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Medicare Part D After Two Years

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Abstract

Objective—To assess the broad impacts of Part D and the extent to which these concerns have been realized.

Methods—We used administrative data to summarize beneficiary enrollment and plan participation in Part D, and compared pharmaceutical use and out-of-pocket spending before and after the introduction of Part D. We characterized the benefit designs of the ten largest Part D plans in 2006 and compared them to seven non-Part D plans often cited as examples of low cost or comprehensive drug benefits.

Results—By 2008, nearly 90% of seniors had drug coverage at least as generous as the standard Part D benefit. Excluding premiums, annual out-of-pocket spending in the ten largest Part D plans was comparable to other private and public drug benefits, with the most prominent differences attributable to out-of-pocket spending on drugs not covered in the plan. Poorer beneficiaries have gained the most from Part D in terms of increased access to medications and reduced out of pocket spending.

Conclusions—Coverage under Part D is comparable to non-Part D plans with respect to key features that are likely to be important to Medicare beneficiaries access to medications and outof-pocket costs. Nonetheless, concerns remain over drug pricing and gaps in coverage. The government should continue to monitor the competitiveness of the Part D market to ensure it meets the diverse needs of Medicare beneficiaries.

INTRODUCTION

Prior to the introduction of Medicare Part D in 2006, there were concerns that the program would not appeal to all types of beneficiaries, nor entice a sufficient number of health plans to offer a benefit. Failing to attract a broad cross-section of beneficiaries could jeopardize the long-term viability of the program, if, for example, only the sickest enrolled. Similarly, failing to attract a sufficient number of plan sponsors would diminish competition, which was rightly viewed as the cornerstone of a well-functioning program. Other concerns

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focused on low income beneficiaries, many of whom were previously covered by Medicaid's prescription drug benefit. Would they be negatively affected by potentially more expensive private plans with more restrictive formularies? And would seniors be able to navigate the myriad of plan choices and benefits options, including the gap in coverage ("doughnut hole") in Part D? Finally, many analysts feared that the cost of the program would exceed original Congressional Budget Office estimates if private plans could not obtain sufficient price discounts or constrain growth in per capita utilization.

Nearly three years into the Medicare Part D program, data are starting to accumulate on the program's performance; enough so that a preliminary picture is starting to emerge. This paper provides a perspective on participation by both beneficiaries and health plans, and identifies areas that need to be watched more carefully.

METHODS

Beneficiary Enrollment and Plan Participation

We used data from the Centers for Medicare and Medicaid Services (CMS) to characterize beneficiaries' drug coverage and plan participation in Medicare Part D. Estimates of Medicare beneficiaries with prescription drug coverage are from enrollment files. Data on plan participation were derived from the Prescription Drug Plan Landscape File.

Benefit Design & Formulary Coverage

To characterize the Part D program, we examined the ten largest Prescription Drug Plans (PDPs) based on 2006 enrollment. These ten plans accounted for 46% of total Part D enrollment in 2006. We compared formulary coverage, cost-sharing features, and out-of-pocket costs in these ten plans to seven public and private plans often cited as examples of low cost or comprehensive drug benefits. The seven non-Part D plans included the Federal Employees Health Benefits Program (FEP Basic), the California Public Employees' Retirement System (PERS Choice/PERS Care), the California State Medicaid program (Medi-Cal), the Veterans Affairs (VA National Formulary), Department of Defense (TRICARE), Anthem (Blue Cross), and Kaiser Permanente.

We used data from the Fingertip Formulary and internet sources to characterize the benefit designs and cost-sharing arrangements of each of these 17 plans. The Fingertip Formulary is an online database of formulary designs for nearly all commercial, Medicare, Medicaid, and public insurance plans. The data in our analysis contain formulary designs as of July 16, 2007. In cases where there were discrepancies between sources, we contacted the plans directly to resolve any ambiguities.

