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# Issue Brief

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## Medicare Prescription Drugs: Making the New Program Work

by *Jim Jaffe, EBRI*

- This *Issue Brief* reports on the progress that has been made and questions that have been raised about the new Medicare prescription drug benefit that became law in late 2003. The focus is on issues raised during the National Medicare Prescription Drug Congress held in Washington, DC, in February 2004.
- The first phase of the program, the discount drug card, became effective on schedule in May and June 2004, but this initial step did not end the ongoing partisan debate about whether the new legislation is a significant positive development for seniors or whether it will work as intended.
- Most questions about the logistics and operation of the prescription drug program will remain unanswered until the second—and more expensive—phase of the program (government-subsidized prescription drug insurance) begins in 2006.
- There's disagreement about the impact the program will have on state budgets. Supporters of the new law say it relieves the states of current responsibilities of providing needed medicines to medically indigent Medicare beneficiaries. But states fear that residual responsibilities (not all drugs will be covered under the new programs), coupled with reductions in federal aid, will ultimately increase their costs.
- The use of drug formularies may pose potential problems, particularly for beneficiaries who are unaccustomed to such restrictions on drug purchases. Whether such beneficiaries will be willing to switch drugs in order to take advantage of discounted prices remains to be seen. This reaction will partly depend on how restrictive the formularies are.
- Critics believe that the new law lacks mechanisms that could drive drug prices down by an appreciable amount and continue to pursue other strategies, including permitting imports from other nations (especially Canada) where drugs cost less.
- While the law contains language mandating drug counseling, there's little agreement on whether such advice will have much impact on consumption patterns or beneficiary satisfaction.
- It is still unclear how many firms will offer to provide prescription drug insurance under the Medicare program in 2006 because it is a new and untested product.

## Table of Contents

Introduction .....	3
Uncharted Territory.....	3
Comprehensive Coverage Packages Pushed .....	4
Medicare Insurance Solely for Drugs Is New .....	5
Current Status.....	6
What Happens Next?.....	6
Insurance Plan Begins in 2006 .....	7
Formulary Creation Crucial .....	8
The Dual Eligibles.....	9
How Will States Be Affected? .....	10
Will the Feds Stay the Course? .....	10
Next Steps .....	11
An Unpredictable Future.....	12

## Figures

Figure 1, Senior Spending on Prescription Drugs .....	12
Figure 2, Medicare Beneficiary Drug Coverage.....	13
Figure 3, Impact (by Annual Income Level) of Differentiated Medicare Part B Premium .....	13
Figure 4, Who Pays for Prescription Drugs Under the New Law?.....	14

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The National Medicare Prescription Drug Congress seeks to explain the policy and political debate around the new legislation. The organization also endeavors to assess the tactical and strategic importance of the new law to the major participants in the health care marketplace, including both patent and generic pharmaceutical manufacturers, PBMS, SROs, and CROs, pharmacies, pharmacists, health plans, third-party administration, health care providers, and beneficiaries. More information about the Medicare Congress is available on the Internet at [www.medicarecongress.com](http://www.medicarecongress.com)

## **Introduction**

Shortly before the end of 2003, President Bush signed a law creating a controversial new Medicare drug benefit that promises American seniors assistance in paying their prescription bills.

The question now is precisely how—and how well—the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (P.L. 108-173) will work. That question is a profound and complex one.

From a mechanical perspective, there are hundreds of decisions to be made by the parties involved about how the moving parts will fit together. Lobbying didn't end when Congress passed the bill; it merely shifted to focus on those who will administer the law—primarily at the Centers for Medicare & Medicaid Services (CMS). The political debate hasn't ended, either.

In the months and years ahead, potential beneficiaries will have to decide whether the resulting program meets their needs, contrasting the attractive specifics promoted by advocates of the program against a continuing chorus of criticism from those who opposed the measure. From both the policy and political perspectives, the fledgling Medicare prescription drug program is the start of a great experiment; that's one of the very few conclusions all can agree on.

Anticipating the outcome and operation of the program was one of the primary goals of the National Medicare Prescription Drug Congress held in Washington, DC, Feb. 25–27, 2004, organized by Peter Grant of Davis Wright Tremaine and sponsored by a number of interested organizations, including the Employee Benefit Research Institute (EBRI) and the Milbank Memorial Fund. Presentations made it clear both that success is not assured and that many legislators who opposed the legislation will continue to criticize it. This report summarizes the issues raised at the meeting and analyzes some of their implications.

While participants posed a growing number of questions on an increasingly granular level (What's the minimum number of drug categories permissible in a formulary? What will the appeals process be if a beneficiary prefers a drug not on the formulary? What will happen if the formulary changes immediately after enrollment and a beneficiary is denied benefits for a drug he's come to rely on?), there were no answers beyond cautious optimism that deadlines would be met and that many seniors could benefit.

