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Mending the Medicare Prescription Drug Benefit: Improving Consumer Choices and Restructuring Purchasing

THE BROOKINGS INSTITUTION

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Mending the Medicare Prescription Drug Benefit: Improving Consumer Choices and Restructuring Purchasing

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Abstract

The Part D prescription drug benefit has brought affordable drug coverage to millions of elderly Americans and is a valuable addition to Medicare. But several reforms are needed. To reduce complexity while retaining adequate choice, a set of standardized plans should be created within Part D. New participants should be automatically enrolled in a plan but allowed to opt out. To encourage price competition and discourage adverse selection, Medicare should allow competition for exclusive contracts to sell the standardized plans in each Part D region. To address the stresses on the federal budget, prices paid for drugs purchased on behalf of beneficiaries previously covered by Medicaid should be reduced to near their former Medicaid levels. To limit the ability of manufacturers to name their prices of therapeutically unique drugs, a standby mechanism for establishing temporary administered prices should be developed. Finally, the confusing distinction between Part B and Part D drugs should be ended and all prescription drugs covered under Part D.

Contents

I. Introduction

Prescription drugs play an increasingly central role in health care delivery, accounting for about 12 percent of personal health care spending in 2005 according to the Centers for Medicare and Medicaid Services (CMS 2007). They are critical in managing many chronic diseases and meeting other health needs of the elderly. Yet the original Medicare program, the main federal health care program for the elderly, did not for the most part cover outpatient prescription drugs. In making this choice, Medicare simply followed the lead of the private health insurance plans that existed at its creation in the 1960s, when the importance of drugs was much smaller than it is today.

As a result, at the turn of the twenty-first century, Medicare recipients either paid for most drugs themselves or relied on a patchwork of financing arrangements. In 2000, 25 percent of Medicare beneficiaries had no drug coverage during the entire year, and as many as 40 percent had no coverage for some part of the year.[1] In 1999 about 11 percent relied on an individually purchased private plan to pay for drugs, and the remainder relied on either Medicaid (16 percent), health maintenance organizations (14 percent), employer-provided retiree coverage (30 percent), or other publicly financed programs (4 percent; Congressional Budget Office [CBO] 2002).

In 1999 the average Medicare beneficiary used $1,250 worth of prescription drugs, paying for 38 percent of that amount out of pocket (CBO 2002). Some spent much more: the CBO estimated that, in 2005, about 17 percent of Medicare recipients spent $5,000 or more on such drugs. Meanwhile many of the less affluent elderly bore a particularly heavy burden: the 48 percent of Medicare beneficiaries with incomes between 100 and 300 percent of the federal poverty line were less likely to have any prescription drug coverage than those with higher incomes. (Most of the elderly below the poverty line were covered by Medicaid.) On average this lower-income group paid 43 percent of their drug costs out of pocket (Holtz-Eakin 2003).

Besides putting many elderly Americans at serious financial risk, the absence of insurance coverage for prescription drugs resulted in many elderly failing to get appropriate treatment for major chronic illnesses such as congestive heart failure and diabetes (Safran et al. 2005). This may well have added more to Medicare spending for hospital and physician services than the drugs themselves would have cost. For all these reasons, in the early years of the new century, Congress faced mounting pressure to add a prescription drug benefit to the Medicare program.

In 2003, after a long and contentious debate, Congress passed and President George W. Bush signed the Medicare Modernization Act (MMA), which provided prescription drug coverage under a new Part D of Medicare. The new program embodied several important policy features, some of them controversial. Congress decided to give beneficiaries in traditional Medicare a choice among standalone competing prescription drug plans (PDPs), rather than offer the option of a single, government-administered program as Medicare does for hospital and physician services. Congress also decided against using administered prices such as traditional Medicare applies to almost all other services. In fact, the MMA prohibits government from being directly involved in price negotiations for prescription drugs purchased under Part D. Instead prices are set in negotiations between PDPs (mostly owned by pharmacy benefit management

1. Holtz-Eakin (2003), Congressional Budget Office (2002). The 40 percent estimate is based on CBO's analysis of the Medicare Current Beneficiary Survey 1999.

BOX 1
Medicare, Part D, and the Federal Budget

In 2006 Medicare and Medicaid together accounted for 22 percent of federal outlays and 4.5 percent of GDP (according to the CBO March 2007 baseline). If historical growth rates of spending persist in both health care and the federal budget, by 2016 these programs will account for 32 percent of the federal budget and 7.8 percent of GDP. Under the more optimistic assumption that health care will grow at a rate only 1 percentage point above growth in GDP, by 2016 Medicare and Medicaid would still account for about 30 percent of the federal budget and 6.5 percent of GDP (calculations based on CBO 2006a and 2007). Thus, the growth of Medicare and Medicaid will continue to place enormous strains on the budget.

The Part D benefit is projected to add net claims of about $47 billion to Medicare outlays in 2007, equivalent to about 12 percent of projected Part A and B net outlays for that year. By 2015 Part D is projected to account for 21 percent of net Medicare outlays. Thus, cost-effective purchasing is important to the financial health of the program, and it is critical to consider the balance of where the burden of paying for drugs rests.

companies [PBMs] or health insurance companies) and drug manufacturers.

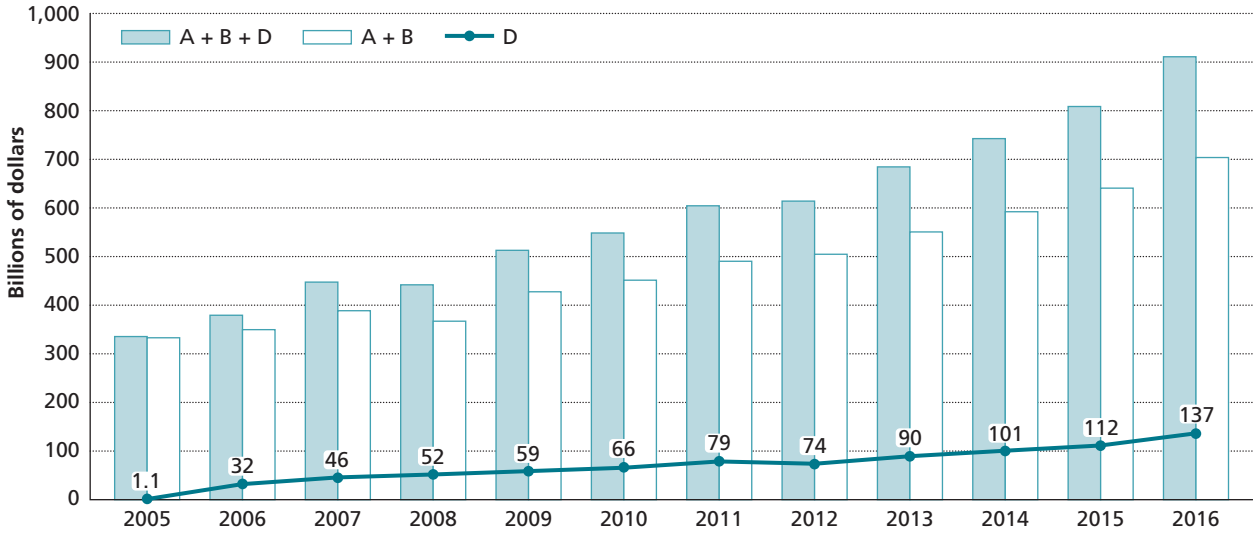
These policy choices, along with the chosen design for cost sharing between beneficiaries and plans, described below, were made against the background of a federal budget projected to run substantial deficits far into the future, and a Medicare program forecast to grow from 2.5 percent of gross domestic product (GDP) in 2003 to 4.4 percent in 2016 under current law (CBO 2006a; see also box 1). Congress also set an explicit limit of $400 billion for the forecast ten-year cost (2004-13) of Part D. Figure 1 shows spending projections for Medicare with and without Part D based on the March 2006 CBO forecasts. Cumulative spending projections now exceed $700 billion for 2006-15, in part simply because the budget window has shifted forward: the years 2004 and 2005, when the program was not in effect, have been replaced by 2014 and 2015, when it is.

