

# Falling into the Doughnut Hole: Drug Spending among Beneficiaries with End-Stage Renal Disease under Medicare Part D Plans

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The Medicare Part D prescription drug benefit may facilitate provision of medications by subsidizing drug costs. However, beneficiaries with higher drug utilization may face higher out-of-pocket (OOP) costs under the benefit's "doughnut hole" provisions that substantially increase beneficiary cost-sharing. The Medicare Current Beneficiary Survey Cost and Use data for 1997 through 2001 were used to estimate the impact of the standard Part D benefit on drug expenditures. The sample consisted of adults who were not dually enrolled in Medicaid (41,617 without ESRD, 256 with ESRD). Outcomes were annual total and OOP drug spending projected to 2006, as well as estimates of individual spending changes under Part D. In 2006, ESRD beneficiaries will have mean annual total and OOP expenditures that are approximately twice that of their Medicare peers. The overall impact of Part D on OOP expenditures is similar among all beneficiaries; however, many individuals with employer-sponsored coverage and those with higher costs (especially those with ESRD) may face cost increases with significant monthly variability as a result of reaching the "doughnut hole," a no-coverage gap in the standard benefit. Therefore, ESRD beneficiaries face substantial total and OOP annual expenditures for medications, causing most to reach the Part D benefit gap. Higher OOP costs may lead to reductions in spending and medication use with subsequent treatment gaps that may lead to increased use of medical services. As the new legislation takes effect, policy makers who are considering modifications in the program may benefit from further research to monitor patterns and gaps in coverage, medication use and spending, and hospitalization and survival trends.

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**A**lthough prescription drugs have improved the care and outcomes for many people with chronic illnesses, the burden of increasing costs has made it difficult for many patients to afford necessary medications (1). Many Medicare beneficiaries have had difficulty affording routine prescription medications, a problem that has worsened with the implementation of cost-sharing methods (2) that shift the economic burden from payers to patients (3). High out-of-pocket (OOP) drug expenditures and capped prescription benefits can lead to reductions in use of essential drugs, resulting in subsequent increased utilization of acute medical services such as emergency room visits and hospitalizations (3–9).

The new comprehensive prescription drug benefit under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 will facilitate purchase of necessary medications through subsidized drug costs (10). Improved access to medications has the potential to improve the length and the quality of life for many people with chronic disease. Individuals with ESRD, in particular, may benefit significantly from the Part D

drug benefit, given their need for greater numbers of prescription drugs. Patients with ESRD require multiple prescription medications because of the complexity of permanent renal failure and the presence of multiple comorbidities. Previous studies have found that the average number of prescription medications for individuals with ESRD ranges from 8 to 13, far more than most other Medicare beneficiaries (4,11).

Until recently, Medicare policy did not include payment for most prescription medications, with a few exceptions. Consequently, many Medicare enrollees had additional coverage through at least one secondary insurer (either a private plan or Medicaid) (4), but the generosity of coverage varied, lapses in coverage were common, and OOP expenditures still could be considerable (1,12). Approximately one fifth of Medicare beneficiaries will be eligible for low-income subsidies that will provide generous coverage with low overall cost-sharing. However, under the "standard" Part D drug benefit that started in January 2006, Medicare pays 75% of the cost of enrollees' drugs up to a limit of \$2250 after a \$250 deductible. Enrollees then enter a no-coverage gap (referred to as the "doughnut hole") in which Medicare pays nothing and beneficiaries pay 100% of drug costs up to a catastrophic limit of \$5100, after which Medicare accepts 95% of costs (10).

