
Ensuring Access to Affordable Drug Coverage in Medicare

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The long-awaited outpatient prescription drug benefit in Medicare began January 2006. Despite its importance, the drug benefit is controversial. Instead of paying directly for prescriptions, the program will operate through competing private plans. Although it is too early to assess the full impact of Part D on beneficiaries, health plans and providers, employers, and taxpayers, we can discuss the major tradeoffs that will determine the success of the program. Key issues include whether market-based approaches will be more effective than direct government intervention in limiting spending; how will beneficiaries, drug plans, employers, and States adapt to the new program; and the balance between cost containment and access to innovative pharmaceuticals.

INTRODUCTION

Passage of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) in 2003 marked a major milestone for Medicare. Beginning January 2006, for the first time, all beneficiaries will have access to outpatient prescription drug coverage under Medicare Part D. Moreover, special low-income subsidies will be available to assure that needy beneficiaries, including those who qualify for Medicaid as dually eligible beneficiaries and persons with incomes up to 150 percent of the Federal poverty level, will have full insurance coverage. The new benefit will be administered by competing private

plans, with the expectation that costs will be contained without sacrificing access to appropriate medications.

Compared with other payers, Medicare was late in adding drug coverage to its benefits. Employers have long offered such coverage to their employees and retirees through private group health insurance, and States offer drug coverage to low-income beneficiaries through Medicaid (Medicare Payment Advisory Commission, 2002). The framers of Medicare considered including drug coverage at the outset, but that provision was dropped from the final legislation on fears that the benefit would prove to have unpredictably high costs. A Medicare drug benefit was enacted as part of the Medicare Catastrophic Coverage Act of 1988, but beneficiary outrage over cost led to repeal one year later. Cost remained a central concern during the 4-year congressional debate leading up to enactment of MMA (Oliver, Lee, and Lipton, 2004).

This article examines the challenges of providing affordable drug coverage to Medicare beneficiaries now and over the coming years when the baby boomers swell the Medicare ranks. A focal point of the article is the controversy over the competitive strategy adopted by MMA. Some commentators believe that costs would be more effectively controlled by direct government negotiation over drug prices, rather than relegating those negotiations to numerous private plans.¹ If the design of the drug benefit fails to constrain cost, the benefit will become unaffordable for

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¹ Democratic members of Congress—including Sen. Edward Kennedy, Rep. Henry Waxman, Rep. Pete Stark, and Rep. Charles Rangel—have been vocal on this point (Pear, 2003; 2004).

beneficiaries and taxpayers alike. Equally important, success of the benefit now and in the future depends on how well beneficiaries, providers, plans, employers, and States navigate a complex new pharmaceutical marketplace.

Drug Coverage Before and After MMA

Prescription drugs have become an increasingly important tool of modern medicine. Between 1994 and 2003, for example, spending for retail prescription drugs grew 13.9 percent a year on average—double the 6.8 percent average annual growth rate of national health expenditures. More patients are using more pharmaceuticals, driving spending on prescriptions up sharply. Newer, more costly (and more effective) drugs and increased utilization contributed to the higher spending growth, although recent evidence suggests that spending has slowed (Smith, 2004).

Medicare beneficiaries are major consumers of prescription drugs, accounting for 36 percent of total outpatient drug spending even though those beneficiaries constitute only 13 percent of the U.S. population (Cook, 1999). Nearly three-quarters of Medicare beneficiaries had prescription drug coverage prior to the passage of MMA (Poisal and Murray, 2001; Safran et al., 2005). About one-third of beneficiaries had drug coverage through an employer retiree health plan, and the remaining beneficiaries were split between Medicaid and Medicare health maintenance organizations (HMOs). Some private Medigap policies also covered prescription drugs, but such plans were expensive and attracted little enrollment. In addition, some low-income seniors received subsidies through State-financed pharmacy assistance programs.

