

November 2000

PRESCRIPTION DRUGS

Drug Company Programs Help Some People Who Lack Coverage



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Abbreviations

AWP	average wholesale price
DEA	Drug Enforcement Administration
HHS	Department of Health and Human Services
PACE	Pharmaceutical Assistance Contract for the Elderly
PhRMA	Pharmaceutical Research and Manufacturers of America
WAC	wholesale acquisition cost



United States General Accounting Office
Washington, D.C. 20548

November 16, 2000

The Honorable Tom Bliley
Chairman, Committee on Commerce
House of Representatives

The Honorable Michael Bilirakis
Chairman, Subcommittee on Health
and Environment
Committee on Commerce
House of Representatives

The Honorable Charles E. Grassley
Chairman, Special Committee on Aging
United States Senate

As the Congress considers Medicare beneficiaries' access to prescription drug coverage, there is increased interest in the options available to help vulnerable populations obtain access to needed medications. Among these options are patient assistance programs operated voluntarily by pharmaceutical companies. These programs are part of many companies' philanthropic efforts to provide prescription medications to those who need, but cannot afford, their products. You asked us to examine pharmaceutical company assistance programs that provide their products to low-income patients, including Medicare beneficiaries. This report describes (1) the scope of the programs, including the amount of assistance provided and eligibility requirements, and (2) the design of the programs, such as the procedures for obtaining assistance.

To develop this information, we surveyed pharmaceutical companies with patient assistance programs that offer outpatient, self-administered prescription drugs. We identified 88 programs and received responses from 72. The programs were identified through pharmaceutical industry groups and other organizations that compile information about patient assistance programs. We also obtained information on patient assistance programs from Pharmaceutical Research and Manufacturers of America (PhRMA).¹ We also interviewed providers who have used patient assistance programs, individuals affiliated with organizations that provide information to the

¹PhRMA is a trade association whose membership represents most large pharmaceutical companies and many smaller biotechnology drug companies.

public about patient assistance programs, and representatives from drug industry, public hospital, and public hospital pharmacy groups. Because of data limitations, we could not determine the proportion of program participants who were Medicare beneficiaries. We did not independently verify the information provided by the survey respondents, providers, or others we interviewed. We conducted our work in accordance with generally accepted government auditing standards between January and October 2000. Appendix I describes our methodology in more detail.

Results in Brief

Patient assistance programs, offered voluntarily by drug companies, are generally designed to provide prescription drugs to low-income persons who lack drug coverage. Almost all large research-based drug companies, as well as some smaller companies, offer these programs and generally consider them to be short-term, last-resort options for people unable to afford their products. Collectively, patient assistance programs offer a wide variety of prescription drugs, including medications commonly prescribed to Medicare beneficiaries. A survey conducted by PhRMA found that its members' programs provided \$500 million worth of products to 1.5 million people in 1998. Our survey of programs yielded similar findings. Programs' eligibility requirements, usually based on income and insurance status, target people in need of financial assistance.

Assistance programs typically rely on health care providers' involvement with some or all stages of applying for and receiving drugs from the programs. Information about these programs and their application rules is typically provided to health care providers by drug company representatives. Once providers and patients learn about the programs, applying for and receiving assistance generally entails a number of procedures that vary among the programs. Half of the programs we contacted require a provider to apply for assistance on behalf of the patient, while some programs allow a patient or patient advocate to apply. Most programs have application forms that request varying amounts and types of information—commonly regarding the patient's income and drug and health insurance coverage. Some programs also require applicants to provide documentation of income or insurance status, while others rely on the provider to verify that the patient is eligible. Once the application is approved, most programs send the drug to the provider, but some programs provide vouchers or send the drug directly to the patient. Patients are rarely required to pay a copayment, dispensing fee, or shipping charges before receiving the drug.

