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# MEDICARE

# Considerations for Adding a Prescription Drug Benefit

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# Medicare: Considerations for Adding a Prescription Drug Benefit

Mr. Chairman and Members of the Committee:

I am pleased to be here today as you consider a prescription drug benefit for Medicare beneficiaries. Over the past several months, this Committee has held a series of hearings on Medicare reform issues to determine the nature and extent of changes needed to modernize the program and control its impact on the federal budget. These discussions come at an important juncture in the program's history—the Congress passed landmark legislation in the Balanced Budget Act of 1997 (BBA) that has the potential to improve 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, thus threatening to crowd out funding for other valued government programs and activities. At the same time, many believe that Medicare's current benefit structure should be updated to include a prescription drug benefit.

Studies suggest that broadening Medicare coverage to include prescription drugs could add between 7.2 and 10 percent to Medicare costs. Such an expansion would occur at a time when Medicare's rolls are growing and are projected to increase rapidly with the aging of the baby boom generation and during a time of major technological advances in medicine and biotechnology. Currently, some Medicare beneficiaries face a significant financial burden for outpatient 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, whereas on the other, the cost implications of including a prescription drug benefit will be substantial. These additional costs would serve to erode the projected financial condition of the Medicare program, which, according to the Medicare trustees, is already unsustainable in its present form.

My remarks today will focus on the factors contributing to the growth in prescription drug spending for both the general population and Medicare beneficiaries and efforts to control that growth. I will also discuss 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.

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. Increased coverage of drugs by health plans and insurers, advances in drug treatments, and aggressive marketing have spurred the growth in the use of pharmaceuticals, while the use of formularies, pharmacy benefit managers, and generic substitutions as cost control approaches have dramatically changed the nature of the market in which prescription drugs are purchased.

What remains unchanged since 1965, however, is the absence of coverage for outpatient prescription drugs by traditional Medicare. A third of the Medicare population lacks the supplemental drug coverage provided to most beneficiaries through employer-sponsored plans, managed care organizations, Medicaid, or Medigap insurance. Moreover, high drug utilization among the Medicare population translates into a potentially daunting financial burden.

The implications of adding prescription drug coverage to Medicare's benefit package depend on the choices made regarding details such as its scope and financing. Its design and implementation will also shape the impact 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 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 cannot effectively influence or steer utilization 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 Medicare program, however, would be difficult due to its size, the need for transparency in its actions, and the imperative for equity for its beneficiaries.

## Many Factors Have Spurred Prescription Drug Spending and Fostered Market Changes

Extensive research and development over the past 10 years have led to the introduction of new prescription drug therapies and improvements over existing therapies that, in some instances, have replaced other health care interventions. The growing importance of prescription drugs as part of health care has made the inclusion of drug benefits an attractive policy feature to consumers with a choice among health insurance products. Most commercial private health insurance products, Medicare+Choice[1] plans, and all Medicaid programs provide their beneficiaries with an outpatient prescription drug benefit. Health plans have found that including prescription drugs as a covered benefit helps attract members and is valuable to their beneficiaries. Prescription drug expenditures have outpaced other components of health care spending in recent years due to several factors. At the same time, the use of new approaches to dampen these expenditures is reshaping the prescription drug market.

## Rise in Prescription Drug Spending

Over the past 5 years, prescription drug expenditures have grown significantly, both in total and as a share of all health expenditures. Prescription drug spending grew, on average, from 1992 to 1997 by 11 percent a year compared with a 5 percent average growth rate for health expenditures overall. (See table 1.) Drug spending during that same period also consumed a larger share of total health care spending—rising from 5.6 percent to 7.2 percent.