Because of zero cost-sharing by Medicare for drug expenses

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during the doughnut hole from \$2250 to \$5100, estimated expenditures for beneficiaries with high annual drug costs, such as ESRD beneficiaries, may remain high under this benefit. For those at the upper end of annual drug expenditures (\$5000 to \$8000), total OOP costs are projected to be 51 to 78% of total medication costs (10). In addition, almost one fifth of beneficiaries are projected to reach the catastrophic-coverage threshold (\$5100) in 2006 (13). However, no previous investigators have distinguished ESRD beneficiaries from other Medicare beneficiaries with high annual drug expenditures. Because many people with ESRD are likely to have drug expenses in the highest range, we chose to examine the potential impact of the new Medicare prescription drug benefit on personal expenditures for medications among those with ESRD.

## Materials and Methods

### Participants

The Medicare Current Beneficiary Survey (MCBS) is a longitudinal panel survey of a representative national sample of the Medicare population that has been conducted by the Centers for Medicare and Medicaid Services (CMS) since 1991 (14). The survey provides detailed self-reported information on Medicare beneficiaries' health care costs, sources of payment, and use of medical care services, including prescription drugs. A sample of approximately 12,000 beneficiaries is selected to be representative of the current Medicare population, including older and disabled beneficiaries who live in the community and in institutions. All MCBS participants are interviewed every 4 mo and followed for up to 3 yr.

Each year, a supplemental sample is drawn for the MCBS, and people are added to the MCBS sample to account for growth in the Medicare population and to replenish the sample for those who were surveyed and died, left the survey population after 4 yr, or were lost to follow-up (14,15). We used the MCBS Cost and Use files from 1997 through 2001 to identify our study sample of community-dwelling adult respondents who were not dually enrolled in Medicaid (unweighted  $n = 41,617$ ). We excluded those who would not be enrolling in the standard Medicare Part D prescription drug plan, because our aim was to study the impact of the standard benefit, not to derive full population estimates.

Another subpopulation that may not enroll in the standard Part D benefit includes individuals with employer-sponsored prescription drug coverage. These individuals largely have been excluded in some analyses by other investigators under the assumption that those with employer-sponsored coverage will maintain that coverage and defer Medicare Part D coverage options (13,16). We chose to consider this possibility in our sensitivity analyses, in which we excluded this group as one of several modifications of our base-case analysis.

From this cohort, 256 (0.6%) were identified as having ESRD according to the following Medicare classifications: Aged with ESRD ( $n = 126$ ), disabled with ESRD ( $n = 76$ ), or ESRD only ( $n = 54$ ). Data were pooled from each year, which allowed some respondents to be followed for up to 3 yr; therefore, the number of unique respondents with and without ESRD was smaller (139 and 21,207, respectively). Because we were not interested in individual changes over time, we used data from each respondent in different years as separate observations. Population proportions were weighted to represent all beneficiaries with Medicare during the study period, equivalent to data regarding 131,700,000 person-years.

### Measurements and Calculations

**Pre-Part D Drug Expenditures.** The numbers of unique prescriptions per respondent per year were derived from monthly medication

data and increased by 17.7% to adjust for known underreporting in MCBS data (17). Similarly, annual total and OOP drug expenditures both were increased by 17% to adjust for underreporting (17). We then used National Health Expenditures data from the CMS Office of the Actuary (18) to project drug spending per person-year in our 1997 through 2001 data set forward to 2006. These figures represent projected expenditures for medications in 2006 that include total costs and OOP costs under the previous conditions (insurance coverage, generosity of coverage, etc.) during the MCBS survey.

**Projected Part D Drug Expenditures.** Next, we imposed the Part D benefit structure onto the estimated total costs to derive estimated OOP costs under Part D. For example, an individual with drug spending that is projected to be \$5500 in 2006 will have OOP costs under Part D as the sum of the following: \$250 deductible, \$500 in cost-sharing up to the benefit gap at \$2250 (25% of \$2000), \$2850 while in the doughnut hole (100% cost-sharing), and \$20 in cost-sharing after the catastrophic threshold at \$5100 (5% of \$400), thereby summing to total OOP expenditures of \$3620. These estimated expenditures under the Part D benefit do not include additional expenses that may be incurred from enrollment fees or account for any changes in drug use related to the generosity of coverage (19).

