

# Part D Coverage Gap Reform: Trends in Drug Use and Expenditures

Joohyun Park, PhD; and Kevin A. Look, PharmD, PhD

Medicare beneficiaries have had access to prescription drug coverage through Medicare Part D since its implementation in 2006, and the majority of Medicare beneficiaries (72% in 2018) are enrolled in Part D plans.<sup>1</sup> Part D plans were created with a unique feature in their benefit called the coverage gap (or “doughnut hole”), in which beneficiaries are required to pay 100% of their drug costs until they reach the catastrophic threshold. Not surprisingly, the coverage gap in Part D plans has unfavorably affected beneficiaries’ out-of-pocket drug costs, drug use, and medication adherence.<sup>2-5</sup> For example, the entry of Part D beneficiaries into the coverage gap has been associated with substantially increased out-of-pocket drug costs, reduced use of drugs, and cost-related nonadherence such as discontinuing a medication, delaying prescription filling, or skipping doses.<sup>2,3</sup>

Responding to these concerns, the Patient Protection and Affordable Care Act (ACA) of 2010 included provisions that initiated a 10-year process of closing the Part D coverage gap from a 100% beneficiary coinsurance rate in 2010 to 25% by 2020.<sup>6</sup> A one-time \$250 rebate was provided to Part D enrollees who reached the coverage gap in 2010, and since 2011 manufacturers have been required to provide a 50% discount on the price of brand-name drugs in the gap, which counts toward a beneficiary’s annual out-of-pocket spending that must be met before catastrophic coverage begins.<sup>7</sup> Additionally, beneficiaries’ coinsurance rates in the gap have gradually decreased, beginning in 2011 for generics and 2013 for brand-name drugs.<sup>8</sup>

Although previous studies have evaluated the effects of entering the Part D coverage gap,<sup>2,3</sup> there is little comprehensive research on the effects of the ACA’s provision to gradually close the Part D coverage gap. Although previous studies have suggested positive effects of the ACA on beneficiaries’ out-of-pocket drug costs, they have focused on very limited populations, such as those taking specialty drugs,<sup>9</sup> diabetes medications,<sup>10</sup> or anticancer medications.<sup>11-13</sup> Additionally, they used short-term data compiled after the ACA’s passage<sup>9,14</sup> and used survey data with limited information on beneficiaries’ eligibility, which may have several limitations in selecting study samples.<sup>14</sup> As the first step to better understand the

## ABSTRACT

**OBJECTIVES:** This study analyzed annual trends in the distribution of beneficiaries entering each benefit phase and the utilization of and expenditures for prescription drugs among Medicare Part D beneficiaries from 2008 to 2015.

**STUDY DESIGN:** Retrospective, repeated cross-sectional analysis using Medicare Current Beneficiary Survey data.

**METHODS:** The study population included elderly Part D beneficiaries without a low-income subsidy, with continuous enrollment in a Part D plan, and with at least 1 prescription fill for a given year. We assessed annual trends for 3 outcomes: (1) proportion of beneficiaries entering each benefit phase and the number of days taken to enter these phases, (2) number of 30-day prescription drug fills, and (3) total and out-of-pocket spending on prescription drugs.

**RESULTS:** The proportion of beneficiaries reaching the catastrophic coverage phase increased after the Affordable Care Act (ACA), and they reached the threshold earlier in the year. The overall number of 30-day drug fills increased over the study period, although no statistically significant changes in utilization were seen among those reaching the catastrophic coverage phase. Total drug spending steadily increased over time, particularly after the ACA, with the largest increase seen in those reaching the catastrophic threshold; however, out-of-pocket spending significantly decreased.

**CONCLUSIONS:** Although this study provides support for reductions in financial barriers to prescription drugs under the ACA, substantial increases in both total drug spending and the proportion of high-cost beneficiaries in the Part D program indicate a growing burden of Part D spending on the Medicare program, which is expected to continue to grow in the future.