Background

As prescription drugs have become an increasingly significant part of medical care and drug costs have continued to rise, access to drug coverage has become an important concern. Total spending on prescription drugs, as well as the share of all health expenditures accounted for by drugs in the United States, has grown steadily in recent years. In 1998, total spending on drugs in the United States was \$90.6 billion. Most private health insurance policies and all Medicaid programs cover outpatient prescription drugs, although the benefits may be limited. However, approximately 15 percent of the U.S. population under age 65, or about 42 million people, did not have any health insurance coverage for the entire year in 1999.² Those with household incomes below \$25,000 were less likely to have health insurance than those in higher income categories.

²Robert J. Mills, *Health Insurance Coverage: 1999*, U.S. Bureau of the Census www.census.gov/Pressrelease/www/2000/cb00-160.html (cited Sept. 29, 2000).

Because of the Medicare program, nearly all Americans aged 65 and over have health insurance. However, the traditional Medicare program³ does not cover most prescription drugs that are self-administered outside of a hospital or doctor's office. In 1996, the latest year for which analyzed data are available, 31 percent of Medicare beneficiaries, approximately 11.6 million people, did not have access to drug coverage, could not afford to purchase coverage, or chose not to purchase coverage. Medicare beneficiaries' higher prevalence of chronic medical conditions and disproportionate use of prescription drugs can translate into a potential financial burden, especially among those without any prescription drug coverage. In 1996, average total spending for outpatient prescription drugs among the over 37 million Medicare beneficiaries was \$674 per person,⁴ compared with an estimated \$156 per person for the nonelderly population.⁵ In that same year, 7 percent of Medicare beneficiaries had \$2,000 or more in total drug costs.⁶

In general, Medicare beneficiaries with low incomes are more likely to lack drug coverage than those with higher incomes. Seventy-three percent of Medicare beneficiaries with incomes above 200 percent of the poverty threshold had drug coverage at some point during 1996, compared with 61 percent of Medicare beneficiaries with incomes between 100 and 150 percent of the poverty threshold.⁷ The exception to this pattern is that a higher percentage (68 percent) of beneficiaries with incomes below the poverty thresholds had drug coverage, which is likely due to coverage through state Medicaid programs for the poorest Medicare beneficiaries.

³Many Medicare+Choice plans—managed care plans available to some Medicare beneficiaries—offer coverage for outpatient, self-administered prescription drugs.

⁴GAO calculation based on J.A. Poisal and G.S. Chulis, "Medicare Beneficiaries and Drug Coverage," *Health Affairs* (Mar./Apr. 2000), p. 252.

⁵Agency for Health Care Research and Quality, Center for Cost and Financing Studies, National Medical Expenditures Survey Data, *Trends in Personal Health Care Expenditures, Health Insurance, and Payment Sources, Community Based Population, 1996-2005* (updated Aug. 1998), [http://www.meps.ahrq.gov/nmes/papers/trends/96-05\(c\).pdf](http://www.meps.ahrq.gov/nmes/papers/trends/96-05(c).pdf), p. 9 (cited Apr. 22, 1999).

⁶Department of Health and Human Services (HHS), Assistant Secretary for Planning and Evaluation, *Prescription Drug Coverage, Spending, Utilization, and Prices* (Washington, D.C.: HHS, Apr. 2000), p. 61.

⁷GAO calculation based on J.A. Poisal and G.S. Chulis, "Medicare Beneficiaries and Drug Coverage," *Health Affairs* (Mar./Apr. 2000), p. 253.

Many Drug Companies Have Programs to Provide Targeted Assistance

Many pharmaceutical companies voluntarily operate patient assistance programs to provide their drugs to people who would not otherwise have access to them. Together, these programs offer a wide variety of prescription drugs, including those drugs commonly prescribed to Medicare beneficiaries. PhRMA's 1999 survey of its members found that the amount of assistance its member companies provided through these programs has increased since 1996 to a total of \$500 million⁸ worth of prescription drugs provided to 1.5 million people in 1998. Our survey of patient assistance programs yielded similar results.⁹ We could not determine the proportion of people served by these programs who were Medicare beneficiaries. Programs generally require applicants to have low incomes and no drug coverage to be eligible.