We compared coverage in each plan for the 300 most widely prescribed drugs to seniors between January-October 2006. The list of medications was based on Verispan's Vector One (VONA) data, a national-level prescription and patient tracking service that collects nearly half of the retail prescriptions dispensed each month in the U.S. The list of 300 drugs was reduced to 252 in some analyses due to 33 generic/brand duplicates and 15 drugs not covered under Part D. We also examined how broadly plans cover medications for chronic diseases of the elderly to assess the potential clinical consequences of formulary exclusions.

Public programs with statutory or regulatory limits on cost-sharing often employ formulary restrictions or other types of administrative requirements to limit access to specific medications. For example, plans may require prior authorization (requiring permission before certain drugs can be dispensed), step therapy (requiring use of lower-cost medications before providing coverage for more expensive alternatives), or quantity limits (which restrict the number of pills or prescriptions dispensed per month or per patient) to control utilization

and improve patient safety. We examined the extent of these restrictions in each of the 17 plans.

Relative Plan Generosity

It is often difficult to translate the stated pharmacy benefit into actual prices that consumers face. Multi-tier formularies are the standard for most private plans, and they also have gaps in coverage, out-of-pocket limits, and discounts for purchases through mail-order or innetwork pharmacies. These added complexities mean that the price a consumer will pay for a given drug depends on which tier it is placed, where it is dispensed, and at what time of year. To address this issue, we estimated average beneficiary out-of-pocket costs in each plan for a standardized set of pharmacy claims. The set of drug claims was generated by drawing a random sample of seniors from 14 large employers providing retiree drug coverage in 2004 (non-Part D plans, national in scope). The sample included beneficiaries age 65 and older who were continuously enrolled in a plan for the entire year and who had at least one pharmacy claim for the 300 most-common drugs. We randomly selected 10 percent of enrollees from each plan, up to a maximum of 500 per plan. We then created a "market basket" of drug claims used by this random sample of retirees, restricted to the 300 most common drugs. This fixed set of pharmacy claims was then processed through the benefit designs of each plan to calculate the average out-of-pocket costs in each of the 17 plans. This approach incorporates the plan's cost-sharing arrangements and other factors such as where the drug was dispensed (e.g., network pharmacy or mail-order) and cumulative spending to date.

Our approach to estimating out-of-pocket costs for a fixed basket of pharmacy claims has two principal limitations. Most importantly, it assumes no demand response, i.e. that patients' drug use or "bundle of claims" is fixed across plans and thus invariant to the benefit design. In reality, patients will alter their choice of drugs in response to changes in cost-sharing ¹. Second, the price we use for uncovered drugs is measured with some error given the limitations on quantity and dosage and our use of average prices in the ten largest Part D plans. Given these limitations, our out-of-pocket estimates provide a useful measure of *relative* plan generosity, but should not be viewed as an accurate measure of the *actual* cost burden to beneficiaries.

Changes in Utilization

We estimated the effects of Part D on pharmacy utilization and spending using a "before and after" design. For the baseline period, we analyzed data from the 2004 Medicare Current Beneficiary Survey (MCBS). For the follow-up period, we analyzed 2006 enrollment and claims data from a large Part D plan. These datasets are not perfectly comparable. First, the MCBS relies on self-reports and has been shown to undercount drug spending². Second, the MCBS is a stratified national sample of Medicare enrollees; whereas the Part D data are a convenience sample, albeit a large one.

To address the first problem, MCBS spending is adjusted upward from 2004 to 2006 using the consumer price index prescription drug series, and both spending and number of fills are adjusted upward by 15% to account for the undercount. To address the second problem, we constructed demographic weights based on age, gender, and state of residence so the Part D enrollees are demographically representative of the Medicare population. We re-weight the Part D data to match the MCBS for each age-sex-state-subsidy cell and use these weights in all reported analyses.

We also approximated low-income subsidy (LIS) eligibility in the MCBS prior to Part D introduction based on a reported household income less than 150% of the federal poverty

line. No asset information is available in the MCBS. Prior work suggests that nearly 14 million Medicare beneficiaries would qualify for the low-income subsidy based on this income test alone, of which 2.4 million (17%) would be ineligible based on assets.³

For each of the three eligibility groups (dual eligible, LIS, general), we examine the distribution of prescriptions and out-of-pocket (OOP) spending before and after the introduction of Part D. In particular, we compare the means, variances, and various quartiles of the distributions of these variables.