*Am J Manag Care.* 2020;26(8):349-356. doi:10.37765/ajmc.2020.44071

## TAKEAWAY POINTS

- ▶ After the Affordable Care Act's coverage gap reform, beneficiary out-of-pocket costs for prescription drugs significantly decreased despite an increase in drug utilization, supporting the intent of the policy.
- ▶ Although high-cost beneficiaries did not experience changes in drug utilization and out-of-pocket costs, the relative proportion of high-cost beneficiaries increased by 50% and their total drug spending nearly doubled.
- ▶ Substantial increases in total drug spending and high-cost beneficiaries reinforce the importance of these issues in national discussions around health reform. Changes to the Part D program are needed to address these issues while still ensuring adequate beneficiary access to prescription drugs.

long-term impact of the ACA's coverage gap reform on drug use and expenditures, the objectives of this study were to examine trends in the distribution of beneficiaries in each benefit phase and the utilization of and expenditures for prescription drugs among Part D beneficiaries.

## METHODS

### Design and Data Source

A retrospective, repeated cross-sectional study design was used to analyze annual trends in the outcomes in each year. The study period was from 2008 to 2015, excluding 2014 for which no data were available.<sup>15</sup> The pre-ACA period was defined as January 2008 to December 2010, and the post-ACA period was defined as January 2011 to December 2015. Trends were analyzed in the outcomes between the pre- and post-ACA periods.

This study used data from the Medicare Current Beneficiary Survey (MCBS), which is a continuous, in-person, longitudinal survey of a nationally representative sample of the Medicare population.<sup>15</sup> For the analysis, the Cost and Use files from 2008 to 2013 and both the Survey File and Cost Supplement File from 2015 were utilized. The survey-reported events on prescription drug use and expenditures were used only if the events were matched to Part D claims data.<sup>16</sup>

### Study Population

The study sample in each year included Part D beneficiaries without a low-income subsidy (non-LIS) who met the following criteria: (1) 65 years or older, (2) not disabled and not having end-stage renal disease, (3) continuous enrollment in a Part D plan for a given year, and (4) having at least 1 prescription fill for a given year in order to target those who were likely to be affected by the ACA reform.<sup>10</sup>

The study sample was further categorized into 3 subgroups: (1) beneficiaries not entering the coverage gap, (2) beneficiaries who entered the coverage gap but did not reach the catastrophic threshold, and (3) beneficiaries who reached the catastrophic threshold. Total drug spending was used to determine whether a person reached the coverage gap and/or the catastrophic threshold during the year.<sup>14</sup> The catastrophic threshold is updated annually by the annual percentage increase in average expenditures for Part D drugs per

eligible beneficiary (\$5726 in 2008, \$6154 in 2009, \$6440 in 2010, \$6484 in 2011, \$6730 in 2012, \$6955 in 2013, and \$7062 in 2015).<sup>14,17</sup> All analyses were conducted separately for each of the populations.

### Outcomes

We assessed annual trends for 3 outcomes from 2008 to 2015. The first outcome was the proportion of beneficiaries entering the coverage gap and catastrophic coverage phase. The number of days taken to enter these phases and the number of days a member stayed in

each phase were also determined using dates of service.

The second outcome was the utilization of prescription drugs, measured as the annual number of 30-day prescription drug fills per person. Each record in the Prescribed Medicine Events and in the Cost and Use files is a single purchase/fill of a single drug in a single container.<sup>16</sup> Because each drug fill was for a different quantity, we standardized them to 30-day fills using the days of supply to account for the variability in the number of days dispensed across fills.

The final outcome was expenditures for prescription drugs and was measured at 2 levels: (1) mean annual total spending per person paid by all payment sources and (2) mean annual out-of-pocket spending per person.

### Statistical Analysis

Descriptive statistics were calculated to describe study sample characteristics for each year and annual trends in the outcomes. Statistical comparisons across each year from 2008 to 2015 were evaluated using  $\chi^2$  tests and analysis of variance.

To obtain nationally representative estimates for the non-LIS Part D population and to account for the complex sampling design of the MCBS (eg, the rotating-panel and multistage-sampling design), the balanced repeated replication of variance estimation was used to adjust for both serial and intracluster correlation in the data, using the replicate cross-sectional weights for each year.<sup>18</sup> All statistical analyses were conducted using Stata 15.1 (StataCorp), and statistical significance was determined by an  $\alpha$  level of 0.05. All estimates of spending and income were converted to inflation-adjusted 2015 dollars using the all-items Consumer Price Index.<sup>14,19</sup>

## RESULTS

The weighted characteristics of the study sample from 2008 to 2015 are presented in **Table 1**. The weighted counts of non-LIS Part D beneficiaries steadily increased over time, with substantial increases in the post-ACA period. Compared with those in the pre-ACA period, beneficiaries in the post-ACA period were more likely to be younger, non-Hispanic black or other racial group, educated, employed, having higher income, living in a metropolitan area, and having a larger number of chronic conditions.

