HEALTH POLICY REPORT

# Medicare Part D Update — Lessons Learned and Unfinished Business

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Since 2006, more than 40 million elderly and disabled people have had the opportunity to enroll in a Medicare Part D prescription-drug plan, as established under the Medicare Modernization Act (MMA) of 2003. Members of Congress, deeply divided by policy and ideological differences, debated several features of the proposed legislation before its passage.[1] Issues that received particular scrutiny were the unprecedented way that the benefit would be delivered (exclusively through private plans) and its design, featuring an unusual gap in coverage (sometimes called the "doughnut hole"). Policymakers questioned whether insurance companies would be willing to offer stand-alone drug plans, how many beneficiaries would choose to enroll in a voluntary program, and how the program would affect drug prices and overall Medicare spending.[2]

With the fourth year of Medicare Part D under way, the Obama administration and the Democratically controlled Congress have an opportunity to review the program and identify areas for improvement. In this article, we return to several key questions raised during the 2003 congressional debate and in the years leading up to the start of the program. We review evidence that has accumulated since the benefit launched in 2006 and discuss issues that may emerge on the policy agenda.

## ASSESSING THE EVIDENCE

### HAS PART D IMPROVED ACCESS TO DRUG COVERAGE?

Medicare Part D provides beneficiaries access to a government-subsidized prescription-drug benefit offered by private insurers and pharmacy benefit managers. This approach stands in contrast

**Table 1. Medicare Part D Plans and Enrollment (2006–2009).***

| Variable | 2006 | 2007 | 2008 | 2009 | Change from 2006 to 2009 |
|---|---|---|---|---|---|
| Medicare D plans (no.)† | | | | | |
| Stand-alone prescription-drug plan | 1429 | 1866 | 1824 | 1689 | +260 |
| Medicare Advantage | 1333 | 1562 | 1898 | 2099 | +766 |
| Low-income subsidy‡ | 409 | 483 | 442 | 308 | –101 |
| Average no. of stand-alone prescription-drug plans per region | 42 | 55 | 54 | 50 | +8 |
| Enrollment in Medicare Part D plans (millions of beneficiaries) | | | | | |
| Total | 22.5 | 23.9 | 25.4 | 26.7 | +4.1 |
| Stand-alone prescription-drug plan | 16.4 | 17.3 | 17.4 | 17.5 | +1.0 |
| Medicare Advantage | 6.1 | 6.7 | 8.0 | 9.2 | +3.1 |
| Low-income subsidy‡ | 9.3 | 9.2 | 9.4 | 9.6 | +0.4 |

* Data are from the Centers for Medicare and Medicaid Services (CMS). Numbers may not add up to the total number in each category because of rounding.
† Data do not include Medicare beneficiaries in U.S. territories.
‡ Low-income Medicare beneficiaries who are also eligible for Medicaid are enrolled by the CMS in a lower-premium stand-alone drug plan with the use of a random-assignment process, unless they have already enrolled on their own.

to the way in which all other Medicare benefits are covered under the traditional fee-for-service program. The MMA authorized the creation of a new insurance product, called stand-alone prescription-drug plans, to supplement the fee-for-service Medicare program; it also authorized Medicare health maintenance organizations and other private plans that provide all Medicare-covered benefits (now called Medicare Advantage plans) to provide the Part D benefit.

*Availability of Part D Plans*

A major source of uncertainty was whether private insurers would be willing to sponsor stand-alone prescription-drug plans. Tom Scully, administrator of the Centers for Medicare and Medicaid Services (CMS) from 2001 to 2003, observed in 2003 that stand-alone drug plans "don't exist in nature and won't work in practice."[3] To encourage plan participation in an untested market, the architects of Part D included a risk-sharing provision (known as "risk corridors") to limit insurers' potential losses. In the event of a lackluster response from insurers, the law also authorized the Secretary of the Department of Health and Human Services to administer a "fallback" drug plan in any region with fewer than two stand-alone plans.

