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MEDICARE'S NEW ADVENTURE: THE PART D DRUG BENEFIT

Jack Hoadley
Health Policy Institute, Georgetown University

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ABSTRACT: The government faces many challenges in implementing the new Medicare prescription drug benefit. First among them is overseeing the enrollment of millions of beneficiaries into private plans, including shifting those currently relying on Medicaid coverage to Medicare drug plans. Medicare must also ensure that plan formularies provide beneficiaries with access to the drugs they need. The drug benefit has the potential to provide prescription coverage for beneficiaries who currently lack it—particularly low-income beneficiaries, who can receive subsidies that minimize their out-of-pocket costs. Ultimately, the program's success will be judged by whether beneficiaries enroll in plans that meet their needs and whether the program's costs are held within reasonable limits. If it fails to meet public expectations, Congress will have the added challenge of making mid-course corrections.

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ABOUT THE AUTHOR

Jack Hoadley, Ph.D., a research professor at Georgetown University's Health Policy Institute, has over 20 years experience as a health policy analyst and researcher. At the Institute, he conducts research projects on health financing topics, including Medicare, Medicaid, and SCHIP, with a particular focus on prescription drug issues. Previously, he held positions at the Department of Health and Human Services in the Office of the Assistant Secretary for Planning and Evaluation, the Physician Payment Review Commission and its successor, the Medicare Payment Advisory Commission, and the National Health Policy Forum. In 2000, Dr. Hoadley headed a team of analysts from the U.S. Department of Health and Human Services that looked at issues relating to prescription drug coverage, spending, and pricing in response to a request by the President to the Secretary. He holds a Ph.D. in political science from the University of North Carolina at Chapel Hill.

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INTRODUCTION

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) became law in December 2003. Among other provisions, the MMA created the Part D drug benefit, which became available to Medicare beneficiaries on January 1, 2006. Passage of the MMA came after extended debate in which policymakers were sharply divided over the design of the drug benefit and its structure—particularly whether it could be restricted to the \$400 billion, 10-year budget established by the Bush Administration.

The Part D benefit involves approaches that are entirely new to Medicare. This is the first time that the program has offered coverage for outpatient prescription drugs. Instead of offering the benefit itself, Medicare relies on private, standalone drug plans that compete among themselves and are at risk for the costs of the benefit. Such plans have few, if any, precedents in public or private sector offerings. As a result, implementing Medicare Part D poses many new challenges for beneficiaries, health plans, and the federal government.

Medicare beneficiaries, especially those who previously had no drug coverage, have much to gain from the new benefit. Low-income beneficiaries, in particular, will be helped by subsidies that should keep their out-of-pocket costs to a minimum. But beneficiaries have much to learn about the new benefit and face a series of decisions: whether to enroll for the Part D benefit, which plan to select, how to work with the formularies and cost-sharing structures, and how to finance the remaining out-of-pocket costs.

The drug benefit is offered by private prescription drug plans and Medicare Advantage (MA) organizations, or private health plans available under Medicare. These organizations will be at risk for the cost of the benefit, although the MMA's risk adjustment, risk-sharing, and reinsurance provisions limit the degree of risk borne by the plans. The general outlines of the standard benefit are established in the law, though plans have the option of modifying the benefit design. Plans are likely to use cost management tools (e.g., formularies and prior authorization) similar to those currently used in the employer-based market. With these tools, they are expected to leverage their buying power to negotiate price discounts and thus manage drug costs and encourage appropriate utilization.

Potential plan sponsors—a mix of health plans, pharmacy benefit managers, and other entities—faced fundamental decisions. Those that chose to enter this market had to decide how to position themselves: what premiums to charge, whether to modify the benefit from the basic design, and how to structure a formulary and cost-sharing tiers. Plans had to determine what design features would allow them to capture and retain an adequate share of the market while maintaining financial stability.

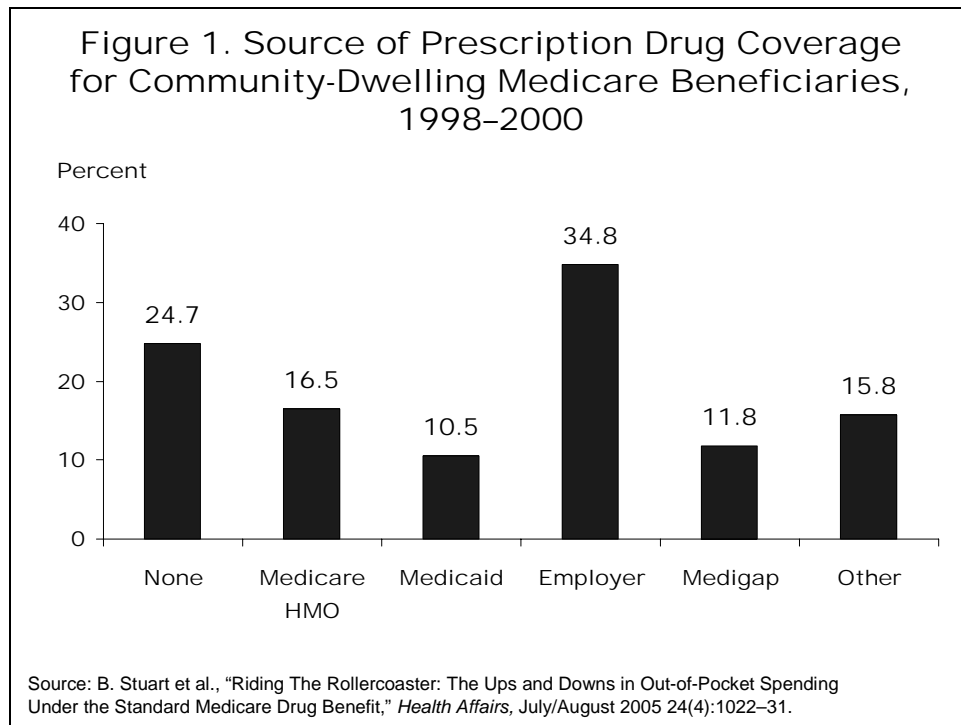
In addition to outlining the basic benefit design, the MMA lays out the competitive market structure, the types of information that should be provided to beneficiaries, quality and access standards that plans must meet, limitations on plans' use of cost-management tools, and a variety of other standards. Despite these details, many operational details were left to regulations. The Secretary of Health and Human Services published a final rule on January 28, 2005, translating provisions of law into regulatory language and elaborating on most of the provisions. However, some issues were left to sub-regulatory guidance. In September, the Secretary entered into formal contracts with the organizations that chose to offer Part D plans, and information on these plans became available to the public in October 2005. Beneficiaries could enroll as of November 15, with open enrollment for the first year available through May 15, 2006. For those enrolling before the end of 2005, the benefit began on January 1, 2006.

The government has thus had to implement a major new program in only two years, including the design of features for which there are few precedents and oversight of the private plans. The government has some experience with private organizations from Medicare Advantage and its predecessor, Medicare+Choice, but these programs never enrolled more than about one of six beneficiaries. In addition, Medicare must now administer subsidies to employers that provide retirees with drug benefits that meet certain criteria.

