United States General Accounting Office

GAO

Testimony

Before the Subcommittee on Health and Environment,
Committee on Commerce, House of Representatives

For Release on Delivery
Expected at 10:00 a.m.
Tuesday, September 28, 1999

MEDICARE

Beneficiaries' Prescription Drug Coverage

Statement of Laura A. Dummit, Associate Director
Health Financing and Public Health Issues
Health, Education, and Human Services Division

GAO/T-HEHS-99-198

Medicare: Beneficiaries' Prescription Drug Coverage

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today as you discuss Medicare beneficiaries' access to prescription drug coverage. Over the past several months, the Congress has focused its attention on Medicare reform issues to determine the nature and extent of changes needed to modernize the program and control its effect on the federal budget. This discussion comes at an important juncture in the program's history. The Congress passed landmark legislation in the Balanced Budget Act of 1997 (BBA) that has improved the financial underpinnings of the program, yet more work remains to ensure Medicare's continued financial viability. Budget projections show health care consuming ever larger shares of the federal dollar, threatening to crowd out funding for other valued government programs and activities. At the same time, many believe that Medicare's benefit structure should be updated to include a prescription drug benefit.

Broadening Medicare's coverage to include prescription drugs could ease the significant financial burden some Medicare beneficiaries face because of outpatient drug costs. However, a recent study suggests that such an expansion could add between 7.2 and 10 percent annually to Medicare's costs.[1] At the same time, Medicare's rolls are growing and are projected to increase rapidly with the aging of the baby boom generation. Major technological advances in medicine and biotechnology may continue to boost the importance of prescription drugs. The policy dilemma before you today is that, on the one hand, Medicare's lack of a prescription drug benefit may impede access to certain treatment advances for beneficiaries who have no access to other coverage. On the other hand, the cost implications of including a prescription drug benefit will be substantial. Additional costs could further erode the projected financial condition of the Medicare program, which, according to its trustees, is already unsustainable in its present form.

My remarks today will focus on how growth in prescription drug spending for both the general population and Medicare beneficiaries has made coverage such an important policy issue. I will also address the sources and extent of Medicare beneficiary drug coverage. I will conclude with a discussion of benefit design and implementation issues to be considered in deliberations about adding a new prescription drug benefit. My comments are based on analyses of recent data and our body of completed work on prescription drugs.

[1]M. E. Gluck, "National Academy of Social Insurance Medicare Brief: A Medicare Prescription Drug Benefit," April 1999, p. 8. http//www.nasi.org/medicare.medbr1.htm (Apr. 22, 1999).

In summary, proposals to add prescription drug coverage to Medicare's benefits come during a period of rapid growth in national spending for pharmaceuticals and transformations in the prescription drug market. Coverage of drugs by health plans and insurers, advances in drug treatments, and aggressive marketing have spurred the growth in the use of pharmaceuticals. Insurers have attempted to manage the cost of the benefit through the use of formularies, pharmacy benefit managers, and generic substitutions—cost control approaches that have dramatically changed the nature of the market in which prescription drugs are purchased.

What remains unchanged since the inception of the Medicare program, however, is the absence of coverage for outpatient prescription drugs by traditional Medicare. High drug use among Medicare's beneficiaries translates into a potentially daunting financial burden, particularly for the third who have no drug coverage. For those who obtain coverage through employer-sponsored plans, Medicare+Choice plans, Medigap policies, or Medicaid programs, the rise in spending can have an effect as well. As these payers attempt to control their outlays, coverage may be scaled back, priced out of the reach of the average beneficiary, or dropped altogether. Shifts in the availability of coverage, its costs, and its adequacy are likely to continue.