In its brief existence to date, Part D has succeeded in providing affordable prescription drug coverage to millions of elderly Medicare recipients for the first time. Approximately 2.7 million low-income Medicare beneficiaries have obtained comprehensive coverage for prescription drugs where previously they had none (Cubanski and Neuman 2006). These are very important benefits. Public opinion about the program overall has been quite positive, but it also points to areas where improvements may be warranted. A recent Kaiser Family Foundation-Harvard School of Public Health poll (Kaiser Family Foundation 2006c) reports that 76 percent of respondents enrolled in a Part D plan had either very positive or somewhat positive views of their plan, and 72 percent said that Part D overall was helpful or very helpful to them. At the same time, however, 75 percent reported that the program was "too complicated," and 60 percent favored reducing the number of plan choices offered.

Although the program's cost to the federal government has been higher than expected, the premiums offered by PDPs to Part D recipients have been on average lower than the CBO and others had projected (CBO 2004). The reasons are somewhat speculative but may relate to the lack of any previous experience with a prescription drug benefit designed like Part D. Also, the number of plans participating in Part D far exceeded projections, generating more price competition than expected, and Part D in practice relied far less on specially constituted "fallback" plans than had been forecast—in fact, fallback plans were not resorted to at all. Moreover, the cost projections were based on the 1999-2000 Medicare Current Beneficiary Survey and CMS projections of prescription drug prices; these projections were made during a time of very rapid price increases, after which price rises unexpectedly moderated. Finally, premiums may also have been lower than expected because the flow of unique drugs (those for which no therapeu-

FIGURE 1

Projected Medicare Outlays by Part, 2005-16



Source: CBO 2007.

tic substitute exists) has dropped dramatically in the last few years, allowing for more competition among drugs.

The program's success in bringing prescription drug coverage to millions, at lower-than-expected costs to the participants, is most welcome. Yet the desire to design a program that would accomplish several important objectives at once—comprehensive coverage, reliance on private PDPs modeled on commercial PBMs, a wide choice of plans, and the use of market forces to establish prices, all within a $400 billion ten-year budget—led to some unfortunate policy choices. In what follows, we first briefly describe some of the problems that Part D has encountered. We then offer some proposals to mend the program's flaws while preserving its achievements.

II. Some Problematic Design Choices

A serious problem with Part D, as the respondents to the KFF-Harvard survey themselves observed, is its complexity. Consider the array of plans now being offered under Part D to the elderly and disabled, many of whom have trouble negotiating complex choices. Although the MMA requires that each plan meet certain minimum standards, discussed below, each has considerable leeway in designing its formulary (the list of specific drugs covered). Each plan also has discretion in the terms of coverage it offers, such as copayments, prior authorization requirements, quantity limits, and requirements to try a lower-priced drug that is therapeutically similar before resorting to a more expensive one (sometimes referred to as step therapy or "fail first" requirements); over thirty-six combinations of the program's key provisions alone are possible.

The result is that a large number of private PDPs that differ in important but often subtle ways are being offered to recipients of traditional Medicare (83 percent of all Medicare participants) across the nation.[2] The actual number of plans differs from state to state and currently ranges from forty-five in Alaska to sixty-six in Pennsylvania and West Virginia (Kaiser Family Foundation 2006c). For an individual beneficiary, the dimensionality of the choice problem rises according to the specific drugs they use (the average Medicare participant uses five different drugs). This complexity has potentially discouraged some enrollment, created confusion, and likely led to choices of coverage that are not cost effective (U.S. Government Accountability Office 2006, Medicare Payment Advisory Commission [MedPAC] 2006, McFadden 2006).

A second problem is that of adverse selection. The reliance on competition among PDPs creates strong incentives for PDPs to seek out those enrollees they believe they can serve at lowest cost, while excluding others (Pauly and Zeng 2004). These incentives may lead PDPs to choose benefit structures, formulary designs, and drug utilization review processes so as to discourage enrollment by expected high-cost individuals. Both the MMA and CMS, which administers the program, recognize this issue, and the law attempts to counter these incentives by providing for some adjustment in payments to plans for varying their mix of risks. But existing risk adjustment technology can account for only a portion of the predictable differences in expected spending across plans. Wrobel et al. (2003-04) show that the risk adjusters used by CMS account for about 23 percent of the variance in drug spending per year among the elderly, or less than half of the total explainable variation of at least 55 percent. (Some variation, of course, is unexplainable.) Thus, even though PDPs are paid more for enrolling people with higher drug needs, strong incentives remain for them to enroll low-utilizing recipients, and the information needed to predict who will be a low-utilizing recipient is readily available.

Four more problems arise from other provisions of the law. First, competition keeps prices down only when there are competitors. Manufacturers of unique drugs face little or no competition, and makers of such drugs that are heavily used by the elderly can essentially name their price. We present below some evidence on how common this may be.

2. The remaining 17 percent of Medicare beneficiaries are enrolled in Medicare Advantage plans and receive their drug benefit through their choice of health plan. The changes we propose in this paper apply only to those enrolled in traditional Medicare; those enrolled in Medicare Advantage receive drug coverage, should they elect it, through their Medicare Advantage plan, and we believe that arrangement should continue.

A second problem arises because some persons are eligible for both Medicare and Medicaid. Before Part D was enacted, Medicaid was already buying prescription drugs for its low-income participants under a "best price" rule: the price at which manufacturers must sell is the lower of the best private price or 15.1 percent below the average manufacturer price, the price at which manufacturers sell to wholesalers net of prompt-pay discounts (Scott-Morton 1997). The MMA effectively shifted the responsibility for paying for prescription drugs for some 6.6 million dually eligible beneficiaries from Medicaid to Medicare. This appears to have resulted in significant price increases for drugs used by Medicare beneficiaries, giving some drug manufacturers a windfall. AstraZeneca, Eli Lilly, Bristol-Myers Squibb, and Pfizer have acknowledged, in recent filings with the Securities and Exchange Commission, reductions in the size of rebates they have granted to Medicaid, implying that the prices they receive have increased.[3]

Third, in order to meet the strict ten-year budget target, Part D could not afford full coverage. Instead Congress created the notorious "donut hole," which, as noted above, leaves a coverage gap for each participant's total annual drug spending between $2,400 and $5,451 (in 2007). Part D "basic" plans are actually prohibited from increasing deductibles and reducing the size of the donut hole, even if doing so keeps the premium constant. The result is that the expected 25 percent of Part D enrollees who will incur at least $2,400 in drug costs in a given year will have to pay 100 percent of their next $3,051 of spending on drugs—this after having already absorbed substantial out-of-pocket spending on premiums, deductibles, and copayments for the first $2,400 (Cubanski and Neuman 2006).[4] Although this design does offer catastrophic coverage, in that most spending beyond the donut hole is covered, it runs counter to fundamental insurance principles that emphasize protection against larger risks (in this case, that of incurring drug expenses between $2,400 and $5,451) over smaller ones (that of incurring less than $2,400).

Finally, before Part D's enactment, Medicare Part B already covered certain drugs, and Congress chose to leave these drugs under Part B rather than consolidate all coverage under the new Part D. The principal criterion for determining whether a drug is covered under Part B or Part D is how it is administered (broadly speaking, whether usually administered by a health professional or self-administered, respectively). As a result, manufacturers have an incentive to game the system, formulating the delivery mechanisms for new drugs so as to generate the greatest reimbursement.

3. Neither the population covered nor cost sharing changed materially for the dually eligible, and therefore these factors cannot explain the rise in drug company revenue. See the 2006 Forms 6-K and 10-Q for AstraZeneca, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Merck, Novartis, Pfizer, and Wyeth, available at www.sec.gov/edgar.shtml.
4. For those with the standardized benefit, cost sharing for those who spend enough to just reach the donut hole amounts to almost $800. This, of course, is in addition to cost sharing for physician visits, hospital stays, and other services.