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

| Year | Prescription drug expenditures (in millions) | Annual growth in prescription drug expenditures (percent) | Annual growth in all health care expenditures (percent) |
|---|---|---|---|
| 1997 | $78,888 | 14 | 5 |
| 1996 | 69,111 | 13 | 5 |
| 1995 | 61,060 | 11 | 5 |
| 1994 | 55,189 | 9 | 5 |
| 1993 | 50,632 | 9 | 7 |
| 1992 | 46,598 | 11 | 9 |
| Average annual growth, 1992-97 | | 11 | 5 |

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

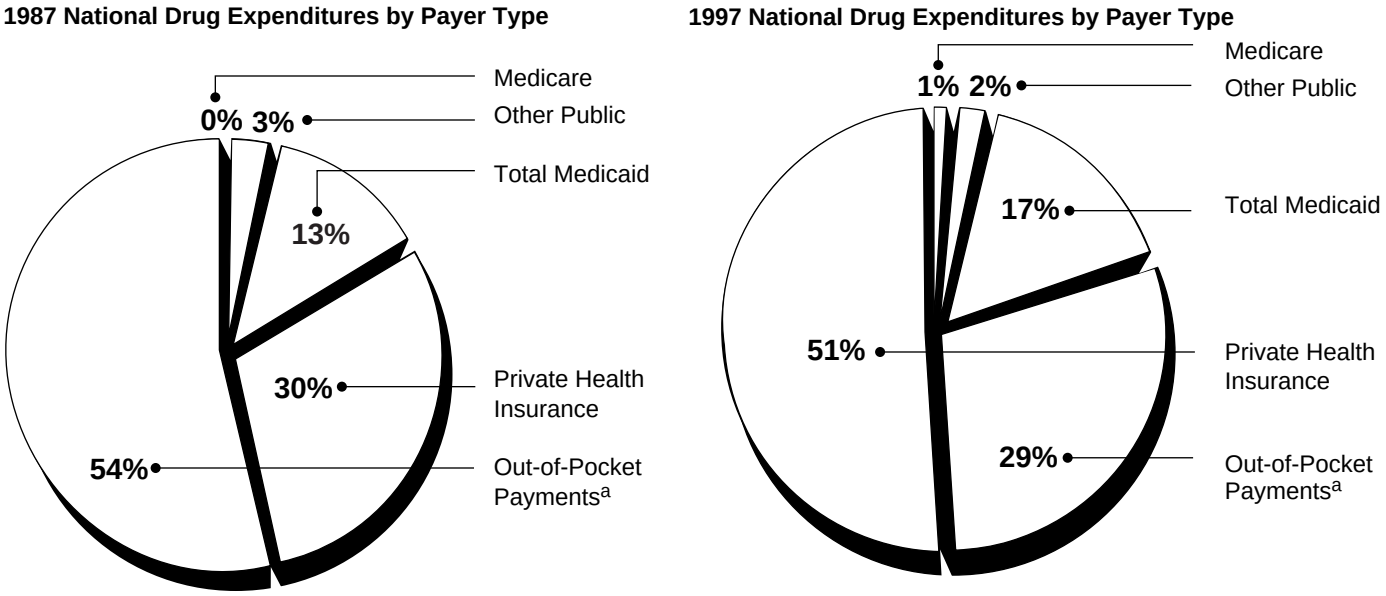
[1]As an alternative to traditional Medicare fee-for-service, beneficiaries in Medicare+Choice plans (formerly Medicare risk health maintenance organizations) obtain all their services through a managed care organization and Medicare makes a monthly capitation payment to the plan on their behalf.

While total drug expenditures depend both on the prices paid and the volume used, the recent spending increases appear to have more to do with stepped up volume than price. A precise determination of how much is due to volume versus price increases is not possible since only data on the retail pharmaceutical prices are widely available. The actual prices paid are often lower than retail levels, as insurers, PBMs, and other purchasers negotiate significant discounts from manufacturers and other suppliers. Market changes in recent years have likely altered the size of those discounts.

Several factors have contributed to increased prescription drug use and the resulting spending increases: namely, more individuals have third-party drug coverage, new drug therapies have been introduced into the market, and manufacturers have marketed drugs more aggressively through advertising directly to consumers.

The increase in private insurance coverage for prescription drugs is a likely factor accounting for the rise in utilization. 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. The average number of new drugs entering the market each year has grown 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 the lay consumer has also likely upped consumers' use of prescription drugs. Between March 1998 and March 1999, industry spending on advertising grew 16 percent, to $1.5 billion.

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




[a]Out-of-pocket expenditures include direct spending by consumers for all health care goods and services, such as coinsurance, deductibles, and any amounts not covered by insurance. Out-of-pocket premiums paid by individuals are not counted here.