## **Uncharted Territory**

Earlier this year, millions of Medicare beneficiaries were offered an opportunity to buy a Medicare drug discount card that could reduce the cost of needed prescriptions. The poorer members of this group will also be given a voucher that will pay for up to \$600 in drug purchases this year. They can carry over unspent money into 2005, when they will receive an additional \$600. This program comes at a time when spending on prescription drugs is increasing, both by seniors and as a percentage of medical expenses (Figure 1).

This program will last until 2006, when a new type of drug insurance policy will be offered to those enrolled in Medicare. While many key details remain undefined, this new insurance has been estimated to cost a Medicare beneficiary, on average, about \$35 monthly (in addition to a required Part B premium that will probably exceed \$70 a month), and will provide aid in buying drugs once a \$250 deductible has been exhausted, as well as a catastrophic benefit that pays 95 percent of drug costs once a \$5,000 threshold has been reached. The premium is not fixed by law and may vary from one region or plan to another. The \$35 monthly cost estimate was made by the Congressional Budget Office.

The plan is structured so that participating beneficiaries will pay roughly 25 percent of the cost of the covered drugs they use and the government will pay the remainder—but the actual ratio depends on the plan selected and the beneficiary's drug needs. Those with annual drug purchases exceeding \$5,000 will do best under the program. The drug program, which will be known as Medicare Part D, will be open only to those who opt for Part B coverage.

It is probable that different coverage packages will be offered in different geographic regions for different prices. That's because there's no mandated standardized package, and costs are higher in some regions. Insurers must offer a program that offers actuarial equivalency to government parameters, which leaves leeway for differences in the precise benefits offered.

The new plan has some characteristics in common with Part B in that it is optional and that three-fourths of expenses are covered by the federal government's general revenues while the remainder comes from beneficiary premium payments. Nearly everyone who is eligible for Part B elects it—and is encouraged to do so early by a premium that rises if the option isn't taken at the first opportunity. No one expects the take-up rate for the drug insurance program to be equally high, although there's a similar adjustment to encourage early enrollment.

Both drug reimbursement products—the card and the subsequent insurance plan—will use formularies that provide assistance in buying a limited menu of drugs. It is possible that some of these formularies may be limited to generic drugs. It is also conceivable that some beneficiaries will be offered options that do not include the drugs they are currently taking. Will beneficiaries be willing to change prescriptions in order to maximize the benefit available from these plans?

Each beneficiary will be offered access to either two prescription drug plans or, when available, to one comprehensive plan covering all medical needs (such as a health maintenance organization [HMO] or preferred provider organization [PPO]) that includes drugs and one stand-alone drug plan.

### *Comprehensive Coverage Packages Pushed*

Many Medicare analysts have long been bothered about the program's reliance on the fee-for-service financing model (health providers being paid on an à la carte basis for services provided). When Medicare was created nearly 40 years ago, this was the standard financing system, and the government program was structured to deliver services in the fashion that both patients and providers were familiar with. But since then, private coverage has moved toward managed care and virtually abandoned fee-for-service payment arrangements. Critics say this is an inefficient model that lacks coordination and fails to encourage patients to visit efficient providers.

While political reality prevents Medicare from embracing PPOs as employer plans typically do, several efforts have been made to persuade Medicare beneficiaries to enroll in such plans. Generally, they're encouraged to do so by plans that offer a wider range of services at no greater cost than conventional Medicare. In essence, beneficiaries who agree to limits on their choice of provider are rewarded with a broader menu of benefits. HMOs in many parts of America have successfully marketed such plans. The major sticking point has been the government's reimbursement level.

Basically, health insurance plans are reluctant to participate in Medicare unless the reimbursement rate is adequate to provide a profit. On the other hand, the government views managed care health plans as a cost-containment device and wants to provide a per-patient reimbursement rate that's below the amount paid for beneficiaries in the conventional fee-for-service plan. Finding a reimbursement level that satisfies both sides has proven to be a challenge. In recent years, comprehensive plans have left the market in response to government reimbursement rates they found inadequate but government regulators insist are more than adequate to provide them with a profit.

In the past year, enrollment in such plans (such as Medicare+Choice) has declined significantly, to the distress of beneficiaries who had been participating; currently, about 17 percent of Medicare beneficiaries are covered by the Medicare+Choice managed care option (Figure 2).

The new law creating the drug program also includes new, higher reimbursement levels to participating health insurance plans that offer comprehensive benefit packages, including physician and hospital services as well as drugs. Some sponsors of the legislation see this as a very significant way to bring Medicare costs under control, by introducing the market forces that already exist in the

private sector. But others note that Medicare costs have been rising more slowly than private-sector expenses and thus doubt that this strategy will make Medicare more efficient.

Whatever the outcome of that broader debate, the growth of comprehensive plans could provide an environment in which the relative merits of prescription drugs or other therapies can be weighed against one another rather than being considered as independent issues.

### ***Medicare Insurance Solely for Drugs Is New***

The freestanding prescription drug insurance program that will begin in 2006—offering a product that does not yet exist—would not be linked to other medical services. So if a beneficiary avoided a hospital admission by using expensive drugs, this would have no financial impact on those providing hospital services. Similarly, if a beneficiary were hospitalized for lack of an expensive drug, this wouldn't affect the pharmaceutical insurer.

