

# Medicare Part D Coverage Gap and Diabetes Beneficiaries

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**T**he Medicare Part D drug benefit, introduced in January 2006, was designed to help address the needs of seniors with high out-of-pocket costs for medication.<sup>1-3</sup> and to provide continuous access to needed medications for chronic illness.<sup>3,4</sup> A unique feature of Medicare Part D is that under the standard benefit structure, enrollees have a potential coverage gap, commonly referred to as a “doughnut hole,” in prescription drug cost coverage. The standard Part D benefit in 2006 began with partial coverage for the first \$2250 of total drug costs in 2006, followed by a period of no coverage until patients reached cumulative out-of-pocket costs of \$3600 in 2006.<sup>5</sup> At the end of the gap, catastrophic coverage begins; patients often pay only 5% of drug costs or a predetermined copayment from that time forward.<sup>6</sup> An estimated 18.2 million beneficiaries (89% of Part D enrollees not receiving a low-income subsidy) in 2006 were enrolled in a Medicare Part D plan with a full coverage gap.<sup>7</sup>

Patients with chronic illnesses such as diabetes are at particularly high risk for facing high drug and other out-of-pocket costs given their need for chronic drug therapy and frequent need for multiple drugs to treat comorbid conditions. Persons with diabetes in particular often require daily medication to control their blood sugar levels, plus concurrent chronic treatment for other conditions.<sup>8-10</sup> The cost of managing chronic illness is high for the government as well, and the diabetes population is of particular interest. While approximately 20% of Medicare beneficiaries have diabetes, the Centers for Medicare & Medicaid Services has estimated that up to 32% of all Medicare spending could be attributed to patients with diabetes.<sup>11</sup> The costs for drugs such as insulin and oral agents to control diabetes account for up to 12% of the healthcare expenditures attributable to the disease.<sup>12</sup>

The high levels of clinical need for drug therapy combined with substantial out-of-pocket costs for patients with diabetes may make them more vulnerable to cost-related medication nonadherence.<sup>3,13</sup> Studies suggest that elderly patients reduce their medication use when faced with limited prescription benefit coverage<sup>1,6</sup> and experience adverse health consequences including nonelective hospitalizations and death.<sup>14,15</sup> Results of current studies examining the effect of Medicare Part D on adherence and cost are mixed. Some studies suggest Medicare Part D's introduction improved adherence and decreased out-of-pocket costs,<sup>16,17</sup>

**Objective:** To examine drug costs and entry and exit rates into the Part D coverage gap for beneficiaries with diabetes in Medicare Advantage managed care plans.

**Study Design:** Cross-sectional observational study.

**Methods:** Study patients were Medicare Advantage Part D beneficiaries with diabetes from 2 large California health plans who were continuously enrolled in 2006 and had a drug coverage gap starting at \$2250. Entry and exit into the gap, total drug costs, and out-of-pocket drug costs were determined using pharmacy databases.

**Results:** In 2006, 26% of the 42,801 beneficiaries with diabetes reached the coverage gap; 2% of beneficiaries exited the gap and qualified for catastrophic coverage. Beneficiaries incurred a mean of \$2182 in total drug costs during 2006. Drug expenditures remained stable over the year for beneficiaries who did not enter the gap. For beneficiaries who entered the gap, total drug costs were higher overall and decreased at year's end as out-of-pocket expenses increased.

**Conclusions:** Fewer diabetes patients in this study entered the coverage gap than had been previously estimated, but the entry rate was much higher than that of the general Medicare Advantage Part D population. Patients entering the gap had lower subsequent monthly drug expenditures; this may be due to lower-than-expected drug prices and greater use of generics in managed care, or it may potentially signal poorer drug adherence. Future work should examine these hypotheses and explore risk factors for entering the Part D coverage gap.

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while others found evidence that drug costs decreased medication adherence, especially for those entering the coverage gap.<sup>1,18</sup> Such effects may be more pronounced in patients with comorbidities and worse health status<sup>19</sup> such as those with diabetes.