Ultimately, concern about the viability of the private-drug-plan market was unwarranted, since plan sponsors seized on the opportunity created by Part D to expand their profit base and market share. In 2006 and each year thereafter, beneficiaries across the country have had access to dozens of stand-alone plans and, in many counties, at least as many Medicare Advantage drug plans (Table 1). Whether the market would have been as robust without the presence of risk corridors, and whether the widening of risk corridors between 2007 and 2008 that shifted greater risk onto insurers will result in fewer plans over time, are unknown.

*Part D Enrollment*

A primary goal of the MMA was to provide access to drug coverage to beneficiaries who did not have such coverage in another plan. Nevertheless, Part D was designed as voluntary, both to forestall political backlash against a compulsory program and to allow beneficiaries to retain their existing drug coverage from employer-sponsored retiree health plans and other sources.

The evidence on Part D enrollment and drug coverage is mainly, but not altogether, positive. By June 2006, just after the first enrollment period ended, approximately 90% of all Medicare beneficiaries had prescription-drug coverage,[4] up from 66% in 2004.[5] By 2009, nearly 60% of Medicare beneficiaries were enrolled in a Part D plan (17.5 million in stand-alone plans and 9.2 million in Medicare Advantage drug plans), and about one third have coverage from retiree health plans or other sources, such as the Department of Veterans Affairs (Fig. 1).[6]

Still, more than 4 million Medicare beneficiaries lacked drug coverage in 2006, and about the same number remain without it in 2009.[4,6] Many of those without coverage report being in good health and having little need for medications.[7-9] However, other beneficiaries could be at increased risk for being exposed to high drug costs or going without needed medications, including those over the age of 75 years, those with low incomes, and those with less education.[7,10] Beneficiaries without drug coverage could face substantial penalties for delayed enrollment in Part D in the future.

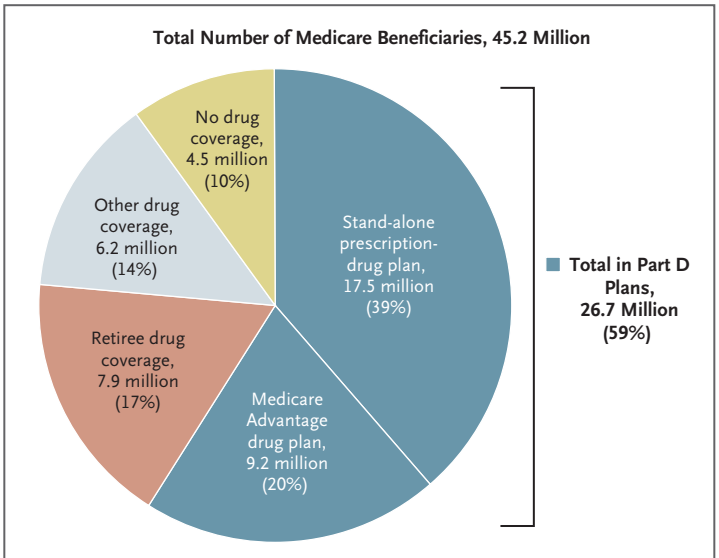


**Figure 1. Prescription-Drug Coverage among Medicare Beneficiaries in 2009.**
Data are from the Centers for Medicare and Medicaid Services (as of February 1, 2009). The category of "other drug coverage" includes the Department of Veterans Affairs, retiree plans without retiree drug subsidies, the Indian Health Service, state pharmacy-assistance programs, employer plans for active workers, Medigap, multiple sources, and other sources. The category of "retiree drug coverage" includes retiree drug-subsidy coverage and coverage for federal workers and members of the military.