The implications of adding prescription drug coverage to Medicare's benefit package depend on details such as its scope and financing. Its design and implementation will also shape the effect of this benefit on beneficiaries, Medicare spending, and the pharmaceutical market. Recent experience provides at least two approaches for implementing a drug benefit. One would involve the Medicare program's obtaining price discounts from manufacturers. Such an arrangement could be modeled after Medicaid's drug rebate program. While the discounts in aggregate would likely be substantial, this approach lacks the flexibility to achieve the greatest control over spending. It could not effectively influence or steer drug use because it does not include incentives that would encourage beneficiaries to make cost-conscious decisions. The second approach would draw from private sector experience in negotiating price discounts from manufacturers in exchange for shifting market share. Some plans and insurers employ pharmacy benefit managers (PBM) to manage their drug benefits, including claims processing, negotiating with manufacturers, establishing lists of drug products that are preferred because of price or efficacy, and developing beneficiary incentive approaches to control spending and use. Applying these techniques to the

entire Medicare program, however, would be difficult because of its size, the need for transparency in its actions, and the imperative for equity for its beneficiaries.

Rising Drug Spending Elevates the Importance of Coverage and Efforts to Control Expenditures

Extensive research and development over the past 10 years have led to new prescription drug therapies and improvements over existing therapies that, in some instances, have replaced other health care interventions. As a result, the importance of prescription drugs as part of health care has grown, as has drug spending as a component of health care costs. To protect against these costs, Medicare beneficiaries can choose to enroll in a Medicare+Choice plan with drug coverage if one is available in their area or purchase a Medigap policy.[2] Many beneficiaries have employer-sponsored health coverage as retirees. Others may receive coverage if they are eligible for Medicaid or other public programs. The availability and breadth of such coverage are changing as the costs of expanded prescription drug use drives payers to adopt new approaches to control these expenditures or cut back on coverage. These approaches, in turn, are reshaping the drug market.

Rise in Prescription Drug Spending

Over the past 5 years, prescription drug expenditures have grown substantially, both in total and as a share of all health expenditures. Prescription drug spending grew an average of 11.1 percent per year from 1992 to 1997, compared with a 5.5 percent average annual growth rate for health expenditures overall. (See table 1.) As a result, prescription drugs account for a larger share of total health care spending—rising from 5.6 percent to 7.2 percent.

[2]As an alternative to traditional Medicare fee-for-service, Medicare+Choice plans (formerly Medicare risk health maintenance organizations) allow beneficiaries to obtain all their services through a managed care organization and Medicare makes a monthly capitation payment to the plan on their behalf.

Table 1: National Expenditures on Prescription Drugs, 1992-97

Year	Prescription drug expenditures (millions)	Annual growth in prescription drug expenditures (percent)	Annual growth in all health care expenditures (percent)
1997	$78,888	14.1%	4.8%
1996	69,111	13.2	4.9
1995	61,060	10.6	4.9
1994	55,189	9.0	5.5
1993	50,632	8.7	7.4
1992	46.598	10.6	9.1
Average annual growth 1992-97		11.1	5.5

Source: Health Care Financing Administration (HCFA), Office of the Actuary.