PhRMA characterizes patient assistance programs as part of the drug companies' mission to provide their drugs to people who might not otherwise have access. Almost all large research-based companies and some smaller companies have patient assistance programs to provide their products free or at a reduced price. Some companies describe their programs in industry literature as a temporary source of assistance.¹⁰

Through these programs, drug companies offer a wide range of drugs to patients who qualify. Among respondents to our survey, 15 percent offered all of the company's outpatient, self-administered prescription drugs through their programs, while the remaining programs offered some of their products. Some companies have separate programs for one or more of their products. Our comparison of medications available through patient

⁸According to a PhRMA representative, this is the value of products provided by their member companies' patient assistance programs, either in terms of wholesale acquisition cost (WAC), which is the actual selling price charged by the manufacturer before discounts to the wholesaler, or average wholesale price (AWP), which is the average list price that a manufacturer suggests wholesalers charge pharmacies. AWP is sometimes referred to as a "sticker price" because it is not the actual price that purchasers with market power normally pay.

⁹We could not determine the total number of persons assisted or the value of products for all companies we surveyed because only 46 of 72 programs provided information on the total number of persons assisted and only 44 programs provided information on the value of the products. In our survey, 20 programs used WAC to value the products they provided, 18 programs used AWP value, and 6 programs used another valuation method.

¹⁰For examples, see PhRMA, *1999-2000 Directory of Patient Assistance Programs* (Washington, D.C.: PhRMA, 2000), pp. 6, 10, 14, 15, 22.

assistance programs with those most commonly prescribed to the enrollees in the largest state-funded and -administered program providing drug assistance to the elderly showed that as of June 2000, drug company patient assistance programs offered all but two of the brand name drugs among the 50 most commonly prescribed to the state program's enrollees.

According to the 1999 PhRMA survey, the number of patients assisted by their members' patient assistance programs increased 30 percent from 1997 to 1998. Similarly, these companies experienced a 34 percent rise in the value of the products provided during this period. A PhRMA official said that the demand for assistance has grown as programs become more widespread and information about the programs becomes more accessible.

Patient assistance programs typically require applicants to have low incomes and no drug coverage to be eligible. Fifty-seven of the programs that responded to our survey said they have established a maximum annual income level for eligibility to target assistance to the neediest applicants. Programs with income limits set them at or above the federal poverty guidelines, which were \$8,050 for an individual and \$10,850 for a family of two in 1998 (see table 1).¹¹ Almost two-thirds of these programs reported that they typically do not disclose income level thresholds to potential applicants. The two reasons most commonly provided for this lack of disclosure were concern about false reporting of applicants' income and variable income thresholds that can depend on other aspects of an applicant's case.

¹¹The federal poverty guidelines are published annually by HHS. They are used by some public programs to determine eligibility and are loosely referred to as the federal poverty level.

Table 1: Reported Annual Income Limits for Eligibility in Patient Assistance Programs, 1998

Individual maximum income limits	Number of programs reporting (n=72)	Family maximum income limits	Number of programs reporting (n=72)
\$8,050-\$14,999	12	\$10,850-\$22,999	19
\$15,000-\$22,999	11	\$23,000-\$34,999	9
\$23,000-\$27,999	6	\$35,000-\$47,999	6
\$28,000-\$35,000	6	\$48,000-\$60,000	1
Income limits vary according to drug provided	2	Income limits vary according to drug provided	3
Unspecified income limit	20	Unspecified income limit	19
Total programs with income limits	57	Total programs with income limits	57
Total programs for which income is not an eligibility criterion	15	Total programs for which income is not an eligibility criterion	15

Note: Categories were developed by dividing the range between the highest and lowest income limits into approximate quarters.

Source: GAO analysis of survey data.

According to a representative from PhRMA, companies generally consider their programs to be a last-resort source of prescription drugs. Consistent with this policy, many assistance programs consider an applicant's current drug coverage status when determining whether applicants may receive assistance from their program. Patients who have some source of drug coverage generally are not eligible for assistance. In addition, one-quarter of all programs responding to our survey reported that they deny assistance if the applicant is eligible for drug benefits from a public program, even if the patient currently does not have public drug coverage. Eighty percent of our survey respondents indicated that patients with insurance who have exhausted their drug coverage could be eligible for assistance, and most programs reported that Medicare beneficiaries without supplemental drug coverage could receive drug assistance through their program.