The drug coverage available to Medicare beneficiaries varied depending on the source of insurance (Medicare Payment

Advisory Commission, 2002). The most generous coverage was available from Medicaid, which paid nearly all of the cost of allowed pharmaceuticals for low-income beneficiaries eligible for full Medicaid benefits. Prescription drug benefits available through Medigap plans were limited, with the plan paying 50 percent of drug charges up to a fixed amount (either \$1,250 or \$3,000 depending on the plan) after a \$250 deductible. Coverage offered by employer retiree plans and Medicare HMOs generally fell somewhere between those extremes.

Opportunities for seniors to obtain prescription drug coverage—and the generosity of that coverage—shrank as health costs rose during the 1990s. Large employers offering retiree health benefits declined from 57 percent in 1987 to 23 percent in 2001 (Stuart et al., 2003). Retiree drug coverage fell off, particularly for younger Medicare beneficiaries. In addition, reductions in Medicare payments to HMOs imposed by the Balanced Budget Act of 1997 led to the departure of several hundred private plans from Medicare (Gold, 2003). The remaining plans cut back on optional benefits, frequently dropping or limiting prescription drug coverage. Many of those plans placed limits on the total drug benefits payable each year, and some restricted benefits to generic drugs only.

The Medicare drug benefit has been superimposed on this mixed collection of coverage options. The new benefit is open to all Medicare beneficiaries on a voluntary basis.² To encourage enrollment, enrollees will pay a subsidized premium modeled after the existing Part B premium. The new Part D premium will equal about 25 percent of the cost of the standard benefit, with the rest paid from general tax revenue. Beneficiaries will pay an average prescription drug premium of \$32.20 a month in 2006.

² A more detailed summary of the Medicare outpatient prescription drug benefit is available from the Medicare Payment Advisory Commission (2005b).

Medicaid will no longer cover prescription drugs for dually eligible beneficiaries who receive full benefits from both Medicare and Medicaid. Instead, they will be automatically enrolled in the Medicare drug program. A special low-income subsidy will cover premiums and cost-sharing (other than nominal copayments) for qualifying beneficiaries with incomes up to 135 percent of the Federal poverty level. Assistance also is offered on a sliding scale to those with incomes up to 150 percent of the Federal poverty level.

Employers will be given an incentive to maintain their retiree drug coverage. Medicare will provide a tax-free subsidy equal to 28 percent of costs between \$250 and \$5,000 in drug spending per retiree to employers offering drug benefits that are at least equivalent to the Medicare Part D benefit. In addition, private Medigap plans will no longer sell prescription drug coverage to new enrollees.

Medicare will spend at least \$700 billion over the next decade, and substantially more than that in later years, to finance the Part D drug benefit (Centers for Medicare & Medicaid Services, 2005b). Much of that spending will substitute Federal taxpayer dollars for private payments and State taxes that would have been used to pay for prescription drugs in the absence of a Medicare drug benefit.³ Part D cost containment mechanisms will substitute for those of private insurers and States. Will Medicare do a better job of constraining prescription drug costs than the programs it replaces?

Cost Containment in Part D

In a break with past practice, Medicare Part D relies on competing private entities to deliver the drug benefit to all ben-

eficiaries—those who remain in traditional Medicare as well as those who choose a Medicare Advantage plan. Instead of paying directly for each prescription purchased by Medicare beneficiaries, as is done for other covered services under traditional Medicare, Part D will pay the drug plans an amount partly determined by what the plan expects its costs will be. Placing the plans at risk for excessive costs gives them an incentive to control drug spending, although it remains to be seen how effective that effort will be.

The MMA specifies a standard benefit design for the Medicare outpatient prescription drug coverage, but allows participating plans to vary the details of that design and to augment the coverage so long as the resulting benefit is at least actuarially equivalent to the standard. Private prescription drug plans and Medicare Advantage prescription drug plans have latitude to vary the drugs carried on their formularies, the structure of copayments or coinsurance that would be paid by enrollees for their prescriptions, other aspects of their delivery system, and the expected cost per enrollee.