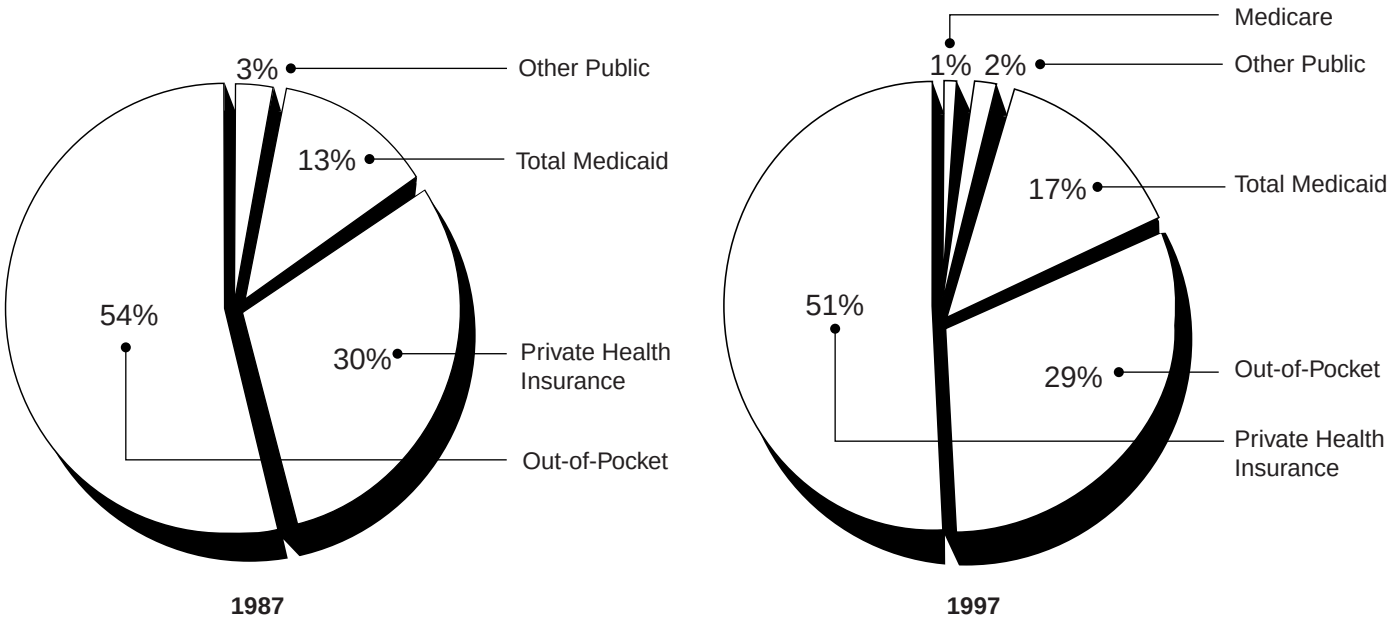
Total drug expenditures have been driven up by both greater use of drugs and the substitution of higher-priced new drugs for lower-priced existing drugs. Several factors have contributed to rising expenditures: more third-party payments for drugs, the introduction of new drug therapies, and more aggressive marketing by manufacturers through direct-to-consumer advertising.

Private insurance coverage for prescription drugs is likely to have contributed to the rise in spending because insured consumers are shielded from the direct costs of prescription drugs. In the decade between 1987 and 1997, the share of prescription drug expenditures paid by private health insurers rose from almost a third to more than half. (See fig. 1.) The development of new, more expensive drug therapies—including new drugs that replace old drugs and new drugs that treat disease more effectively—also contributed to the drug spending growth by driving up the volume of drugs used as well as the average price for drugs used. The average number of new drugs entering the market each year rose from 24 at the beginning of the 1990s to 33 now. Similarly, biotechnology advances and a growing knowledge of the human immune system are significantly shaping the discovery, design, and production of drugs. Advertising pitched to consumers is also likely to have upped their use of prescription drugs. A recent study found that the ten drugs most heavily advertised directly to consumers in 1998 accounted for 22 percent of the total increase in drug spending between 1993 and 1998.[3] Between

[3]Barents Group for the National Institute for Health Care Management Research and Education Foundation, "Factors Affecting the Growth of Prescription Drugs Expenditures," July 9, 1999, p. iii.

March 1998 and March 1999, industry spending on advertising grew 16 percent to $1.5 billion.

Figure 1: Comparison of National Outpatient Drug Expenditures, 1987 and 1997



Note: Out-of-pocket expenditures include direct spending by consumers for prescription drugs, such as coinsurance, deductibles, and any amounts not covered by insurance. Out-of-pocket premiums paid by individuals are not counted here.

Source: HCFA, Office of the Actuary.

Current Medicare Beneficiary Drug Coverage

Prescription drugs are an important component of medical care for the elderly because of the prevalence of chronic and other health conditions associated with aging. In 1995, Medicare beneficiaries had on average more than 18 prescriptions filled.[4] This varies substantially across beneficiaries, however, reflecting the range of their needs and also financial considerations such as third-party prescription drug coverage. In 1995, total average annual drug costs were $600 for elderly persons

[4]M. Davis and others, "Prescription Drug Coverage, Utilization, and Spending Among Medicare Beneficiaries," Health Affairs, Vol. 18, No. 1 (Jan.-Feb. 1999), p. 237.

compared with a little more than $140 for nonelderly persons.[5] For some, prescription drug spending was considerably higher—6 percent of Medicare beneficiaries spent $2,000 or more.[6] A recent report had projected that by 1999 an estimated 20 percent of Medicare beneficiaries would have total drug costs of $1,500 or more—a substantial sum for persons lacking some form of insurance to subsidize their purchases or for those facing coverage limits.[7]