The law attempts to make the entire system more efficient in a way that goes beyond drug discounts by mandating medication therapy counsel for those who have substantial ongoing drug needs.

Employers that offer a drug benefit to their retirees will be eligible for a 28 percent subsidy payment from the government for some of their expenses if their plan is the equivalent of the new plan. Media reports suggest that employers are already revising their anticipated retiree health costs downward as a result of this provision, which was designed to stem the tide of employers cutting this benefit to their retirees.

Nothing approximating the entire 2006 program now exists. Nor does anything precisely like the new drug cards now being distributed. That means all involved in the program are about to take a giant leap into unknown territory.

Questions abound:

- Can a program be developed to give seniors the drugs they want at a price they are willing to pay?
- Will the government be able to afford such a program over time?
- Will this and other changes enhance or undermine the fiscal health of the Medicare program generally?
- Will private firms find it profitable to offer such policies?
- How will employers now offering a retiree drug benefit respond when a new government subsidy becomes available?
- Can the government learn to provide supervisory oversight for the program without resorting to the price setting typical of other aspects of the Medicare program?
- How will this program affect continuing and growing pressure to import cheaper drugs from elsewhere, particularly Canada?
- Will additional plans be offered that provide protection against the cost of the “doughnut hole,” a zone of total noncoverage within the benefit package?
- How will the states be affected and how will they respond?

At this point, equally plausible cases can be made that (a) the program will be a success and become as popular with beneficiaries as other Medicare programs are; (b) it will create pressure to reform the existing Medicare program; (c) it will become a minor adjunct of the current Medicare program; or (d) that the law of unintended consequences will again reveal itself, resulting in an outcome no one anticipates.

## *Current Status*

President Bush signed the drug legislation in early December. That led to a quick increase in the capitation rate paid to plans participating in the old Medicare+Choice program. Basically, such programs agree to provide a beneficiary's care on an as-needed basis in return for a fixed payment from the government. This is an effort to replicate what managed care has done for workers, pushing them toward providers deemed cheaper or more efficient. From the government's perspective, this has advantages: It fixes the cost-per-beneficiary in advance, transferring risk to the provider and thereby giving the provider incentives (not otherwise present in Medicare) to provide efficient care.

Medicare+Choice has now been renamed Medicare Advantage and the reimbursement increase spurred an increased interest in enrollment as benefits rose, premiums charged beneficiaries dropped—or both. But this change was a fairly simple one: The government gave the health insurance plans more money, and required in turn that they offer beneficiaries more services. This is a strategy that has worked in the past, but only insofar as the government is willing to offer generous payments. When providers find the reimbursement insufficient, as they have previously, they exit the program. Many fear this may happen again if Medicare's fiscal problems become more acute.

Sponsors of this provision say they are confident that, ultimately, such plans will be able to provide services more cheaply than the fee-for-services arrangements that now prevail for most Medicare beneficiaries. For the moment, many critics argue, this must be categorized as an optimistic theory.

## *What Happens Next?*

By early 2004, the Centers for Medicare & Medicaid Services (CMS) was busily hiring new personnel to beef up Medicare expertise on pharmaceutical issues even as it was considering applications from organizations that wanted to offer Medicare drug discount cards to beneficiaries who will become eligible for benefits in June. In late March, CMS approved 28 cards, 15 of which would be available nationally, out of 101 applications received, and by May the numbers were significantly higher. The winners had to agree to provide a selection of three drugs in each of 209 treatment categories. In slightly more than half of the categories, there will be a generic option.

Simultaneously, CMS was creating a Web site designed to allow interested beneficiaries to comparison-shop among the cards offered. The site would allow a patient to list his or her prescriptions and then compare what they would cost under competing plans. For those who are not computer-literate, CMS was planning to establish a toll-free telephone number where similar information would be available. But this policy and education program, done on the fly, raised other questions. While CMS promised weekly updates on drug price information, beneficiaries will be allowed to make only one choice a year, and the deal that looks best when they initially select it could be less advantageous a few months later either because their drug needs have changed or the card's offerings have been modified. The Web site began operation on schedule at the start of May, but was quickly criticized about posted prices that seemed high to many observers.

Critics of the program said this provided evidence that the benefit was worthless, but those offering cards responded that inaccurately high prices were listed.

Additionally, many beneficiaries already have cards that don't have the Medicare endorsement. Whether they would retain these and how they would interact with the new Medicare cards is unknown. Pharmacists are concerned that customers will slap a handful of cards on the counter and ask them to come up with the best possible deal, putting them in a situation where they'll be asked to do more work that will pay them less.

To win approval, prescription drug card applicants are required to guarantee convenient access, which generally means having a participating pharmacy within two miles of those living in urban areas, five miles in suburban areas, and 15 miles in rural areas.

Thomas Scully, who headed CMS when the bill was debated and helped negotiate the ultimate compromise, says that seniors typically overpay 15 percent to 20 percent for the drugs they buy today because they don't have access to the discounts typically available to other purchasers. So the cards could provide them with significant savings—if the drugs a beneficiary is using are covered by the card.