**TABLE 1.** Characteristics of Study Population, Non-LIS Part D Beneficiaries, Medicare Current Beneficiary Survey, 2008-2015<sup>a</sup>

	2008		2009		2010		2011		2012		2013		2015		
Sample size (n)	3260		3076		3084		3317		3736		4126		4320		
Population size (N)	12,400,843		13,123,739		13,599,760		14,563,427		16,304,256		19,376,540		24,751,318		
	Mean or %	SE	Mean or %	SE	Mean or %	SE	Mean or %	SE	Mean or %	SE	Mean or %	SE	Mean or %	SE	P <sup>b</sup>
Age in years	76.4	0.1	76.3	0.1	76.1	0.1	76.2	0.1	76.1	0.1	75.9	0.1	75.2	0.1	<.001
Female, %	59.3	0.8	60.4	0.8	60.4	0.8	59.8	0.8	58.1	0.7	58.3	0.8	57.6	0.8	.05
Race/ethnicity, %															<.001
White, non-Hispanic	91.8	0.5	91.3	0.5	91.7	0.5	91.1	0.5	91.6	0.5	90.3	0.5	88.5	0.6	
Black, non-Hispanic	5.1	0.4	5.1	0.4	5.3	0.4	5.4	0.4	4.6	0.3	5.7	0.3	6.5	0.4	
Hispanic	1.2	0.2	1.3	0.2	1.8	0.2	1.2	0.1	1.1	0.2	1.1	0.2	1.1	0.2	
Other, non-Hispanic	1.9	0.3	2.3	0.3	2.3	0.3	2.3	0.3	2.7	0.4	3.0	0.4	3.9	0.5	
Married, %	56.7	0.9	56.6	0.9	56.8	0.8	57.7	0.9	57.5	0.8	57.9	0.8	59.5	0.9	.10
Education, %															<.001
Less than high school	20.5	0.8	19.2	0.8	19.2	0.9	18.2	0.7	17.0	0.8	15.7	0.7	12.8	0.5	
High school graduate	32.9	1.0	32.8	1.1	32.4	0.9	30.5	0.9	28.4	0.8	28.4	1.0	26.2	0.9	
Some college or more	46.6	1.2	48.0	1.2	48.3	1.2	51.3	0.9	54.6	0.9	55.9	1.0	61.1	1.0	
Job status (having a job), %	12.7	0.6	12.9	0.7	12.5	0.7	12.8	0.6	14.3	0.7	14.3	0.7	15.0	0.9	
Household income in \$ <sup>c</sup>	45,524	1133	42,725	712	42,871	817	43,631	844	46,290	870	51,132	2374	59,534	2025	<.001
Census region, %															.19
Northeast	18.5	0.7	18.6	0.7	18.5	0.7	16.7	0.8	17.6	0.8	18.5	0.6	19.0	0.8	
Midwest	23.9	0.7	24.6	0.8	22.6	0.8	23.9	0.7	24.4	0.8	24.4	0.7	24.9	0.8	
South	33.0	0.8	33.0	0.9	34.7	1.1	34.8	1.1	32.9	1.0	33.6	0.8	33.7	0.8	
West	24.7	0.7	23.8	0.8	24.2	1.0	24.6	1.0	25.2	0.8	23.5	0.8	22.5	0.8	
Living in Metro area, %	79.6	0.7	80.3	0.8	80.1	0.8	78.8	0.7	78.2	0.6	78.4	0.6	81.4	1.0	.01
No. of chronic conditions, %															
0-2	40.3	1.0	39.7	1.0	38.7	1.1	37.9	0.9	36.6	0.9	37.0	0.8	28.2	0.8	
3-4	41.0	1.0	42.2	1.0	42.9	0.9	44.4	0.9	44.8	1.0	43.9	0.9	48.7	1.0	
>5	18.7	0.7	18.1	0.8	18.4	0.8	18.6	0.7	18.6	0.6	19.1	0.6	23.2	0.7	

LIS, low-income subsidy; SE, standard error.

<sup>a</sup>No Medicare Current Beneficiary Survey data were released in 2014. All numbers, except the sample size (n), are weighted estimates using the balanced repeated replication method.

<sup>b</sup>P values reflect analysis of variance or  $\chi^2$  tests for comparisons across the years.