The success of the Medicare drug benefit ultimately will be judged by a number of factors, only a few of which will be known within the next year. Furthermore, this program is likely to undergo administrative and potentially legislative changes in its early years and thus will remain a moving target. This issue brief considers the types of plans that initially entered the market; the shape the market and the benefit are taking; the drugs initially available through the plans offering the benefit; the success in enrolling beneficiaries; whether beneficiaries will have improved access to needed drugs; and the impact on the larger marketplace for prescription drugs.

THE NEED FOR A DRUG BENEFIT

Prior to the creation of the new benefit, beneficiaries had several ways to obtain prescription drugs. Some obtained drug benefits through private sources, including former employers and privately purchased Medicare supplemental (Medigap) benefits. According to data from the 1998–2000 Medicare Current Beneficiary Survey, about one-third of beneficiaries had coverage through their former employers (Figure 1).¹ While there is a long-term trend of employers dropping this coverage, employer-based plans continue to be the largest single source of drug coverage, although the number of individuals enrolled in Part D plans is likely to surpass the number with job-based drug coverage. About one of 10 beneficiaries purchased coverage through Medigap plans. Unlike employer-sponsored coverage, Medigap is expensive and fails to offer catastrophic coverage for heavy users of prescription drugs.



Under state Medicaid programs, beneficiaries who met income and eligibility standards were able to obtain drugs at a minimal cost. About one-tenth of Medicare beneficiaries are enrolled as “dual eligibles,” meaning they also receive full Medicaid coverage. Another one of six beneficiaries received coverage through other government programs, including the Veterans Administration, Tricare (the U.S. military health plan), the state pharmacy assistance programs available in some states, and other sources of private coverage.

Among those with none of these sources of public or private drug coverage, about one of six beneficiaries in 1998–2000 was enrolled in Medicare private plans (e.g., HMOs or private fee-for-service plans), then known as Medicare+Choice plans. This period marked the peak in private plan enrollment, which fell by more than one-fourth in the following few years. Since 2000, the proportion of private plan enrollees with drug coverage for brand and generic drugs dropped from 84 percent to 25 percent. Both of these downward trends, however, have begun to turn around. Due to large federal subsidies in the MMA, the number of MA plans has increased substantially, and plans had begun to expand their drug coverage even before Part D coverage became effective. As a result, enrollment has grown by about 10 percent from its 2003 low as of December 2005.²

Despite all these potential sources, about one-fourth of Medicare beneficiaries still had no drug coverage at all from 1998 to 2000. When taking into account beneficiaries who lacked coverage for part of a year, this figure increases to nearly one-half of all beneficiaries.³ For some, coverage was unavailable: no former employer offered retiree drug benefits, their income was too high for Medicaid eligibility, and their state had no pharmacy assistance program. For others, the available coverage was unaffordable. Medigap coverage can cost as much as the maximum value of the benefit, especially for older beneficiaries with preexisting medical conditions. Without coverage, seniors and the disabled struggled to purchase drugs with limited resources or chose to leave some prescriptions unfilled.⁴ The gaps in coverage, especially for low-income beneficiaries, were a major motivation for policymakers to create a drug benefit.

THE SHAPE OF MEDICARE PART D

The MMA calls for the creation of a new market in which to offer prescription drugs. Private drug plans compete in 39 regions established by the Secretary (34 covering the states and five others, each covering one of the territories) to make the benefit available to beneficiaries covered under traditional Medicare. In addition, MA organizations are required to offer at least one plan with a qualified drug benefit to enrollees in each area they serve.

Under the standard benefit, beneficiaries are subject to an initial deductible (\$250 in 2006) and then must pay 25 percent of drug costs up to an initial coverage limit (\$2,250 in 2006) (Table 1). Above the initial coverage limit, beneficiaries are responsible for paying the entire cost of their drugs until they reach \$3,600 in out-of-pocket costs, equivalent to \$5,100 in total drug costs under the standard benefit. This coverage gap is often referred to as the “doughnut hole.” After reaching the threshold for out-of-pocket

spending, catastrophic coverage kicks in with only modest cost-sharing, generally 5 percent of the cost of the drug.

Plans have the option of substituting their own benefit designs for this standard coverage as long as their design is actuarially equivalent, that is, covers the same amount of drug costs on average. Substitute coverage might eliminate the deductible or replace percentage coinsurance with flat copayments. Plans also could enhance their coverage by adopting a more generous benefit structure—for example, by paying some drug costs in the coverage gap. The value of enhanced coverage, however, must be paid in full by beneficiary premiums, not by federal dollars. Moreover, payments made by the plan under the enhanced benefits are not included as part of the out-of-pocket costs counted toward the threshold for catastrophic coverage.

Table 1. Shape of the Standard Benefit

	Amount of Drug Spending	Amount Paid by Beneficiary Under Standard Benefit	Amount Paid by Low-Income Beneficiary
Premium		Average of \$32.20 per month	None for eligible plan
Deductible	\$250	\$250	No deductible
Initial coverage period	\$250 to \$2,250	25% coinsurance	\$1 to \$5 (varies by type of drug, income, Medicaid status)
Coverage gap	\$2,250 to \$5,100	Pay full cost	No cost-sharing
Catastrophic coverage	Over \$5,100	Greater of 5%, \$2 (generic), \$5 (brand)	None for eligible plan

Note: Excludes those eligible for partial subsidies.

Source: Medicare Modernization Act of 2003 and author’s calculations.

Beneficiaries will pay a premium to the drug plan they select. Each plan’s premium will differ depending on a variety of factors. In 2006, the premiums paid by beneficiaries for the standard benefit average \$32.20 per month, while the federal government will pay the plans an average of \$94.08 in monthly premium costs.

The drug benefit represents a significant change for Medicare: unlike other parts of the program, the benefit varies according to income. Previously, eligible Medicare beneficiaries could receive extra assistance through Medicaid, which paid portions of their Medicare cost sharing. Under Part D, a subsidy, called “extra help for beneficiaries,” is available to beneficiaries with incomes below 135 percent of the federal poverty level

(\$12,920 for a single person and \$17,321 for a couple in 2005) and assets below a specified level (\$6,000 for an individual and \$9,000 for a couple in 2005). Qualifying low-income beneficiaries are eligible for a subset of plans that have no premiums, deductibles, or coverage gaps and limited cost-sharing (no more than \$5 per drug purchase). Those with Medicaid coverage do not have to meet the asset test beyond any asset test that applies to Medicaid eligibility in their state. Partial subsidies are available to beneficiaries with incomes between 135 and 150 percent of the federal poverty level (\$14,355 for individuals and \$19,245 for couples) and with somewhat higher assets (up to \$10,000 for individuals and \$20,000 for couples).