Finally, we assumed uniform spending throughout the year to derive cumulative total medication costs over time throughout the calendar year. We used the cumulative medication costs to estimate when individual respondents will reach the benefit gap (at \$2250 in total medication costs) and the catastrophic threshold (at \$5100 in total medication costs).

### Statistical Analyses

Categorical variables were expressed as a percentage and compared using the Pearson  $\chi^2$  test, which corrects for the survey design and is converted into an F statistic (20). Continuous variables were expressed as mean  $\pm$  SEM and compared using adjusted Wald tests using an F statistic. Linearization-based methods were used to derive variance estimates for nonlinear functions. Estimates of differences of subpopulation means were computed from linear combinations of parameter estimates (21).

We performed several sensitivity analyses for our estimates of costs and the proportion of beneficiaries who will reach the Part D coverage thresholds, including analyses after (1) excluding beneficiaries with employer-sponsored drug coverage (unweighted  $n = 15,988$ ; with ESRD [ $n = 116$ ] and without ESRD [ $n = 15,872$ ]); (2) using the medical care component of the Consumer Price Index (CPI), which results in a conservative estimate of cost growth relative to the National Health Expenditures projections (22); (3) excluding beneficiaries with extremely high medication use (unweighted  $n = 142$ ; total annual expenditures  $>$ \$24,000 [ $n = 85$ ], annual OOP expenditures  $>$ \$12,000 [ $n = 44$ ], or both [ $n = 13$ ]); and (4) inclusion of estimated policy premiums (\$32/mo) with the OOP expenditures (23).

The study data set was compiled using SAS 8.2 (SAS Institute, Cary, NC), and analyses were conducted using Stata 8.2 (Stata Corp., College Station, TX). We considered two-sided  $P < 0.05$  statistically significant.

## Results

Baseline characteristics by ESRD status are listed in Table 1. Study participants with ESRD compared with Medicare beneficiaries without ESRD generally were more likely to be younger, male, unmarried, nonwhite, less well-educated, and less healthy and to require more prescription medications. Both groups of Medicare beneficiaries had similar proportions of prescription drug coverage in the pre-Part D era, and sources

Table 1. Baseline characteristics for Medicare beneficiaries with and without ESRD, 1997 through 2001

Beneficiary Characteristics	With ESRD (Unweighted <i>n</i> = 256)	Without ESRD (Unweighted <i>n</i> = 41,361)	<i>P</i>
Age (yr)			<0.0001
<65	50.7	7.8	
65 to 79	35.8	66.5	
>80	13.5	25.7	
Female	40.2	56.0	0.004
Married	83.0	89.2	0.042
White	65.5	90.6	<0.0001
Education			0.007
less than or some high school	37.7	28.8	
high school diploma	23.9	37.5	
at least some college	38.5	33.7	
Income <sup>a</sup>			0.37
<\$20,000	45.9	41.6	
\$20,000 to \$40,000	30.5	36.2	
>\$40,000	23.7	22.2	
Prescription coverage <sup>b</sup>			
none	26.3	31.0	0.20
HMO <sup>c</sup>	25.0	27.5	0.58
employer sponsored	46.7	39.9	0.15
other	12.5	7.7	0.004
Self-reported health			<0.0001
excellent to good	29.6	74.8	
fair to poor	70.4	25.2	
No. of medications			<0.0001
<3	5.2	20.7	
3 to 6	15.5	32.9	
7 to 10	25.6	22.6	
>10	53.6	23.8	

<sup>a</sup>In 2001 dollars.

<sup>b</sup>Totals may be >100% because of multiple sources of coverage.

<sup>c</sup>Includes private and Medicare HMO. HMO, health maintenance organization.

of coverage generally were similar, although more beneficiaries with ESRD had prescription coverage from other sources.