<sup>c</sup>All amounts are in 2015 US dollars and rounded off to the nearest whole number.

### Distribution of Beneficiaries Entering Each Benefit Phase

More non-LIS Part D beneficiaries were reaching the catastrophic threshold in the post-ACA period than in the pre-ACA period, and fewer beneficiaries fell into the coverage gap without reaching the catastrophic threshold (Table 2). In 2008, 547,018 (4% of total non-LIS Part D beneficiaries) reached the catastrophic threshold, compared with about 1.6 million beneficiaries (6% of total non-LIS Part D beneficiaries) in 2015. Although the absolute number of beneficiaries entering the coverage gap without reaching the catastrophic threshold also increased in the post-ACA period, the proportion of beneficiaries reaching this phase actually decreased (23% in 2008 vs 17% in 2015). Correspondingly, for those not reaching the coverage gap, both the number and proportion

increased in the post-ACA period (2348 and 73% in 2008 vs 3242 and 76% in 2015).

Table 2 also shows trends in how quickly beneficiaries reached the coverage gap and catastrophic threshold and how long they stayed in each benefit phase. In the post-ACA period, beneficiaries reached the coverage gap and the catastrophic threshold more quickly (ie, earlier in the year) than in the pre-ACA period. Accordingly, beneficiaries entering the coverage gap without reaching the catastrophic threshold were more likely to stay in the coverage gap longer (101 days in 2008 vs 123 days in 2015), whereas those entering the catastrophic coverage phase spent less time in the gap but longer in the catastrophic coverage phase (98 days in 2008 vs 139 days in 2015). The Figure shows the cumulative percentage of beneficiaries reaching these phases

**TABLE 2.** Distribution of Non-LIS Part D Beneficiaries Entering Each Benefit Phase, Medicare Current Beneficiary Survey, 2008-2015\*

	2008		2009		2010		2011	
	Mean or %	SE	Mean or %	SE	Mean or %	SE	Mean or %	SE
<b>All beneficiaries</b>								
Days to reach coverage gap	241	2.0	240	2.8	237	2.4	233	3.3
Days stayed in coverage gap	108	2.6	109	2.6	113	2.1	112	2.4
Days to reach catastrophic coverage	267	6.4	263	8.5	262	10.3	264	7.1
<b>Not reaching coverage gap</b>								
Sample size (n)	2348		2259		2346		2489	
Population size (N)	9,012,863		9,685,520		10,394,938		11,086,617	
Total as % of all non-LIS enrollees	73%		74%		76%		76%	
<b>Reaching the gap, not catastrophic</b>								
Sample size (n)	764		696		628		681	
Population size (N)	2,840,962		2,908,349		2,733,057		2,855,364	
Total as % of all non-LIS enrollees	23%		22%		20%		20%	
Days to reach coverage gap	264	2.8	261	2.8	257	2.3	259	2.7
Days stayed in coverage gap	101	2.9	104	2.8	108	2.3	106	2.7
<b>Reaching catastrophic coverage</b>								
Sample size (n)	148		121		110		147	
Population size (N)	547,018		529,870		471,765		621,445	
Total as % of all non-LIS enrollees	4%		4%		3%		4%	
Days to reach coverage gap	124	4.5	121	5.7	119	5.1	119	4.1
Days stayed in coverage gap	141	4.6	138	5.5	143	6.4	140	4.7
Days to reach catastrophic coverage	267	6.4	263	8.5	262	10.3	264	7.1
Days stayed in catastrophic coverage	98	6.4	102	8.5	101	10.3	101	6.7

[continued >>]

and highlights the gradual increase seen over the study period. In 2008, 4% of beneficiaries reached the coverage gap by May, whereas 7% reached the gap by May in 2015. Similarly, 0.4% of beneficiaries reached the catastrophic threshold by May in 2008, compared with 1.5% in 2015.

**Drug Utilization**

For all non-LIS beneficiaries, the mean annual number of 30-day drug fills increased over time, increasing by 10% from 2008 to 2015 (Table 3). When comparing the changes from year to year after the ACA, the number of drug fills remained relatively unchanged between 2010 and 2011 and then increased considerably in 2012 and 2013 but slightly decreased in 2015.