As a result, low-income beneficiaries will likely experience far greater savings than other beneficiaries. According to a recent study, those receiving the subsidy will spend about 83 percent less on drugs under MMA than they would without the law.⁵ The savings will be most substantial for those who did not receive coverage previously from Medicaid. Savings for higher-income beneficiaries will be more modest, with out-of-pocket drug spending falling from \$1,495 to \$1,081—an annual savings of \$414, or 28 percent. These savings estimates do not take into account the Part D premiums paid by beneficiaries—averaging \$386 annually for standard benefits—or the premiums they previously paid under other coverage arrangements. Those without previous coverage should see their out-of-pocket drug costs reduced by 50 percent, but only by 23 percent when Part D premiums are taken into account.⁶

PLANS IN THE PART D MARKET

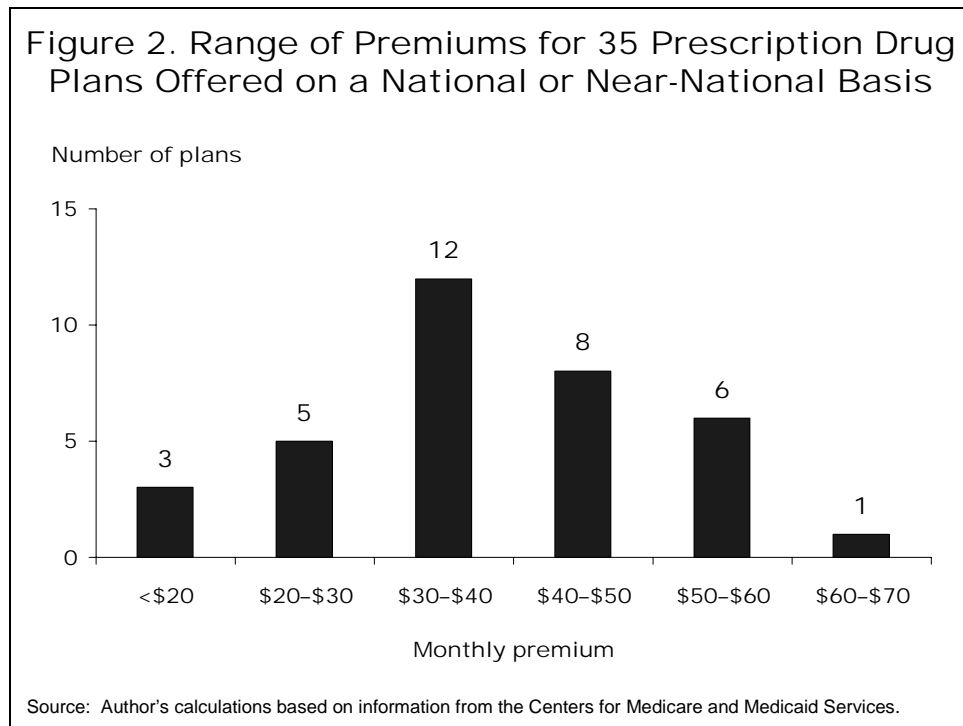
During the debate over the drug benefit, some policymakers questioned whether organizations would agree to provide it. There was extensive discussion of how to structure fallback plans to ensure that beneficiaries would have at least two options, only one of which could be an MA plan. In fact, many organizations have entered the marketplace—so many that some experts have raised concerns about beneficiaries having too many choices.

About 65 different organizations chose to participate in the prescription drug plan market. Ten organizations are offering plans in all 34 regions covering the states.⁷ They include large insurance companies (Aetna, Cigna, Coventry, Pacificare, Unicare, United HealthCare, and Wellcare), pharmacy benefit managers (Medco, Caremark), and a pharmacy benefit manager affiliated with the National Community Pharmacists Association (MemberHealth). Four other organizations (Sterling, Humana, United American, and Prescription Pathway) are offering plans in at least 30 of the 34 regions. Most of these organizations are offering three plan options in each region, thus

guaranteeing that beneficiaries across the country have a choice of options. Nationally, there are more than 1,400 plan options participating in Part D (86 percent of which are sponsored by the 14 organizations with national or near-national offerings). A typical state has between 15 and 20 organizations offering plans, for a total of 40 to 45 plan options. Alaska and Hawaii have the fewest options (27 and 29, respectively), while beneficiaries in the Pennsylvania/West Virginia region have the most (52).

In addition to the options offered for standalone prescription drug plans, all MA plans are required to offer their enrollees a drug benefit option to accompany their private plan. In most parts of the country, there are multiple MA options available to beneficiaries, sometimes as many as 30 or 40.

Although monthly premiums average around \$32 for the standalone drug plans, these premiums vary substantially. Premiums across all standalone prescription drug plans range from \$2 to \$100 (Figure 2).



Some plans are available at no charge to enrollees who are eligible for the low-income subsidy. These plans qualify because their premiums are below a regional benchmark that is defined as the average of plan premiums, including MA premiums. Benchmarks range from \$23.25 in California to \$36.39 in Mississippi.⁸ On average, subsidy-eligible beneficiaries have about eight plan options, ranging from five in Arizona

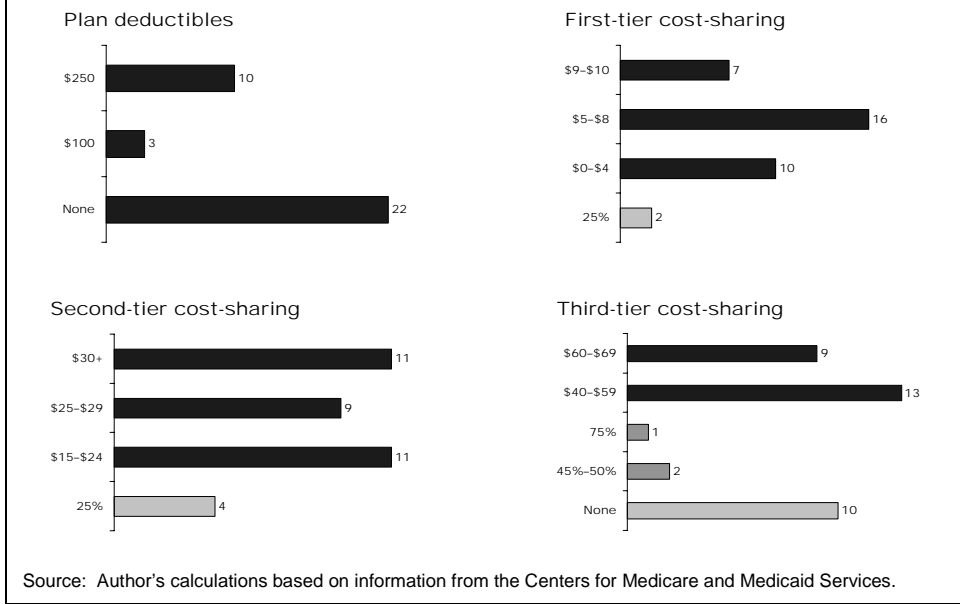
to 14 in several regions. Several national organizations have eligible plans in nearly every region.