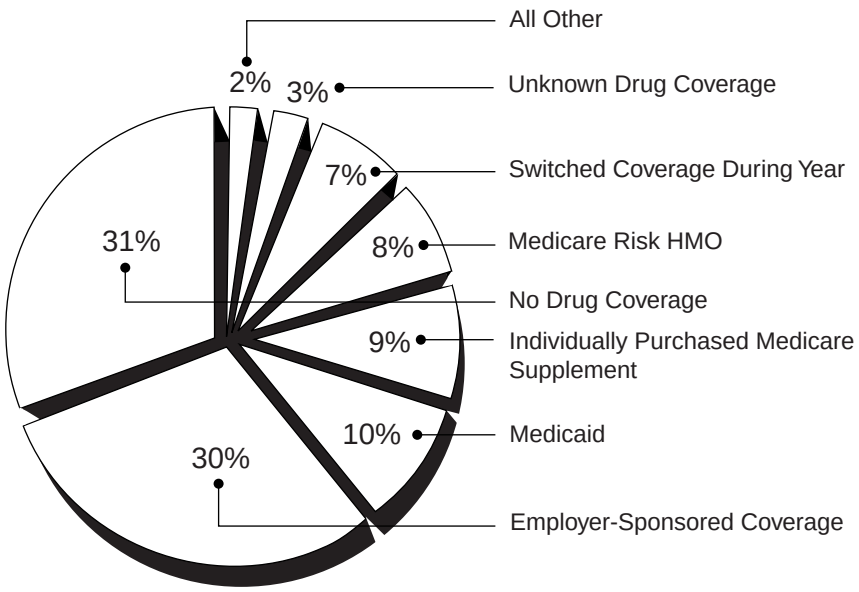
In 1996, almost a third of Medicare beneficiaries lacked drug coverage altogether. (See fig. 2.) The remaining two-thirds had at least some drug coverage through other sources—most commonly employer-sponsored health plans. The proportion of beneficiaries who had drug coverage rose between 1995 and 1996 because of increases in the numbers of persons with Medicare health maintenance organization (HMO), individually purchased supplemental, and employer-sponsored coverage. However, recent evidence indicates that this trend of expanding drug coverage is unlikely to continue.

[5]M. Davis, p. 239, and Agency for Health Care Policy and Research Center for Cost and Financing Studies, National Medical Expenditure Survey data, "Trends in Personal Health Care Expenditures, Health Insurance, and Payment Sources, Community-Based Population," Mar. 1997, p. 10. http://www.meps.ahcpr.gov/nmes/papers/trends/intnet4d.pdf (June 10, 1999).

[6]J. A. Poisal and others, "Prescription Drug Coverage and Spending for Medicare Beneficiaries," Health Care Financing Review, Vol. 20, No. 3 (Spring 1999), p. 20.

[7]M.E. Gluck, p. 2.

Figure 2: Sources of Drug Coverage for Medicare Beneficiaries, 1996



Note: "All other" includes nonrisk HMOs, state-based plans, the Department of Defense, and the Department of Veterans Affairs.

Source: HCFA data based on the 1996 Medicare Current Beneficiary Survey.

Although employer-sponsored health plans provide drug coverage to the broadest segment of the Medicare population, there are signs that this could be eroding. Fewer employers are offering health benefits to retirees eligible for Medicare and those that continue are asking retirees to pay a larger share of costs. The proportion of employers offering health coverage to retirees eligible for Medicare declined from 40 percent in 1993 to 30 percent in 1998. Of the employers offering health coverage in 1998, 72 percent included prescription drug coverage. However, 90 percent of employers with 10,000 or more employees offered prescription drug coverage to their retirees in 1998.

In 1999, 13 percent of Medicare beneficiaries obtained prescription drug coverage through a Medicare+Choice plan, up from 8 percent in 1996. Medicare+Choice plans have found drug coverage to be an attractive benefit that beneficiaries seek out when choosing to enroll in managed care organizations. However, owing to rising drug expenditures and their

effect on plan costs, the drug benefits the plans offer are becoming less generous. According to a recent HCFA report, many plans will restructure drug benefits in 2000, increasing enrollees' out-of-pocket costs and limiting their drug coverage.