Total annual drug costs in 2006 were estimated to be more than two-fold higher for Medicare beneficiaries with ESRD compared with those without (Table 2). At the aggregate level, the impact of Part D on mean OOP expenditures will be similar among all beneficiaries in this cohort; many will have a slight increase. At the individual level, however, many of those without previous prescription drug coverage are likely to benefit

from substantial reductions in OOP costs under Part D (Table 3), whereas a greater proportion of those with employer-sponsored prescription coverage are likely to face a substantial increase in OOP costs under Part D. Most of those with health maintenance organization or other sources of drug coverage are likely to have small increases in OOP costs under Part D.

Although the overall impact of Part D on OOP costs is similar among those with and without ESRD, the higher absolute drug costs that will be incurred by beneficiaries with ESRD will have

Table 2. Estimated 2006 mean total and OOP drug costs before and after Part D, by ESRD status<sup>a</sup>

Estimate	With ESRD (Unweighted <i>n</i> = 256)	Without ESRD (Unweighted <i>n</i> = 41,361)	<i>P</i>
Total drug spending	\$6488 ± 765	\$2705 ± 35	<0.0001
OOP spending without Part D	\$2153 ± 255	\$1146 ± 18	0.0003
OOP spending under Part D	\$2329 ± 133	\$1311 ± 16	<0.0001
Absolute change under Part D	\$ 176 ± 226	\$ 121 ± 20	0.81

<sup>a</sup>Data are means ± SEM. OOP, out-of-pocket.

Table 3. Estimated 2006 mean total and OOP drug costs before and after Part D, by prescription coverage<sup>a</sup>

Estimate	No Coverage (Unweighted <i>n</i> = 13,657)	HMO (Unweighted <i>n</i> = 11,068)	Employer-Sponsored (Unweighted <i>n</i> = 15,988)	Other (Unweighted <i>n</i> = 2,915)
Total drug spending	\$2169 ± 37	\$2340 ± 43	\$3343 ± 59	\$2676 ± 37
OOP spending without Part D	\$1713 ± 30	\$ 871 ± 20	\$ 932 ± 20	\$1205 ± 20
OOP spending under Part D	\$1079 ± 17	\$1117 ± 16	\$1580 ± 22	\$1294 ± 15
Absolute change under Part D	−\$ 634 ± 21	\$ 246 ± 21	\$ 649 ± 24	\$ 89 ± 20

<sup>a</sup>Data are means ± SEM.

a marked impact on the proportion of those who reach the Part D coverage thresholds. Specifically, the majority of beneficiaries with ESRD will reach the doughnut hole compared with fewer than half of those without ESRD (70 *versus* 43%, respectively; Table 4). In addition, nearly three times as many beneficiaries with ESRD will reach the catastrophic threshold when compared with those without ESRD (39 *versus* 14%, respectively). Given that beneficiaries with ESRD have much higher drug spending, on average they will reach both the benefit gap and catastrophic coverage earlier in the calendar year when compared with their Medicare peers (June *versus* July, and July *versus* September, respectively).

Depending on their medication expenditures relative to the benefit gap, Medicare beneficiaries with and without ESRD are likely to encounter substantial month-to-month variability in OOP drug costs (Figure 1). For those who remain under the benefit gap by the end of the calendar year, OOP costs likely will be highest in the first few months of the year followed by lower monthly expenditures through the remainder of the year (Figure 1A). However, for those who fall within the doughnut hole by the end of the calendar year, OOP costs will be high initially, then decrease substantially for the subsequent 3 mo, then increase until the final quarter, and end the year with decreases over each of the remaining few months (Figure 1B). Finally, for those who will exceed the upper limit of the benefit gap (*i.e.*, the beginning of the catastrophic coverage threshold), month-to-month expenses will be even more highly variable, with a nearly 10-fold difference between the months with the lowest and highest expenses (Figure 1C).