Although most regions have a similar array of plan offerings, the premiums vary by region. Regions with the lowest average premiums are mostly in the West, including California, Hawaii, Arizona, and New Mexico, although New York also falls into this category. The most expensive regions are mainly in the South—Louisiana, Mississippi, and North Carolina—and cost nearly \$10 more per month than the cheapest regions. These differences may reflect health differences beyond those captured by risk adjusters, variations in the prescribing practices of physicians, and the extent of expected competition from MA plans.

The drug plans that have entered the Part D market have taken full advantage of the flexibility allowed by law to vary their benefit designs. A majority of plans chose to eliminate (at least in part) the standard deductible, substitute flat copayments (e.g., \$25 for a one-month supply) for coinsurance (e.g., 25 percent of the cost of the drug), and adopt tiered cost-sharing where the beneficiary pays different amounts for different types of drugs. Most plans made all three changes. The most common approach was to use three or four tiers with different copayment amounts for generic drugs, preferred brand-name drugs, non-preferred brand-name drugs, and sometimes specialty drugs (e.g., biotechnology products or injectable drugs).

Among the organizations offering plans on a national or near-national basis, the median copayment levels for 2006 are about \$5 for generic drugs, \$26 for preferred brand-name drugs, and \$53 for non-preferred drugs. But there is substantial variation among plans. Several have no copayments for generic drugs, while others charge \$10. Copayments range from \$15 to \$40 for preferred brand drugs and from \$40 to \$73 for non-preferred drugs. Among plans not using a three-tier copayment structure, one plan charges \$4 for generics and \$17 for preferred brand drugs, but 75 percent coinsurance for non-preferred drugs, while another plan charges nothing for generics, 25 percent coinsurance for preferred brand drugs, and 45 percent coinsurance for non-preferred drugs (Figure 3).

Figure 3. Cost-Sharing Designs—35 Prescription Drug Plans Offered on a National or Near-National Basis



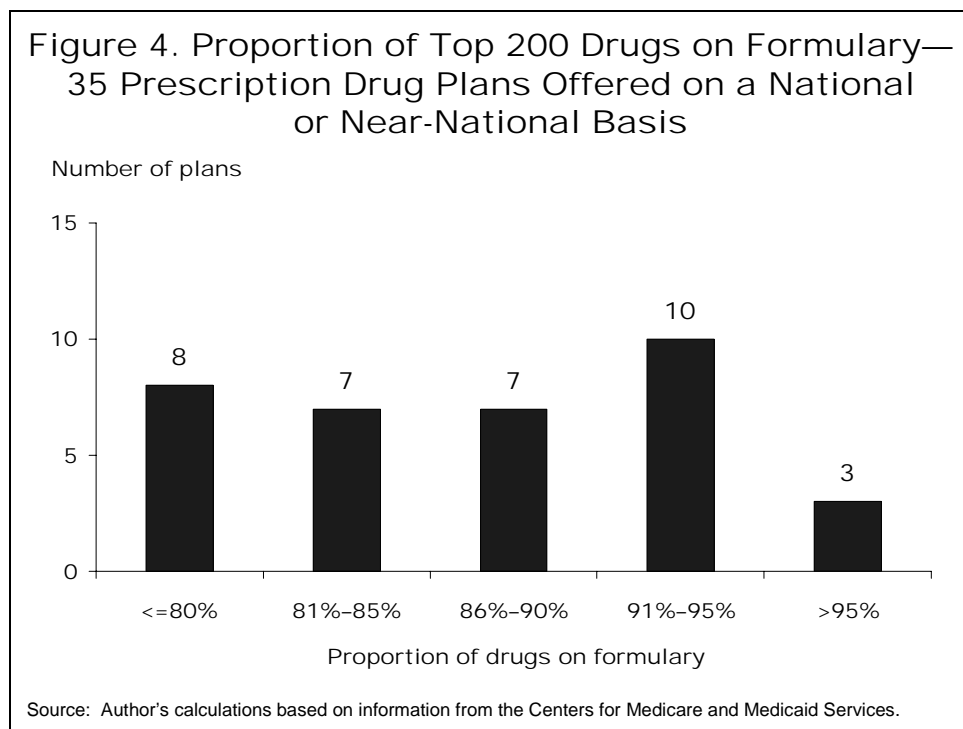
Relatively few plans chose to fill in the doughnut hole at all, and most that did only cover generic drugs in this gap. However, most regions have at least one plan option with coverage in the gap for both generic and brand-name drugs. These plans tend to have substantially higher premiums than the average for all plans in the same region.

In addition to varying their benefit designs, plans have taken a variety of steps to control drug costs. Keeping costs down has the potential to benefit the plans, since they are at some risk for the overall cost of the drugs their enrollees use. But it could also save money for the Medicare program, which reimburses plans for a share of their drug costs, and for plan enrollees, in the form of lower premiums and cost-sharing. Of course, beneficiaries could be disadvantaged if cost savings result from increased difficulty in obtaining needed drugs.

Plans did not have full flexibility around formulary decisions and other approaches to cost management. The MMA requires that plan bids be turned down if the proposed design and benefits are “likely to substantially discourage enrollment by certain beneficiaries.” The Centers for Medicare and Medicaid Services (CMS) stated in the final rule governing the benefit that there must be “adequate coverage of the types of drugs most commonly needed by enrollees, as recognized in national treatment guidelines.” This rule aims to protect beneficiaries through measures ensuring that formularies are not overly restrictive.⁹ A plan must at minimum cover two drugs in each therapeutic class, and

it must cover most or all drugs in certain designated classes, such as those for drugs used to treat certain mental health conditions, HIV/AIDS, and some cancers. Beneficiaries are also protected by rules that allow them to request exceptions to plan formularies and to appeal most situations where coverage of a drug is denied.

The competing drug plans appear to have made significantly different decisions about their formularies. Most plans cover a high proportion of the most commonly used drugs, but still do not cover all of the top 200 or even the top 10 drugs (Figure 4).¹⁰ Plans may have chosen to omit some drugs that have therapeutically similar competitors, for example, covering Lipitor but not Zocor as a treatment for high cholesterol.



Plans may also choose to use cost management tools such as prior authorization (i.e., plan approval of a particular drug before the prescription can be filled), step therapy (i.e., requirement that a less expensive drug be used before the originally prescribed drug can be obtained), or quantity limits (i.e., restrictions on how many pills can be obtained at one time).¹¹ Early evidence suggests that some plans are flagging a substantial number of drugs with these restrictions, while other plans use them far more sparingly. Currently, however, it is not possible to determine exactly how these restrictions will work.

Beneficiaries have a wide choice of plans with considerable differences in terms of premiums charged, cost-sharing, availability of drugs, and restrictions on drug use.

Although the law and regulations were designed to ensure basic standards in terms of drug costs and availability, it is too early to know whether certain plan benefit designs will place a substantial burden on beneficiaries to get the drugs they need; whether plans will succeed in obtaining meaningful discounts on the price of preferred drugs; or whether the cost of the benefit to beneficiaries and taxpayers will be close to the levels estimated at the time the law was passed.