Beneficiaries may purchase Medigap policies that provide drug coverage, although this tends to be expensive, involves significant cost sharing, and includes annual limits. Standard Medigap drug policies include $250 deductibles, 50 percent coinsurance requirements, and $1,250 or $3,000 annual limits. In 1999, the annual premium for one type of Medigap policy with drug coverage ranged from approximately $1,000 to $6,000. Furthermore, premiums have been increasing in recent years.

All beneficiaries who have full Medicaid benefits receive drug coverage that is subject to few limits and low cost-sharing requirements. For beneficiaries whose incomes are slightly higher than Medicaid standards, 14 states currently offer pharmacy assistance programs that provided drug coverage to approximately 750,000 beneficiaries in 1997. The three largest state programs accounted for 77 percent of all state pharmacy assistance program beneficiaries.[8] Most pharmacy assistance programs, like Medicaid, have few coverage limitations.

The burden of prescription drug costs falls most heavily on the Medicare beneficiaries who lack drug coverage or those who have substantial health care needs. Drug coverage is slightly less prevalent among beneficiaries with lower income. An analysis of 1995 data shows that drug coverage is slightly higher among those with poorer self-reported health status. At the same time, however, beneficiaries who had no drug coverage and were in poor health had drug expenditures that were $400 lower than beneficiaries who had drug coverage and were in poor health. This might indicate access problems for this segment of the population.

Even for beneficiaries who have drug coverage, the extent of protection it affords varies. The value of a beneficiary's drug benefit is affected by the benefit design, including cost-sharing requirements and benefit limitations. Evidence suggests that premiums are on the rise for employer-sponsored benefits, Medigap policies, and, most recently, Medicare+Choice plans. Copayments, deductibles, and annual coverage limits can reduce the value of drug coverage to the beneficiary. Harder to measure is the effect on beneficiaries of drug benefit restrictions brought about through formularies designed to limit or influence the choice of drugs.

[8]These programs are operated in New Jersey, New York, and Pennsylvania.

Cost Control Approaches Are Reshaping the Pharmaceutical Market

During this period of rising prescription drug expenditures, third-party payers have pursued various approaches to control spending. These efforts have initiated a transformation of the pharmaceutical market. Whereas insured individuals formerly purchased drugs at retail pharmacies at retail prices and then sought reimbursement, now third-party payers influence which drug is purchased, how much is paid for it, and where it is purchased.

A common technique to manage pharmacy care and control costs is to use a formulary. A formulary is a list of prescription drugs, grouped by therapeutic class, that a health plan or insurer prefers and may encourage doctors to prescribe. Decisions about which drugs to include in a formulary are based on their medical value and their price. Both the inclusion of a drug in a formulary and its cost can affect how frequently it is prescribed and purchased and, therefore, can affect its market share.

Formularies can be open, incentive-based, or closed. Open formularies are often referred to as "voluntary" because enrollees are not penalized if their physicians prescribe nonformulary drugs. Incentive-based formularies generally offer enrollees lower copayments for the preferred formulary or generic drugs. Incentive-based or managed formularies are becoming more popular because they combine flexibility and greater cost-control features than open formularies. A closed formulary limits insurance coverage to the formulary drugs and requires enrollees to pay the full cost of nonformulary drugs prescribed by their physicians.

Another way in which the market has been transformed is the use of PBMs by health plans and insurers to administer and manage prescription drug benefits. PBMs offer a range of services, including prescription claims processing, mail-service pharmacy, formulary development and management, pharmacy network development, generic substitution incentives, and drug utilization review. PBMs also negotiate discounts and rebates on prescription drugs with manufacturers.

Issues to Consider in Benefit Design and Administration

Policymakers considering proposals for including a prescription drug benefit in the Medicare program are facing myriad options. Assessing the merits of whether and how to implement a drug benefit will depend, in large measure, on whom the benefit covers and how it is financed. In any such assessment, five criteria should be considered. (1) Affordability: A benefit should be evaluated in terms of its effect on the sustainability of program expenditures for the long term. (2) Equity: A benefit should be

fair across groups of beneficiaries and providers. (3) Adequacy: A benefit should foster cost-effective and clinically meaningful innovations, furthering Medicare's tradition of supporting technology development. (4) Feasibility: A benefit should incorporate such administrative essentials as implementation and monitoring techniques. (5) Acceptance: A benefit should account for the need to educate the beneficiary and provider communities about its costs and the realities of trade-offs required by significant policy changes.