Health Care Providers Are Often Needed to Facilitate Program Access

Many programs have application and distribution procedures that require health care provider involvement beyond writing the prescription. Information about these programs and their application rules is typically given to health care providers by drug company representatives. Several sources of information are also available on the Internet. Half of the programs we surveyed said that the only way to enroll in the program is for a health care provider to apply on behalf of the patient.¹² Other programs allow patients to apply to the program on their own or through a social worker or patient advocate. Most programs have an application form and many require information about an applicant's income, drug coverage, or other information about the patient or health care provider¹³ to determine eligibility for the program. Almost half of the programs rely on the provider to confirm the validity of the patient's information, but others require accompanying documentation to support the information provided on the application. Once the application is approved, most programs send the drugs to the health care provider to distribute to the patient. Patients are rarely obligated to pay for drugs from the assistance programs.

Program Information Sources

Among programs responding to our survey, the most frequently cited method of disseminating program information is having company representatives discuss the program with health care providers. However, several providers we interviewed noted that drug companies do not advertise these programs and that they must ask drug company representatives for the program information. Some companies offer additional ways for providers, and in some cases, potentially eligible patients or others, to obtain information about the programs. For example, approximately half of the patient assistance programs in our survey reported listing their program in the PhRMA directory.¹⁴

¹²Our survey did not distinguish between different types of health care providers, for example, physicians, nurse practitioners, or physician's assistants, in questions about who is permitted to perform the tasks required to access program assistance.

¹³Forty-two of the 47 program applications we received specified that a section of the form must be completed by a "physician" or required information about the "physician." Five programs' applications indicated that another provider such as a "health care practitioner" or "licensed practitioner" could provide information on the application.

¹⁴ This directory contains information about PhRMA member companies' patient assistance programs. According to PhRMA representatives, the directory may not be a complete list of all assistance programs, because it contains only information about PhRMA member companies and lists only those programs that ask to be included.

Information about these programs is also available on the Internet. Several Internet sites target their information to providers or instruct the provider to call for information about the programs. Twelve programs responding to our survey provide some information about their programs on their companies' Web sites. Another site, which became operational in March 2000 and receives some funding from PhRMA, allows providers who register¹⁵ to access information about patient assistance programs and, in some cases, request assistance on behalf of their patients. Currently, one company allows drugs to be ordered from its patient assistance program directly through this site. In addition, we identified two organizations, not affiliated with individual drug companies, that provide frequently updated information about pharmacy assistance programs in a standardized format on their Web sites.¹⁶

Program Application Requirements

Programs we surveyed differed in their application procedures. Half of the programs we surveyed responded that the health care provider must apply on behalf of the patient, while others said they allow patients to apply through a social worker or patient advocate, or on their own. While some programs said that a letter or telephone call is adequate, most responding programs reported that an application form is required to apply for assistance. Most respondents to our survey said that refills are available to patients who have successfully applied for assistance, although most programs require patients to reapply (see table 2). Similarly, most programs that offer more than one product allow patients to receive more than one drug at a time, with half requiring a separate application for each drug. A few programs enroll patients for a fixed amount of time, for example, 1 year, and require patients to reapply when that time has elapsed.

¹⁵To register with the site, a physician or certain patient advocates must enter an identification number and password as well as the prescriber's Drug Enforcement Administration (DEA) registration number, which is linked to a database that allows the site to identify the physician.

¹⁶The Needy Meds Web site, established and maintained by a physician and a social worker, is a compilation of drug company assistance programs. The site is funded by the sale of manuals containing the information collected about the programs. The RxAssist Web site is intended to help health care providers identify programs offering free pharmaceuticals for their eligible low-income patients. It is operated by Volunteers in Health Care, a national, nonprofit program that is funded by the Robert Wood Johnson Foundation.

Table 2: Programs Offering and Requiring Applications for Refills and Multiple Products

	Prescription refills	Multiple concurrent products ^a
Program offers option (n=72)	70 ^b	46 ^c
Program requires reapplication or separate application (n=72)	48	23

^aSixteen programs that reported offering only one drug were excluded from this analysis.