Medicare's payment to the plans will equal 74.5 percent of the average cost of providing the standard benefit to a typical enrollee, based on information provided in an annual bidding process. Since enrollees will pay the difference between that subsidy and the plan's expected cost, lower-cost plans will be able to charge lower premiums and will have an advantage in attracting enrollment.

A fixed prospective payment based on the average cost of all drug plans would give the plans a strong incentive to control costs since they would be fully at risk for any operating losses. However, plans might avoid enrolling higher-cost beneficiaries with greater than average needs for

³ Although Medicaid will no longer provide a drug benefit to dually eligible beneficiaries, States will continue to pay much of those costs through clawback payments to the Federal Government.

prescription drugs.⁴ Moreover, in the first few years of a new benefit, it likely will be difficult for plans to make accurate cost projections. To maintain stability in Part D, MMA limits the financial exposure of the plans by paying a high proportion of the costs for exceptionally high-cost beneficiaries and by sharing in any large aggregate losses (or gains) that a plan might experience. Those provisions reduce somewhat the financial incentive to control cost.

Part D drug plans will limit cost growth using many of the management tools developed by pharmacy benefits managers (PBMs) for private insurers (Draper, Cook, and Gold, 2003; Atlas, 2004). For example, plans may use tiered cost sharing (with lower copayments for generic drugs or lower-cost brand-name drugs) and step therapy (which requires patients to try lower-cost drugs first). Such tools promote the use of the least expensive pharmaceuticals that are effective in the treatment of a disease. Since these tools can steer demand toward specific products, they enhance the plan's ability to negotiate better prices from manufacturers.

PBMs have achieved significant savings by managing the drug benefit for private insurers. The Government Accountability Office found that PBMs in the Federal Employees Health Benefits Program obtained substantial discounts, ranging from 18 percent below the cash price for brand-name drugs purchased at retail pharmacies to 53 percent for generic drugs purchased through mail-order pharmacies (Government Accountability Office, 2003). In addition, PBMs received manufacturer rebates of 3-9 percent, and saved 1-9 percent through interventions such as prior authorization and drug utilization review.

⁴ Such behavior has been observed among HMOs and other private plans participating in Medicare (Greenwald, Levy, and Ingber, 2000).

The largest pharmacy benefits managers have considerable market power, enabling them to negotiate effectively for low pharmaceutical prices. For example, Caremark, the largest PBM in the U.S. and one that is likely to sponsor or manage a number of Part D plans, represents 80 million covered lives in its private business (Atlas, 2004). Two other PBMs have more than 50 million covered lives each. Adding Medicare beneficiaries to the mix could strengthen the hand of such companies in bargaining with manufacturers.

Despite these favorable indications, Part D plans might not use their cost management tools aggressively to achieve comparable savings. MMA and subsequent regulations have circumscribed the use of those tools to some extent. For example, formularies may not be overly restrictive and must contain at least two drugs per class. CMS recently clarified that formularies must include most drugs in six therapeutic categories to avoid the possibility of interrupting therapy for affected patients (Centers for Medicare & Medicaid Services, 2005a).

This decision illustrates the policy tradeoff between controlling cost and assuring access to sufficient drugs. Broadening the formulary could limit the plan's ability to shift market demand toward preferred products. The potential to move consumers to competitors' products is the basis for negotiating with manufacturers for lower drug prices.

The alternative to market-based pricing is direct price negotiation by CMS with manufacturers. Some argue that CMS could effectively use the market power of 42 million beneficiaries to secure lower drug prices than would be attainable through competing private plans. However, such savings would impose other costs on beneficiaries.