In our first sensitivity analysis, we excluded individuals with employer-sponsored coverage (Table 5). Under this condition, total drug spending decreases, fewer beneficiaries will reach

the Part D coverage thresholds, and the average absolute change in OOP costs under Part D becomes cost saving for those with and without ESRD. Under the next two sensitivity analyses (using the Medical Care CPI for inflating expenditure estimates and excluding beneficiaries with high drug use), total drug spending also decreases with a consequent decrease in the proportions of beneficiaries who reach Part D thresholds, but the absolute change in OOP costs under Part D remains similar to those in the base-case analysis. Finally, including estimated policy premiums only increases OOP costs under Part D and, in turn, has an unfavorable impact on the absolute change in OOP costs under Part D.

## Discussion

Our study demonstrates that under the standard Medicare Part D benefit, the majority of ESRD beneficiaries will reach the benefit gap and many will reach the catastrophic threshold. Their mean annual total and OOP expenditures will be significantly higher than those of their Medicare peers as a consequence of higher drug use. Most beneficiaries with employer-sponsored coverage before Part D are likely to face cost increases, whereas those without prescription coverage are likely to pay less under Part D. In addition, monthly OOP drug expenditures are likely to be highly variable among those with moderate to high total drug costs.

These findings have important policy implications for the subgroup of beneficiaries who do not qualify for low-income subsidies and also have moderate to high drug use. Specifically, whether Medicare Part D provides better coverage than existing plans for this group is not clear, mostly because of the benefit structure. Many Medicare beneficiaries with moderate to high medication use will enter Part D's benefit gap. The

Table 4. Proportions and time estimates of Medicare beneficiaries who will reach Part D coverage thresholds, by ESRD status

Coverage Threshold	With ESRD (Unweighted <i>n</i> = 256)	Without ESRD (Unweighted <i>n</i> = 41,361)	<i>P</i>
Proportion who will reach (%)			
benefit gap	70	43	<0.0001
catastrophic coverage	39	14	<0.0001
Mean month enrollees will reach			
benefit gap	June	July	<0.0001
catastrophic coverage	July	September	<0.0001