### ***Insurance Plan Begins in 2006***

The cards will be good through the end of 2005, at which time the new optional Medicare drug insurance plan will become available. Unlike the discount drug cards, which are already on the market from various sources aimed at specific markets, the prescription drug insurance is a product that has never been offered before. Basically, the government is saying, “if we fund it, they will come,” even as it prepares a backup plan that can be used if no acceptable plans are offered in particular markets.

This creates a major challenge for the pharmaceutical benefit managers (PBMs) that have typically run drug discount subsidy programs in the past. They've become adept at squeezing discounts from drug manufacturers, but they are not legally recognized as insurance companies and have not assumed risk. If a beneficiary group increases its pill use, the sponsor is simply billed more and the PBM may actually earn more because of the increased number of transactions. But that's not how the Medicare program will work.

One of the larger firms, Express Scripts, says it will enter the program and assume risk. There's speculation that some PBMs will form joint ventures with existing insurance firms that are more expert at risk management. Whether drug producers will enter such arrangements in an effort to maximize sales of their products remains to be seen. Plans with a bias toward a particular producer are not precluded—and indeed are anticipated, replicating a practice now found in the private PBM market. But the fact that sponsors of the legislation were unable to get a single drug benefit managing firm to commit to participating prior to the law's enactment raises the question of how robust the market response ultimately will be.

Scully believes that PBMs will dominate the market, which will be characterized by greater transparency because of government regulation, and will learn, along with the rest of the industry, to live with lower profit margins that will be offset by higher sales volume.

A successful program must marry broad participation by Medicare beneficiaries of varying health status with the opportunity for firms offering it to make an attractive profit. Low participation would probably skew toward the sickest beneficiaries who use the most drugs. Such a bias could undermine and ultimately destroy the entire program. The success of any insurance program partly depends on how many people who file only modest claims can be enrolled.

How will the newly hired staff at CMS deal with these challenges:

- Creating a program with a structure that will seem potentially profitable enough to lure private firms into participating.
- Approving a benefit structure that appears sufficiently generous to convince a broad section of Medicare beneficiaries to participate in this optional program. About three-fourths of beneficiaries are already receiving some aid in paying for drugs. (Slightly more than a fifth with such drug coverage currently are receiving it from state Medicaid programs.) If they are to join the new program, they'll have to view it as an improvement. The multi-billion dollar government subsidies will help, but don't guarantee success.
- Responding to review and revision of current decisions if a new president takes office next January.

Leading the government's initial effort to answer these questions was CMS's Acting Deputy Director Leslie V. Norwalk, who pointed out that issues that seemed administrative—such as how the maps delineating regions would be drawn or what the formulary appeal process would be—could have a major impact on the program's popularity.

Changes in administration have proven disruptive in the past. In 1988, President Reagan signed a Medicare expansion that included prescription drugs, which had easily won congressional approval. While the White House initially suggested adding catastrophic coverage, which would benefit only a small number of beneficiaries, drug insurance was added as part of an attempt to give the legislation more popular appeal by providing benefits to a wider population. As a political strategy, this failed.

The following year, when Reagan's vice president, George Bush, won the White House, he signed repeal legislation that reflected widespread opposition to the program by Medicare beneficiaries. The program never became fully effective. One provision that then generated a lot of controversy had wealthy beneficiaries paying significantly more than others for the drug benefit. An echo of that—the income-based Part B premium—is contained in the new law (Figure 3). The dynamic involved with this change is more fully discussed in a previous *EBRI Notes* article (“Medicare Program Takes On More Income-Related Features,” May 2004).

A replay of that scenario is conceivable, particularly if a Democrat becomes president. A majority of Democrats in Congress voted against the new Medicare prescription drug law and more than a few based subsequent campaigns on the argument that the bill was a big step in a bad direction. And more than a few Republicans who voted for the bill (some reluctantly) are expressing remorse as questions surface about its cost or benefit structure.

While not directly related, the public response to the drug cards issued this year could have a big impact on the regulations that will be created to impose a new structure on the Medicare program beginning in 2006. From one perspective, the cards are a trial run in determining what types of restrictions on benefits will be acceptable to beneficiaries.

In an apparent paradox, broad participation and approval could create new problems, at least in the fiscal area. As conflicting cost estimates between those in Congress and the administration confirmed, different assumptions about how many will choose to participate can increase the program's costs by 25 percent or more.

### ***Formulary Creation Crucial***

“We didn't want to let government decide what drugs seniors would receive,” explained Patrick Morrissey of the House Energy and Commerce Committee at the Prescription Drug Congress. While that goal was achieved, he said, the resulting law contains a lot of unanswered questions about who will make that decision—and how.

Existing prescription drug subsidies are typically based on a formulary, which drives beneficiaries to use certain drugs that the plan finds most advantageous. A common plan design involves three tiers. Cost to beneficiaries is lowest when they elect to use a generic drug on the list. If they select a preferred proprietary drug, they pay more. And if they insist on a proprietary drug that is not included in the formulary, they pay a higher price yet.