^bOne program did not respond to the question regarding the availability of refills.

^cThree programs did not respond to the question regarding the availability of multiple concurrent products.

Source: GAO analysis of survey data.

The programs exercise varying degrees of control over the distribution of their application forms. Thirty-two of the 72 programs said they distribute application forms to health care providers to use when needed, while 39 programs reported that an application form must be requested from the program for a specific patient. One program makes the application forms available over the Internet. Additionally, a nonprofit group makes application forms available on its Web site for 26 patient assistance programs that expressly state that they accept photocopied forms.

Providers and individuals who compile program information told us that some programs are more difficult to access than others. They cited several factors that can increase the difficulty of applying, such as when the program accepts only original application forms or requires a large amount of information on the form. They also noted that separate applications are needed for patients who need medications from different companies and that these applications differ. In addition, providers and advocates told us that program rules that require physicians to complete all or some of the application can be particularly burdensome to providers who treat a large number of indigent patients and may create a barrier to program access for some patients. One provider who uses these programs for his patients said that routinely using assistance programs can be difficult without staff to manage the application process because the process can take up to 30 minutes to complete. Providers and advocates we talked with reported that facilities with staff or volunteers dedicated to helping patients access these programs were the most successful in securing assistance from them.

Many programs said they require information about the patient's income and drug and health insurance status to determine eligibility for assistance (see table 3). Some programs reported that they request other information from the applicant and most programs said they require a physician's name and signature. Almost half of the programs reported that they rely solely on the health care provider to validate the patient's information, while 31 programs said that the patient must provide some type of documentation to support the information on the application. For example, some programs require documentation of the patient's income, such as a tax return, or require documentation that the patient is ineligible for public programs such as Medicaid.

Table 3: Patient Assistance Programs' Information Requirements

Type of information	Programs that require information (n=72)
Patient information	
Income	53
Existing drug coverage	48
Existing health insurance coverage	43
Diagnosis	32
Medical expenses	19
Ineligibility for prescription drug coverage	16
Assets	14
Physician information	
Name	67
Signature	64
DEA or license number	59

Source: GAO analysis of survey data.

Drug Distribution and Payment Requirements

More than three-quarters of the patient assistance programs responding to our survey indicated they distribute drugs to approved patients through health care providers. Most of the remaining programs indicated they send the drug directly to the patient or give the patient a voucher or card that allows him or her to obtain the drug from a pharmacy. Some providers said that it can be difficult for them to manage the storage and distribution of drugs. Several providers said that drug distribution is simpler when a program gives them coupons or vouchers for drugs, which they then give

patients to take to pharmacies, rather than when the program ships an individual product for an individual patient to the provider's office. One program reported that once the program's eligibility decision is made during a telephone conversation between the provider and the program, the patient is immediately given a card to take to a pharmacy.

The amount of time it takes for the program to ship the drug, and thus the minimum time until the drug is available to the patient, varied among programs. Twenty-eight of the 72 programs said it can take 7 or fewer days between the program's receipt of the application and shipping the drug. One program representative said that it can take up to 42 days from the date an application is received to the date the medication is shipped to the health care provider. A clinic director noted the clinic uses the programs only for medications for chronic illnesses because it can take too long to receive medications needed for acute conditions. The five programs that provide patients with a prescription card to take to a pharmacy, rather than sending drugs to providers, indicated that it takes 5 or fewer days, on average, to process the application and issue the card. One program that operates in cooperation with community health centers makes drugs available immediately through the health centers' pharmacies, rather than shipping the drugs after the patient has applied.

While most programs responding to our survey said that patients are not required to pay for drugs from the programs, 14 of the 72 programs indicated that patients may be required to pay some amount before the drug is dispensed. Some of these programs base the patient's required payment on the patient's income. For example, one program requires a patient contribution based on a sliding scale when the patient's income is between 140 and 300 percent of the federal poverty guidelines. Five programs that distribute the drug through a pharmacy said that the patient must pay a copayment or dispensing fee to the pharmacy, generally between \$5 and \$10. Five additional programs require the patient to pay shipping and handling charges.

