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PRESRIPTION DRUG BENEFITS

Applying Private Sector Management Methods to Medicare

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Mr. Chairman and Members of the Committee:

I am pleased to be here as you discuss issues related to a potential Medicare outpatient prescription drug benefit. In previous hearings before this and other committees, GAO has addressed considerations for adding a prescription drug benefit to Medicare, in light of the fiscal imbalance of the Medicare program and the need to implement major reforms to ensure the sustainability of the program. Today, you asked us to provide information on the methods used by private insurers, managed care plans, and employers to control their prescription drug expenditures, and the applicability of those approaches to Medicare. My remarks will focus first, on the factors contributing to the rise in prescription drug spending and the impact of the rise in spending on Medicare beneficiaries, particularly those without coverage. Next, I will outline the methods private insurers, including those offering Medicare+Choice managed care products to Medicare beneficiaries, have developed to manage these rising costs. Finally, I will discuss whether and how Medicare can adapt these methods to control spending, should an outpatient prescription drug benefit be added to Medicare.

In summary, private insurers, managed care plans, and employers have tried to manage the high and rising costs of prescription drugs by adopting cost and utilization control techniques. In many cases, insurers and managed care plans contract with a pharmacy benefit management company (PBM) to develop and implement these strategies. If a prescription drug benefit were added to the Medicare program, the federal government would face similar cost pressures and would need to employ methods to control spending. The experience gained in the private sector can provide useful insights into options for managing a possible Medicare benefit. However, the unique responsibilities and characteristics of the Medicare program raise a number of issues and introduce questions about applying private sector tools to the traditional Medicare fee-for-service program and the appropriate roles of the Health Care Financing Administration (HCFA) and other entities, such as PBMs, in managing a drug benefit. In adapting these cost and utilization management techniques, it is important to keep in mind that: (1) strategies involving coverage restrictions impose an obligation to provide beneficiaries with adequate information about the benefit; (2) the size of the Medicare program and the need for transparency in its actions may reduce the effectiveness of some cost-control techniques; (3) using private sector entities to implement a drug benefit introduces concerns related to beneficiary equity and concentrating market power; and (4) private sector management tools require a capacity to process and scrutinize a large amount of data.
number of claims more quickly than is typical of the traditional Medicare program.

**Rising Drug Spending Elevates Beneficiary Access Concerns and The Importance of Cost Controls**

Extensive research and development over the past 10 years has led to the introduction of new, more expensive drug therapies—including improvements upon existing drug therapies and drugs that treat diseases more effectively—which have contributed to the increase both in prescription drug use and drug spending. For example, new drug treatments for arthritis and depression have therapeutic advantages over older medications, but they are also more expensive than the drugs they replace. Biotechnological advances and a growing knowledge of the human immune system are significantly shaping the discovery, design, and production of drugs. As a result of these innovations, the importance of prescription drugs to health care delivery has grown.

**Rise in Prescription Drug Spending Caused by Many Factors**

Prescription drug expenditures have grown significantly in the past 5 years, both in total and as a share of all health care expenditures. From 1993 to 1998, prescription drug spending rose an average of 12.4 percent a year, compared to a 5 percent annual growth rate for overall health care expenditures. Consequently, drug spending comprised a larger share of total health care spending by 1998—rising from 5.6 percent to 7.9 percent. 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 coverage of drugs, the introduction of new drug therapies, and more aggressive marketing by manufacturers through direct-to-consumer advertising. The increase in prescription drug coverage provided by private insurance is a likely contributor to the rise in utilization because insured consumers are shielded from the direct costs of prescription drugs. In 1988, private health insurers paid almost a third of all prescription drug expenditures. By 1998, that share had risen to more than a half. 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 of medications. Advertising pitched to consumers is also a likely contributor to the increased utilization of prescription drugs. Between March 1998 and March 1999, the pharmaceutical industry's spending on advertising grew 16 percent, to $1.5 billion. A 1999 study found that the 10 drugs most
heavily advertised to consumers in 1998 accounted for about 22 percent of the total increase in drug spending between 1993 and 1998.\(^1\)