**Table 2. Medicare Part D Plan Features, Cost Sharing, and Premiums (2006–2009).***

| Variable | 2006 | 2007 | 2008 | 2009 |
|---|---|---|---|---|
| Standard benefit measure ($) | | | | |
| Deductible | 250 | 265 | 275 | 295 |
| Initial coverage limit | 2,250 | 2,400 | 2,510 | 2,700 |
| Catastrophic limit | 5,100 | 5,451 | 5,726 | 6,154 |
| Coverage gap† | 2,850 | 3,051 | 3,216 | 3,454 |
| Prescription-drug plans (% with feature)‡ | | | | |
| Deductible | 42 | 40 | 42 | 45 |
| Defined standard-benefit design | 9 | 12 | 12 | 10 |
| Gap coverage | | | | |
| Stand-alone prescription-drug plan | | | | |
| No gap coverage | 85 | 72 | 71 | 75 |
| Generic drugs only | 13 | 27 | 29 | 25 |
| Brand-name and generic drugs | 2 | 1 | 0 | 0 |
| Medicare Advantage plan | | | | |
| No gap coverage | 72 | 68 | 49 | 49 |
| Generic drugs only | 23 | 27 | 34 | 34 |
| Brand-name and generic drugs | 5 | <1 | 17 | 17 |
| Median cost sharing ($) | | | | |
| Stand-alone prescription-drug plan | | | | |
| Generic drugs | 5 | 5 | 5 | 7 |
| Preferred brands | 28 | 28 | 30 | 37 |
| Nonpreferred brands | 55 | 60 | 72 | 75 |
| Medicare Advantage plan | | | | |
| Generic drugs | 5 | 5 | 5 | 5 |
| Preferred brands | 27 | 29 | 30 | 30 |
| Nonpreferred brands | 55 | 60 | 60 | 60 |
| Stand-alone prescription-drug plan premium ($) | | | | |
| Weighted average per month | 25.93 | 27.39 | 29.89 | 35.09 |
| Range | 1.87–104.89 | 9.50–135.70 | 9.80–107.50 | 10.30–136.80 |

* Amounts for measures of standard benefit and cost sharing have been rounded to the nearest dollar. Data are from the Kaiser Family Foundation, Hoadley et al.,[11] Hargrave et al.,[12] and the Centers for Medicare and Medicaid Services.
† The coverage gap is the difference between the initial coverage limit and the catastrophic limit.
‡ The values for the deductible and defined standard-benefit design are for stand-alone prescription-drug plans only.

## DOES PART D PROVIDE SUFFICIENT BENEFITS?

### *Standard Benefit*

The MMA defined a "standard benefit" for Part D plans, consisting of a deductible, 25% coinsurance up to an initial coverage limit, a gap in coverage in which enrollees pay the full cost of their prescriptions, and catastrophic coverage (Table 2 and Fig. 2). Most Part D sponsors, however, do not offer the standard benefit: a majority of stand-alone plans have no deductible, charge a fixed dollar amount for generic and brand-name drugs, and place high-priced "specialty" drugs on a separate cost-sharing tier.[11] Yet, despite these commonalities, plans vary widely from one another, particularly with regard to tier placement of covered drugs and cost-sharing

amounts.[12,13] For example, in 2009, patients with Alzheimer's disease who were taking Aricept could have paid as little as $20 for a month's supply in one prescription-drug plan or as much as $88 in another.

*Gap Coverage*

As of 2009, the majority of Medicare drug plans — 75% of stand-alone plans and 49% of Medicare Advantage plans — did not offer coverage of the gap between the initial coverage limit and the catastrophic limit, the so-called doughnut hole (Table 2). Gap coverage is primarily limited to generic drugs.[14] The dearth of plans offering gap coverage has been a persistent feature of the Part D marketplace since 2006. Adverse selection has taken its toll on the small number of insurers that have offered full coverage of brand-name drugs in the gap. Two insurers that sponsored stand-alone drug plans with full gap coverage in most states in 2006 (Humana) and in 2007 (SierraRx) withdrew these plans after the first year because of revenue losses driven by higher-than-expected costs.