Concluding Observations

The patient assistance programs operated voluntarily by many drug companies may provide valuable assistance to a small share of the uninsured population that complies with program procedures and meets program requirements. Drug companies characterize their programs as a last-resort source of prescription drugs, and most programs are not designed to provide long-term prescription drug coverage. To comply with programs' eligibility criteria, which are intended to target patients who are

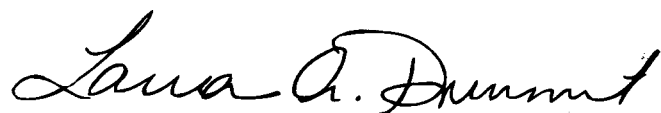
in need of assistance, application procedures require information about the patient's financial and insurance status. The provider's role in the application process often is significant, involving obtaining applications, completing all or part of the forms, and receiving and dispensing drugs.

Comments From External Reviewers

We obtained comments on a draft of this report from representatives from PhRMA and the Public Hospital Pharmacy Coalition, and the Director of the Anderson Free Clinic in Anderson, South Carolina. The reviewers provided technical comments, which we incorporated into the report where appropriate.

We are sending copies of this report to interested committees and Members of Congress. We will make copies available to others on request.

If you or your staffs have any questions about this report, please call me at (202) 512-7119 or John Hansen at (202) 512-7105. Major contributors to this report are Cristina Boccuti, Kathryn Linehan, Myrna Pérez, and Tricia Spellman.



Laura A. Dummit
Director, Health Care—Medicare Payment Issues

Scope and Methodology

To determine the extent of the assistance provided by drug company programs and programs' eligibility and other requirements, we sent surveys to patient assistance programs operated by 82 pharmaceutical companies. The pharmaceutical companies were identified through member lists from four pharmaceutical industry groups.¹ We identified additional pharmaceutical companies from two Internet sites that track drug company patient assistance programs, Needy Meds (www.needymeds.com) and the Cost Containment Research Institute (www.institute-dc.org/prescrip.htm).² After contacting each company on our list, we identified 115 potential programs to survey. We excluded 27 from our final sample because they did not fit the criteria for our analysis.³ Of the 88 remaining programs, we received responses from 72, yielding a response rate of 82 percent.

We also obtained information about the programs from a PhRMA survey of its members. The PhRMA survey included only PhRMA member companies and may have included programs that were nonrespondents to our survey. Our survey included both PhRMA and non-PhRMA member companies but excluded information about programs that did not provide outpatient, self-administered prescription drugs.

To gain an understanding of providers' experiences using drug company assistance programs, we interviewed health care providers who have used these programs, as well as representatives from the Anderson Free Clinic, the National Association of Public Hospitals and Health Systems, the Public Hospital Pharmacy Coalition, and organizations that collect information on and inform potential users about the programs. We asked them to discuss how these programs are used and, when possible, to describe their experiences with using patient assistance programs, including obtaining information, applying to the programs, and distributing the drugs to the patient.

¹The groups were the Pharmaceutical Research and Manufacturers of America (PhRMA), the Generic Pharmaceutical Industry Association, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Association.

²Using all of our sources, we likely identified most programs, although some programs may not be represented.

³Twenty-seven surveys were excluded from our final sample because they were sent to programs that did not meet our study criterion of dispensing outpatient, self-administered prescription drugs or they were duplicate surveys for the same program.

Appendix I
Scope and Methodology

To compare the drugs available through patient assistance programs with those used by Medicare beneficiaries, we compared the drugs available through these programs, as reported by the Needy Meds Web site as of June 18, 2000, with the brand-name drugs commonly prescribed to enrollees in Pennsylvania's Pharmaceutical Assistance Contract for the Elderly (PACE) Program in 1999. PACE is the largest state-funded and -administered pharmaceutical assistance program for the elderly in the nation.

We did not independently verify the information provided by the survey respondents, providers, or others we interviewed. We conducted our work in accordance with generally accepted government auditing standards between January and October 2000.

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