RELATIONSHIP OF PART D TO EXISTING COVERAGE

The role of Medicare Part D differs substantially depending on a beneficiary’s situation. For some people, the best option will be to stay with current coverage. For others, Medicare Part D will provide coverage not previously available or will replace their current source of coverage (Table 2).

Table 2. Part D Options Based on Source of Current Coverage

Source of Existing Coverage	Future Under Part D
Former employer	Retain if creditable coverage and not discontinued
Medicaid	Auto-enrolled in a Part D plan
Medicare Advantage (MA)	Obtain coverage through the MA plan
Medigap plan	Option of switching to a Part D plan
State pharmacy program	In most states, use state plan as a wrap-around to Part D
VA, Tricare	Retain current coverage
No coverage	Option of joining a Part D plan

Source: Author’s calculations based on the Medicare Modernization Act of 2003.

Most beneficiaries with coverage through former employers can expect to retain it, at least for a while.¹² Employers must determine whether their coverage is at least equivalent to that provided under Part D. Enrollees are allowed to keep creditable employer coverage and avoid the late penalties charged to those who do not sign up during the initial enrollment period. As an incentive for employers to continue offering retiree drug coverage, Medicare is offering a tax-free subsidy equal to 28 percent of allowable drug costs between \$250 and \$5,000.

Most beneficiaries with an employer-based option are expected to keep this typically richer coverage and avoid the disruption of moving into Part D. About four of every five large employers report that they are accepting the subsidy and continuing to provide benefits in 2006, although only about half of these say they are likely to do so in 2010. Ten percent of employers will move retirees into Part D plans and provide wraparound coverage, and nearly 10 percent will discontinue drug coverage. Overall,

employers typically anticipate savings in the range of 7 percent of the overall costs of retiree health benefits as a result of Part D.¹³

About 6.3 million dually eligible beneficiaries—who had been receiving drug coverage from Medicaid—are now required to switch to Part D plans. State Medicaid agencies may still receive federal matching dollars to cover drugs excluded from the Medicare benefit, but not for drugs that are excluded from a plan’s formulary.¹⁴ A few states will pay for off-formulary drugs with state dollars.¹⁵

To ease the transition, dually eligible beneficiaries were automatically enrolled for the low-income subsidy and were randomly auto-enrolled in a Part D plan if they did not choose one by January 1, 2006.¹⁶ Medicaid beneficiaries, if they are enrolled in one of the eligible Medicare drug plans, will not have to pay premiums or deductibles, not face a coverage gap, and make copayments of between \$1 and \$5 (depending on their income level and whether a drug is generic or brand name) until they reach the catastrophic threshold. Although some of these beneficiaries had no copayments at all under Medicaid, they will now face nominal per prescription costs and could find that some of the drugs they have been taking are not on their new plan’s formulary. The MMA contains provisions designed to ease the transition from Medicaid to Medicare under these circumstances.

Beneficiaries currently enrolled in MA plans should receive drug coverage that is at least as good as standard Part D coverage through an MA drug plan option. Many MA plans are offering coverage without an added premium and many are providing enhanced coverage. Because many plans had reduced the scope of their coverage in recent years, most enrolled beneficiaries will see improvements.

Most beneficiaries with privately purchased supplemental insurance, called Medigap, are expected to switch into Part D plans. No new Medigap policies with drug coverage can be sold, although those with such coverage have the option of retaining it. Medigap policies have high premiums for relatively thin benefits and do not qualify as creditable coverage. As a result, policyholders have a strong incentive to switch to Part D plans and should get better coverage at a lower price.

In some states, beneficiaries have had the option of obtaining coverage through state pharmacy assistance programs. Typically, these programs, which are operated with state funds, provided coverage to beneficiaries with incomes below a certain threshold but not low enough to make them eligible for Medicaid. Most of the larger state programs

will continue to be available, though most are shifting to coverage that wraps around Part D.¹⁷ Beneficiaries eligible for these state pharmacy assistance programs typically will maintain coverage at least as generous as they had previously, while the states will have reduced costs because Medicare will now pay a portion of the drug costs.

There are limited options for beneficiaries who wish to supplement the coverage offered by Part D plans. In most cases, supplemental coverage is discouraged as Medicare catastrophic coverage only applies after a beneficiary's out-of-pocket costs exceed the threshold (\$3,600 in 2006). Generally, costs paid by a supplemental insurer do not count toward this total. Qualified state pharmacy assistance programs are an exception to this rule, in that the costs they cover do count toward a beneficiary's out-of-pocket costs. Costs paid by family members or charitable organizations also count, but the government has ruled that costs paid by the patient assistance programs run by drug manufacturers generally do not count toward out-of-pocket costs.

Some private drug plans are offering plan options with enhanced benefits. For example, some are offering coverage for at least some expenses in the gap. Premiums for these plans are normally higher than those for standard coverage, and federal funds cannot subsidize this added premium amount. In addition, the costs that are paid under this coverage are not included in out-of-pocket costs, thus effectively increasing the threshold for catastrophic coverage.

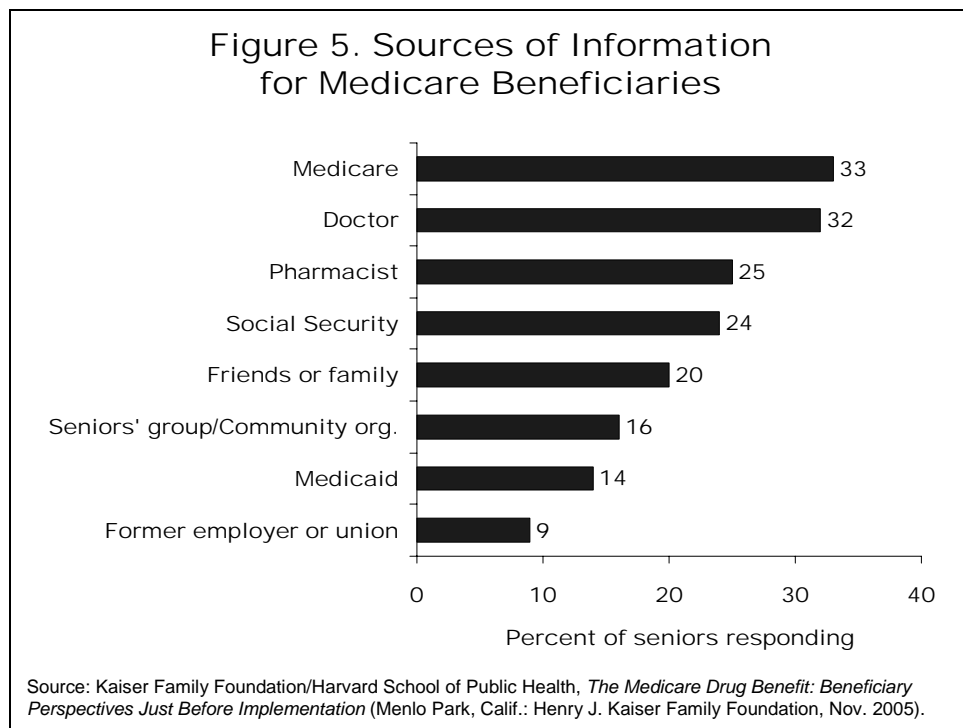
EDUCATION, MARKETING, AND ENROLLMENT

The Medicare program faces a great challenge in educating beneficiaries about the new benefit. Because it represents a major departure from other benefits under Medicare, this task is quite different than previous situations when beneficiaries were informed about new preventive health benefits or health plan options under Medicare+Choice and MA.