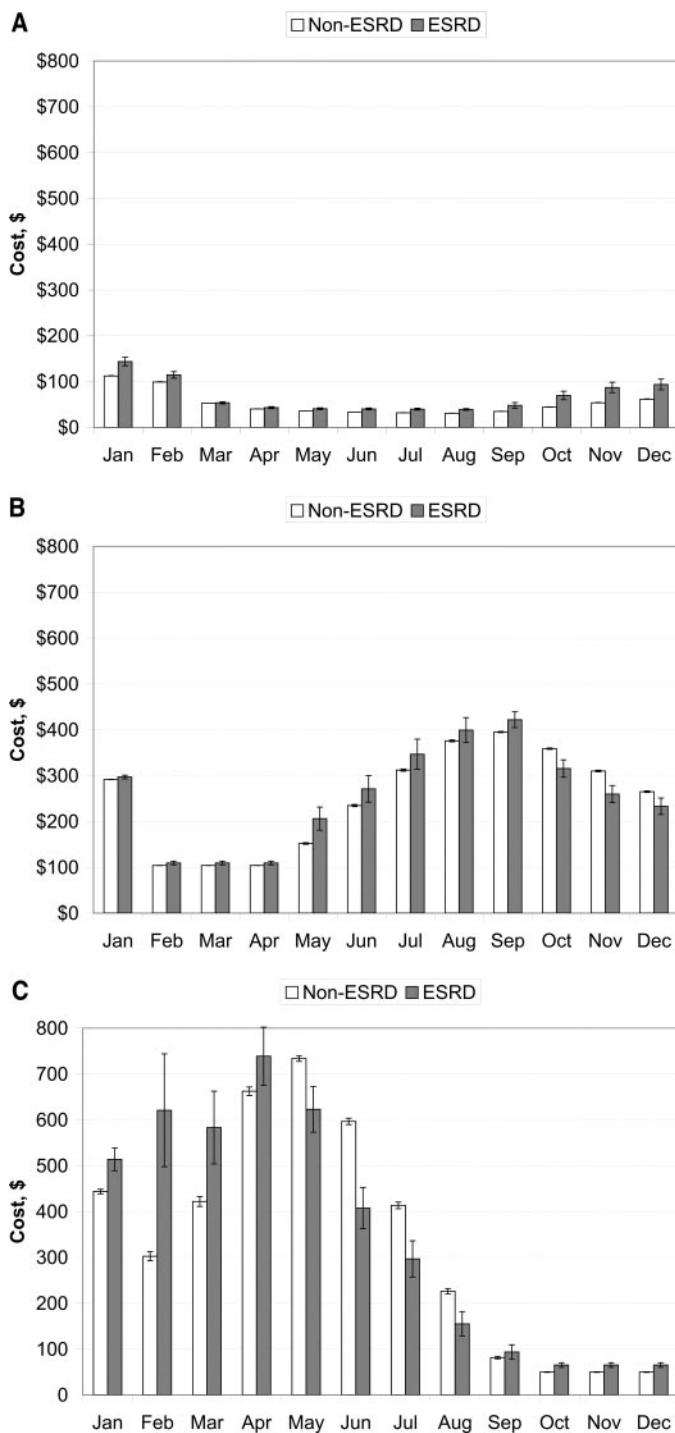


Figure 1. Estimated monthly out-of-pocket drug expenditures for Medicare beneficiary-years, by level of total annual costs compared with the benefit gap thresholds and ESRD status. Total annual costs per person-year were compared with the Part D benefit gap thresholds and categorized as remaining under the benefit gap (total medication costs <\$2250; A), remaining in the doughnut hole (total medication costs between \$2250 and \$5100; B), or exceeding the catastrophic coverage threshold (total medication costs >\$5100; C).

absence of drug coverage that will occur within the doughnut hole will simulate a loss of coverage, as a result of full cost-sharing. Enrollees who enter this gap will need to spend through it before obtaining relief from catastrophic coverage that is available beyond \$5100 in total spending on medications. Beneficiaries will have difficulty finding other sources of relief while in the gap, because they will not be permitted to buy additional coverage to bridge the coverage gap under Part D.

Because far greater numbers of Medicare enrollees who have ESRD *versus* those who do not will reach the benefit gap, people with ESRD are at increased risk for being affected by the negative financial pressure under this new cost structure. Not only are patients with complex chronic illnesses (*e.g.*, ESRD) more likely to forego medications because of cost, but also the combination of complex chronic illness together with limited or no prescription coverage leads to even greater nonadherence because of cost (5,24,25). Strategies to cope with the gaps in coverage may include nonadherence to prescription regimens (specifically, avoiding refills, skipping or taking smaller dosages to make prescriptions last longer, or spending less on basic needs to afford prescription drugs) or use of reimported prescriptions from abroad (5,6,24–26).

Our estimates of drug costs under Part D are higher than expected when compared with analyses that have been published in reports by the Henry J. Kaiser Family Foundation (16) and American Association of Retired Persons (13). Our sensitivity analysis indicates that the discordance between our estimates and these studies results from including beneficiaries with employer-sponsored coverage in our primary analysis. Gellad *et al.* (27) also found such a divergence. They estimate that those with employer coverage are likely to spend \$132 more in OOP drug costs under the part D benefit (27), a valuation that is similar to our estimates (\$121 among those without ESRD). The assumption under which those with employer-sponsored coverage were widely excluded in the Henry J. Kaiser Family Foundation and American Association of Retired Persons reports presumes that coverage as it existed during the various study periods largely will persist in the future. However, this premise may not be valid in the near future. On the basis of recent challenges to retiree health care coverage, many firms that have accepted the retiree drug subsidy in 2006 are uncertain about whether they will continue to provide coverage in future years (28).