RESULTS

Enrollment

Table 1 shows the breakdown of prescription drug coverage among Medicare beneficiaries as of January 2008. Nearly 90% of seniors had drug coverage at least as generous as the standard Part D benefit. More than 55% were enrolled in a Part D plan (15% dual-eligibles), with the remainder covered by employer plans (15%) or some other creditable plan (17%).

Plan Participation

Widespread enrollment in Part D is partly attributable to robust plan participation across states. In January 2006 alone, there were on average 43 PDPs in each state, with states at the 25th percentile having 41 plans. In 2007 and 2008, this number rose to 54 plans, with states at the 25th percentile having 53 plans on average. Despite the large number of plan offerings, beneficiaries enrolled in Part D were highly concentrated in a few plan sponsors. Nearly 44% of enrollees in 2007 were in plans offered by UnitedHealth and Humana, while almost a quarter were covered by Universal American Financial, WellPoint, WellCare, Kaiser Permanente, and Coventry. A similar degree of concentration occurred in the Medicare Advantage market prior to Part D.⁴

Formulary Design and Coverage

Table 2 characterizes the formulary coverage and cost-sharing arrangements of the ten largest Part D plans, as well as the seven comparison plans. For each of the plans, we show the number of covered drugs in each tier (or single tier in plans where only one tier exists) as well as the number of drugs not covered. Among the ten largest Part D plans, between 147 and 157 of the 300 most common medications were covered in Tier 1. Further, the most (least) expansive plans excluded 4 to 6 (24 to 41) medications. There was little variation across plans in the number of drugs assigned to the first two tiers. Thus, variation in the number of covered drugs across Part D plans was driven by how many products were assigned to the third tier versus not covered at all. Coverage under the largest Part D plans was comparable to many of the non-Part D plans such as Blue Cross, FEP, CALPERS, and TRICARE, which excluded 0 to 6 medications. By contrast, the Kaiser and VA plans excluded 75 and 84 medications, respectively.

Because certain drugs are more widely used than others, excluded medications may account for relatively smaller or larger fraction of total prescriptions. The last column of Table 2 shows the proportion of total national prescriptions accounted for by the list of excluded drugs in each plan. For example, the 84 drugs excluded from the VA formulary accounted for nearly one-quarter (24.7%) of all prescriptions dispensed to seniors in 2006 among the 300 most common medications. By contrast, drugs excluded from even the most restrictive Part D plan accounted for only 12.6% of total prescriptions, and drugs excluded from the least restrictive Part D plan accounted for just 4.4% of total prescriptions. To assess the potential clinical consequences of excluding drugs from the formulary, we also examined how broadly plans cover medications for chronic diseases of the elderly, specifically diabetes, heart disease, hypertension, and high cholesterol. Table 3 shows the number of excluded drugs in each plan. The ten largest Part D plans covered the vast majority of the drugs in these therapeutic classes, with the exception of ACE/ARBs. The most restrictive Part D plan excluded just 4 of 11 antihyperlipidemics; 1 of 13 antidiabetics; and 1 of 10 beta-blockers. While coverage was less generous for ACE/ARBs, even the most restrictive Part D plans covered 14 to 18 of the 22 drugs in the class. In contrast, the VA formulary excluded 7 of 13 antidiabetic agents; 12 of 22 ACE/ARBs; and 5 of 11 antihyperlipidemics.

Plans can also place administrative restrictions on specific drugs or classes of medications that can greatly limit access. Table 4 shows the number of drugs in each plan subject to prior authorization requirements, quantity limits, step therapy and other restrictions. The most common formulary restriction in Part D plans is a quantity limit, where the plan will only cover a drug up to a designated quantity. If prescribing physicians feel it is medically necessary to exceed the set limit, they must get prior approval from the plan. Among the ten largest Part D plans, the median quantity limit applies to 54 of the top-300 drugs.