First, beneficiaries need to learn enough about the program to decide whether to enroll. Next, they must determine their possible eligibility for the low-income subsidy. Finally, beneficiaries who enroll in Part D must sort through the array of choices—both the standalone prescription drug plans and the MA plans. One incentive for enrollment, even for those with modest drug costs, is a penalty that will be imposed for late enrollment. Beneficiaries who sign up after the end of the initial open enrollment season (May 15, 2006) and do not have creditable coverage from another source will pay a larger premium (increased by 1 percent of the premium amount for each month not enrolled) for the duration of their participation in the program.¹⁸ Thus, a beneficiary without creditable coverage who decides in July 2006 that he or she wants to enroll must wait for

the November open season to choose a plan effective in January 2007; in addition, this beneficiary will pay a premium surcharge of about 7 percent. This is to discourage people from deferring enrollment until they have substantial drug costs. If those with lower drug costs enroll along with beneficiaries whose costs are higher, then both plan premiums and total costs to the federal government should be lower.

According to a survey conducted in October 2005 by researchers at the Kaiser Family Foundation and the Harvard School of Public Health, beneficiaries are expected to turn to a variety of sources when deciding whether to enroll in a Medicare drug plan (Figure 5).¹⁹ After the Medicare program itself, the two sources cited most frequently were doctors and pharmacists, followed by the Social Security office, friends or family members, and local seniors' groups or community organizations. Doctors and pharmacists have needed to become informed about the new program, as they are among the preferred information sources for many beneficiaries. This has presented a challenge for these busy professionals, given the complexity of the program. In addition, many pharmacies are partnering with drug plans, which sometimes creates conflicts of interest.



CMS is running an extensive information campaign that includes mailings, flyers, advertising, a toll-free telephone line (1-800-Medicare), and Web site (www.medicare.gov). The Social Security Administration also has been conducting extensive outreach, especially to individuals likely to be eligible for the low-income

subsidy. Yet, according to the Kaiser survey, half of seniors were unfamiliar with the toll-free line and two-thirds were unfamiliar with the Medicare Web site. Few of the seniors who were aware of the resources had ever used them.

Other sources of information are available, though it is unclear whether they are sufficient to meet the demand. State health insurance assistance programs receive state and federal funding to provide general outreach and individualized counseling. Yet, the strength of these programs varies from state to state, and most states rely on volunteers to do much of the work. While such programs can provide the one-on-one counseling that many beneficiaries need, they generally lack the resources to reach large numbers of people.

Other state agencies also play critical roles in reaching out to beneficiaries. State Medicaid programs are typically helping to educate dually eligible beneficiaries and state pharmacy assistance programs (operating in nearly half the states) are trying to ensure their enrollees know what they need to do. Although states—many already facing increased costs due to the new benefit—have found it difficult to take on additional educational campaigns, many stepped in with help when dually eligible beneficiaries ran into problems with the benefit's startup in January.

Private organizations are playing critical roles. AARP, a key backer of the legislation in 2003, has committed significant resources to educating beneficiaries through its local chapters and national media campaigns. At the same time, because AARP is a plan sponsor, their advice may not be viewed as unbiased. Many health-related groups (i.e., those focused on specific health conditions such as cancer, diabetes, or HIV/AIDS) are working to educate their constituencies. In addition, over 100 organizations in about 35 states are participating in the Access to Benefits Coalition to educate Medicare beneficiaries with lower incomes.

Finally, individual plan marketing is playing a role in the educational process. Some plan sponsors are taking an aggressive approach to marketing their products, while others appear to be more passive players. Some organizations are using television and radio advertising or mass mailings and some are working with partners, such as pharmacy chains. For others, marketing may take place more quietly, working through insurance agents and the supplemental insurance policies with which beneficiaries already have relationships.

It remains to be seen how successful the educational efforts will be in helping beneficiaries make decisions. When the legislation was passed, the Congressional Budget

Office (CBO) forecast that about 29 million beneficiaries, including those enrolled in MA plans, would sign up by the end of 2006. It is not yet known whether this goal will be met, particularly during the initial open enrollment period. Early numbers reported by CMS place enrollment (as of January 13, 2006) at 14.3 million, three-fourths of whom were dually eligible beneficiaries assigned to plans or beneficiaries adding Part D coverage to existing Medicare Advantage coverage.²⁰

CBO further estimated that 8.7 million beneficiaries, or about 60 percent of those eligible, would receive the low-income subsidy in 2006, rising to 11.2 million beneficiaries, or 70 percent of those eligible, by 2013. This total includes dually eligible beneficiaries, who qualify automatically for the subsidy; CBO estimated that only about 45 percent of the remaining eligible population would receive the subsidy by 2013.²¹ As of the end of 2005, 1.1 million beneficiaries (in addition to the 6.2 dually eligible beneficiaries) were determined to be eligible for the subsidy. Another 2.5 million applicants were rejected as a result of excess income, assets, or both.²²

Several factors are likely to influence enrollment in Part D and determine which plans achieve the highest enrollment levels. In general, enrollment is most likely to reach forecast levels if marketing and education efforts increase general awareness and help beneficiaries to sift through the wide array of choices. Making beneficiaries more aware of the late enrollment penalty could also become a factor in convincing those with lower costs to enroll.

Previous programs have not met enrollment expectations. For example, enrollment for the Medicare prescription drug discount card amounted to some 6.4 million beneficiaries, including 1.9 million low-income beneficiaries who signed up for the \$600 annual transitional assistance benefit. CBO estimated that “15 percent of Medicare beneficiaries would be eligible for such transitional benefits under the MMA, and about 20 percent of those eligible (or nearly one million individuals in 2005) will ultimately enroll.”²³ Nearly two-thirds of those receiving cards were auto-enrolled by MA plans, state pharmacy assistance programs, or CMS. Two factors associated with this low enrollment—beneficiary confusion and the large number of options—potentially apply to the Part D program.²⁴ Enrollment in the Medicare Savings program, which helps low-income beneficiaries with premiums, is estimated to be only about half of those eligible. In this case, a key barrier is the use of asset tests, which complicate the application process and could do the same in the drug benefit.²⁵

Medicare Part D is getting more attention from the general public than these programs and could see different results. But lower-than-expected enrollment not only could have political implications, but could also lead to higher premiums in future years if enrollment is concentrated among those with high drug costs.²⁶

Low enrollment could also lead to some plans exiting the market in 2007, threatening the program's stability and forcing some beneficiaries to change plans. Plans that do not achieve levels of enrollment necessary to support their operational costs cannot be expected to stay in the market unless their continued presence serves other corporate goals. It is too soon to speculate which plans will succeed, but low premiums, low overall costs for typical beneficiaries, name recognition, and successful marketing and partnership strategies seem likely to be key factors.