Although the Congress will likely examine a number of alternative benefit designs and administrative options, I would like to briefly discuss two approaches that may be considered. One would be similar to how drug benefits are provided in state Medicaid programs, which rely on federal authority to lower drug prices through rebates paid by drug manufacturers to control spending. The other would be modeled after approaches adopted by private sector health plans in which PBMs are used to administer various techniques to control pharmacy benefit costs. Each approach has some advantages and disadvantages.

Medicaid Programs Rely on Discounts and Have Limited Utilization Controls

As the largest government payer for prescription drugs, Medicaid makes drug expenditures that account for about 13 percent of the domestic pharmaceutical market. Before the enactment of the Medicaid drug rebate program under the Omnibus Budget Reconciliation Act of 1990 (OBRA), state Medicaid programs paid close to retail prices for outpatient drugs. Other large purchasers, such as HMOs and hospitals, negotiated discounts with manufacturers and paid considerably less.

The rebate program required drug manufacturers to give state Medicaid programs rebates for outpatient drugs. The rebates were based on the lowest or "best" prices they charged other purchasers. In return for the rebates, state Medicaid programs must reimburse for all drugs manufactured by pharmaceutical companies that entered into rebate agreements with HCFA.[9]

After the rebate program's enactment, a number of market changes affected other purchasers of prescription drugs and the amount of the rebates that Medicaid programs received. For example, the prices many large private purchasers, such as HMOs, paid for outpatient drugs increased substantially. Moreover, the lowest prices in the market increased faster than the drugs' average prices as drug manufacturers significantly reduced

[9]OBRA allowed the states to exclude certain classes of drugs.

the price discounts they offered private purchasers. As a result, within 2 years the rebates paid to state Medicaid programs fell to the minimum percentage required by OBRA.

Although the states have received billions of dollars in rebates from drug manufacturers since OBRA's enactment, state Medicaid directors have expressed concerns about the rebate program. The principal concern involves OBRA's requirement to provide access to the drugs of all manufacturers that offer rebates, which limits the utilization controls Medicaid programs can use at a time when prescription drug expenditures are rapidly increasing. Although the programs can require recipients to obtain prior authorization for particular drugs and can impose monthly limits on the number of covered prescriptions, they cannot take advantage of other techniques to steer recipients to less expensive drugs. The few cost-control strategies available to state Medicaid programs can add to the administrative burden on state Medicaid programs.

Other Payers Employ Various Techniques to Control Expenditures

Other payers such as private and federal employer health plans and Medicare+Choice plans have taken a different approach to managing their prescription drug benefits. They typically use closed or incentive-based formularies and copayments to control prescription drug use and obtain better prices by concentrating purchases on selected drugs. In many cases, these plans and insurers retain PBMs' services to manage their pharmacy benefit and control spending.

Beneficiary cost sharing has had a central role in attempts to influence drug use. Copayments are frequently structured to influence both the choice of drugs and purchasing arrangements. While formulary restrictions can channel purchases to preferred drugs, closed formularies, which provide reimbursement only for preferred drugs, have generated substantial dissatisfaction among consumers. As a result, many plans link their cost-sharing requirements and formulary lists. The fastest growing trend today is to use a formulary in which all drugs are covered but beneficiary cost-sharing varies for different drugs—typically a smaller copayment for generic drugs, a larger one for preferred drugs, and an even larger one for all other drugs. Reducing copayments has also been used to encourage enrollees using maintenance drugs for chronic conditions to use particular suppliers, like a mail order pharmacy.

Plans and insurers have turned to PBMs for assistance in establishing formularies, negotiating prices with manufacturers and pharmacies,

processing beneficiaries' claims, and reviewing drug utilization. Because PBMs manage drug benefits for multiple purchasers, they often may have more leverage than individual plans in negotiating prices as they combine the purchasing power of multiple purchasers.