**Medicare Beneficiary Drug Coverage and Utilization**

Elderly individuals, with their greater prevalence of chronic conditions, represent a disproportionate share of drug spending. On average, in 1996, Medicare beneficiaries had estimated annual drug spending of about $674 per person,\(^2\) compared to an estimated $156 per person for the nonelderly population.\(^3\) A more recent estimate projected that 20 percent of Medicare beneficiaries would have drug costs of $1,500 or more in 1999, a substantial sum for those lacking some form of insurance to subsidize their drug purchases.\(^4\) In 1996, beneficiaries who had no drug coverage and were in poor health had estimated mean annual drug expenditures that were $591 lower than beneficiaries with similar health status who had drug coverage.\(^5\) This indicates that the lack of prescription drug coverage may cause access problems, particularly for those in poor health.

Although the Medicare benefit package, largely designed in 1965, provides virtually no outpatient drug coverage, more than two-thirds of Medicare beneficiaries had at least some prescription drug coverage in 1996. Almost one-third of beneficiaries had employer-sponsored health coverage, as retirees, that included drug benefits. About 17 percent of Medicare beneficiaries had coverage because they chose to enroll in a Medicare+Choice plan or purchase a Medigap policy with such coverage. About 10 percent of beneficiaries received coverage through Medicaid.

The rising cost of prescription drug benefits has driven employers, insurers, and managed care plans to adopt new approaches that limit total drug coverage or increase enrollees' out-of-pocket costs. Although employer-sponsored health plans provide drug coverage to the largest

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1 Barents Group LLC for the National Institute for Health Care Management Research and Educational Foundation, *Factors Affecting the Growth of Prescription Drug Expenditures* (July 9, 1999), p. iii.


segment of the Medicare population with coverage, there are signs that this could be eroding. Fewer employers are offering health benefits to retirees eligible for Medicare and those that continue to offer coverage are asking retirees to pay a larger share of costs. In addition, the drug benefits offered by Medicare+Choice plans have become less generous. Many plans restructured their benefits in 2000, increasing enrollees' out-of-pocket costs and limiting their total drug coverage.

Private-Sector Techniques for Controlling Drug Expenditures

During this recent period of rising prescription drug spending, insurers and HMOs have adopted a variety of techniques to control enrollee utilization and the prices they pay for drugs. Many insurers and HMOs contract with PBMs to develop and implement these cost control techniques and to perform other activities related to managing the drug benefit. Direct negotiations with drug manufacturers yield lower prices through manufacturer rebate agreements. Because rebates generally depend on the volume of the products purchased, employers or HMOs use techniques to concentrate their enrollees' drug purchases to be able to use market power to maximize rebates. This is accomplished through the use of a formulary. Cost-control techniques also extend to the drug distribution network, with emphasis on negotiating reimbursement rates and dispensing fees with pharmacies and encouraging the use of mail-order pharmacies to lower distribution costs. Insurers or PBMs also perform other functions to manage a drug benefit, control spending, and ensure quality of care such as monitoring drug use when the pharmacist is filling the prescription to enable the substitution of lower-priced products or to identify possible adverse drug reactions. They also use claims data to monitor patterns of patient use, physician prescribing practices, and pharmacy dispensing practices.

PBMs originated as claims processors and mail-order or managed care pharmacies. Today, they provide a wide range of services—such as claims processing, formulary management, and pharmacy network development—to HMOs, insurance carriers, Blue Cross Blue Shield plans, plans that cover federal and state employees, and union members. According to the Pharmacy Care Management Association, the PBM industry's trade association, PBMs manage about 1.8 billion prescriptions annually, or about 70 percent of all prescriptions dispensed to ambulatory care patients. According to a recent estimate, PBMs are responsible for managing the drug benefits for about 71 percent of the 194 million people with third party pharmacy coverage.6 There are more than 140 PBMs,

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which range in size, scope, and services provided. Some administer prescription drug benefits nationwide; others focus on serving clients in particular regions of the country.