Drugs win a preferred place in the formulary if they are more efficacious or can be purchased more cheaply by the plan, more typically the latter. While some comprehensive plans have an incentive to reimburse high-cost drugs that may lead to lower hospital and doctor bills (and this will remain true under the Medicare Advantage program), the new drug insurance plans will have no such incentive. Whether a preferred drug leads to more or less hospitalization will be a matter of indifference to them.

But seniors are already consuming a lot of drugs and bring pre-existing preferences to the table. A plan that helps pay for drugs they're already using will be more attractive than one that pushes



them to get new prescriptions. But some believe that such a push may be appropriate, and perhaps required.

The situation is particularly confusing for the so-called “dual eligibles.” In the past, federal law has barred state Medicaid programs from using a formulary (although they can sneak up on the issue by using a procedure that requires prior authorization for drugs not on a preferred list). Now, it will be mandatory. There’s considerable concern about how today’s Medicaid beneficiaries using drugs not included in formularies will be treated. In fact, the policy will probably vary from state to state.

A quick look at Cox-2 inhibitors—including Celebrex and Vioxx—anti-inflammatory drugs used by many who suffer from arthritis, explains why formularies are critical to any cost-containment effort. The Cox-2 drugs have won about half the prescriptions written in their class of nonsteroidal anti-inflammatory drugs (NSAIDs), notwithstanding the fact that researchers at Kaiser Foundation Health Plan and elsewhere believe they’re only required in 4 percent to 5 percent of cases. Perhaps appropriately, they comprise only 5 percent of Kaiser NSAIDs prescriptions. If one could get the national consumption pattern to mirror Kaiser’s, the national drug bill could be cut by more than \$1 billion, advocates say. But such a drastic change won’t come quickly or easily, if it comes at all.

From yet another perspective, the program will be a political success if a maximum number of those eligible decide to participate. But, given today’s budget pressures, it is more likely to be seen as a fiscal success if fewer opt in and therefore limit the government’s costs.

The law requires the U.S. Pharmacopoeia, which now sets standards for medicines, to create an exemplary formulary, but no PBM is required to follow this pattern. In fact, a series of decisions are involved: For instance, there is the issue of how many categories of approved drugs there ought to be (theoretically, one could put all heart medications into a single broad category or divide them into smaller groups). A subsequent issue is whether there will be any requirement that each group include at least one nongeneric (newer and more expensive) drug. Some observers believe the regulations will mandate this, but the law is silent.

From the insurer’s perspective, the smaller the number of drugs included the better. That’s because part of their strategy involves squeezing big discounts from producers in return for wholesale purchases: The larger the number of pills purchased, the greater the anticipated discount. For best results, the insurer wants to buy for the largest possible number of beneficiaries and provide them with the smallest list of acceptable drugs.

As is normal in insurance, it is anticipated that a small number of beneficiaries will make a disproportionate share of the claims. Leonard Schaeffer, president of Wellpoint Health Systems and a former Medicare administrator when CMS was known as the Health Care Financing Administration, noted that 88 percent of the prescriptions written are for patients with chronic conditions.

### ***The Dual Eligibles***

For most Medicare beneficiaries, participation in the drug insurance plan will be optional, require a monthly premium payment, and be contingent on participation in the Part B outpatient program, which is also optional. Rules for poorer participants, who are insured both by Medicare and state Medicaid programs, will be different, though.

For many poor beneficiaries, participation in the new program will be virtually mandatory. That’s because beneficiaries under Medicaid (the federal-state health care program for poor) who are now eligible for aid under the Medicare program as well will all be shifted to the Medicare drug program, relieving the states of their current responsibility (the states, in turn, will be required to return to the federal government most of the money they save, and many states see themselves as net losers in this transaction, for reasons explained below). This program is not unlike the older premium subsidy program that gives low-income seniors discounts in the Part B program as well.

But what will happen when the old state program is more expansive than the new federal program? And what will be the outcome if a beneficiary is dependent on a drug now paid for by the

state that is not included in the formulary of the plans available in the area? Some states will probably resume aid, even without federal reimbursement, so as to allow patients to continue taking the drugs they're familiar with. But it is unlikely that all will.

Beneficiaries living in an area where the formulary doesn't include the drug they require and in a state that doesn't pick up this residual responsibility could find themselves in a situation worse than they face today. This was one of the arguments made by opponents during the legislative debate who feared that the new law could make things worse for some seniors; during the Medicare Congress, many speakers acknowledged that this might indeed happen.

### ***How Will States Be Affected?***

When the law was enacted, there was a substantial difference of opinion about the impact it would have on the states. This is not a minor issue for them. As noted by S. Peter Mills, who has worked on such issues for years as a Maine legislator, health costs are the top budget priority for many states. It will take a few years to determine whether the Medicare drug program makes things better or worse for state Medicaid program and the result may vary significantly from one state to another. Washington-based backers of the legislation saw it as advantageous to the states because it totally federalizes today's shared responsibility of buying drugs for the elderly poor.