III. Steps toward Mending the Drug Benefit

The enactment of a Medicare drug benefit was a major political accomplishment. But as we have just documented (as have others; see, for example, Huskamp et al. 2000), the policy that was politically acceptable has numerous undesirable properties. It is tempting to propose starting over, and many ideas have been offered for how to do that. But a radical change in the program's architecture at this point would require refashioning a delicate political compromise, which could endanger the gains that have been made. Starting over would also add to the confusion and frustration of the beneficiary population. Fortunately, important steps can be taken within the existing architecture of Part D to mend the program and improve its impact. We focus on four such steps: simplifying beneficiary choices; improving the benefit design and filling the donut hole; enhancing the purchasing power of PDPs and reducing costs to the government; and ending the confusing distinction between Part B and Part D drugs.

Better Informing Consumers and Simplifying Choices

Although many Americans under 65 have a choice of health plan, virtually none has an independent choice of a drug plan. For most people under 65, drug coverage comes packaged with their employer-provided health insurance plan. (Indeed, even where a choice of health plan is offered, the employer may have carved out the drug benefit and given all the business to one PBM, in which case employees have no choice of drug plan.) The same used to be true for Medicare: before Part D, except for the small minority who purchased individual Medigap plans, Medicare beneficiaries with supplemental coverage for drugs had no choice of drug plan. Thus Part D presents Medicare beneficiaries with a very different setting for purchasing insurance against drug spending than had previously existed in the marketplace. (Most beneficiaries who have employer-provided retiree health insurance have continued with that coverage and thus do not face the situation we are about to describe.)

How PDP Choice Works. Under Part D the nation is divided into thirty-four geographic regions that define PDP markets. Within these markets PDPs may offer Medicare beneficiaries electing to participate in Part D a choice of three types of plan: a standardized benefit plan; a plan that is actuarially equivalent to the standardized benefit plan;[5] or a plan that offers enhanced benefits. In 2007 the standardized benefit plan consists of a $265 deductible, 75 percent coverage (a 25 percent copayment) up to $2,400 in total spending, zero benefits between $2,400 and $5,451, and "catastrophic" coverage above $5,451. In the catastrophic range (which comes into effect after a total of $3,850 in out-of-pocket spending), beneficiaries with incomes over 150 percent of the poverty line pay either a 5 percent coinsurance or $2 per generic prescription ($5 per branded prescription), whichever is greater. (Cost sharing for those with incomes under 135 percent of the poverty line is nominal, and between 135 and 150 percent of poverty there is a sliding scale.) The dollar values for the deductible, coverage thresholds, and copayment obligations will increase annually with growth in total Part D spending.

Actuarially equivalent PDPs may offer a variety of plan designs where deductibles, copayment and coinsurance arrangements, and the availability of mail order services vary. PDPs have considerable discretion in designing such benefits. For example, copayment arrangements frequently involve tier-

5. Regulations limit the ways in which actuarial equivalence can be realized. Most significantly plans that do not offer enhanced benefits cannot increase the deductible above that in the standardized plan.

TABLE 1

Distribution of Key Plan Features across Medicare Part D Plan Types, 2006 and 2007

	Percent of all plans with indicated feature[a]			
Feature	All plans	Standardized plans	Actuarially equivalent plans	Enhanced plans
Deductible				
Zero	60 (58)	NA	(18)	(40)
Reduced	8	NA	(5)	(3)
$250	32 (34)	9	(25)	(0)
Cost sharing				
25 percent copay	10 (9)	(9)	(0)	(0)
Tiered	90 (91)	NA	(48)	(43)
Coverage in donut hole				
Generics only	27	NA	(0)	(0)
Generics and branded	1	NA	(0)	(2)
None	71	(9)	(48)	(27)
Memorandum: share of all plans	100	12 (9)	41 (48)	47 (43)

Source: Hoadley et al. 2006.
a. Values are 2007 values, except those in parentheses, which are 2006 values.
NA = not applicable.

ing, which means that the copayment varies according to the formulary status of the drug. Generics carry the lowest copayments, followed by preferred branded drugs, with nonpreferred branded drugs and so-called specialty tier drugs carrying the highest copayments. The definition of preferred branded drugs can differ substantially across plans. PDPs may also offer enhanced benefits (such as coverage in the donut hole), but the premium must then reflect the full additional cost—Medicare will not subsidize coverage that is above the actuarial value of the basic benefit. Table 1 presents a distribution of plans by major benefit design features, illustrating the variety of choices available.

Across the thirty-four regions, a total of 1,875 PDPs are offered in 2007. Of these, 228 offer the standardized benefit, 760 offer benefits that are actuarially equivalent to the standardized benefit, and 887 plans offer enhanced benefits (Hoadley et al. 2006). Sixteen large PBMs or health insurance companies offer most of these plans (MedPAC 2006). In each region, plans with sufficiently low premiums can qualify to receive low-income subsidies and accept people who are automatically enrolled because they are dually eligible for Medicare and Medicaid (see below). The number of such plans in each region currently ranges from five to twenty (Hoadley et al. 2006).

As described above, PDPs also have some discretion over the formulary designs they offer. Before Part D went into effect, all PDPs were required to submit their proposed formulary design to CMS for approval. This requirement was put in place to limit PDPs' ability to use formulary design to compete for good risks and thereby discourage enrollment by Medicare beneficiaries with high expected levels of prescription drug spending. Administering this condition forced CMS to make a determination about whether a given plan's proposed breadth of coverage within particular therapeutic classes was adequate. This was a scientifically and economically complicated and difficult task. Because formularies involve choices among 1,000 or more major drugs, the potential number of acceptable formularies is likely to be quite large. In addition, PDPs can use a variety of management

techniques that assist efficient prescribing but may also make their plans more or less attractive to certain beneficiaries. These techniques include prior authorization requirements, stepped care protocols, and fail-first policies, among others. These dimensions create numerous other permutations in the number and types of drugs that can be used to treat specific conditions, especially for people with multiple conditions.[6]

In short, Medicare beneficiaries in a typical region face a choice of roughly fifty different drug plans, including standardized benefit plans, actuarially equivalent plans, and enhanced plans. In choosing a plan, beneficiaries must make comparisons across the numerous features that distinguish one plan from another, and must understand which features are most important to the management of their own drug needs. An important body of research documents that the typical consumer can become overwhelmed by such a large number of complicated choices (Camerer 2000, McFadden 2006, Thaler 1999). Although CMS and other agencies have assisted beneficiaries in choosing plans, such complexity makes it likely that consumers will still make important errors in choosing a PDP.

McFadden (2006) reports on a survey of older Americans undertaken in November 2005, just before the launch of the Part D benefit. Respondents were given a hypothetical choice among no drug coverage, the standardized plan, and three actuarially equivalent alternatives. Only about 36 percent of respondents chose a plan that offered them the best financial protection (that is, the lowest expected out-of-pocket costs). In fact, only 26 percent preferred the plan with the best catastrophic protection, even though it was the plan with the lowest out-of-pocket costs for 51 percent of respondents. These results are troubling because the choices studied by McFadden are far simpler than those actually faced by Medicare beneficiaries.[7]

Initial CMS data on Part D enrollment show that nearly 25 percent of Medicare recipients who were estimated to qualify for a low-income subsidy for drug coverage did not enroll in any Part D plan (Kaiser Family Foundation 2006b). This is a surprising result, given that coverage was essentially free to this population. The complexity of the decision may have discouraged enrollment among this group of Medicare recipients, who typically have less education than others and frequently live alone.

A survey conducted for MedPAC in February 2006 asked Medicare beneficiaries about their decisions to join a Part D plan. Most beneficiaries were aware of the benefit but expressed difficulty in understanding how it worked. They frequently relied on family members for help in choosing, but the family members, too, were generally poorly informed about the Part D benefit. The survey reported that 41 percent of those who signed up, 65 percent of those who considered signing up, and 28 percent of those who did not consider signing up found it either difficult or very difficult to understand the choices. The survey also asked those who did not enroll their primary reason for that decision. Among those without some other form of coverage, 36 percent said they did not fill many prescriptions, 9 percent said they were too confused, 7 percent did not know enough to join, and 24 percent thought the program would not save them much money (MedPAC 2006). It is not clear whether this pattern of responses is what would be observed with the introduction of any new product, or whether it reflects the complex structure of choices within Part D specifically. The additional enrollment experience gained during 2007 will allow further understanding of this issue.