PBMs and insurers negotiate rebates from drug manufacturers and thus lower the net prices they pay for drugs. According to a 1996 study, manufacturers’ rebates averaged 5 to 6 percent of total drug costs. This average masks what may be considerable variation across products. The negotiated rebate is typically dependent on the purchasing power of the PBM or insurer, the availability of several brand-named drugs in a therapeutic class, and assurances of a particular level of utilization of the product.

Insurers or PBMs employ various strategies to channel drug utilization to products for which they have rebate agreements that are based on market share. Generally, this is done by using a formulary, a list of prescription drugs, grouped by therapeutic class, that a health plan or insurer prefers and may encourage physicians to prescribe and beneficiaries to use. A particular product may be included on the formulary because of its medical value or because of a favorable price negotiated with the manufacturer. The inclusion of a particular drug on a formulary can affect its utilization, which can increase the level of manufacturer discounts or rebates, and lower a drug's net cost.

Formularies are structured and implemented to steer drug choice when therapeutically equivalent options are available. Closed formularies, which restrict insurance coverage to only selected drugs and require enrollees to pay the full cost of nonformulary drugs, may be the most effective in channeling utilization. However, closed formularies have faced resistance from beneficiaries and providers because they can lead to higher enrollee costs or restrict access to certain medicines. As a result, more insurers are moving to incentive-based formularies that offer enrollees lower copayments for the preferred product or generic drugs. The insurer continues to cover drugs that are not on the formulary, but the beneficiary faces a higher copayment. A third type, open formularies, is often referred to as “voluntary” because physicians and beneficiaries may be informed about preferred drugs, but beneficiaries pay no more for using nonformulary drugs. Formularies that provide the strongest financial incentives to beneficiaries to choose one product over another offer more

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cost control potential. They can be used to steer utilization to lower-priced products, including generics, and concentrate market share to elicit the best prices or largest rebates on particular products. In doing so, however, they may produce dissatisfaction among consumers, who have to pay more out-of-pocket for nonformulary drugs, and physicians, who believe formularies restrict their prescribing practices.

PBMs and private insurers have also targeted drug distribution costs as an area for cost savings. Similar to their negotiations with manufacturers, PBMs negotiate with retail pharmacies to obtain prices that are well below pharmacies’ usual price for customers without drug coverage. PBMs attempt to enhance their leverage with retail pharmacies by limiting the size of the pharmacy network. Restricting the number of pharmacies in the network can benefit participating pharmacies by increasing each one’s market share, and as a result, make them more willing to provide larger discounts on the prescriptions they fill. Potential savings from this cost-control technique, however, must be balanced with the inconvenience of a limited pharmacy network. PBMs may also operate mail-order pharmacies that allow enrollees to obtain prescriptions by mail. This is a cost-effective way of dispensing drugs, particularly maintenance drugs for chronic health conditions, such as high blood pressure or asthma.

The claims processing capabilities of PBMs enable them to engage in other activities that may help control overall health care expenditures or improve quality of care. For example, drug utilization review (DUR) programs analyze patterns of drug use on a real-time basis when a pharmacist is actually filling a prescription. These programs use databases and computer systems that include a patient’s entire drug utilization history for all network and mail-order pharmacies. These systems identify instances in which a drug may be inappropriate for a particular patient given a person’s medications or age. Most PBMs use system edits specifically tailored to particular types of beneficiaries, such as people who are 65 years of age or older who may have a difficult time tolerating certain medicines. Such interventions can both improve quality of care and prevent additional health care costs by reducing drug interactions or flagging evidence of inappropriate use, such as early refills. DUR can also be conducted retrospectively, usually on a monthly or quarterly basis, to profile physician prescribing practices, pharmacy dispensing practices, or patient utilization. The results of retrospective DUR programs are used to encourage physicians to prescribe less costly therapeutic alternatives or generics, encourage pharmacies to substitute generics or preferred formulary drugs for more expensive nonformulary drugs, and ensure that some patients are not overutilizing prescription medicines.
Applying Private-Sector Techniques to a Drug Benefit Within Medicare