Prior authorization is commonly used in state Medicaid programs as a cost containment tool, but is far less common in Part D plans. Half of the ten largest plans do not impose prior authorization requirements on any drug, while the most restrictive Part D plan requires it for just 7 medications. Step therapy is used in some Part D plans, but is typically applied to a small number of drugs. While the VA does not use any of these formulary restrictions, it imposes other types of restrictions to control utilization. For example, 34 of the 180 formulary drugs in the VA national formulary (among the top-300 drugs) are only covered for specific indications, dosages or intake formulations.

Table 5 presents average annual out-of-pocket costs (excluding premiums) under each plan for our "market basket" of claims and decomposes these costs into out-of-pocket expenditures for covered and non-covered drugs. Out-of-pocket spending for the five least expensive Part D plans (A through E) was roughly \$1,000 annually, which was modestly higher than spending in Blue Cross, FEP, and CALPERS. With the exception of Part D plan J, out-of-pocket spending in the remaining Part D plans was between \$1,300 and \$1,400 annually, making these plans more comparable in spending to the VA.

Changes in Pharmacy Use and Spending

A critical question is how Part D affected pharmaceutical use and spending, both overall and for specific groups of beneficiaries. Our analyses comparing MCBS data in 2004 to Part D claims in 2006 suggest that Part D was associated with a 16% annual decrease in out-of-pocket spending and a 7% increase in the number of prescriptions (results not shown). These estimates are consistent with other findings using 2006 data from a large national pharmacy chain.^{5, 6} Our analysis also suggests that these changes were concentrated among the poor. Average OOP spending among the dual-eligibles and LIS population declined markedly, but was largely unchanged for the general Part D population. Equally important, Part D was associated with reduced financial risk for low-income populations, as measured by the variance of out-of-pocket spending (Table 6). Prior to Part D, the probability of having OOP drug spending greater than \$1,000 in a year was 24% in the LIS population and 3.6% in the dual-eligible population. After Part D, those probabilities were less than 1% for each group.

DISCUSSION

Medicare Part D generated much confusion at the time of its introduction in January 2006. Some beneficiaries did not understand the benefit designs, and were not sure how Part D interacted with existing drug coverage or whether they might gain or suffer financially from enrolling.⁷ However, after more than two years experience, the assessment has changed. Nearly 90 percent of Medicare beneficiaries have prescription drug coverage at least as generous as the standard Part D benefit. Policies to protect plans from excessive losses in the first few years (through reinsurance and risk corridors) as well as efforts to educate beneficiaries about plan choices led to a large number of sponsors and a wide array of options for beneficiaries to choose from. Despite the large number of plans, it appears that most beneficiaries who enroll in the program are making plan choices reflecting both their health status and the market circumstances.⁷

Enrollment in Part D was widespread for several reasons. First, the large federal subsidy for Part D plans--74.5% of the premium is paid by Medicare--dramatically reduced the cost of coverage for most beneficiaries. Second, individuals previously covered under Medicaid were automatically enrolled in a private Part D plan. Third, the widespread availability of low premium plans (less than \$20/month) combined with penalties for late enrollment, made coverage more appealing to healthy seniors who might otherwise have been dissuaded from enrolling. However, there remains a substantial core of seniors who need to be educated that Part D is in their own interest, and reaching them should continue to be a health policy priority.⁷

Despite the variation across Part D plans, annual out-of-pocket spending in the ten largest plans was comparable to other private and public drug benefits, with the most prominent differences attributable to out-of-pocket spending on drugs not covered in the plan. Poorer beneficiaries, specifically dual-eligibles and those eligible for additional low-income subsidies, have gained the most from Part D in terms of increased access to medications and reduced financial risk.