A recent study of PDP premiums shows that, holding benefit design and formulary structure constant, premiums were not lower in markets with

6. Formulary design and the use of other utilization management techniques are not part of the assessment of actuarial equivalence in benefit design.
7. Ironically, however, the weaker the ability of consumers to make effective choices between plans, the less of a problem adverse selection poses.

more plan offerings (Simon and Lucarelli 2006). The study also finds only a weak relationship between expected out-of-pocket costs (a measure of plan generosity) and the premium charged. A possible explanation of the latter finding is that expected out-of-pocket costs may vary considerably depending on the placement of the drugs that the person takes on the plan's formulary. But one plausible interpretation consistent with both findings is that the choice environment is so complex that consumers cannot effectively respond to market signals, and thus the expected relationships among prices, choice, and product characteristics either do not hold or hold only weakly.

There is as yet no direct evidence on PDP responses to selection incentives. The June 2006 MedPAC report suggests that it may be too early to tell how benefit structure, utilization management, and formulary design tools will be used and what their ultimate impact on enrollment patterns will be.

Improving the Plan Choice Process. Clearly, Part D benefits confront participants with a far more complex set of options than people face in most employment-based health insurance programs. We believe that their choices could be reduced and simplified without harming price competition among PDPs.[8] Indeed, simplification of choice would most likely result in more effective consumer choice and enhanced competition.

Choices can be made simpler and clearer by developing a set of standardized benefit packages *within* the groups of actuarially equivalent and enhanced PDPs and reducing the number of choices within each grouping, including the existing standardized plan. During 2006, CMS floated the notion of reducing the number of plans being offered under Part D, because of concerns about confusion. But in fact the number of PDPs offered increased by 31 percent in 2007 (Hoadley et al. 2006).

Benefit standardization has already proved effective in health insurance for the elderly, in the so-called Medigap market where Medicare recipients can purchase supplemental insurance. The aims of standardization for Part D parallel those originally pursued in regulating the Medigap market (Rice and Thomas 1992). The Baucus Amendments to the Omnibus Budget Reconciliation Act of 1990 stated that Medigap plans must:

> provide benefits that offer consumers the ability to purchase the benefits that are [currently] available in the market [and] balance the objectives of (i) simplifying the market to facilitate comparisons among policies, (ii) avoiding adverse selection, (iii) providing consumer choice, (iv) providing market stability, and promoting competition. (P.L. 96-265, Sec. 507)

The 1990 legislation required that Medigap plans conform to one of ten standardized plans. The National Association of Insurance Commissioners (NAIC) was assigned the task of developing the standardized plans (Fox, Rice, and Alecxih 1995). The NAIC designs required all Medigap plans to cover benefits viewed as important but unavailable in the market because of adverse selection incentives (for example, home health and prevention services). The result was a more stable market that offered a set of benefits that had been eroded in the unregulated market (Rice and Thomas 1992).

We propose a similar process leading to formulation of a set of seven to nine standardized PDPs. A panel conceived for that purpose would include a mix of individuals representing various segments of the industry (PBMs, health insurers, drug manufacturers, and pharmacies) as well as consumer interests. The NAIC panel that designed the Medigap plans consisted of six individuals representing insurers and six representing consumers; a similar composi-

8. Research on the impact on price competition as choices increase shows that, after four or five competitors are present, additional entry offers little in the way of additional price reductions (Bresnahan and Reiss 1991). Reiffen and Ward (2005) offer some empirical evidence of this in the pharmaceutical market.

tion would be sensible in this case. The standardized plans would include the existing one specified in the MMA plus three to four new plan types that would be actuarially equivalent and another three to four enhanced plans. We further propose that, within the groups of actuarially equivalent plans and extended plans, there be one or two different tiered formulary structures, one or two different deductible arrangements, and one or two different approaches to donut hole coverage (for example, coverage of generics only, and coverage of generics and branded drugs).[9]

We believe that the resulting six to eight additional plans would allow for meaningful variation in plan offerings with respect to deductibles, cost sharing, and mail order coverage among both the actuarially equivalent and the enhanced plans. In addition, research on effectiveness of choice in 401(k) retirement plans indicates that employers offering ten or fewer plan choices have significantly *higher* employee participation than those offering more choices (Sethi-Iyengar, Huberman, and Jiang 2004).

Finally, standardization of plans would allow CMS to address another problem. Recall that a substantial proportion of people who did not enroll in Part D would have been eligible for a low-income subsidy, and that many who did enroll likely selected a plan that did not offer the lowest expected out-of-pocket costs. The behavioral economics literature suggests that modifying default options for benefit plans can help increase enrollment and improve choices (Thaler and Sunstein 2003), and the use of specific default options to improve decisionmaking in Part D and in Medicare generally has been suggested by McFadden (2006) and Frank (2007), respectively. Under this approach, all new Medicare beneficiaries would be automatically assigned to a designated default plan from among the new standardized plans; the default plan would be an actuarial equivalent of the standardized plan offering the "best" insurance features for the average enrollee. New Medicare beneficiaries not interested in participating in Part D would have to actively opt out.

This approach is not so dissimilar from the automatic enrollment option now used with the Medicaid eligible and other identified low-income individuals. We expect that it would result in expanded enrollment among beneficiaries eligible for the low-income Part D subsidy, and perhaps others as well. In addition, it would require participants to make an active choice to enroll in a plan that lacked attractive financial properties for the average beneficiary. The approach thus preserves freedom of choice but reduces some negative outcomes associated with human inertia or confusion.

Competition for Regional Plan Contracts. We also propose reorienting the nature of PDP competition, from competition for enrollees toward competition for contracts to offer the standardized plans. Although standardization of plans would simplify choices and allow enrollees to make more effective price-coverage comparisons, important dimensions of the care management process would remain that cannot be contracted for in advance. Formulary designs and utilization management arrangements cannot be completely regulated; hence important selection incentives will persist.[10]

Therefore we propose that, in each region, one contract be awarded to a single insurer for a limited period, on the basis of price, quality, and formulary design criteria. The duration of the contract should be set so that the threat of contract loss with poor performance is credible. Each insurer seeking the contract would submit a separate bid for each of the seven to nine standardized plans, along with formulary design plans.[11] The price bids would be evaluat-

9. It has been argued that plan standardization might dampen innovation in benefit design. To address this issue, one standardized plan in each category might be designated an "experimental" plan, which a firm could propose and try out for a limited period. That firm could add no other new plan unless one was eliminated.
10. The reduced number of generous enhanced plans in the second year of Part D suggests selection behavior is at work in this market.
11. The formulary design criteria might include an assessment of whether a majority (or a supermajority) of potential enrollees would find the drugs they take on the proposed formulary.

ed by considering, for each bidder, the weighted average of its bid prices across the standardized plans. The initial weights could be based on current enrollments in the major classes of existing plans. Under standard models of competition, however, it is welfare improving for low-option plans to subsidize high-option plans (Rothschild and Stiglitz 1976). Some incentive in this direction could be given if the evaluation overweighted enrollment in high-option or generous plans, thereby giving bidders an incentive to increase enrollment in these plans. But even if this wrinkle were not adopted, one insurer would be granted all of an entire region's PDP business for the contract period. This would considerably reduce its adverse selection incentives. This proposal has the further advantage of maintaining considerable choice of plan types and creating incentives for price competition in premiums.[12]

This model of purchasing more closely resembles the PBM procurement methods of private health insurance plans than does the existing Part D structure, and in fact it is very similar to that of an employer that carves out its drug benefit. (Again, almost no such employer offers a choice of drug plan, but the arrangement we propose here would be identical to such a benefit.) Given competition across thirty-four separate regions, there is little chance that a single plan sponsor would become dominant nationally; thus, competition would be preserved for future contract negotiations. Maintaining robust future competition for contracts could be further strengthened by limiting the aggregate national Medicare PDP market share of a single firm (for example, to 30 percent).

This proposal would require CMS to run thirty-four regional procurement processes for the standardized plans, similar to those it now runs for intermediaries and carriers to administer Parts A and B. It would clearly add to the agency's responsibilities. Recall, however, that the agency in 2006 reviewed and processed premium bids, formulary design plans, and a utilization management arrangement for 1,429 plans, and even more in 2007. We recognize that selecting the "winner" of a franchise-like competition in each region would be more administratively demanding than simply approving plans, and that therefore our proposal could result in higher administrative costs.