Traditional fee-for-service Medicare has generally established reimbursement rates for services like those provided by physicians and hospitals and then processed and paid claims with few utilization controls. Adopting some of the techniques private plans and insurers use might have the potential for better control of costs. However, how to adapt those techniques to the characteristics and size of the Medicare program raises questions.

Negotiated or competitively determined prices would be superior to administered prices only if Medicare could employ some of the utilization controls that come from having a formulary and differential beneficiary cost-sharing. In this manner, Medicare would be able to negotiate significantly discounted prices by promising to deliver a larger market share for a manufacturer's product. Manufacturers would have no incentive to offer a deep discount if all drugs in a therapeutic class were covered on the same terms. Without a promised share of the Medicare market, these manufacturers might reap greater returns from higher prices and concentrating marketing efforts on physicians and consumers to influence prescribing patterns.

Implementing a formulary and other utilization controls could prove difficult for Medicare. Developing a formulary involves determining which drugs are therapeutically equivalent so that several from each class can be included. Plans and PBMs currently make those determinations privately—something that would not be possible for Medicare, which must have transparent policies that are determined openly. Given the stakes involved in selecting drugs, one can imagine the intensive efforts to offer input to and scrutinize the selection process.

Medicare may also find it impossible to delegate this task to a PBM or multiple PBMs. A single PBM contractor would likely be subject to the same level of scrutiny as the program. Such scrutiny could compromise the flexibility PBMs have used to generate savings. An alternative would be to grant flexibility to multiple PBMs that are responsible only for a share of the market. Contracting with multiple PBMs, though, raises other issues. If each PBM has exclusive responsibility for a geographic area, beneficiaries who need certain drugs could be advantaged or disadvantaged merely because

of where they live. If multiple PBMs operated in each area, beneficiaries would choose one to administer their drug benefit. This raises questions of how to inform beneficiaries of the differences in the PBMs' policies and whether and how to risk-adjust payments to PBMs for differences in the health status of beneficiaries using them.

Concluding Observations

As the Congress continues its deliberations on Medicare prescription drug coverage, it will need to consider the needs of beneficiaries and the fiscal health of the program. The lack of prescription drug coverage for some Medicare beneficiaries may cause hardship. Yet, ensuring the sustainability of the Medicare program is paramount. Balancing these competing concerns may require the best from government-run programs and private sector efforts to modernize Medicare for the future.

Mr. Chairman, this concludes my prepared statement. I will be happy to answer any questions you or other Members of the Subcommittee may have.

GAO Contacts and Acknowledgments

For future contacts regarding this testimony, please call Laura A. Dummit at (202) 512-7119 or John Hansen at (202) 512-7105. Other individuals who made key contributions include Tricia Spellman, Kathryn Linehan, and Lara Carreon.

Ordering Information

The first copy of each GAO report and testimony is free. Additional copies are $2 each. Orders should be sent to the following address, accompanied by a check or money order made out to the Superintendent of Documents, when necessary. VISA and MasterCard credit cards are accepted, also. Orders for 100 or more copies to be mailed to a single address are discounted 25 percent.

Orders by mail:

U.S. General Accounting Office
P.O. Box 37050
Washington, DC 20013

or visit:

Room 1100
700 4th St. NW (corner of 4th and G Sts. NW)
U.S. General Accounting Office
Washington, DC

Orders may also be placed by calling (202) 512-6000 or by using fax number (202) 512-6061, or TDD (202) 512-2537.

Each day, GAO issues a list of newly available reports and testimony. To receive facsimile copies of the daily list or any list from the past 30 days, please call (202) 512-6000 using a touchtone phone. A recorded menu will provide information on how to obtain these lists.

For information on how to access GAO reports on the INTERNET, send an e-mail message with "info" in the body to:

info@www.gao.gov

or visit GAO's World Wide Web Home Page at:

http://www.gao.gov

United States
General Accounting Office
Washington, D.C. 20548-0001

Bulk Rate
Postage & Fees Paid
GAO
Permit No. G100

Official Business
Penalty for Private Use $300

Address Correction Requested