Despite these successes, several concerns remain^{8, 9} First and foremost is the "doughnut hole" or gap in Part D coverage whereby beneficiaries with intermediate levels of spending face full co-insurance prior to reaching catastrophic coverage.^{10–12} Recent work suggests that more than 3 million Part D enrollees reached the coverage gap in 2007, and about 20 percent of them either stopped taking a medication, skipped doses, or switched to a different medication in the class.¹³ Second, given the significant amount of consolidation that has occurred in plans offering Part D coverage (eight organizations accounted for nearly 65% of enrollment in 2007), one must question the future impact of consolidation on competition. Further consolidation is likely inevitable given the sheer number of plans operating. Will competition diminish and prices rise with increased market power in the hands of a few plans? Or will consolidation lead to increased ability of plans to negotiate lower drug prices that ultimately get passed down via lower premiums? These are open questions that warrant careful monitoring in the future, especially given the importance of competition in justifying a privately administered benefit.

Some members of Congress argue that the federal government could provide a simpler benefit at lower cost by negotiating directly with drug manufacturers¹³. Currently under Part D, prices are determined through negotiations between drug manufacturers and prescription drug plans. The forces of competition tend to result in larger rebates and lower net prices (prices net of the rebates) for drugs that have closer available substitutes and for insurers that establish narrower lists of preferred drugs or are more effective in steering doctors and patients toward those drugs.

By contrast, the government negotiating lower prices for all Medicare beneficiaries would have to be thought through very carefully. The process of choosing which drugs to exclude from the national Medicare formulary would likely be dominated by stakeholders such as manufactures and patient advocacy groups, and in some cases, might determine whether particular manufacturers stay in business¹⁴. However, in the absence of a formulary, Medicare would be unable to exclude any drug and thus would have no bargaining leverage. It was for this reason that the Congressional Budget Office (CBO) estimated that the Secretary would not be able to negotiate prices significantly lower than those already achieved by the private plans¹⁵.

Our analysis has several limitations. First, we compared pharmaceutical use and out-ofpocket spending from the 2004 Medicare Current Beneficiary Survey (MCBS) to a large Part D plan in 2006. Because these datasets are not perfectly comparable and there is likely to be some selection into Part D plans, these results are not definitive. However, our estimates are consistent with other findings using 2006 data from a large national pharmacy chain^{6,7}. Second, our sample consists of the ten largest Part D plans, which accounted for 46% of total Part D enrollment in 2006. The profiles of smaller PDPs may be different. Third, offering enrollees a narrower list of preferred drugs like the VA and Kaiser is not necessarily detrimental. A narrow, but well designed formulary can help steer doctors and patients towards more cost-effective medications, reducing overall drug costs. Finally, we do not examine coverage of specialty drugs, which is a small, but growing fraction of total drug spending.

Our analysis suggests that coverage under Part D is comparable to selected non-Part D plans with respect to key features that are likely to be important to Medicare beneficiaries access to medications and out-of-pocket costs. However, the government should continue to monitor the competitiveness of the Part D market to ensure it meets the diverse needs of Medicare beneficiaries.

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Drug Coverage Among Medicare Beneficiaries

Type of Coverage	Number of Eligible Beneficiaries (millions)	Percent of Eligible Beneficiaries
Medicare Stand Alone Coverage (PDP)	17.4	39.4
General Beneficiaries	9.5	21.5
Dual-Eligibles	5.3	12.0
Low Income Subsidy	2.6	5.9
Medicare Advantage with Rx Coverage (MA-PD)	8.0	18.1
General Beneficiaries	6.5	14.7
Dual-Eligibles	1.3	2.9
Low Income Subsidy	0.2	0.5
Medicare Retiree Drug Subsidy (RDS)	6.7	15.2
Other Drug Coverage	7.5	17.0
No Creditable Coverage	4.6	10.4
Total	44.2	100.0

Source: Authors' calculations based on CMS enrollment data as of January 2008.

PDPs are stand-alone Medicare Part D Prescription Drug Plans; MA-PD refers to Medicare Advantage Plans with Prescription Drug Coverage; RDS refers to employer coverage with Medicare Retiree Drug Subsidy; Creditable coverage refers to a plan other than a Part D plan that offers prescription drug coverage and which meets certain Medicare standards.

Bolded percentages do not sum to 100.0 due to rounding.