Private-sector entities have attempted to control the growth of prescription drug expenditures while preserving or enhancing the value of drug coverage for beneficiaries. As you consider methods to manage a potential Medicare benefit, these private sector techniques offer a useful starting point. I would like to discuss four issues to consider in adapting these methods to the unique characteristics of Medicare and its beneficiaries.

- In a competitive model for Medicare—such as exists today with Medicare+Choice or the models envisioned in some reform proposals—cost-containment strategies involving restrictions on coverage through formularies or pharmacy networks impose an obligation to adequately inform beneficiaries about plan policies.

- Adaptation of PBM techniques within the traditional fee-for-service Medicare program could be difficult given its size and the need for transparency in its actions.

- Contracting with private-sector entities to administer a drug benefit for traditional Medicare using cost and utilization controls would raise other challenges.

- The efforts of PBMs to control expenditures involve a capacity to scrutinize claims more effectively and quickly than is typical of Medicare today.

Medicare Beneficiaries’ Experiences With Drug Benefit Management In Medicare HMOs

The efforts of PBMs to control costs through the use of formularies and restricted pharmacy networks can affect beneficiaries’ access to the drugs they need, their out-of-pocket costs, and the overall value of the benefit. When beneficiaries have a choice of health plans with drug coverage, it is imperative that they have sufficient information to select the plan that best suits their needs. Our work on the Medicare+Choice program has demonstrated that attention and vigilance are required to ensure beneficiaries can make such informed choices.

Our previous work has identified a number of factors that make it difficult for beneficiaries to determine which Medicare+Choice plan best meets their needs. In some cases, detailed information about plans’ benefits and out-of-pocket fees is provided only after a beneficiary enrolls in a plan. In other cases, detailed information may be available before enrollment from plan sales agents and member literature, but beneficiaries may find it difficult to compare available options because plans present the information in different formats and use different terms to describe covered benefits. The lack of comparative information can be particularly
problematic when evaluating plans’ drug benefits, because many design characteristics determine the true value of the drug coverage.

Comparing plans’ drug benefits can be difficult because formulary types and management techniques differ considerably, affecting the benefit. A beneficiary may not be aware of formulary changes until they are at the pharmacy counter. Aggressive formulary management may control spending, but beneficiaries need to be aware of how it may affect their access to a particular medicine and the prescribing practices of their physicians. Such issues present even greater challenges in the management of a drug benefit for the entire Medicare population.

Adding a Drug Benefit to the Traditional Medicare Program Raises Issues About the Feasibility of Applying PBM Techniques

It may be difficult for the traditional fee-for-service Medicare program to administer a drug benefit using private-sector management techniques such as formularies. Traditional Medicare has generally established administrative prices for services such as 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 cost-control. However, adapting those techniques to deal with the unique characteristics and size of the Medicare program raises many questions. Because the traditional Medicare program may be unable to operate with the flexibility that PBMs have in the private sector, it may rely on other pricing strategies to try to exact lower prices from manufacturers, such as the Medicaid rebate agreements.