One recent study conducted in a Medicare Advantage Prescription Drug (MAPD) plan offered by an integrated delivery system included in this study reported that 8% of beneficiaries overall entered the coverage gap in 2006,<sup>18</sup> a rate much lower than pre-2006 projections of gap entry rates for the general population.<sup>6</sup> One pre-Part D implementation study of diabetic Medicare beneficiaries estimated that 64% would enter the coverage gap in the first year.<sup>20</sup> However, there is currently no empirical information on how many seniors with diabetes enter and exit the doughnut hole of prescription drug coverage in Medicare Part D plans.

This study examined total drug costs, out-of-pocket drug costs, and the rates of entry and exit into the Medicare Part D coverage gap in an important subset of Medicare beneficiaries, those with diabetes, for patients from 2 large health plans offering MAPD benefits in California.

## METHODS

Patients from 2 large California health plans offering MAPD benefits in 2006 were included in the study if they were age 65 years or older, were identified as having diabetes, and were beneficiaries of the Medicare Part D program. The first plan (plan A) is a for-profit network model HMO serving patients primarily in Southern California. The second plan (plan B) is a not-for-profit integrated delivery system HMO model that serves patients in Northern California.

Patients were determined to have diabetes if they had filled a prescription for at least 1 glucose-lowering medication (eg, insulin, metformin) at some point during 2005. Fifteen percent of Medicare beneficiaries in both plans had diabetes based on this criterion. In order to be eligible for the study, these diabetes patients also were required to have been continuously enrolled in the health plan between January 1, 2006, and December 31, 2006, so that complete pharmacy data could be captured (11% of patients were excluded from the study on this basis). An additional 26% were excluded from the study if they had any type of drug cost coverage during the gap, including a supplemental retiree benefit plan or a low-income supplement provided by Medicaid or through the Part D program.

Patient age, sex, and Medicare Part D enrollment were determined from automated databases on demographics and coverage status maintained by both plans. Comorbidity data were determined by using 2005 claims data for patients in

plan A and 2005 automated outpatient clinical records for patients in plan B.

Individual entry and exit into the Medicare Part D coverage gap were determined by using pharmacy claims data for patients in plan A and automated outpatient pharmacy records for patients in plan B. In both plans, patients reached the coverage gap after total drug costs exceeded \$2250, which included drug acquisition costs and dispensing fees. Patients exited the gap once out-of-pocket costs reached a total of \$3600 during the year.

This study was developed and approved by the Steering Committee of the Translating Research in Action for Diabetes (TRIAD) Study and conducted by researchers in 2 TRIAD Translational Research Centers. The study protocol was approved by the Kaiser Permanente Northern California and University of California at Los Angeles institutional review boards.

## RESULTS

The MAPD plans had a total of 42,801 beneficiaries with diabetes who met study criteria. Almost half (47%) were between 65 and 74 years of age, 43% were between 75 and 84 years of age, and 10% were age 85 years and older. Fifty-one percent of study subjects were female. Most patients (81%) were using only oral hypoglycemics to manage their diabetes. Eighty percent had an *International Classification of Diseases, Ninth Revision* diagnosis of hypertension, and 65% had hyperlipidemia. The percentage of elderly patients, percentage of female patients, diabetes drug use patterns, and comorbidity burden were similar in both plans. During 2006, 26% of diabetes patients entered the coverage gap. Only 2% of all beneficiaries in the study had \$3600 in total drug costs, therefore qualifying for catastrophic coverage drug cost assistance in 2006.

**Figure 1** shows the cumulative percentage of diabetes patients entering the coverage gap by month. Fewer than 1% of patients entered the prescription drug coverage gap in the first quarter of 2006 (January-March); by the end of the second quarter (June) only 5% had entered the coverage gap. More than half of the patients who entered the coverage gap during the year did so after August 31.