MONITORING IMPLEMENTATION, MAKING MID-COURSE CORRECTIONS

The overall success of the Medicare Part D program will be measured in the court of public opinion by enrollment numbers and the general satisfaction of beneficiaries. Congress will have the opportunity to make mid-course corrections or more fundamental changes to the program's design.

There are several measures beyond enrollment that should be examined as indicators of success. One is the overall cost of the program. Low costs can indicate success if they signify that plans have negotiated low prices and managed drug utilization successfully. However, they can also be the result of low enrollment or the failure of beneficiaries to fill needed prescriptions. It will also be important to monitor drug utilization as a measure of success—perhaps looking at overall rates of prescriptions filled, individual reports on whether needed drugs are skipped, and utilization rates of clinically important medications.

Although difficult to measure in the short term, another key indicator is the drug benefit's impact on the use of Medicare hospital and physician services and the resulting costs to the broader Medicare program. Appropriate use of drugs should eliminate some avoidable use of these services. Because standalone private drug plans are shielded from the impact of these effects, program officials and outside researchers may want to study whether and how these effects play out and create measures that track these trends.

The stability of the program and the satisfaction of beneficiaries are also important indicators. Is there a high level of switching from one plan to another at the end of the

first year, and is that due to dissatisfaction with plan performance? Is there heavy reliance on exceptions and appeals processes to obtain needed drugs? If so, are beneficiaries and their doctors satisfied with how these processes work? Do the operational aspects of drug plans work well, including call centers, prior authorization processes, and claims processing? CMS has mandated that plans report some of these measures each year but has not revealed much about how it will use these measures and whether information will be available to outside researchers or to the public.

Over time, the success of the market-based approach will be determined by the evolution of the Part D plan market. Almost certainly, there will be market consolidation after the first year or two as plans modify their offerings and less successful plans leave the market or are bought out by other companies. But a substantial amount of plan instability and market shifting over time would have longer-term consequences. If beneficiaries are forced to change plans on a regular basis, dissatisfaction will be high and costs could rise as well. If plans find that costs are difficult to manage, substantial premium increases could become a regular feature, with consequences for both beneficiaries and taxpayers.

As policymakers monitor the program in 2006, there are at least two likely legislative scenarios. If enrollment is high, beneficiaries are happy with the benefits provided, and costs do not escalate wildly, then significant legislative changes are probably unlikely. On the other hand, if expectations are not met, Congress may consider making adjustments.

Should enrollment fall below expected levels, especially for low-income beneficiaries, Congress could act on proposals to extend the initial enrollment period beyond May 15, 2006; delay imposition of the late-enrollment penalty for the first year; and take measures to ease transitions for dually eligible beneficiaries.²⁷ Most of these provisions could potentially gain bipartisan support, particularly if low enrollment appears to threaten the benefit's success. If asset tests appear to be an impediment to beneficiaries applying for the low-income subsidy, Congress may consider modifying or eliminating them. If confusion over plan choices appears to be a key factor in low enrollment, policymakers could propose standardization or constraints on plan flexibility.

The issue for most dually eligible beneficiaries is not enrollment—they are auto-enrolled if they do not pick a plan themselves—but whether they will have difficulty navigating the system and obtaining drugs. It will be important to monitor whether the plans eligible serve the needs of these beneficiaries. Many dually eligible beneficiaries faced difficulties when first going to a pharmacy in January to fill a prescription. Most such

problems occurred either because they were not properly recognized in plan data systems as enrollees or as eligible for reduced cost-sharing, or because their drugs were absent from plan formularies. Many states stepped in to provide temporary assistance, and CMS has strengthened the requirements on plans to fill initial prescriptions in these transition situations. But many of these beneficiaries are discovering that the plan to which they were randomly assigned is not the best plan for them. If these types of problems persist, Congress may consider changing the rules that affect these beneficiaries.

Understanding the system and getting needed drugs could be a concern for all beneficiaries. Some members of Congress may seek to add more protections beyond those now in the law. Steps are already under way to reexamine the regulatory guidance around formularies and the drug classification system on which formularies are based. However, if significant access problems are discovered, more substantial changes could result.²⁸

According to some members of Congress, program enhancements have the potential to improve access to drugs at an affordable price. Some Democrats are pushing for an expansion of the benefit—for example, by filling in the coverage gap.²⁹ Democrats can also be expected to continue their push to give the Secretary the authority to negotiate over Part D drug prices—a provision that has a lot of popular support but generates strong opposition from pharmaceutical manufacturers, among others.

To those interested in monitoring the implementation of the benefit, data issues are critical. The private drug plans will generate considerable individual drug utilization data. Although the government will receive claims data from the plans, use of these data appears limited by law to the refinement of the risk adjustment system and other uses related to payment. Drug claims data can have broader value in monitoring quality of care and provider performance. They have potential value in the management of other Medicare services (e.g., disease management programs) or for monitoring the effectiveness of different drugs and drug regimens in treating major health conditions. Policymakers may consider expanded uses for drug claims data beyond the narrow auditing and oversight purposes envisioned at present. In fact, CMS has already indicated its intent to consider use of claims data for certain types of post-market drug studies.

The projected cost of the Medicare Part D benefit was a major political issue surrounding the enactment of the MMA, and actual costs will have a huge impact on the benefit's future. These issues could become more acute in light of the “Medicare trigger.” Created by the MMA, the trigger provision calls for the Medicare Trustees to issue a warning when general revenues are projected to finance more than 45 percent of total

Medicare spending. If this warning were issued in two consecutive years, the president would be required to submit a legislative proposal to address the problem, which would have special fast-track consideration in Congress. Current forecasts suggest that this second warning will occur in the next few years. This could reopen broader Medicare reform issues, and the Medicare drug benefit might be at the center of this debate.

Some fiscal conservatives have already proposed repealing Part D, while others have revived prior proposals to restrict it to low-income beneficiaries. Other policy leaders may use this debate to push proposals to integrate the drug benefit into the broader Medicare package, such as by offering beneficiaries a comprehensive benefit option that eliminates the need to purchase private drug coverage or Medigap (e.g., a new Medicare Part E).³⁰

CONCLUSION

Policymakers will have at least some high-level measures of Medicare Part D's success within the first year of the program, and beneficiaries' reactions to the benefit could play an important role in the 2006 congressional elections. Other signs of success or failure will only be available after a full year, when various types of data can be collected and made available to Congress and the public. As is true for many complex public policy issues, political decisions may have to be made more quickly than the measurements can be collected and analyzed. One thing is certain: Medicare Part D will continue to receive considerable attention from researchers, beneficiaries, and policymakers throughout its first year and beyond.