Similar trends were seen in the number of drug fills for 2 subgroups: those not reaching the coverage gap and those entering the gap without reaching the catastrophic threshold. Their number of drug fills increased by 13% and 11% in 2015 compared with 2008, respectively. However, for those reaching the catastrophic threshold, there was no significant change in the number of drug fills over the study period.

**Drug Expenditures**

For all non-LIS beneficiaries, mean annual total drug spending steadily increased over time, particularly after the ACA, while mean annual out-of-pocket spending decreased. Total spending increased by 16% in 2015 compared with 2008, whereas the out-of-pocket spending decreased by 18%. For those not reaching the coverage gap, both total and out-of-pocket spending decreased in the post-ACA period; both decreased by approximately 30% in 2015 compared with 2008.

Similar to the trends seen among all non-LIS beneficiaries, there were significant increases in total spending and decreases in out-of-pocket spending over the study period among those entering the coverage gap without reaching the catastrophic threshold and those reaching the catastrophic threshold. For those entering the coverage gap without reaching the catastrophic threshold, total spending increased by 12% in 2015 compared with 2008 and out-of-pocket spending decreased by 13%. For those reaching the catastrophic threshold, total spending increased by 66% in 2015 compared with 2008, whereas out-of-pocket spending decreased by 15%.

**TABLE 2.** (Continued) Distribution of Non-LIS Part D Beneficiaries Entering Each Benefit Phase, Medicare Current Beneficiary Survey, 2008-2015<sup>a</sup>

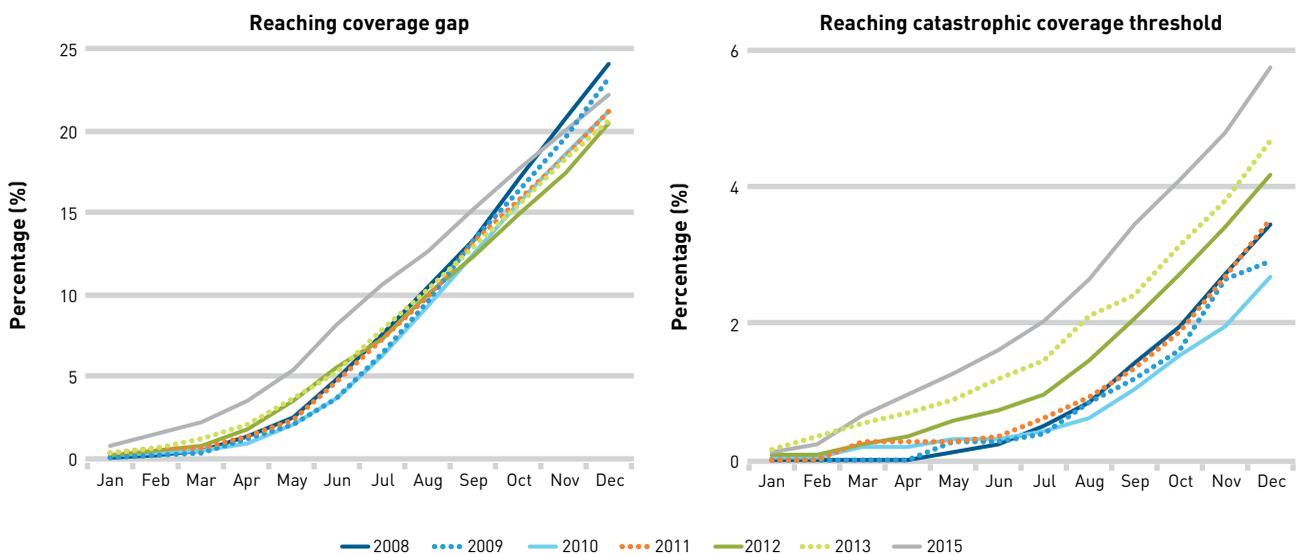
	2012		2013		2015		P <sup>b</sup>
	Mean or %	SE	Mean or %	SE	Mean or %	SE	
<b>All beneficiaries</b>							
Days to reach coverage gap	224	3.8	221	2.9	206	2.6	<.01
Days stayed in coverage gap	113	2.7	116	2.3	123	2.7	<.05
Days to reach catastrophic coverage	249	6.7	239	6.8	226	7.3	<.01
<b>Not reaching coverage gap</b>							
Sample size (n)	2887		3169		3242		
Population size (N)	12,675,994		14,964,161		18,831,931		
Total as % of all non-LIS enrollees	78%		77%		76%		
<b>Reaching the gap, not catastrophic</b>							
Sample size (n)	662		751		786		
Population size (N)	2,822,810		3,432,878		4,326,968		
Total as % of all non-LIS enrollees	17%		18%		18%		
Days to reach coverage gap	257	3.1	254	2.5	242	3.0	<.01
Days stayed in coverage gap	108	3.1	111	2.5	123	3.0	<.01
<b>Reaching catastrophic coverage</b>							
Sample size (n)	187		206		292		
Population size (N)	805,452		979,501		1,592,419		
Total as % of all non-LIS enrollees	5%		5%		6%		
Days to reach coverage gap	106	4.3	105	3.9	102	3.7	<.01
Days stayed in coverage gap	130	4.8	131	4.9	123	4.5	.06
Days to reach catastrophic coverage	249	6.7	239	6.8	226	7.4	<.01
Days stayed in catastrophic coverage	116	6.7	126	6.8	139	7.3	<.01