Competition for exclusive contracts for all Part D participants within a region may not be achievable politically. In that case a useful fallback would be to employ it only for the institutionalized population. Before Part D, nursing homes mainly dealt with their state's Medicaid plan and their long-term care pharmacy provider when obtaining drugs for their residents. They now must deal with many plans with different formularies, potentially causing confusion and adding administrative cost. We see little advantage to this situation and believe there is an even stronger case to implement competition for contracts in the nursing home setting than for Part D generally. Whether the competition takes place at the level of the individual nursing home, the nursing home chain, or the region is a question we leave open. Given the needs of nursing home residents and their relatively high prevalence of cognitive impairment, a single plan might also be required to have a more open formulary than Part D plans presently offer. This would effectively set up an entirely separate drug benefit for the institutionalized, but we believe there is much to be said for this approach.

Filling the Donut Hole

The coverage gap or "donut hole" in the standard Part D plan requires enrollees to pay 100 percent of their expenditure on prescription drugs between $2,400 and $5,451 in total drug spending. This leaves beneficiaries exposed to out-of-pocket costs totaling $3,850 before the catastrophic coverage provisions kick in. As already noted, standardized and actuarially equivalent PDPs are prohibited from increasing the size of the deductible to reduce the size of the donut hole.

12. For a general discussion of the advantages of competition for contracts in prescription drugs, see Huskamp et al. (2000).

Projections for 2006 indicated that in that year about 4 million Part D participants, or 25 percent of the total, would incur expenses in the donut hole not covered by low-income subsidies (Cubanski and Neuman 2006).[13] Among these participants, average out-of-pocket spending was estimated to be approximately $2,530 (PriceWaterhouseCoopers 2006). Roughly 70 percent of those who encountered the donut hole would not cross the catastrophic coverage threshold, and only about one-third were expected to incur spending of $1,500 or less.

The donut hole awkwardly balances concerns about the cost of providing a truly valuable drug insurance benefit with the desire to extend that benefit to as many recipients as possible. But relaxing the prohibition on increasing the deductible can increase the welfare of recipients even while adhering to existing budget rules. In other words, benefit designs that are actuarially equivalent to the current standardized design can offer typical Medicare beneficiaries better protection (McFadden 2006).

We propose shifting this trade-off—between offering more insurance protection and providing more people with benefits—in the direction of the former. This could be accomplished by relaxing restrictions on the ability of PDPs to offer actuarially equivalent plans that provide greater coverage in the donut hole. In particular, allowing larger deductibles in combination with more complete donut hole coverage would move plans toward more valuable protection against larger losses, and away from less valuable up-front, first-dollar protection. This is exactly what basic insurance principles imply.

A second measure would be to mandate coverage of generic medications in the donut hole, the most common form of coverage offered by enhanced benefit plans. Generic drugs are widely prescribed: about 50 percent of all prescriptions are for generics, and the rate is even higher among the lower-income elderly (Thomas, Ritter, and Wallack 2003).

Few precise data are available on the cost of extending coverage of generic drugs in the donut hole, but the incremental premiums required for such coverage appear quite modest (MedPAC 2006, table 7-8). Existing data suggest that such coverage would increase premiums by at most $21 a month for existing plans (Hoadley et al. 2006).[14] But the benefits of such a reform could be great. Coverage in the donut hole may result in higher rates of adherence to treatment regimens among those with chronic disease. This, in turn, might mean financial savings for Parts A and B of Medicare through averted spending, not to mention better health outcomes for beneficiaries (Hsu et al. 2006, Fendrick et al. 2001).

Improving the Cost Effectiveness of Purchasing

One of the promises of Part D was that elderly Americans could benefit from the bargaining power of larger and more sophisticated purchasers. PDPs were expected to build on advances in purchasing practices observed in the private sector, and in particular the emergence of the PBM industry and its use of formularies. Thus the design of Part D represents a substantial departure from the take-it-or-leave-it pricing that Medicare uses for all other medical goods and services, as well as from the principle that services from all providers should be available for almost the same price.[15] The private sector approach to purchasing, however, works best when there is robust competition. That requires the existence of multiple therapeutic substitutes, so that PDPs can obtain a favorable price by steering greater numbers of people to buy one drug rather than another in response to favorable price offers from manufacturers (Frank 2001, Newhouse 2004).

13. This estimate is based on the assumption that 15 percent of enrollees in Part D are in enhanced plans that offer coverage in the donut hole; it excludes the low-income group from the denominator since there is no donut hole for them.
14. This is an upper bound because of selection against existing plans by those expecting to spend in the donut hole and use generic drugs.
15. The 20 percent coinsurance in Part B creates modest differences among prices charged by physicians for the minority of beneficiaries who pay the coinsurance, and some further difference is created by the minority of physicians who do not accept assignment.

Expectations for Drug Prices under Part D. The design features of Part D were based on some specific conceptions of price dynamics in the market for prescription drugs (CBO 2002). In general, the expectation was that most prices would fall with the introduction of Part D, or at least not increase notably. These expectations relied on notions of how prices are set for various segments of the market.

Medicare recipients who had no drug coverage before 2006 generally paid the highest prices in the market, because they purchased through retail pharmacies. Retail pharmacies have little bargaining power over the prices they pay for branded prescription drugs, reflecting their inability to implement a formulary that would enable them to shift purchases among competing products (Frank 2001). These recipients were therefore expected to benefit from lower drug prices under Part D, because their drug purchasing would now be made through PDPs, which do have formularies and other means of steering demand toward products on which price concessions are offered. For this group the shift in purchasing arrangements has the effect of making demand for individual products in most drug classes more price responsive.

In contrast, drug prices for those dually eligible for Medicare and Medicaid were expected to rise, but only modestly (CBO 2002, Chapter 3), because of two offsetting factors. Before 2006, dually eligible individuals had drugs purchased for them through Medicaid's "best price" rebate system, described above (Scott-Morton 1997). Under Part D, these beneficiaries were automatically shifted to PDPs, which operate under special rules. If they negotiate prices below Medicaid's "best price," these prices are not counted under the best price system. This creates a bargaining advantage for PDPs over other private plans, which should lower prices. At the same time, however, the enactment of Part D meant that demand for prescription drugs generally was sure to increase, creating upward pressure on prices because of the market power of most branded drugs. The expected net effect was a modest price rise.

Finally, unique drugs that offer important clinical advantages to elderly users pose a challenge to the Part D approach to prices, because of the monopoly power such drugs enjoy (Newhouse 2004). Nevertheless, it was expected that this issue would have little overall effect on prices paid, for three reasons. First, it was thought that unique drugs were few in number and would remain unique for only a short time (CBO 2002, Newhouse, Seiguer, and Frank 2007). Second, the substantial cost sharing within the donut hole under Part D was expected to serve as a constraint on pricing. Third, the private sector would purchase a substantial volume of such medications and would use more powerful negotiating tools to contain costs (CBO 2002).

What Actually Happened. As we describe below, prices actually paid by Medicare in the initial phases of the Part D program appear to differ from expectations in some respects. In particular, for the 29 percent of Part D enrollees who are dually eligible for Medicare and Medicaid, the shift from the "best price" model of purchasing to the commercial PDP models seems to have resulted in significant rather than modest increases in the prices paid to manufacturers. Why this may be so is a matter of speculation. Because the market for PDPs is for now quite fragmented, because PDPs receive substantial subsidies from Medicare, and because they face only small levels of financial risk, their ability to shift between similar drugs and bargain hard with manufacturers may be more limited than previously expected. As a result, the impact on Part D spending may be greater than was anticipated.

The prices obtained by PDPs for drugs that had been heavily used by dually eligible beneficiaries can offer some insight into the ability of PDPs to get the best private prices. Unfortunately, these prices cannot be directly compared, because both Medicaid and PDP prices are confidential. Some information about the pricing environment, however, can be gleaned from examining the public financial statements of drug manufacturers during the first six months of 2006, which assess the impact

on manufacturer revenue from shifting the dually eligible from Medicaid to PDP pricing arrangements.