The decrease in total medication costs among beneficiaries with ESRD with the exclusion of employer-covered beneficiaries suggests that ESRD beneficiaries with employer-sponsored coverage may use more medications than ESRD beneficiaries with other sources of drug coverage. It is not clear whether this increase is due to moral hazard (29) *versus* selection of individuals who have a greater comorbid burden and gain coverage through spousal insurance.

The unique contribution of this study is that although previous studies have demonstrated that OOP costs for enrollees with high or catastrophic costs are likely to be covered modestly by Medicare Part D (30), the potential impact on those with ESRD has not been described previously. Our estimates of the overall impact of the new drug benefit are consistent with

Table 5. Impact of sensitivity analyses on estimates of expenditures and proportion of Medicare beneficiaries who reach Part D coverage thresholds, by ESRD status

Modified Analysis	Total Drug Spending	OOP Drug Spending before Part D	OOP Drug Spending after Part D	Absolute Change under Part D	Proportion Reaching Benefit Gap (%)	Proportion Reaching Catastrophic Gap (%)
Excluding beneficiaries with employer-sponsored drug coverage <sup>a</sup>						
with ESRD	\$3570 ± 306	\$1927 ± 183	\$1746 ± 152	−\$181 ± 164	57	24
without ESRD	\$2312 ± 31	\$1369 ± 23	\$1140 ± 14	−\$229 ± 19	37	10
Medical care CPI for inflating expenditure estimates <sup>b</sup>						
with ESRD	\$4217 ± 501	\$1385 ± 160	\$1757 ± 133	\$372 ± 146	54	26
without ESRD	\$1769 ± 23	\$ 775 ± 12	\$ 863 ± 11	\$ 88 ± 14	27	5
Excluding beneficiaries with high drug use <sup>c</sup>						
with ESRD	\$5288 ± 525	\$1916 ± 150	\$2206 ± 121	\$326 ± 130	69	36
without ESRD	\$2619 ± 32	\$1167 ± 18	\$1301 ± 15	\$135 ± 20	43	14
Including estimated policy premiums						
with ESRD	\$6488 ± 765	\$2703 ± 263	\$2713 ± 133	\$560 ± 226	70	43
without ESRD	\$2705 ± 35	\$1658 ± 20	\$1695 ± 16	\$505 ± 20	43	14

<sup>a</sup>A total of 15,988 beneficiaries were excluded (unweighted  $n = 25,629$ ).

<sup>b</sup>CPI, Consumer Price Index.

<sup>c</sup>A total of 142 beneficiaries were excluded (unweighted  $n = 41,475$ ).

several other recent reports. Stuart *et al.* (30) estimated that among all enrollees, approximately 38% will reach the benefit gap and 14% will exceed the catastrophic threshold. Among enrollees who will fall into the doughnut hole, 38% are estimated to exceed the catastrophic threshold. In addition, our estimates of total annual drug spending and the variability of projected monthly OOP spending are similar for beneficiaries with moderate, high, and catastrophic drug expenditures. After considering two notable differences, our overall findings also are reasonably consistent with several other reports (13,16,27,31): First, we excluded beneficiaries who are likely to be eligible for low-income subsidies because our goal was to examine the impact of the standard benefit. Second, we included beneficiaries who are covered by employer health plans because we believe that employer health plan coverage for retirees is likely to become less common. Together, these two differences produce a cohort that includes more individuals who are less likely to benefit tremendously from the Part D benefit from low-income subsidies and who are more likely to have had lower OOP spending under existing employer-based coverage, which often is more generous than the benefit that is provided by Part D. Therefore, our findings indicate that more beneficiaries may do worse under Part D than some others have found.