Over the short term, CMS could establish below-market prices for prescription drugs, but economic theory suggests that such prices would not be sustainable. Below-market prices could cause shortages of high-demand pharmaceuticals and discourage manufacturers from bringing new drugs to market. If shortages were severe, Congress would feel pressure to take action. Even the potential for supply shortages could result in an easing of price limitations, as demonstrated by recent experience with mandated cuts in Medicare physician fees under the sustainable growth rate formula (Medicare Payment Advisory Commission, 2005a). Fee reductions were reversed in 2003, 2004, and 2005, and Congress continues to seek ways to provide rate relief for physicians (Thomas and Johnson, 2005).

There is no guarantee that government negotiation or price setting would be more effective than MMA's structure of competing plans in controlling Part D cost, even in the short term. Medicare's experience in setting prices for Part B drugs, which are administered by physicians on an outpatient basis, is not encouraging. Until recently, CMS paid physicians for those drugs 5 percent below their average wholesale price—a price well above what the drugs actually sold for. The GAO found that Medicare overpayments for most physician-administered drugs ranged from 8-29 percent of the average wholesale price (Government Accountability Office, 2001).

It is uncertain whether private drug plans will be able to rein in Part D prescription costs given the substantial differences between private insurance and Medicare. The average beneficiary in Medicare has both a lower income and greater health needs than the average beneficiary in employer-sponsored insurance. Standard cost management techniques may be less effective in an older population that faces

greater health risks. Moreover, CMS and Congress will be looking over the shoulders of the Medicare drug plans, and that scrutiny could discourage vigorous cost control efforts that might adversely affect the course of some patients' treatment.

ADDITIONAL CHALLENGES

Cost containment is just one of the objectives that must be met if we are to ensure affordable prescription drug coverage through Medicare. Although monumental efforts have been made to implement the benefit, the program will face many hurdles in its first year and additional challenges in the years to come. Carefully deliberated policy actions will be needed over a sustained period of time to ensure that future Medicare beneficiaries will be able to obtain affordable prescription drug coverage. The following discussion summarizes some of those other challenges that will contribute to the success or failure of the new program.

Enrollment

Medicare beneficiaries must decide whether to enroll in a Part D plan, and if so, they must choose from what might be dozens of plan options. Such decisions are likely to be difficult for most beneficiaries, who are facing them for the first time this year (Biles, Dallek, and Nicholas, 2004). Insurance provisions are complex and difficult to compare across plans. Many beneficiaries also should consider whether the coverage they now have from a retiree plan is their best choice, which adds another complication.

Adding to the difficulty, Part D is a new program with no prior history. Beneficiaries will not be able to ask friends or relatives about their experience with the program, which will lead to a wait and see attitude.

That is likely despite the late enrollment penalty, which permanently increases Part D premiums by 1 percent for every month that a beneficiary enrolls past his or her initial enrollment period.⁵

The first year's enrollment process will be the most difficult for beneficiaries and the program alike. Every one of Medicare's 42 million beneficiaries will be faced with a decision they have not previously had to make. In subsequent years, only those newly entering Medicare by turning age 65 or becoming eligible through disability—perhaps 1 or 2 million people—will enroll in Part D for the first time. In addition, only a fraction of previous enrollees will actively consider changing plans.

If the experience with the Medicare drug discount card is an indication, enrollment rates for Part D will probably be low initially (Bureau of National Affairs, 2005). Although there will be aggressive public outreach efforts coordinated by CMS and private organizations (such as the Access to Benefits Coalition), they may not produce immediate results. There is a risk of information overload, particularly if that information is not geared to the average person rather than an insurance expert (Biles, Dallek, and Nicholas, 2004). The demand for consumer-friendly information is likely in time to spawn new and more useful guides to Part D's annual open season, akin to information comparing plans in the Federal Employees Health Benefits Program that has long been available from private sector rating organizations.

Low enrollment in the first year should not be taken as a sign of failure, since it is the inevitable outcome of a learning process that every beneficiary must go through. Early adopters will set the example by which the majority of beneficiaries

learn about their options. A more valid test of Part D's success is the enrollment rate for drug benefits in 2007.