NOTES

¹ B. Stuart, B. A. Briesacher et al., “Riding the Rollercoaster: The Ups and Downs in Out-of-Pocket Spending Under the Standard Medicare Drug Benefit,” *Health Affairs*, July/Aug. 2005 24(4):1022–31.

² In addition, plans that covered brands and generics nearly always subjected coverage to a cap. L. Achman and M. Gold, *Are the 2004 Payment Increases Helping to Stem Medicare Advantage’s Benefit Erosion?* (New York: The Commonwealth Fund, Dec. 2004). See also B. Biles, G. Dallek, and L. H. Nicholas, “Medicare Advantage: Déjà Vu All Over Again?” *Health Affairs* Web Exclusive (Dec. 15, 2004):W4-586–W4-597.

³ B. Stuart, D. Shea, and B. Briesacher, *Prescription Drug Costs for Medicare Beneficiaries: Coverage and Health Status Matter* (New York: The Commonwealth Fund, Jan. 2000).

⁴ D. G. Safran, P. Neuman et al., “Prescription Drug Coverage and Seniors: Findings from a 2003 National Survey,” *Health Affairs* Web Exclusive (Apr. 19, 2005):W5-152–W5-166.

⁵ J. Mays, M. Brenner et al., *Estimates of Medicare Beneficiaries’ Out-of-Pocket Drug Spending in 2006: Modeling the Impact of the MMA* (Washington, D.C.: Kaiser Family Foundation, Nov. 2004).

⁶ Actual premiums average less than the projections used in this study, so savings would be somewhat larger.

⁷ There are five regions for the territories. The market in these regions is quite different than that for the other regions. Among the national plans, only United Healthcare offers plans in all of these five regions.

⁸ These qualifying plans cannot offer enhanced benefits. If they do, beneficiaries must pay for the value of the enhanced benefit even if the premium is lower than the benchmark.

⁹ J. Hoadley, *The Effects of Formularies and Other Cost Management Tools on Access to Medications: An Analysis of the MMA and the Final Rule* (Washington, D.C.: Kaiser Family Foundation, Mar. 2005).

¹⁰ CMS provides information on the Medicare.gov Web site on how many of the top 200 drugs are covered by the competing plans. These drugs are defined as the drugs most commonly obtained by Medicare beneficiaries through the Medicare discount card program.

¹¹ J. Hoadley, *Cost Containment Strategies for Prescription Drugs: Assessing the Evidence in the Literature* (Washington, D.C.: Kaiser Family Foundation, Mar. 2005).

¹² Similarly, beneficiaries receiving drug coverage through the Veterans Administration or Tricare will be able to maintain their current coverage.

¹³ Kaiser Family Foundation and Hewitt Associates, *Prospects for Retiree Health Benefits as Medicare Prescription Drug Coverage Begins: Findings from the Kaiser/Hewitt 2005 Survey on Retiree Health Benefits* (Washington, D.C.: Kaiser Family Foundation and Hewitt Associates, Dec. 2005).

¹⁴ The MMA excludes coverage for several categories of drugs, including benzodiazepines, barbiturates, drugs used for weight loss or weight gain, and drugs used for cosmetic purposes. Many states have decided to continue using Medicaid dollars to cover some of these categories, especially benzodiazepines.

¹⁵ States are also required to pay for a share of the Medicare benefit through a mechanism known as the clawback. Many states maintain that their clawback costs will be higher than their costs in providing benefits through Medicaid, since many had taken effective steps to manage their costs. See, for example, A. Schneider, *The “Clawback”: State Financing of Medicare Drug Coverage* (Washington, D.C.: Kaiser Family Foundation, June 2004).

¹⁶ About 200,000 dually eligible beneficiaries who are enrolled in Medicaid managed care plans may be auto-enrolled in that plan's Medicare Advantage plan unless they opt out.

¹⁷ C. Williams, S. Goodell, J. Hoadley, et al., *State Pharmacy Assistance Programs at a Crossroads: How Will They Respond to the Medicare Drug Benefit?* (Washington D.C.: AcademyHealth, July 2005). A forthcoming paper will highlight final state decisions in this area.

¹⁸ Individuals who first become eligible for Medicare after December 31, 2005, have until three months after their date of eligibility to enroll before they are subject to a late enrollment penalty.

¹⁹ Kaiser Family Foundation and Harvard School of Public Health, *The Medicare Drug Benefit: Beneficiary Perspectives Just Before Implementation* (Nov. 2005).

²⁰ Kaiser Family Foundation, *Medicare Prescription Drug Coverage Enrollment Update* (Washington, D.C.: Kaiser Family Foundation, Jan. 2006).

²¹ Congressional Budget Office, *A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit* (Washington, D.C.: U.S. GPO, July 2004).

²² Kaiser Family Foundation, *Medicare Prescription Drug Coverage Enrollment Update* (Washington, D.C.: Kaiser Family Foundation, Jan. 2006).

²³ Congressional Budget Office, *A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit* (Washington, D.C.: U.S. GPO, July 2004).

²⁴ Enrollment was that projected by CMS, although above CBO's projection. Government Accountability Office, *Medicare: CMS's Beneficiary Education and Outreach Efforts for the Medicare Prescription Drug Discount Card and Transitional Assistance Program* GAO-06-139R, Nov. 18, 2005. See also Medicare Payment Advisory Commission, *Report to the Congress: Issues in a Modernized Medicare Program* (Washington, D.C.: MedPAC, June 2005).

²⁵ L. Summer and L. Thompson, *How Asset Tests Block Low-Income Medicare Beneficiaries from Needed Benefits* (New York: The Commonwealth Fund, May 2004).

²⁶ Avalere Health LLC, *The Impact of Enrollment in the Medicare Prescription Drug Benefit on Premiums* (Washington, D.C.: Kaiser Family Foundation, Oct. 2005).

²⁷ Proposals for these types of changes have already been introduced; in fact, one such measure received 51 votes in the Senate (although under rules that required 60 votes for passage).

²⁸ Proposals have already been advanced in Congress to make adjustments to drugs covered under Part D. In October 2005, Congress excluded drugs for erectile dysfunction from Part D effective in 2007. In addition, bills have been introduced to add some categories of drugs that are excluded from the benefit (such as benzodiazepines), and there is also interest in addressing the interaction between physician-administered drugs that are potentially covered in either Part B or Part D.

²⁹ The coverage gap is expected to affect at least one-fourth of those enrolled in Part D. This group will draw disproportionately from those with chronic health conditions. See J. Mays, M. Brenner et al., *Estimates of Medicare Beneficiaries' Out-of-Pocket Drug Spending in 2006: Modeling the Impact of the MMA* (Washington, D.C.: Kaiser Family Foundation, Nov. 2004); M. Moon, *How Beneficiaries Fare Under the New Medicare Drug Bill* (New York: The Commonwealth Fund, June 2004).

³⁰ K. Davis, M. Moon, B. S. Cooper, and C. Schoen, "Medicare Extra: A Comprehensive Benefit Option for Medicare Beneficiaries," *Health Affairs* Web Exclusive (Oct. 4, 2005): W5-442-W5-454.