But from the state capitals, there was wariness at best. Some saw the states as having a residual responsibility for needed drugs that the federal program wouldn't pay for. Others saw the states' wholesale bargaining power reduced because they would be buying smaller quantities and existing guarantees that ensure the states of the lowest possible drug prices would be repealed. States providing drugs to those without dual eligibility would be buying fewer pills, probably leading to a higher cost per pill.

G. Lawrence Atkins, senior director of public policy and reimbursement Schering-Plough, agreed that state rebates would decline as a result of these changes.

This debate may well be subsumed by efforts to reorganize the state-federal partnership that characterizes Medicaid. But other, broader factors (including whether private health coverage will continue to decline and the fiscal health of the states generally) will all play a role in that debate.

Idaho Gov. Dirk Kempthorne has made the issue of long-term care (a growing Medicaid burden for the states) a focus of his chairmanship of the National Governors Association. The success the states have in solving this problem, which may be affected by the drug program, will likely prove more important to them than drug costs. If states believe they've conquered the long-term care cost problem, they'll be less concerned about what's happening to their drug budget, Kempthorne suggests.

Some states that have a growing interest in containing costs by importing drugs from Canada were frustrated that the Medicare prescription drug legislation did nothing to make such initiatives easier. This view was expressed by Kevin Concannon, director of Iowa's Department of Human Services. But Mark McClellan, who will play a pivotal role as he moves from director of the Food and Drug Administration to assume new duties as administrator of CMS, took a safety-first stance: "Legal drugs in this country don't carry 'buyer-beware' labels," he noted, and the government lacks the resources to certify that drugs from other nations are safe. In his confirmation hearings to the CMS, McClellan seemed to moderate his position, saying the safety of drug imports could be guaranteed if government agencies had adequate resources to monitor their source. That's the system now used for many food imports.

### ***Will the Feds Stay the Course?***

Cost projections for such programs have an inherent weakness because they assume that the benefit will not be amended for a decade or more. But such stability is quite rare, and several legislators have made it clear that they're committed to an ongoing effort to change this program.

Some members of Congress are already committed to working for a more generous benefit, while others are trying to repeal the new prescription drug law before it fully takes effect. The history of Medicare suggests that the government will become concerned about costs and attempt to ratchet them down. Its success in doing so is largely dependent on how much control it has over the market. Efforts to restrain increases for hospital and physician services have been generally successful because providers usually think the government is making them an offer they cannot refuse: They're simply unwilling to risk losing the large patient base that the government provides.

On the other hand, Medicare HMOs have quickly quit the program when they found reimbursement inadequate.

Which precedent, if either, will apply to the drug program remains to be seen. In today's environment, it is hard to see the government spending significantly more than anticipated on the program, either by meeting higher-than-predicted costs or by liberalizing benefits. Concerns about continuing big federal deficits and the fiscal health of Medicare in particular will color the debate for the next few years. On the other hand, if the legislation succeeds in making Medicare more efficient (as its sponsors predict), that could free dollars for program expansions.

Rep. Nancy Johnson (R-CT), who chairs the House Ways and Means Health Subcommittee, stressed the importance of other changes in the law, including an emphasis on disease management, which will begin with the new free physical examination available to all new Medicare beneficiaries. Earlier, Schaeffer pointed to studies done at Dartmouth suggesting Medicare could save up to 30 percent by squeezing out overutilization.

Rep. Johnson also criticized the existing Medicare reimbursement mechanisms for doctors and hospitals, noting a need for major reform of both.

### **Next Steps**

Several speakers said a case could be made that the real test of this legislation lies in whether it modifies Medicare patient behavior and drives beneficiaries toward delivery systems in which more efficient decisions are made. That's the hope of the sponsors who stress the importance of the Medicare Advantage, which includes the drug benefit within a more comprehensive package. Sponsors are hopeful that they can make Medicare respond to changes in the marketplace the way the private sector has done. Traditionally, Medicare has lagged behind the private sector; for instance, it began by mirroring the fee-for-service reimbursement system that was the norm in the mid-1960s and has remained there, although private insurance has long since embraced managed care models designed to push patients to efficient providers.

Now Medicare is embracing the type of drug coverage common in the private sector with the use of PBMs. But, noted Anthony Barrueta, senior counsel for government relations for the Kaiser Foundation Health Plan, the new legislation codifies current policy but doesn't leave Medicare free to move with the market.

Kaiser, which already offers a drug discount card, spends nearly \$3 billion annually on drugs, with 98 percent of prescriptions written for drugs included in the Kaiser formulary. But, Barrueta noted, such a reliance on a formulary inevitably curbs physician autonomy and can be difficult to impose in situations, unlike Kaiser's, that involve the creation of a preferred drug list.