Plan Stability

Contrary to some initial concerns that there may be too few plan choices, more than 600 sponsors will participate in Part D and most sponsors are likely to offer several benefit options (Centers for Medicare & Medicaid Services, 2005c). The industry's response may not be surprising. Much like the 1889 Oklahoma land rush, there will not be a second chance for plans to stake a claim to 42 million brand new customers.

Plans face a largely untested Part D market in 2006. They were required to arrange the details of their offerings and make bids based on insufficient information about the likely patterns of enrollment, drug utilization, and cost. Without adequate information about market conditions in the first year, not all of the plans will survive. Consolidation in the Part D market in 2007 and later means fewer sponsors offering fewer options.

High plan turnover could be disruptive to affected enrollees, particularly if the remaining options offer less generous benefits, have a more restrictive formulary, or require higher premiums than the exiting plan. Since the highest turnover likely will occur among plans with the lowest enrollment, the number of adversely-affected beneficiaries might be small.⁶ CMS monitoring coupled with protections built into the law, such as appeal rights, ought to be adequate to ensure a continuation of affordable coverage for beneficiaries in most cases. Plans with sizeable enrollments are unlikely to drop out of Part D, but unexpected cost pressures could force their bids up in subsequent years.

⁵ Beneficiaries who initially enroll in a retiree or other plan offering creditable drug coverage are not charged the late enrollment penalty.

⁶ Lake and Brown, 2002, found that Medicare+Choice plans with high enrollment were least likely to withdraw.

Retiree Drug Benefits

Rising health costs and tougher accounting rules have led to erosion in employer-sponsored health benefits for retirees. The Financial Accounting Standards Board requires that employers recognize liabilities for the benefits of retirees in their annual financial statements. That provision, known as FAS 106, has triggered reductions in retiree health benefits, with many companies paring back or placing lifetime caps on coverage.

Congress attempted to slow or reverse that erosion by offering a subsidy to employers whose retiree drug coverage was at least as good as Part D. Many retiree plans offer comprehensive drug coverage at reasonable prices, representing a better deal than Part D for those who are eligible. The employer subsidy is likely to reduce, but not eliminate the decline in retiree coverage, however. The long-term liability facing employers is lower and more certain (since it falls to zero) if they drop their retiree drug benefit completely.

Because of the newness of the program, most employers are likely to continue their retiree benefits in 2006 and apply for the Medicare subsidy (Mercer Human Resource Consulting, 2005). Once again, the relationship between Part D and employers is a work in progress. If Congress reduces the value of the subsidy in future years, or if employers find that administering their plans becomes overly complex because of Medicare rules, the erosion of employer-sponsored retiree coverage could accelerate.

Dually Eligible Beneficiaries

State Medicaid Programs will no longer provide prescription drug coverage for dually eligible beneficiaries who will volun-

tarily enroll or be automatically assigned to Part D plans. There is a strong possibility that problems in the assignment process or confusion on the part of the beneficiaries early in 2006 could interrupt necessary drug therapy for some patients.

CMS has encouraged States to issue more than 1 month's supply of pharmaceuticals to dually eligible beneficiaries who fill their prescriptions in December 2005, giving those patients a cushion if there were such a problem (Reichard, 2005). States might be willing to do that, but this imposes extra cost on them (through the Medicaid matching formula) that would otherwise be fully borne by Medicare.

A related issue is the challenge of ensuring that Medicare beneficiaries living in nursing homes or other institutions—many of them dually eligible beneficiaries—receive their medicines in a seamless fashion. Part D includes specialized drug plans that are expected to provide services to institutionalized beneficiaries, but there remain concerns about the early performance of those plans and the ability of institutionalized beneficiaries to find the best plan for their specific needs.