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

## Current Medicare Beneficiary Drug Coverage

Prescription drugs are an important component of medical care for the elderly because of the greater prevalence of chronic and other health conditions associated with aging. In 1995, Medicare beneficiaries had on average more than 18 prescriptions filled. This varies substantially across beneficiaries, however, reflecting the presence of chronic and other conditions that respond to drug treatment and also financial considerations such as third-party prescription drug coverage. In 1995, annual drug costs were $600 for the elderly, compared to just over $140 for the nonelderly population. For some, spending is considerably higher. In 1999, an estimated 20 percent of Medicare beneficiaries will have total drug costs of $1,500 or more—a substantial sum for those lacking some form of insurance to subsidize the purchase.

This financial burden is due, in part, to gaps in insurance coverage for prescription drugs. One third of the Medicare population lacks drug

coverage altogether. Those with third-party protections often face deductibles, cost sharing, or limits on total benefit payments. The vast majority of the approximately 17 percent of Medicare beneficiaries enrolled in a Medicare+Choice plan have drug coverage, as do retirees who have employer-sponsored insurance. All beneficiaries who are enrolled in Medicaid receive drug coverage. Other beneficiaries may purchase Medigap policies that provide drug coverage, although Medigap policies involve significant cost sharing, impose annual limits, may contain significant exclusions, and can be expensive. A Medigap policy with drug coverage can cost $1,500 more per year than an otherwise comparable policy.

Medicare beneficiaries with drug coverage use more prescription drugs and have higher overall drug expenditures than those without drug coverage. This may be because beneficiaries with higher prescription drug needs may be more likely to obtain third-party protections. Alternatively, the lack of coverage for some may inhibit appropriate drug utilization.

## Cost Control Approaches Reshaping Pharmaceutical Market

During this period of growth in the volume of prescription drugs used, third-party payers, which have been the primary purchasers, have pursued various approaches to controlling spending. These efforts have initiated a transformation of the pharmaceutical market. A world in which insured individuals purchase drugs at retail pharmacies at retail prices and then seek reimbursement is giving way to third-party payers influencing which drug is purchased, how much is paid for a drug, 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 to be prescribed for its enrollees. Decisions about which drugs to include on a formulary are based on their medical value and their price. Both inclusion of a drug on 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 formulary drugs only and requires enrollees to pay the full cost of nonformulary drugs prescribed by their physician.

Many health plans or insurers also contract with a PBM to administer and manage their prescription drug benefit. 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 have successfully negotiated 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 a myriad of options. Assessing the merits of whether and how to implement these reforms will depend, in large measure, on whom the benefit covers and how it is financed. In such an assessment, it may be appropriate to recall the criteria that the Comptroller General enunciated before this Committee in testimony on March 10. These criteria could guide deliberations on expanding coverage to include prescription drugs: (1) affordability—a benefit should be evaluated in terms of its impact on the sustainability of program expenditures for the long term; (2) equity—a benefit should be fair across groups of beneficiaries and to providers; (3) adequacy—a benefit should foster cost-effective and clinically meaningful innovations, furthering Medicare's tradition of technology development; (4) feasibility—a benefit should incorporate such administrative essentials as implementation and monitoring techniques; and (5) acceptance—a benefit should account for the need to educate beneficiary and provider communities about its costs and the realities of trade-offs required when significant policy changes occur.

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 typically used to administer various techniques to control pharmacy benefit costs. Each approach has some advantages and disadvantages.

## Medicaid Programs Rely on Discounts, Limited Utilization Controls

Before the enactment of the Medicaid drug rebate program as part of the Omnibus Budget Reconciliation Act of 1990 (OBRA), state Medicaid programs paid close to retail prices for outpatient drugs. As the largest government payer for prescription drugs, Medicaid drug expenditures comprised about 13 percent of the domestic pharmaceutical market. Other purchasers, such as health maintenance organizations (HMO) 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 maintain open formularies that permit reimbursement for all drugs manufactured by pharmaceutical companies that entered into rebate agreements with the Health Care Financing Administration.