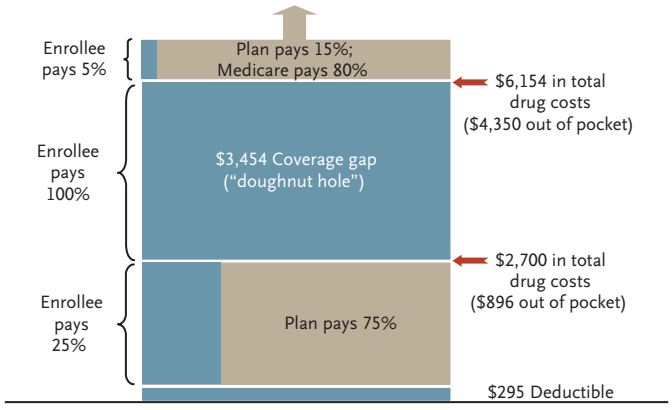


**Figure 2. Standard Medicare Prescription-Drug Benefit in 2009.**
Data are from the Centers for Medicare and Medicaid Services. The amounts for the coverage gap and the catastrophic coverage threshold have been rounded to the nearest dollar.

## HAS PART D MADE DRUGS MORE AFFORDABLE?

*Out-of-Pocket Spending*

A primary aim of Part D was to make prescription drugs more affordable for Medicare beneficiaries. Before the implementation of Part D, seniors who lacked drug coverage typically spent more for their medications than did those with drug coverage, despite filling fewer prescriptions.[15,16] Several studies have confirmed that out-of-pocket spending on medications by those who previously lacked drug coverage declined after the implementation of Part D.[17-20] These findings are in accordance with data on the substantial level of subsidies for Part D coverage, including extra help for low-income beneficiaries and those with catastrophic drug expenses.

Affordability continues to be a concern for Part D enrollees, particularly those who reach the coverage gap, where they are exposed to the full cost of their medications. One study reported that an estimated 3.4 million Part D enrollees reached the coverage gap in 2007, and most of these enrollees did not qualify for catastrophic coverage before the end of the year.[21] Among those who reached the coverage gap, average monthly out-of-pocket spending nearly doubled when they entered the gap.[21]

*Rising Premiums and Cost Sharing*

The financial protection offered by Part D could be undermined by increases in Medicare Part D premiums and cost-sharing requirements over time. Between 2006 and 2009, the weighted average monthly premium for prescription-drug plans increased by 35%, from $25.93 to $35.09 per month, with some of the more popular plans posting much steeper increases. The premium for AARP's MedicareRx Preferred plan, with 2.7 million enrollees in 2008, has increased by nearly 41% since 2006, whereas the premium for Humana Standard, with 1.5 million enrollees in 2008, has quadrupled.[22] Between 2008 and 2009, the increase in average monthly premiums was greater for more expensive, enhanced-benefit plans with some gap coverage (from $63.29 to $73.36, a 16% increase) than for less expensive, basic plans without gap coverage (from $30.14 to $33.80 per month, a 12% increase).

Since 2006, the standard benefit measures (deductible, initial coverage limit, and catastrophic limit) have increased by about 20%, reflecting growth in Medicare's per capita drug costs and automatically increasing the out-of-pocket liability of Part D enrollees (Table 2). Although cost sharing for generic drugs has remained low, median cost sharing in stand-alone plans for brand-name drugs is substantially higher and has increased by about 36% since 2006. Furthermore, since 2006, a growing share of Part D plans have

placed high-priced medications on a specialty tier, with coinsurance rates as high as 33%.[11,23] Available evidence suggests that rising cost-sharing requirements in Part D could result in the decision of some beneficiaries to forgo needed medications.

### HAVE BENEFICIARIES MADE "GOOD" CHOICES?

With the unexpectedly high number of Part D plans available in 2006 and each year thereafter, government officials have encouraged beneficiaries to review their drug needs and compare plans annually, taking into account costs, coverage, and convenience.[24] Yet skeptics continue to question how well this consumer-choice paradigm works for the Medicare population.