Having a formulary would enhance Medicare’s ability to control costs by enabling it to negotiate significantly discounted prices with manufacturers by promising to deliver a larger market share for a manufacturer’s product. Yet, implementing a formulary and other utilization controls could prove difficult for Medicare. Determining whether a drug should be on the formulary and which drugs should be preferred, typically involves clinical evaluations based on a drug’s safety and effectiveness, and decisions on whether several drugs are therapeutically equivalent. A pharmacy and therapeutics committee within the health plan or a PBM may make these decisions. Plans and PBMs currently make formulary determinations privately—something that would not be tolerable for Medicare, which must have transparent policies that are determined openly. Given the stakes involved in a drug being selected as preferred on a Medicare formulary, one can imagine the intensive efforts to offer input to and scrutinize the selection process. In addition, once the formulary is in place it may be difficult to steer utilization or withstand pressure to allow access to non-formulary drugs, especially in the fee-for-service environment, where it may be hard to influence prescribing practices.
If Medicare covered all drugs in a therapeutic class on the same terms, beneficiaries may not be influenced toward particular drugs and thus manufacturers would have no incentive to offer deep discounts. Without a promised share of the Medicare market, manufacturers may determine they could reap greater returns from charging higher prices and concentrating marketing efforts on physicians and consumers to influence prescribing patterns.

If Medicare cannot effectively operate a formulary, it may have to rely instead on administratively determined prices. These could be similar to the manufacturer rebates received by the Medicaid program, which is currently the largest government payer for outpatient prescription drugs, comprising about 17 percent of national expenditures on outpatient drugs. Since the enactment of the Omnibus Budget Reconciliation Act of 1990 (OBRA), drug manufacturers are required to provide rebates to state Medicaid programs on outpatient drugs 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. Although 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 for open formularies, which limits the utilization controls Medicaid programs can use at a time when prescription drug expenditures are increasing rapidly.

Using PBMs or other similar entities to administer a Medicare drug benefit could potentially mitigate some of the likely difficulties that the program would face in attempting to apply private sector strategies. But such an arrangement raises additional questions about how private sector techniques could be applied within Medicare. PBMs could potentially face some of the same difficulties mentioned previously—namely, their usual cost and utilization management tools may be blunted in the Medicare context due to the scrutiny their policies may face. Moreover, the decision to use a single or multiple PBMs for the entire country or one or multiple PBMs per region has the potential to affect the ability of the PBM or PBMs to control the cost of a Medicare drug benefit and to alter the value of the benefit available to different beneficiaries.

A single PBM contractor administering a Medicare drug benefit would likely be subject to the same level of scrutiny as a government entity. Such scrutiny may compromise the flexibility PBMs typically 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.
multiple PBMs, though, raises other issues. If each PBM had exclusive responsibility for a geographic area, beneficiaries who want certain drugs could be advantaged or disadvantaged merely because they live in a particular area. This kind of geographic variability may be difficult for Medicare to sustain. While it is true that such variability exists in the Medicare+Choice program, individuals enrolled in a Medicare+Choice plan have chosen to enroll and accept the terms of the benefit. For beneficiaries in traditional Medicare, their regional PBM may be their only drug coverage option. To reduce variation, Medicare could, like some private-sector purchasers, specify core benefit characteristics or maintain clinical control over formulary decisions instead of delegating those decisions to the PBMs. However, without the ability to create and manage a formulary, PBMs would have less flexibility to use techniques that have been integral to their efforts to maximize price discounts and control overall costs.

If multiple PBMs operate in each area, beneficiaries would choose one to administer their drug benefit. PBMs would compete for consumers directly, unlike the private-sector where they normally compete for contracts with insurers or other purchasers. With multiple PBMs, issues would arise regarding informing beneficiaries about the differences in each PBM’s policies, monitoring the PBMs’ marketing and recruitment strategies, and accounting for differences in health status of beneficiaries using each PBM. Having more than one PBM in an area may also dilute the market power of each PBM, because they would individually control fewer beneficiaries and need to be concerned about retaining beneficiaries. Having PBMs compete for beneficiaries may create an incentive for the PBM to have less stringent formularies, if all beneficiaries are subject to the same cost-sharing requirements regardless of the PBM they use.