After the rebate program's enactment, a number of market changes occurred that affected other purchasers of prescription drugs and the amount of the rebates 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 the price discounts they offered private purchasers. As a result, within 2 years the rebates paid to state Medicaid programs fell to the minimum amount required by OBRA.

Although states have received billions of dollars in rebates from drug manufacturers since the enactment of OBRA 1990, state Medicaid directors have expressed concerns about the rebate program. The principal concern involves OBRA's requirement for open formularies, which limits the utilization controls Medicaid programs can use at a time when prescription drug expenditures are rapidly increasing. Although they can require recipients to obtain prior authorization for particular drugs and impose monthly limits on the number of covered prescriptions, other techniques to steer recipients to less expensive drugs are not available to them. These approaches can add to the administrative burden on state Medicaid programs, lead to purchasing more expensive drugs, and create access problems for certain individuals.

## Other Payers Employ Various Techniques to Control Expenditures

Other payers, such as private employer health plans, Medicare+Choice plans, and insurance products for federal employees have taken a different approach to managing their prescription drug benefits. They use

formularies and copayments to control drug utilization and obtain better prices by concentrating purchases on selected drugs. In many cases, these plans or insurers retain the services provided by a PBM to implement their pharmacy benefit.

Beneficiary cost sharing has had a central role in attempting to influence drug utilization. Copayments frequently are structured to both influence the choice of a drug and purchasing arrangements. While formulary restrictions can channel purchases to preferred drugs, closed formularies, which provide reimbursement only for preferred drugs, have generated significant consumer dissatisfaction. As a result, many plans link their cost sharing requirements and formulary lists. The fastest growing trend today is to maintain an open formulary in which all drugs receive some coverage, with beneficiaries paying different levels of cost sharing 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 the required copayments may also 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 their expertise in establishing formulary lists, negotiating prices with manufacturers and suppliers, and processing beneficiary claims, as well as a variety of clinical services, such as drug utilization review. PBMs bring expertise and economies of scale to these tasks that individual plans or insurers may not have. In addition, 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 administrative prices for services like physician or hospital care and then processed and paid claims with few utilization controls. Adopting some of the techniques used by private plans and insurers might have the potential for better control of costs. However, how to adopt those techniques to deal with the unique characteristics and enormity of the Medicare program raises many 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 manufacturers' 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 may 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 selected as preferred. Plans and PBMs currently make those determinations privately—something that would not be tolerable for Medicare, which must have transparent policies that are determined openly. Given the stakes involved in being selected, 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 may compromise the flexibility PBMs have utilized 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 had exclusive responsibility for a geographic area, beneficiaries who need certain drugs could be advantaged or disadvantaged merely because they live in a particular area. If multiple PBMs operated in each area, beneficiaries would choose one to administer their drug benefit. Then, how to inform beneficiaries of the differences in each PBM's policies and the possible need to risk adjust payments to PBMs for differences in health status of beneficiaries using them would become issues.

## Concluding Observations

Adding prescription drug coverage to the Medicare program would have a substantial impact on the costs of the program, in addition to the financial well being and health of many of its beneficiaries. The challenge will be in designing and implementing drug coverage to minimize the financial implications for Medicare while maximizing the positive effect of such coverage on Medicare beneficiaries. Most importantly, this substantial benefit reform must be consistent with efforts to ensure the sustainability of the program so that Medicare does not consume an unreasonable share of our productive resources and does not encroach on other public programs or private sector activities. Reconciling these needs will take the kind of leadership and creativity demonstrated by the Congress as it

designed and implemented the BBA reforms that extended Medicare's financial viability.

It may also be instructive to return to lessons learned in implementing the BBA reforms. From those efforts, it is clear that major changes to the Medicare program need to be effective, flexible, and steadfast. Effectiveness must include the collection of necessary data to assess impact—separating the transitory from the permanent and the trivial from the important. Flexibility is critical to make changes and refinements when conditions warrant and when actual outcomes differ substantially from the expected ones. Steadfastness is needed when particular interests pit the primacy of their needs against the more global interests of preserving Medicare.

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

## GAO Contact and Acknowledgements

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 Hannah Fein.

# Related GAO Products

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