Assessing whether beneficiaries are making "good" choices is difficult, since the answer depends on each enrollee's preferences and circumstances, and little evidence has accumulated to resolve this question. To the extent that cost matters, a recent study found that most Part D enrollees did not enroll in one of the lowest-cost plans offered in their area in 2006.[25] And although low premiums appealed to many enrollees in 2006,[26] a relatively small share of enrollees (6%) switched to another Part D plan voluntarily between 2006 and 2007[27] and between 2007 and 2008,[28] despite fairly substantial increases in premiums in some of the more popular plans over time.[22,29] Plan "stickiness" could indicate that enrollees are satisfied with their current plan, regardless of changes in medication use or plan premiums and benefits. It could also indicate that enrollees doubt they could get better coverage from another plan or that they view the process of changing plans as too burdensome.[30]

### HOW HAVE LOW-INCOME BENEFICIARIES FARED?

The MMA included two key provisions related to Medicare beneficiaries with low incomes and limited assets. First, it established a low-income subsidy program to help qualified beneficiaries pay Part D premiums and cost sharing, including costs in the coverage gap. Second, it shifted the source of drug coverage for Medicare beneficiaries who are also enrolled in Medicaid (dual eligibility) from Medicaid to Medicare Part D. Enrollees with dual eligibility are automatically deemed eligible for the low-income subsidy program and are enrolled by the CMS in a lower-premium stand-alone drug plan with the use of a random-assignment process, unless they have already enrolled on their own.

By 2009, more than 9 million low-income beneficiaries were receiving additional Part D subsidies, which offered an important layer of protection. Recipients of low-income subsidies reported having substantially lower out-of-pocket drug costs than did low-income enrollees who were not receiving a low-income subsidy.[7] However, some concerns related to the experiences of low-income beneficiaries in Part D have emerged that remain to be resolved.

Foremost of these concerns is that about one fifth of the 12.5 million Medicare beneficiaries who are estimated to be eligible for a low-income subsidy are not receiving it.[6] Another concern is associated with the random-assignment process that is used to enroll beneficiaries with dual eligibility and certain other recipients of a low-income subsidy. This process has been criticized for not matching enrollees' medications to the formulary of their assigned plans. A third concern relates to annual changes in the availability of Part D plans for recipients of a low-income subsidy, which disrupted coverage or increased premiums for more than 2 million low-income beneficiaries between 2008 and 2009.[31] These changes result from the annual bidding process between the CMS and plan sponsors that determines which plans will be available to recipients of a low-income subsidy for no premium (known as "benchmark" plans because their monthly premium falls below a specified benchmark amount). Each year, some plans lose benchmark status, whereas others attain it, but the overall number of benchmark plans has declined since 2007 (Table 1). This instability can be attributed to sponsors' changing business strategies, premium increases reflecting higher total costs, and the unpredictable outcome of the annual bidding process.

### HOW HAS PART D AFFECTED DRUG PRICES?

Despite general agreement that adding a drug benefit to Medicare would help to make prescriptions more affordable for beneficiaries, policymakers who debated the design of Part D were deeply divided on how best to lower the level of drug prices. Many Democrats proposed authorizing the federal government to negotiate drug prices with pharmaceutical companies, leveraging the purchasing power of more than 40 million

Medicare beneficiaries. The Republican majority countered that private plans would be more effective at driving down prices because plans could use devices such as formulary design, tier placement, and cost sharing to influence the use of specific products. In the end, the MMA explicitly prohibited the federal government from engaging directly in the negotiation of drug prices with pharmaceutical companies. This provision was intended to assuage pharmaceutical-industry concerns about government intervention.