On average, diabetes patients incurred \$2182 in total drug costs during 2006, with a mean of \$807 in out-of-pocket drug costs to patients. **Figure 2** shows the amount of total and out-of-pocket drug expenditures for the MAPD beneficiaries in the study who did and did not reach the coverage gap in 2006. For those who did not reach the gap, both total drug expenditures and out-of-pocket drug expenditures remained stable over time during the year. For the 26% of MAPD pa-

tients in the study who reached the coverage gap in 2006, total drug costs were much higher overall and decreased toward the end of the year as out-of-pocket drug expenses increased. Analysis-of-variance tests of the differences in drug costs showed that the decrease in total drug costs between quarter 3 and quarter 4 of 2006 and the quarterly increases in out-of-pocket costs for these patients were significant ( $P < .01$ ).

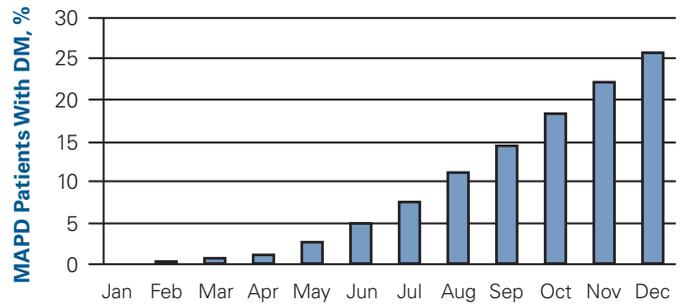
## DISCUSSION

Data from both Medicare Advantage plans in this study suggests that Medicare Advantage beneficiaries with diabetes are entering and exiting the doughnut hole of drug coverage at a far lower rate than originally expected. One study projected that 64% of patients with diabetes who were eligible for Medicare Part D would have drug costs exceeding \$2250 and incur significant out-of-pocket spending in 2006.<sup>20</sup> We found a much lower rate of gap entry than this original prediction (26% of patients entered the gap in 2006).

There are many potential explanations for the disparity between previous projections and the actual experience of diabetes patients in these Medicare Advantage plans. One possible reason is that patients in these managed care plans are receiving more generic therapies than those in the general diabetes population previously studied. These managed care plans may provide appropriate drug therapies in ways that lower costs through methods such as through formulary management, generic substitution, or multitiered copayments.<sup>21,22</sup>

Another potential explanation for the difference between projected and actual rates of entering and exiting the coverage gap is that patients could use fewer medications up front to avoid entering the coverage gap, and then continue to use fewer medications once the doughnut hole is reached. Previous projections of gap entry rates were based on assumptions that patient drug spending would

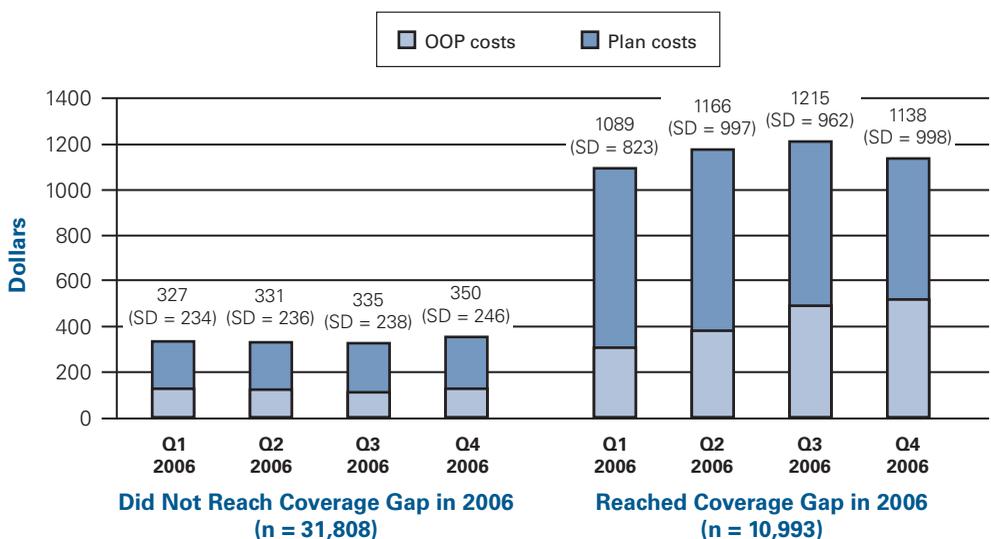
**Figure 1.** Cumulative Percentage of Patients Reaching Medicare Part D Coverage Gap in 2006, by Month