We reviewed manufacturers' Form 10-Q filings with the Securities and Exchange Commission and looked for commentary or data on drugs that are heavily used by dually eligible Part D participants. One class of such drugs is antipsychotic medications, 70 percent of which were purchased by Medicaid before January 2006. AstraZeneca (maker of Seroquel), Bristol-Meyers Squibb (Abilify), Eli Lilly (Zyprexa), and Pfizer (Geodon) all noted favorable (for them) changes in prices resulting from the shift of large numbers of users of antipsychotic medications from Medicaid to Part D. For example, Bristol-Meyers Squibb stated that the shift in patient enrollment to Part D had a positive impact on the company's bottom line, which was partly offset by a negative impact in the managed care side of the business. Similarly, Lilly noted an increase in effective net selling prices for Zyprexa, partly due to the transition of certain low-income patients from Medicaid to Medicare. Finally, Pfizer pointed to a more general impact of the price gains from the payment shift: the company saw a $325 million increase in revenue from this source for the first six months of 2006 compared with the same period in 2005, or approximately an 8 percent increase in net revenue. A clear inference from these figures is that PDPs are not obtaining prices that approximate the best price in the private market. Manufacturers have realized significant gains simply from the change in responsibility for purchasing from Medicaid to Medicare.[16]

In the case of unique drugs, as already noted, PDPs are potentially in a weak bargaining position because they have limited ability to redirect demand away from the unique product. Moreover, in the Medicare context there will surely be strong political pressure not to allow PDPs to leave such unique—and presumably superior—products off the formulary. Thus the threat of exclusion because of a high price is unlikely to be credible—and because of the formulary regulations, which are set on clinical, not economic, considerations, it may even be precluded. The incentive for a PDP to bargain hard with the manufacturer is further blunted by the fact that the government is responsible for 80 percent of an individual beneficiary's drug costs above $5,450, and the beneficiary for 5 percent. Thus the PDP faces only a 15 percent liability for beneficiaries in this range of spending. (In the case of specialty drugs, which frequently carry high prices, the consumer is responsible for 25 percent of the cost and the government 75 percent.)

Because the insurer shares the cost with others, the manufacturer of a unique drug, especially one heavily used by the elderly, may be able to set a price that is much higher than that of a monopolist selling to an uninsured market, and still sell the same quantity.

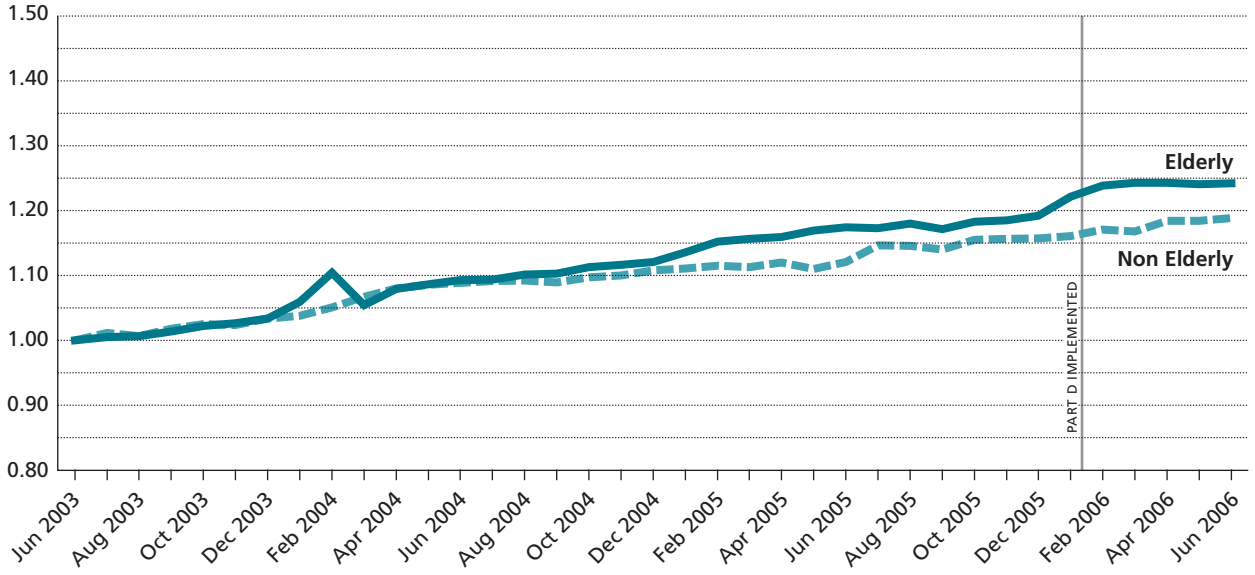
In other words, the manufacturer's market power comes not only from the patent(s) it holds, but also from the patient's insurance coverage: outside the donut hole, the patient faces little or no incremental cost from a higher price. As a result, consumer demand for drugs is markedly less responsive to the monopolist's price than it would be in a market of uninsured consumers, the usual case outside of health care. The combination of a lack of competing drugs and insurance that covers a high percentage of the patient's cost effectively puts the patent system on steroids.

How important are unique drugs in the marketplace? New drugs with important therapeutic advantages are regularly introduced into existing therapeutic classes, and some new products result in the creation of new classes. Significant market power can arise in either case. In other work we have identi-

16. It is highly unlikely that the higher prices represent a move to an efficient price, because for several drug classes that relied largely on sales to Medicaid, such as the antipsychotic class described in the text, there were high rates of entry of new drugs. We infer that expected revenue at Medicaid prices was sufficient to encourage R&D for new products in those classes.

FIGURE 2

Price Indexes for Drugs Used by the Elderly and the Nonelderly



Source: Authors' calculations based on CMS data.
Note: Price indexes are Laspeyres indexes.

fied drugs that were the first to appear in their class. Between 1970 and 2000 the number of such drugs averaged about 3.5 a year (Newhouse, Seiguer, and Frank 2007). Recently that number has dropped markedly: only five drugs brought to market were first in their class in the entire period between 2000 and 2004, or just one a year on average. In recent years, drugs that were first in their class have remained in that position for about three years.

Identifying drugs that offer unique therapeutic advantages within an existing class is more difficult than identifying first-in-class drugs. But we can point to some recent examples, including Forteo, which treats osteoporosis, and Plavix, which treats heart disease. In addition, some drugs maintain a dominant position in sales to elderly Americans despite having therapeutic competitors. Such drugs include Norvasc, an antihypertensive, Xalatan for glaucoma, and Toprol for heart disease. Thus, we believe the enhanced market power for manufacturers created by Part D has the potential to create a distributional imbalance, offering substantially greater economic rents to the manufacturers of some drugs than would be observed in an uninsured market. Any such rents, of course, further aggravate the parlous future financial health of Medicare.

There are indications that prices have responded in the anticipated fashion. Some of the most significant price changes during the first half of 2006 reported by manufacturers of branded prescription drugs occurred in drugs that were relatively unique and had high shares of elderly buyers. Examples include Plavix, Forteo, and Evista (another drug used in preventing osteoporosis).

To explore such price effects more systematically, we compared two subgroups of drugs selected from the top fifty best-selling prescription drugs in the United States. The first subgroup consisted of ten branded drugs with elderly usage shares of 55 percent or greater, and the second of ten branded drugs with elderly shares of less than 35 percent. None of the drugs in either group has generic equivalents on the market. Figure 2 plots price indexes for the two groups. These indexes moved at identical rates during the year before passage of the MMA but began to diverge during 2004 and to move further apart around January 2006, when Part D was imple-

mented.[17] By June 2006 there was a 6-percentage-point difference between the indexes, favoring the drugs with high elderly shares. We attribute this divergence to the changes in Part D for the dually eligible population and enhanced pricing power for unique drugs.[18] The extent to which these prices will continue to diverge in the future, of course, remains unknown.

Obtaining Better Prices While Preserving Innovation Incentives. Any proposal to alter approaches to setting prescription drug prices must recognize the threat posed to research and development (R&D) incentives and to the industry's ability to attract capital if prices are set "too low." Pharmaceutical R&D has produced enormous economic value in recent decades (Murphy and Topel 2003). Moreover, many important diseases, including Alzheimer's disease and many cancers, still have little effective therapy, so further R&D will likely prove valuable. Thus, the key trade-off sets the risk of reduced R&D incentives against bestowing additional economic rents on the pharmaceutical industry and creating greater stress on an already troubled federal budget.