The evidence on the effects of Part D on drug prices is mixed. One study reported that Part D has helped to reduce the average price of prescription drugs used by enrollees who previously lacked drug coverage but also that prices decreased less (or increased more) for medications with limited substitutes.[32] Another study showed that price increases for drugs that are used disproportionately by the elderly were steeper than for drugs that are used primarily by the nonelderly during the period leading up to and after the implementation of Part D.[33] Studies have also documented higher prices for some drugs in Part D plans than in programs sponsored by the Department of Veterans Affairs[34] and higher prices and lower rebates under Part D than under Medicaid.[35-37] Critics argue that such comparisons are not entirely relevant and that efforts to use the other programs as benchmarks for Part D would dampen incentives for pharmaceutical research and development.[38]

Ultimately, the question of how Part D has affected drug prices is difficult to answer conclusively because critical pieces of information are not available to researchers. Plan sponsors are not required to publicly disclose information about price discounts and rebates, so nothing can be gleaned about the financial arrangements between the sponsors and pharmaceutical companies to evaluate whether some plans negotiate greater price discounts for certain drugs than for others. With insufficient data, it is difficult to assess whether the federal government and consumers are getting a good deal from pharmaceutical companies and Part D plans — and there is no way to measure what constitutes a good deal in this context.

### HOW HAS PART D AFFECTED MEDICARE SPENDING?

The effect of the Medicare drug benefit on government spending was, and continues to be, an issue of concern, particularly among fiscal conservatives who are apprehensive about the open-ended nature of the government's financial commitment that comes with expanding entitlement programs. Part D has been characterized as "the largest expansion of the welfare state since President Johnson's Great Society gave birth to Medicare in 1965."[39] Some conservatives viewed the $400-billion price tag for Part D as unaffordable, whereas some liberals proposed higher spending for more generous coverage that did not include a doughnut hole.

With a recent reduction in the national growth rate for prescription-drug costs and a shift in use from brand-name to generic drugs,[40] government spending on Part D has been lower than initially projected. In 2004, the Medicare actuaries projected that net Part D benefit payments would be $66 billion in 2007,[41] but actual payments that year were considerably lower, at $40 billion.[42] Medicare's actuaries have attributed lower-than-projected expenditures to a combination of factors, including lower-than-projected Part D enrollment, slower growth of drug prices in recent years, greater use of generic drugs, and higher-than-expected rebates.[42,43] With lower program costs now incorporated into future projections, it is unclear whether Medicare Part D spending can be further ratcheted down in the future under the current system, especially in light of recent projections that the growth in national spending on prescription drugs will rebound in the coming years as the generic dispensing rate levels off and new, expensive specialty drugs are approved.[44]

### HAS PART D IMPROVED QUALITY OF CARE AND HEALTH OUTCOMES?

Before the implementation of Part D, surveys confirmed that beneficiaries without drug coverage were not filling prescriptions, were skipping doses, and were splitting pills at troubling rates, which raised concern about the quality of care for patients who could not afford their medicines.[15,16] Extending drug coverage to beneficiaries who had no or inadequate drug coverage held the potential for an improved quality of care and better health outcomes by increasing the use of needed medications and reducing preventable and costly medical events.

Research to date has shown an increase in the use of medications attributable to Part D cover-

age, particularly among enrollees who previously lacked drug coverage.[17-20] As utilization rates have increased, rates of cost-related noncompliance have declined somewhat,[45] both of which are viewed as positive quality indicators. Yet, experience with the doughnut hole raises a red flag. Research has shown that medication adherence declines after Part D enrollees reach the coverage gap,[21,46,47] which poses health risks for the subgroup of beneficiaries with relatively high drug costs who stop taking medications for various chronic conditions, such as diabetes and depression.

To date, no evidence has accumulated about the longer-term effects of Part D on health outcomes or preventable admissions to hospitals or nursing homes among Medicare beneficiaries. Longitudinal analysis of individual-level Medicare Part D claims data that are linked to other Medicare claims for hospital and physician services will be critical in addressing questions about quality of care and health outcomes.