DM indicates diabetes mellitus; MAPD, Medicare Advantage Prescription Drug.

stay steady as patients approach the gap, as well as after the gap was reached.<sup>20</sup> Our findings demonstrate that total drug costs were decreasing in the latter part of the year as out-of-pocket costs were rising, which suggests that medication use by diabetes patients could be decreasing once they hit the coverage gap. This observation would support the findings of other Medicare Part D studies, which found evidence of decreased drug adherence based on cost,<sup>1,18</sup> especially for patients with worse health status such as those with diabetes.<sup>19</sup> Because cost-related medication nonadherence is associated with poorer health status, greater rates of cardiac adverse events, and increased use of emergency services,<sup>3</sup> particular attention should be paid to addressing this potential risk for diabetes patients in Medicare Part D plans.

**Figure 2.** Average per-Patient Quarterly Total Drug Costs in 2006



OOP indicates out-of-pocket; Q1, quarter 1.

### Take-Away Points

Patients with chronic illnesses such as diabetes may be particularly vulnerable to “coverage gap” benefit designs such as those in Medicare Part D.

- We observed that 26% of diabetic patients in major California Medicare Advantage Part D plans reached the drug coverage gap in 2006.
- These patients’ overall drug costs dropped as their out-of-pocket costs increased, a pattern that may signal cost-related medication nonadherence.
- Future work should examine the effects of Part D on medication nonadherence in patients with chronic illness and risk factors for entering the coverage gap.

patients, and their providers, and further research should examine specific patient responses to gaps in prescription drug coverage in Medicare.

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This study has a number of limitations that should be noted. This study only examines patients in MAPD plans, which make up 28% of the total Part D population; most Medicare Part D enrollees are covered by stand-alone Prescription Drug Plans (PDPs).<sup>23</sup> Further research will be required to examine gap entry rates, drug costs, and risk for cost-related medication nonadherence in PDP patients with diabetes. This study identified diabetes patients through drug claims data rather than diagnosis codes; however, a sensitivity analysis showed that requiring a diabetes diagnosis in addition to antidiabetic drug use resulted in a very small number of patient exclusions (<5%). This study only examined the experience of Medicare Part D enrollees in 2 California plans, who may differ from enrollees nationally. However, examination of plan A data on enrollees with diabetes in 7 other states (Arizona, Colorado, Nevada, Oklahoma, Oregon, Texas, and Washington) showed that the plan A gap entry rate for all western states combined was almost identical to that of California alone. This result suggests that the results presented here are representative of the overall MAPD enrollees’ experience.

Finally, this study did not specifically demonstrate that decreases in drug spending lead to adverse outcomes such as increased mortality and morbidity. Future research is required to examine this important issue.

### CONCLUSION

This study is the first to examine actual total and out-of-pocket drug costs, and empirical rates of entering and exiting the coverage gap, in a Medicare Advantage population with chronic illness. Our findings suggest that diabetes patients are more vulnerable to entering the coverage gap than MAPD beneficiaries in the general population, but are entering the gap at lower-than-expected rates for diabetes patients. These lower-than-expected costs and rates of experiencing the doughnut hole may reflect efforts by Medicare Advantage plans to provide appropriate drug therapies in ways that lower costs, or may suggest that seniors are significantly lowering their use of prescription medications in response to high out-of-pocket costs. This is a critically important question for policy makers,

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