States are increasingly upset about the clawback, which requires them to pay to the Federal Government a portion of the cost of prescription drugs that States would have incurred absent MMA (Smith, Gifford, and Kramer, 2005). The payment is based on the cost of prescription drugs incurred for dually eligible beneficiaries in 2003. That calculation does not credit the States for cost cutting steps, such as preferred drug lists and negotiations for larger discounts from manufacturers, which only became effective after 2003. This financing issue will not directly impact Medicare beneficiaries, but remains a contentious point for Congress and CMS.

Price Transparency and Information Technology

Unlike any other item bought and sold in this country, health care products and services are routinely provided to consumers who do not know what they cost. Without knowing the price, the consumer can hardly be expected to purchase wisely. The Medicare drug benefit will begin to fill that gap, and the program could be the catalyst for systemwide improvements in the use of health information technology (IT) to promote cost consciousness and better medical care.

As part of a broader effort to provide consumer information, CMS developed an internet site <http://www.medicare.gov/AssistancePrograms/home.asp> that provides beneficiary-specific information on the benefits and costs (including prices of covered drugs) of different options under the Medicare drug discount card program. For the first time, individuals in any part of the country could easily determine the prices they would pay for their prescriptions. Similar information on prices and plan options will be available to beneficiaries for Part D at <http://www.medicare.gov/MPDPF/Public/Include/DataSection/Questions/MPDPFIntro.asp>

Price transparency could revolutionize the way prescription drugs are sold. Once prices can be compared with little difficulty, consumers inside and outside Medicare will begin to ask whether they are getting their money's worth. Oversight of Part D will be facilitated by the availability of price data that can be tracked over time and compared across Part D plans.

Other information needs must be met if we are to assure high quality treatment as well as cost savings under the new benefit. Electronic prescribing can eliminate errors caused by misreading handwritten prescriptions. Prescriptions can be screened

for drug interactions or other contraindications and that information can be sent to the physician for evaluation in a matter of seconds. Pricing information can be made available to both the physician and patient, and lower-cost alternatives can be identified before a prescription is finalized. Eventually, information about prescribing patterns and the resulting impact on patient health can be gathered to improve the medical knowledge base. A host of difficult issues—including confidentiality of patient information, provider reluctance to adopt health IT, the high cost of financing health IT investments, and other barriers to shifting from a paper-based health system—must be resolved before the benefits of health IT can be realized.

Pharmaceutical Innovation

Offering affordable Medicare prescription drug coverage puts the most innovative medicines within the grasp of all beneficiaries—at a price. The high cost of some of those medicines could lead to policies that would limit their availability, reducing the growth in Part D spending but reducing the value of the drug benefit to some patients. Imposing below-market prices for specific high cost drugs, for example, or directly restricting access to particular pharmaceuticals might slow the growth of drug spending. However, that might also lead to higher costs elsewhere in Medicare if less effective medicines are used. Such policies could also reduce the incentives for pharmaceutical research and development, which would discourage the flow of innovative new products to the marketplace. This tension between Part D's cost and the value of innovative pharmaceuticals is likely to be one of the biggest challenges facing the Medicare prescription drug benefit over the long term.

FINDING THE BALANCE

Over the past two decades, new pharmaceuticals have dramatically improved our ability to prevent or treat major diseases associated with aging. Future innovations in prescription medicines could have an even greater impact on the health of Medicare beneficiaries. The Medicare drug benefit that begins in 2006 will provide substantial assistance to millions of seniors and disabled persons with the cost of their prescriptions.

The program will not be an instant success. Beneficiaries and drug plans alike will face the uncertainties of a new program, and the first year's experience will shape the future evolution of the drug benefit. The long-term performance of the drug benefit will depend on whether competing private plans are able to establish a reasonable degree of cost control for Part D without unduly restricting access to pharmaceuticals. Finding and maintaining the right balance between cost and access is essential if Medicare is to meet the health needs of future generations.

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