methods can be even more valuable for uninsured patients. Uninsured patients do not face the insurer's electronic edit at the pharmacy counter that imposes the

substitution (although some state laws do require generic substitution). So if uninsured patients are not savvy about asking for less expensive alternatives, they must rely on physicians or pharmacists to suggest appropriate substitutes. Sometimes neither the physician nor the patient is aware of the potential for lower costs.⁸⁹ Physicians may also be concerned that they are not practicing good medicine if they switch patients to a less expensive medicine. But according to one family physician, “it is necessary to redefine the practice of ‘best medicine’ to include helping patients balance their drug costs with benefits. While new, expensive drugs may offer greater benefits for some patients, they may not offer those improved benefits for all patients. By helping patients use medications cost-effectively, physicians can help keep medications affordable for everyone.”⁹⁰

Similarly, pill splitting is not often suggested by physicians, some of whom have concerns that not all pills can be split easily or safely. Nevertheless, studies have suggested the safety of this approach.⁹¹

CONCLUSION

The safety net that helps uninsured patients get access to medications relies on a mix of public and private components. Manufacturers create part of the safety net through their provision of free drugs and by making drug samples available to prescribers, while the federal government uses its leverage to obtain reduced prices for qualifying providers in the 340B program. Some other players in system, including pharmacy benefit managers, retail pharmacies, and health plans, play a role as well when they sponsor discount cards or price certain drugs at affordable levels. But in the end, uninsured patients face a fragmented safety net system for prescription drugs that can require considerable effort and determination to administer.

In the absence of coverage expansions that would increase access to a full array of health services, including prescription drugs, federal or state policymakers might consider an expanded role for pharmacy assistance programs, discount cards, or other discounted pricing arrangements for the general uninsured population. Some elderly or disabled beneficiaries receiving benefits from these state programs are now getting some of their drugs through Medicare Part D coverage. To the extent that states operating such arrangements achieve savings, they may consider making these programs available to broader low-income populations.

Policymakers may also consider incremental changes to address the efficiency of the manufacturer PAPs or the federal 340B program. For example, standardized application forms and simplified eligibility requirements for the manufacturer PAPs might help more uninsured patients access these programs to obtain more of their drugs. Pharmaceutical manufacturers could take such steps on their own, or policymakers could identify a mechanism or incentives to encourage such steps. Because generic drugs are generally unavailable through these programs, policymakers might

want to seek innovative ways to make generic drugs more accessible to low-income uninsured populations.

Although the 340B program is successful in making prescription drugs available to safety net providers at discounted prices, recent studies by the HHS OIG have identified gaps in enrolling all eligible providers and ensuring that providers always get the correct prices. Policymakers may want to consider ways of replicating some of the innovative ideas that been tested in the HRSA demonstrations, as well as testing other approaches to expanding and strengthening the 340B program.

Prescription drugs can be a lifeline in keeping a patient's diabetes or asthma in check, controlling hypertension, or limiting cholesterol levels. But filling prescriptions may be beyond the means of many persons without drug coverage. The safety net today includes valuable resources to help these individuals get the drugs they need. Policy measures that fill the gaps in the current safety net have the potential to make a significant difference for patients with limited resources.

ENDNOTES

1. Some states have created pharmacy assistance programs that focus on help for Medicare-eligible populations. Since the implementation of Medicare Part D, they generally provide coverage that wraps around the Part D benefit. Some programs offer assistance to elderly or disabled individuals that are not enrolled in Medicare, but few provide assistance to nondisabled individuals under the age of 65.
2. These results were based on a 2001 telephone survey conducted for the Commonwealth Fund. Claudia L. Schur, Michelle M. Doty, and Marc L. Berk, "Lack of Prescription Coverage Among the Under 65: A Symptom of Underinsurance," Issue Brief, Task Force on the Future of Health Insurance, The Commonwealth Fund, February 2004; available at www.cmwf.org/usr_doc/Schur_under65.pdf.
3. These data are from the Medical Expenditure Panel Survey Household Component and are based on some special questions that were asked on the 1996 survey but have not been asked since then. U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (DHHS/ASPE), *Prescription Drug Coverage, Spending, Utilization, and Prices: Report to the President*, April 2000; available at <http://aspe.hhs.gov/health/reports/drugstudy>.
4. Schur, Doty, and Berk, "Lack of Prescription Coverage Among the Under 65." The analysis of this survey provided less detailed income breakdowns, reporting that 44 percent of those with incomes under 200 percent of the FPL lacked drug coverage, compared with just 12 percent of those with higher incomes.
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