## UNFINISHED BUSINESS

Although few policymakers are pushing for an overhaul or outright repeal of the Part D program, we anticipate that a number of issues related to the Medicare drug benefit will be on the health policy agenda of the 111th Congress.

### IMPROVING COVERAGE

Part D has made substantial inroads in reducing the number of people on Medicare who lack prescription-drug coverage, but 4.5 million beneficiaries still have no such coverage. The lack of full participation in Medicare Part D could be an inevitable outcome of a purely voluntary program. To boost enrollment, government officials could intensify ongoing outreach activities involving a wide array of federal and state agencies and private entities, such as physicians and other health care providers. Some observers argue that education and outreach go only so far and advocate for a modified enrollment process, with a default private plan or a new public plan to cover those who do not enroll on their own.

### SIMPLIFYING CHOICES

Amid uncertainty about how well Medicare beneficiaries are served by a market-based system of competing private plans, there is some interest in simplifying Part D to make the program more consumer friendly. A number of policy options have been suggested, some involving more fundamental changes to the program than others. Some policymakers propose to simplify Part D by offering the drug benefit directly under original Medicare, either replacing the existing system of private plans or operating alongside it. Other proposals include limiting the number of drug plans that could be offered in any given area and standardizing Part D benefit packages to facilitate comparisons, similar to how Congress standardized Medigap policies in 1990.[48]

### CLOSING THE COVERAGE GAP

The coverage gap has been a widely criticized feature of the Part D benefit.[49] With growing evidence that the gap is posing problems for enrollees, several policymakers, including President Obama, have favored a reduction in the size of the gap or an elimination of the gap. Under "pay-as-you-go" rules, eliminating the coverage gap would require a substantial increase in federal spending: $134 billion over 10 years.[50] House Democrats have proposed to close the gap gradually over a 15-year period as part of their comprehensive health reform plan,[51] whereas the Obama administration and the pharmaceutical industry have agreed to an arrangement that would provide most Part D enrollees with discounts off the price of brand-name drugs covered by their plan when they reach the coverage gap.[52]

### IMPROVING COVERAGE FOR LOW-INCOME BENEFICIARIES

With more than 2 million Medicare beneficiaries who are estimated to be eligible for but not receiving low-income drug subsidies, more could be done to improve participation rates. In addition to undertaking more aggressive outreach efforts, some observers have proposed an elimination of the asset test for participation in the low-income subsidy program. To address potential access problems that have resulted from the random assignment of low-income enrollees to Part D plans, some observers have proposed a patient-centered assignment process that would take the medication use of each enrollee into account. Ensuring that low-income enrollees have access to multiple plan options and greater stability in offerings from year to year could also be a focus of policymakers' attention.

### LOWERING PRICES AND SPENDING

Although federal spending on Medicare Part D has been lower than initially projected, some policymakers favor additional measures to reduce drug prices and rein in overall drug spending. During the 2008 presidential election campaign, then-candidate Obama and other Democratic candidates revived the proposal to give the government negotiating authority with pharmaceutical companies on behalf of Medicare beneficiaries. The Congressional Budget Office recently estimated that this proposal would produce "negligible" savings but noted that the secretary of Health and Human Services might be able to negotiate small savings for single-source drugs with no close substitutes.[50] Given the ongoing concern about federal spending on Medicare, the issue of government negotiation could gain traction in the current legislative session.

## FUTURE OUTLOOK

As Medicare spending lays claim to a growing share of the federal budget and as rising health care costs place a growing strain on families, employers, and government, policymakers could face increasing pressure to take a more aggressive stance in dealing with pharmaceutical costs, particularly as broader discussions of health policy shift toward Medicare as a key lever in controlling the growth of health care costs. Yet, with attention intently focused on economic recovery and health reform, Medicare Part D is more likely to be tweaked than transformed in the near future.

No potential conflict of interest relevant to this article was reported.

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