This perspective was reinforced by Robert S. Galvin, director of Global Healthcare for General Electric (which spends \$2 billion annually on health benefits for its employees), who estimates that between 10 percent and 20 percent of today's drug benefit is misspent. But, Galvin stressed, any strategy for saving must focus on the number of pills consumed and whether people were taking the right product, rather than on the price per pill. Making these decisions is more complex than merely using wholesale purchasing power to drive unit prices down, he said.

## An Unpredictable Future

Predicting the impact of a new law is difficult in the best of times. Hovering over all new programs is a dynamic beyond the control of the American political system: the law of unintended consequences.

From one perspective, a lot of bets are being made on the new Medicare program. The government is betting that the private sector will see the new program and respond in a positive fashion. Commercial firms will be betting that they can enter a new line of business and prosper. And millions of Medicare beneficiaries will bet that the program they select will help them meet their drug needs. But none of these bets is a sure thing.

The program is getting off to a rough start, with many Democrats uncharacteristically continuing to oppose it. Critics demanded a probe into why the Bush administration refused to release projected cost estimates in a timely fashion, and the initial price-comparison Web site was flawed. But these questions could be quickly forgotten if the card program makes a strong start this year rather than providing a basis for concerns that have already been voiced.

There are clear stresses, some of which are quite basic. The government and insurers see this as an insurance program, which presupposes that many will get back less than they put in so that a few with very large expenses can be protected from catastrophic bills. But beneficiaries view the program as a drug purchase subsidy and may do a cost-benefit analysis to determine whether they as individuals are likely to get back more than they put in. The fact that the program is heavily subsidized tends to blur this conflict, but how the program will be perceived by beneficiaries remains a major question (Figure 4).

There may ultimately be cost considerations that will cause legislators to revisit the entire issue, but that will come later. For now, the most basic questions are these:

- Will insurers offer the product?
- Will beneficiaries find it attractive?

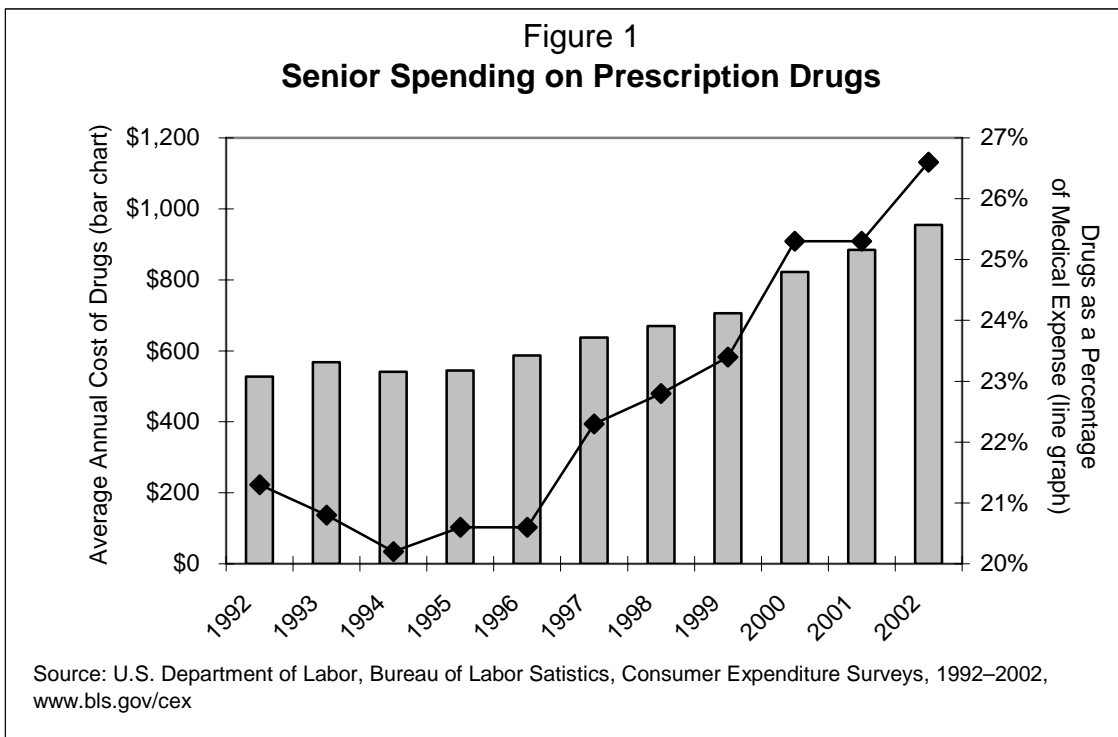
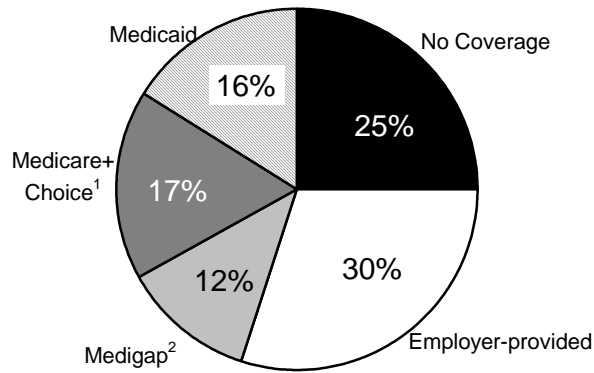