LIS, low-income subsidy; SE, standard error.

<sup>a</sup>No Medicare Current Beneficiary Survey data were released in 2014. All numbers are weighted estimates using the balanced repeated replication method.

<sup>b</sup>P values reflect analysis of variance or  $\chi^2$  tests for comparisons across the years.

**FIGURE.** Cumulative Percentage of Beneficiaries Reaching the Coverage Gap and Catastrophic Coverage Threshold, 2008-2015



**TABLE 3.** Drug Utilization and Expenditures Among Non-LIS Part D Beneficiaries, Medicare Current Beneficiary Survey, 2008-2015<sup>a</sup>

	2008		2009		2010		2011		2012		2013		2015		P <sup>b</sup>
	Mean	SE	Mean	SE	Mean	SE	Mean	SE	Mean	SE	Mean	SE	Mean	SE	
All beneficiaries															
Annual number of 30-day Rx fills	43.1	0.8	44.5	0.5	45.2	0.6	45.3	0.6	47.4	0.6	48.7	0.5	47.6	0.7	<.01
Total drug spending, \$ <sup>c</sup>	2167	51	2248	67	2201	67	2164	80	2252	93	2354	89	2518	119	<.001
OOP spending, \$ <sup>d</sup>	760	21	751	18	717	17	701	20	680	18	634	17	621	17	<.01
Not reaching the gap															
Annual number of 30-day Rx fills	33.9	0.6	35.3	0.5	37.3	0.6	37.1	0.6	39.1	0.5	39.4	0.5	38.2	0.6	<.001
Total drug spending, \$ <sup>c</sup>	1183	21	1203	19	1187	21	1051	21	1004	18	927	17	810	18	<.001
OOP spending, \$ <sup>d</sup>	383	8	389	8	400	9	349	7	329	6	299	6	270	5	<.001
OOP/total drug spending, % <sup>e</sup>	39	0.5	39	0.6	42	0.6	43	0.5	43	0.6	44	0.7	46	0.7	<.001
Reaching the gap, but not catastrophic															
Annual number of 30-day Rx fills	63.9	0.8	67.0	1.0	67.3	1.0	67.0	1.0	71.3	1.2	74.8	1.2	70.9	1.5	<.001
Total drug spending, \$ <sup>c</sup>	3904	36	4093	44	4245	41	4211	40	4274	53	4384	39	4383	52	<.001
OOP spending, \$ <sup>d</sup>	1543	43	1552	43	1566	39	1567	40	1490	53	1371	38	1337	40	<.01
OOP/total drug spending, % <sup>e</sup>	38	0.7	37	0.8	36	0.7	36	0.7	34	0.9	31	0.7	30	0.8	<.01
Reaching catastrophic coverage															
Annual number of 30-day Rx fills	96.0	3.0	97.3	4.4	101.5	3.3	100.3	2.9	97.8	3.1	102.7	3.8	97.0	2.7	.65
Total drug spending, \$ <sup>c</sup>	10,738	609	12,501	1532	14,063	1899	13,925	1412	15,493	1534	17,515	1508	17,843	1484	<.001
OOP spending, \$ <sup>d</sup>	3348	175	3355	228	3148	228	3378	198	3534	158	3289	163	2860	127	.012
OOP/total drug spending, % <sup>e</sup>	36	2.1	32	2.4	30	2.0	31	1.8	31	1.6	27	1.4	23	1.2	<.001

LIS, low-income subsidy; OOP, out-of-pocket; Rx, prescription; SE, standard error.