The competitiveness of a bidding process for contracts to administer a Medicare drug benefit would depend, in part on, the size of the region for which PBMs compete. One recent study showed that the PBM industry is competitive, but that it is dominated by a few large companies. If a contract were awarded for the entire country or a few large regions, these large companies may have an advantage. Large regional contracts would concentrate Medicare's market power in these few firms, giving them more leverage to negotiate with manufacturers. If PBMs competed for smaller areas, more regional PBMs may bid to provide services in their

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region. Awarding more contracts that cover fewer beneficiaries may encourage participation by a greater number of PBMs, but may also dilute the overall market power associated with providing a drug benefit to Medicare beneficiaries. It may also be more burdensome to administer more PBM contracts.

Drug Benefit Administrative Functions are Unlike Traditional Medicare Activities

PBMs’ ability to administer formulary policy and impose other utilization controls involves a capacity to process and scrutinize claims that is very different from traditional Medicare’s handling of claims for other services. For example, PBMs have the ability to provide on-line, real-time drug utilization reviews. These serve as a quality- and cost-control function by supplying information to pharmacists regarding such things as whether a drug is appropriate for a person based on his or her age, medical conditions, and other medications, as well as whether the drug is covered on the formulary, and what copayments will apply. Currently, Medicare does not typically manage utilization of services in this fashion. It does not have the capacity to conduct real-time review of most services. Instead, Medicare pays claims after services have been delivered. In the current Medicare program, analysis of utilization patterns for individual services or providers is only possible after all claims have been submitted and assembled. Nevertheless, Medicare’s administrative costs historically have been extremely low, averaging about 2 percent of the cost of the services themselves.9

Duplicating the type of controls PBMs have exercised over private-sector drug benefits will likely involve devoting a larger share of total expenditures to administration than is currently expended in the traditional Medicare program. The magnitude of the increase is difficult to estimate. Much depends on what services PBMs are asked to provide and how much of the Medicare drug benefit each PBM will administer. Even if the dimensions of the PBM’s or contractor’s role are specified, estimating the likely costs remains problematic. A Medicare drug benefit will be a large-scale endeavor. The number of prescriptions for Medicare beneficiaries could easily approach the current number of claims for all other services combined or about 900 million annually. It is unclear how much PBMs or others would have to increase current capacity or instead use more of the capacity already built into their information and claims processing systems—a consideration that could significantly affect the administrative costs that may be incurred.

9 Medicare: HCFA Faces Challenges to Control Improper Payments, (GAO/T-HEHS-00-74, Mar. 9, 2000).
There is growing consensus that Medicare needs to change its benefit structure to include outpatient prescription drug coverage. Yet such an undertaking has substantial consequences for the cost of the program. In fact, one recent study suggests that such an expansion would add between 7.2 and 10 percent annually to Medicare outlays.\textsuperscript{10} The structure of such a new benefit—whom it would cover and the extent of its coverage—is an important determinant of the added cost. This is why, in previous hearings, the GAO has emphasized the need to make prescription drugs more affordable to beneficiaries who lack coverage by expanding access to group rates, extending discounts associated with group purchasing, and targeting government subsidies for those most in need. To the extent that this is accomplished through expanding Medicare’s benefit package, cost-control methods need to be incorporated into the management of the benefit. The private sector has developed and refined techniques, which have been implemented in some Medicare+Choice plans and private health plans, to control prescription drug costs. Applying these techniques to the larger Medicare population will require adaptations that may diminish their effectiveness.

The challenge in adding prescription drug coverage to the Medicare program 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 benefit expansion must be consistent with efforts to ensure the long-run sustainability of Medicare so that the program does not consume an unreasonable share of our productive resources and does not encroach on other public programs or private sector activities. Private sector tools for controlling drug expenditures provide options for controlling drug expenditures. However, how to apply these tools effectively to a Medicare drug benefit presents a number of challenges and requires careful consideration of the nature and magnitude of the Medicare program.

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

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\textsuperscript{10} Gluck, p. 8.
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