Figure 2  
**Medicare Beneficiary Drug Coverage**

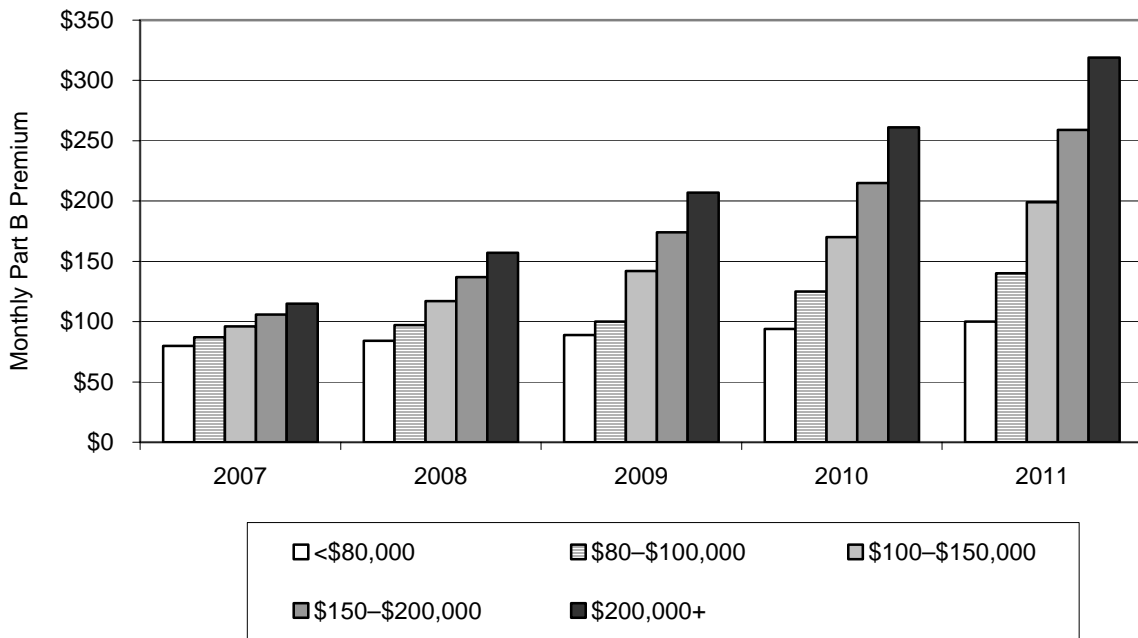


Source: Congressional Budget Office analysis of the Medicare Current Beneficiary Survey (MCBS); Douglas Holtz-Eakin, Congressional Budget Office, testimony before the U.S. House Committee on Ways and Means, April 9, 2003.

<sup>1</sup> Medicare+Choice or another state or federal program.

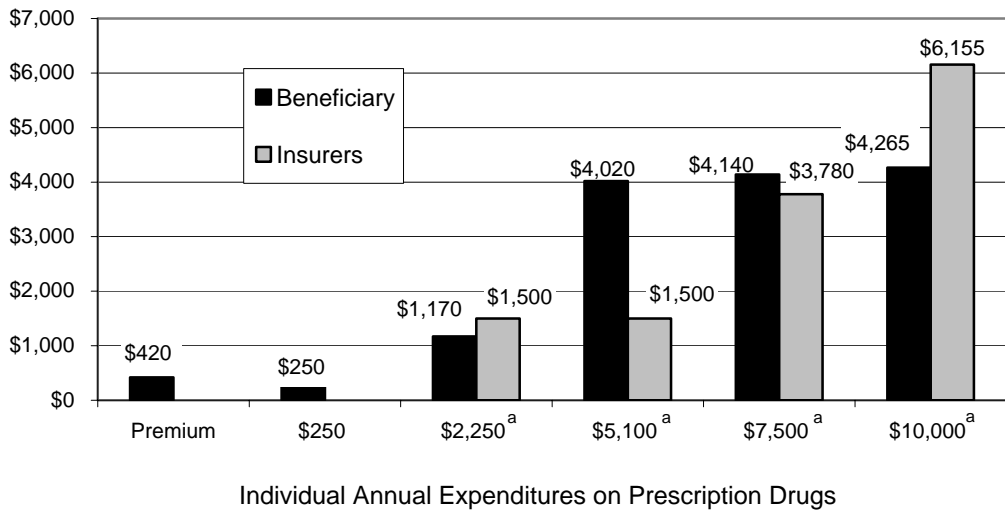
<sup>2</sup> Individually purchased.

Figure 3  
**Impact (by Annual Income Level) of Differentiated Medicare Part B Premium**



Source: Employee Benefit Research Institute.

Figure 4  
**Who Pays for Prescription Drugs Under the New Law?**



Source: The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (P.L. 108-173).  
<sup>a</sup> Excludes the estimated \$420 annual premium.

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