Joyce et al.

TABLE 2

Coverage of the 300 Most Common Prescription Drugs for the Elderly, by $Plan^*$

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Note: The names of the ten largest Part D plans are omitted from the table at the request of a sponsor. Since this information is publicly available, we would reconsider this omission at the editor's request.

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Formulary Coverage Within the Top 5 Therapeutic Classes, by $Plan^*$

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Am J Manag Care. Author manuscript; available in PMC 2013 September 09.

* Among the Top-300 selling drugs based on total scripts. NC=Not covered. ACE refers to Angiotensin-converting enzyme inhibitors. ARBs refer to Angiotensin II Receptor Blockers.

Formulary Restrictions on the 300 Most Common Prescription Drugs for the Elderly, by Plan

	Type of Formulary Restriction				
Plan	Prior Authorization	Quantity Limits	Step Therapy	Other	
Part D Plans					
А	0	90	5	0	
В	0	90	5	0	
С	0	90	5	0	
D	0	55	12	0	
Е	2	59	12	0	
F	2	53	14	0	
G	1	14	0	0	
Н	0	0	0	0	
Ι	3	34	0	0	
J	7	7	7	0	
Non-Part D Plans					
Medi-Cal	70	6	4	6	
TRICARE	4	12	0	4	
CALPERS	0	0	0	0	
Blue Cross	4	8	0	0	
FEP	35	8	0	3	
VA	0	0	0	36	
Kaiser	0	0	0	0	

Sources: Fingertip Formulary, 2007.

Prior authorization requires permission from the plan before certain drugs can be dispensed; Step therapy requires use of lower-cost medications before providing coverage for more expensive alternatives; Quantity limits restrict the number of pills or prescriptions dispensed per month or per patient. Other restrictions typically include coverage only for a specific indication or dosage/form.

Mean Out-of-pocket Expenses for Covered and Non-covered Drugs in the "Market Basket" of Drug Claims †

	Average Out-of-Pocket Spending (\$)				
Plan	All Drugs	Covered Drugs	Uncovered Drugs		
Part D Plans					
А	995	994	1		
в	1,020	1019	1		
С	1,047	1,046	1		
D	1,064	1063	1		
Е	1,176	895	281		
F	1,324	869	455		
G	1,376	832	544		
Н	1,452	909	543		
Ι	1,458	840	618		
J	1,943	753	1,190		
Non-Part D Plans					
Medi-Cal	38	38	0		
TRICARE	454	252	202		
CALPERS	755	747	8		
Blue Cross	769	769	0		
FEP	846	846	0		
VAŹ	1,348	188	1,160		
Kaiser	2,006	276	1,730		

Sources: Authors calculations based on formulary restrictions and benefit designs of 10 major Part-D plans and 7 non-Part D plans. Because the 300 most common drugs sometimes included branded and generic versions of the same drug, the calculated expenditure in the VA plan treats branded drugs as covered if a generic equivalent is covered.

 † For drugs that were not covered by the plan either because they were excluded from the formulary or because the beneficiary's cumulative spending was below the deductible or in the doughnut hole we assigned an out-of-pocket payment equal to the full price of the drug (excluding rebates). We used the full price of the drug for each Part D plan as reported on the Medicare website in July 2007.

⁷Our "market basket" of drug claims includes multi-source brands (brand drugs with generic equivalents) that may not be covered under the VA formulary. We assumed that patients in the VA received the generic equivalent and paid an \$8 copayment.

Changes in Out-of-Pocket Spending and Utilization Before and After Medicare Part D, By Eligibility Status

Flightlite	Annual Out-of-Po	ocket Spending (\$)	Number of Fill	ed Prescriptions
Eligibility	2004	2006	2004	2006
Dual	164	45*	41.3	38.9
LIS	741	160*	32.7	38.8*
General	842	897	30.8	31.1

Sources: 2004 Medicare Current Beneficiary Survey and 2006 claims and enrollment data from a large Part D plan.

* P-value < .01 for change in outcome between 2004 and 2006. All expenditures are in 2006 dollars.