Negotiating the decision of whether to enroll in Part D immediately or continue one's current coverage has been daunting for many patients given ever-changing premiums, deductibles, coinsurance, copayments, and formularies with each plan (32,33). As a result, most potential enrollees have sought guidance from their doctors (34). Unfortunately, even physicians have had difficulty determining the optimal strategy given numerous caveats. For example, many employers have urged beneficiaries who are covered under their plans to retain their

present coverage because of greater generosity when compared with Part D (28), a message that is consistent with our finding that many enrollees likely will pay more under Part D, yet those who waited beyond the deadline to enroll on May 15, 2006, will face penalties in the form of higher premiums.

For those who have chosen to enroll in the Part D benefit, avoiding the doughnut hole will be vital to many beneficiaries with moderate to high total drug expenditures. However, meaningful support is not likely to come from physicians who fail to identify patients who face medication cost problems (35,36), do not routinely consider costs of common prescriptions when prescribing (37), and face significant barriers to assisting patients with high costs even when recognized (38). Physicians may help to reduce patient cost burdens by improving their prescribing patterns to include use of more generic medications and first-line therapies (39). In addition, they can become educated about the Part D benefit design, logistics, and enrollment considerations to support their patients and provide information that will optimize their decision-making.

The accuracy of our projections about this drug benefit is limited by the quality of the prescription drug expenditure data on which it is based. Although previous surveys have had concerns about misreporting of expenditures by household respondents (40), the MCBS has been used extensively for similar projections (12,13,16,26,30). Our estimates take expected price inflation into account, but confounding factors that remain difficult to account for include trends in use of prescribed medications in the ESRD population and size of an insurance effect, or moral hazard, attributable to the new drug coverage (29). Individuals with lower levels of health status may increase prescription drug use once copayments decrease (41). Although the impact of increased drug coverage among Medicare beneficiaries has the potential to stimulate inappropriate use rather

than fill previously unmet needs (29,42), drug coverage is likely to lower OOP expenditures among beneficiaries with chronic illnesses that require greater numbers of prescription medications (42). Although more medications are not always better (43), most patients with ESRD use numerous medications that are essential for managing their disease and comorbid illnesses. Despite excluding those who are covered by Medicaid, some beneficiaries in our analyses with modest assets and incomes <150% of the federal poverty line still may qualify for drug coverage subsidies (27,31). Excluding these beneficiaries is not likely to change our overall findings, but it may have contributed to an underestimation of the potential benefit that is provided through Part D coverage.

In addition to these limitations related to our cost estimates, many variables that may modify the impact of the Part D legislation on expenditures among eligible Medicare beneficiaries remain unknown: Enrollment rates and variability in premiums, enrollment rates and individual premiums for Medicare Advantage plans, employer-sponsored and private insurance discontinuation rates, rates of drug benefits for members who are covered by Medicare, and future modifications to the current legislation enacted by ongoing congressional modifications (10). Furthermore, few plans actually mirror the standard benefit design on which our analyses are based. Instead, insurers are offering a wide variety of plan designs, including some that have higher premiums and include coverage in the doughnut hole (32). Nonetheless, our study has several notable strengths. We consider many factors that may have an impact on the validity of our results and address these through sensitivity analyses that do not alter our major conclusions (Table 5). Finally, our findings are likely to be generalizable to other Medicare subgroups of people who have chronic illnesses and also have high medication use persistently.

## Conclusion

ESRD beneficiaries face substantial total and OOP annual expenditures for medications, and most will reach the doughnut hole under Medicare Part D. OOP costs will be highly variable from month to month for those with moderate to high drug expenditures. Higher absolute OOP costs within the benefit gap and dramatic monthly variation of those costs may lead to reductions in spending and medication use with subsequent treatment gaps that may lead to increased use of medical services. As the Part D legislation continues to take effect in 2006, policy makers who are considering modifications in the program may benefit from further research to monitor patterns and gaps in coverage, medication use and spending, and hospitalization and survival trends.

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