Recent assessments of the evidence suggest that the pharmaceutical industry's profitability does modestly exceed that of the Fortune 500, even after adjusting for intangible capital and differences in risk (CBO 2006b, chapter 6). Further, analyses of incentives in prescription drug markets that stem from patents and insurance subsidies suggest that incentives for excessive innovation exist (Garber, Jones, and Romer 2006). Since Part D represents an important expansion of insurance subsidies in pharmaceuticals, any preexisting incentive to overinvest in R&D is an important consideration.

On the other hand, unique, clinically important drugs are by definition exactly those from which society benefits most by offering large rewards to drug manufacturers. Focusing cost control efforts on these drugs may impose particular risks on precisely the R&D that should be most encouraged.

We propose, as a first step toward establishing a better balance between control of Medicare spending and protection of R&D incentives, that manufacturers be required to sell drugs to PDPs for use by dually eligible beneficiaries at prices that approximate the previous Medicaid prices. This would serve to restore the balance to its pre-January 2006 level, a set of prices that appeared acceptable to all parties. The impact on Medicare spending would likely be significant, given that the dually eligible account for an even larger share of Part D drug purchases than their 29 percent share of the Medicare population. There should be little additional administrative cost. PDPs would report their purchases on behalf of dually eligible enrollees, and the manufacturer would provide a corresponding rebate to the federal government, much as rebates are now provided to Medicaid.

We believe that it is premature to conclude that enough unique drugs exist today to create a meaningful budget problem. Therefore we propose that the prices of such products be carefully monitored and that government be prepared to intervene if such a problem arises. If it does, we propose that the government put in place temporary administered prices for unique drugs. The goal would be to establish a price for Medicare Part D that preserves R&D incentives, recognizes the potential health benefits of new products, and limits the economic rents paid by the Medicare program. The establishment of this price could be accomplished through a system of binding arbitration or via rate setting as in the rest of Medicare. Under either case the government would develop a price proposal.

The first step in developing a temporary price proposal for a given unique drug would be to project

17. By contrast, Berndt et al. (1998) found that during the early 1990s price indexes for drugs used by the elderly did not differ significantly from those for drugs used by others.
18. Other sources offer consistent observations. For example, AARP (2006) reports larger increases in the average cost of treating chronic conditions of the elderly between 2005 and 2006 than in any of the previous five years.

the per unit price that would allow the manufacturer to recoup its R&D costs given the expected volume of sales, in the United States and abroad, and the average cost of developing a new drug with the specific attributes in question. We recognize that most drug R&D involves joint costs across a number of products, making any such calculation inherently arbitrary to some degree. We propose, for simplicity's sake, that the joint costs be allocated according to the ex ante volumes of sales across the drugs in question. The aim of using the expected costs and domestic and foreign sales volumes in the calculation is to arrive at a base price that supports an expected breakeven point plus some margin. This was the method used by the Office of Technology Assessment (1990) to recommend a Medicare reimbursement level for erythropoietin (an antianemia drug). Using such a price preserves incentives for manufacturers to conduct both R&D and product launch activities efficiently.

We would then propose an adjustment to the base price to take account of the drug's unique health benefits. This would be done by calculating the improvement in cost per quality-adjusted life year offered by the new drug over the average existing treatment and adjusting the price accordingly. The adjustment would thus reflect any increase in willingness to pay for the drug's clinical advantages, such as would be expected to occur in a well-functioning market (Lu and Comanor 1998, Reinhardt 2004). The aim here is to offer greater economic rewards for new products that offer more important benefits. This would serve to give greater weight to R&D that promises relatively better health outcomes per dollar.

The temporary administered price would remain in place until the entry of two additional drugs offering meaningful therapeutic competition to the drug in question (Bresnahan and Reiss 1991). At that point, price determination would revert to the market.

Regulation of price and insurance coverage of new prescription drugs in other nations uses some similar concepts in establishing prices for new drugs. In Australia the government negotiates prices based on evidence on cost effectiveness (also measured in cost per quality-adjusted life year), prices of alternative products, cost information provided by manufacturers, prescription volume, overseas prices, and the importance of the selling firm to the Australian economy. The relative cost effectiveness of the new drug is used to establish a price premium for any therapeutic advantages it offers (Birkett, Mitchell, and McManus 2001).

U.K. pharmaceutical regulation establishes a rate-of-return corridor for firms across the whole of their business in the United Kingdom. An important feature is that new products are exempted for their first five years on the market. The accounting is complicated, in part because of the problem of allocating joint costs of R&D, noted above. This approach seems impractical for application in the limited context that we propose, since our proposal would apply primarily to newer products, and the rate of return at the firm level will by and large not be relevant. Because the proposal focuses on pricing above the expected breakeven point, the new products will contribute positively to the rate of return of the innovating firm.

Finally, a variety of commentators have suggested that Medicare set prescription drug prices based on those currently obtained by the Department of Veterans Affairs (VA). We think this approach would be unwise, for four main reasons. First, the VA not only purchases drugs but also dispenses them from centralized pharmacies staffed by VA employees. This is dramatically different from relying on retail pharmacists to distribute prescription drugs as is done under Medicare and Medicaid. For this reason alone, Medicare beneficiaries would not have prescription drugs available to them at VA prices. Yet the costs of dispensing are typically left out of price comparisons in the literature. In addition, the VA uses closed formularies for a number of drug classes and exerts a great deal of management control over its employee physicians to ensure adherence

to formulary rules. Such procedures would likely not be acceptable to either Medicare beneficiaries or their physicians.

Third, Medicare is a very large purchaser, acquiring prescription drugs for over 40 million people. Extending the VA discount beyond purchases for veterans would certainly change the economics of the bargaining between the VA and prescription drug manufacturers, such that prices to the VA would rise. Such a change in bargaining occurred following the implementation of Medicaid's "best price" scheme, resulting in higher prices to the VA and the Department of Defense. In short, if Medicare based prescription drug prices on VA prices, the VA would no longer be able to negotiate prices as advantageous as those it obtains today. Finally, even if VA prices could be negotiated for Medicare, those prices might be so low as to threaten incentives for R&D, thereby compromising the future supply of innovative new drugs.

Consolidating Drug Benefits under Part D

Medicare Part B has long covered drugs that are usually administered by clinical personnel, as opposed to those taken orally or otherwise self-administered. In 2004, Part B drugs accounted for over $10 billion in Medicare outlays (MedPAC 2006), and spending on these drugs has risen at a rapid rate, roughly doubling between 2001 and 2004. Cost sharing for Part B drugs differs from that under Part D: beneficiaries simply pay 20 percent of the cost of the drug, with no upper limit. Some beneficiaries have additional retiree health insurance that covers this cost, as does Medicaid.

Medicare currently reimburses purchasers of Part B drugs, typically physicians, a fixed 106 percent of the average sales price (ASP). Especially for drugs with a high Medicare share, this is an open invitation for the manufacturer to name a high price, since that price can simply be passed through to the government, except for any copayment. Not only does the manufacturer reap the direct benefit of a high price, but the physician also has a greater incentive to dispense a high-priced drug despite the availability of cheaper therapeutic competitors, because the physician earns 6 percent of the ASP (Jacobson et al. 2006).[19]

We propose abolishing the distinction between Part B and Part D drugs and instead covering all drugs under Part D.[20] To minimize transition issues, existing cost sharing for Part B drugs could be grandfathered for a period of time. ASP reimbursement, however, would end: PDPs would negotiate a price with manufacturers for current Part B drugs as they do now for Part D drugs. We propose, however, that whatever is done with cost sharing for these drugs be done on a budget-neutral basis; that is, projected federal spending for Part B drugs would simply be added to the federal subsidy for Part D.

Consolidating all drug coverage under Part D would end the confusing and arcane regulations surrounding what qualifies a drug for coverage under Part B rather than Part D. It would also end the incentive a manufacturer now has, when a choice of delivery mechanism arises for a new drug, to consider whether Part B or Part D coverage would maximize reimbursement. Clearly reimbursement should not influence that choice. More generally, the distinction between Part B and Part D drugs does not meet the "how-would-you-explain-it-to-your-mother" test. It is simply an anachronism from the time when Medicare did not cover most drugs but did cover some under Part B.[21]

19. This discussion ignores the incentive of the physician to account for the burden to the patient from any coinsurance.
20. For the institutionalized population, a small step in this direction has been taken by shifting some drugs previously covered by Part B to Part D, namely, those defined as "incident to" a physician's service. See CMS 2006a.
21. If Part B drugs are moved to Part D, PDPs would have to demonstrate adequate capabilities to contract with those dispensing the drugs and to deliver them appropriately (many need refrigeration). However, major PDPs now handle such drugs for their commercial enrollees, sometimes through a separate specialty pharmacy entity, so we do not see this requirement as an important barrier to entry.

IV. Conclusions

Medicare Part D has benefited millions of elderly Americans who, before 2006, either had no insurance coverage against prescription drug spending or had very limited and expensive coverage. It has been especially helpful to lower-income elderly Americans (those below 135 percent of the poverty line) who did not qualify for Medicaid, because under Part D they receive generous subsidies to aid in purchasing prescription drugs.

Elements of the design of Part D, however, force it to underachieve. It presents Medicare beneficiaries with an overwhelming array of choices and a large variety of different and complicated benefit structures. The result for many is confusion, which discourages some from enrolling at all and leads others to choose plans that do not best serve their financial interests. The program allows a great deal of leeway for PDPs to design their own formularies and adopt a variety of drug utilization management strategies. Although this freedom should lead to better tailoring of plans, it can also enable PDPs to engage in risk selection.

The design of the program also shifted several million dually eligible people away from Medicaid's drug purchasing arrangements, resulting in a substantial price increase for the drugs they use. Furthermore, by prohibiting the government from direct involvement in price negotiations for Part D drugs, the law has put manufacturers in a position where, for drugs with few or no therapeutic competitors, they can more or less name their price. This is a potentially untenable situation given the serious looming pressures on the federal budget. Finally, the legislation preserved a confusing and anachronistic distinction between Part B and Part D drugs.

We therefore propose a set of seven measures that should improve consumers' ability to choose among PDPs, reorient price competition to discourage adverse selection by plan sponsors, improve the insurance features of the basic coverage, and change the basis of price negotiations for an important subset of prescription drugs so as to lower their cost. The specific policy changes we propose are as follows:

- Standardize benefit designs to between seven and nine plan types. This would simplify plan offerings while still maintaining meaningful choice in coverage.

- Reorient competition from competition for enrollees to competition for exclusive contracts to sell the standardized plans in each of the designated thirty-four regions. This would remove the strong incentives for sponsors to compete for low-risk enrollees. If this is not acceptable politically, then at a minimum implement such a reform for the nursing home population.

- Assign every new Medicare enrollee a Part D plan as a default option. This should correct some errors now often made by consumers, especially failure to enroll, or to enroll in the "best" plan, because of misunderstanding, while still preserving free choice for those who want to exercise such choice.

- Alter the regulations governing the basic benefit so that actuarially equivalent plans can offer coverage in the donut hole. This could be done by allowing PDPs to offer plans with higher deductibles together with donut hole coverage, or by extending the basic benefit so that generic drugs are covered in the donut hole.

- Return prices paid on behalf of dually eligible beneficiaries to levels that approximate pre-Part D Medicaid prices. This would serve to balance concerns over the growing Medicare budget

with the legitimate need of the pharmaceutical industry to recoup its R&D costs.

- Monitor the prices of therapeutically unique drugs and develop a standby method of establishing temporary administered prices for such drugs. Such prices would be used only if unique drugs create important budget strains and would be removed when sufficient competition emerged to make price competition likely.

- Move all drugs now covered under Part B to Part D, on a budget-neutral basis. If desired, existing Part B cost sharing could be grandfathered for some period.

Taken together, these measures would preserve the basic principles of private provision, price competition, and enrollee choice upon which Part D was founded, while redressing imbalances that we believe have served to place consumers and public budgets at an excessive disadvantage. These measures also focus explicitly on the need to balance responsible pricing and the burdens placed on the federal budget with the critical need to maintain incentives for innovation that will result in new and better prescription drugs for future generations of Americans.

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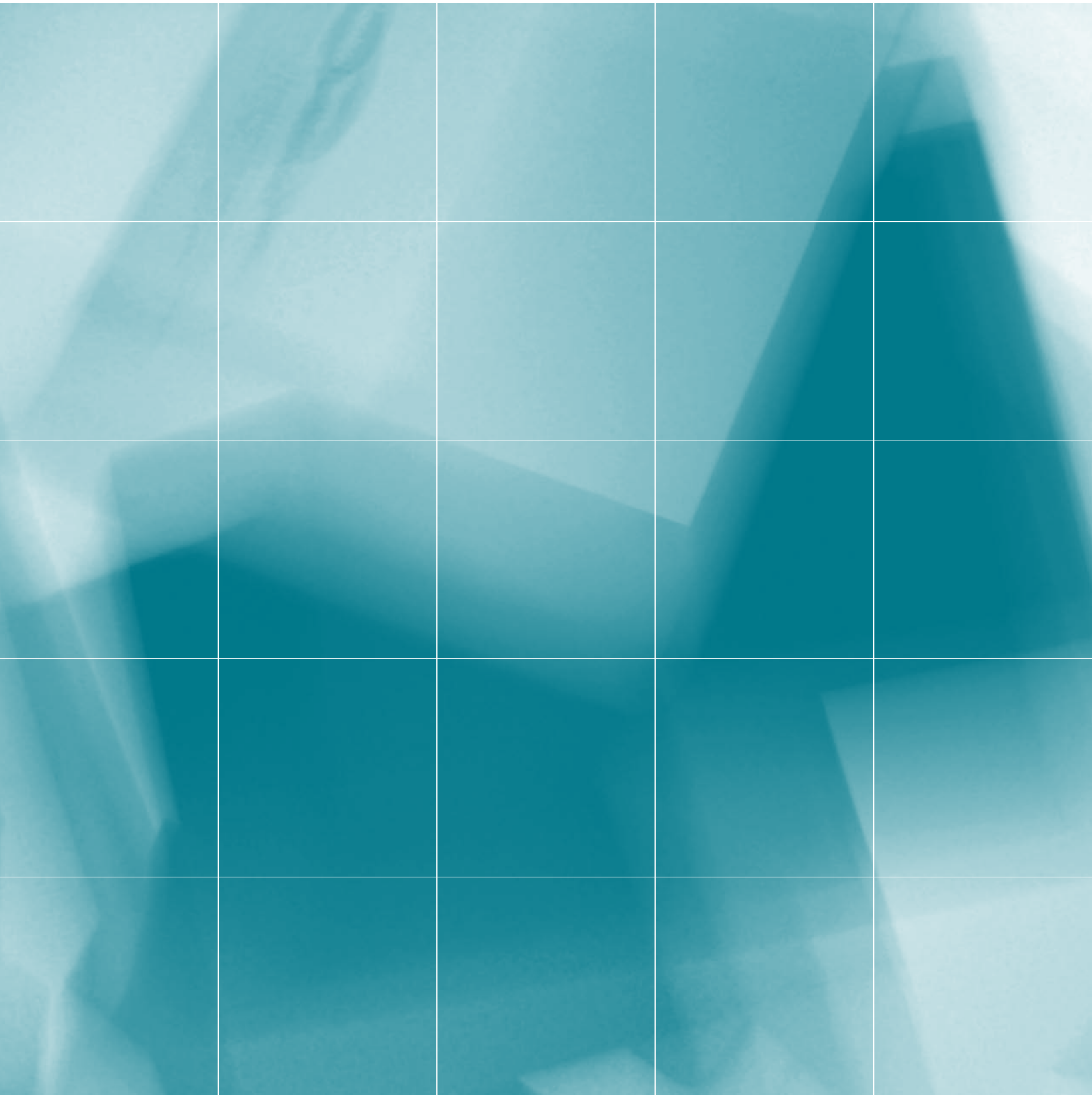

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