<sup>a</sup>No Medicare Current Beneficiary Survey data were released in 2014. All numbers are weighted estimates using the balanced repeated replication method.

<sup>b</sup>P values reflect analysis of variance test for comparisons across the years.

<sup>c</sup>Mean annual total drug spending per person paid by all payment sources, such as Medicare, Medicaid, private, other public health insurance, OOP, and uncollected liabilities.

<sup>d</sup>Mean annual OOP spending per person.

<sup>e</sup>The proportion (%) of mean annual OOP drug spending relative to mean annual total drug spending was estimated for each of the subgroups to see how the proportion of OOP spending changed over the study period.

## DISCUSSION

This study analyzed Medicare Part D data from 2008 to 2015 to examine the trends in the distribution of beneficiaries entering each benefit phase, as well as beneficiary drug utilization and expenditures after the ACA's coverage gap reform beginning in 2010. We found that the number of non-LIS Part D beneficiaries who reached the catastrophic threshold (ie, high-cost beneficiaries) substantially increased after the ACA, and they reached the threshold earlier in the year. Additionally, although total drug spending increased, beneficiary out-of-pocket drug spending decreased and prescription drug utilization increased. However, the growth in total drug spending for high-cost beneficiaries rapidly outpaced that seen among other beneficiaries.

Overall, the trends in out-of-pocket costs and drug utilization reported in this study suggest that provisions to phase out the Part D coverage gap have helped to improve the affordability of prescription

drugs for beneficiaries. The significant decreases in out-of-pocket drug costs may indicate financial relief for beneficiaries due to reductions in beneficiaries' cost sharing in the coverage gap and the 50% manufacturer discount on the price of brand-name drugs. In addition, beneficiaries significantly increased their prescription drug use after the ACA, which was mainly due to the increases seen among those who did not enter the coverage gap and those who entered the gap without reaching the catastrophic threshold. As many previous studies found an inverse association between cost sharing and drug utilization,<sup>10,20-23</sup> the increased drug use found in this study may be due in part to the reduction in cost sharing in the coverage gap after the ACA. These findings are particularly relevant given the recent increase in the manufacturer discount to 70%.<sup>24</sup>

Although our findings provide support for improved financial protection and drug affordability for beneficiaries under the ACA, it is important to note that the trends in drug utilization and out-of-pocket costs remained relatively unchanged among high-cost

beneficiaries. This implies that high-cost beneficiaries were mainly unaffected by the closure of the coverage gap, which might be due to the characteristics of the beneficiaries. High-cost beneficiaries are more likely to have severe, complex, or life-threatening diseases such as HIV/AIDS, multiple sclerosis, viral hepatitis, and cancer, resulting in high drug use including use of high-priced drugs such as specialty drugs.<sup>25</sup> They are more likely to pass through the initial coverage and the coverage gap quickly (ie, spent less time in the coverage gap where the policy effect occurred), which might be accelerated in the post-ACA period due to drug price inflation and the greater availability of high-priced drugs.<sup>26</sup> Furthermore, because the high-cost beneficiaries are still responsible for up to 5% of their drug costs in the catastrophic coverage phase, some beneficiaries could still be exposed to a high out-of-pocket drug cost burden for very high-priced drugs.<sup>25</sup>

The findings of substantial increases in the proportion of high-cost beneficiaries and in total drug spending provide evidence supporting the recent attention focused on the growth in Part D drug spending and highlight significant growth in spending for high-cost beneficiaries.<sup>9,26-28</sup> The increased number of high-cost beneficiaries may be due in part to the ACA's provision of manufacturer discounts in the coverage gap that count as beneficiary out-of-pocket spending. This provision has helped beneficiaries move through the coverage gap faster and use more brand-name drugs, resulting in more people reaching the catastrophic threshold more quickly.<sup>26,29</sup> Additionally, the ACA provision slowing the growth rate of the annual out-of-pocket spending threshold between 2014 and 2019 allowed more beneficiaries to qualify for the catastrophic coverage phase with less out-of-pocket spending.<sup>29</sup>

Along with the increased number of high-cost beneficiaries, overall annual total drug spending steadily increased over the study period, which seems to be mainly due to the increases in total drug spending among beneficiaries reaching the catastrophic threshold. A combination of several factors has contributed to the growth in total drug spending. First, as shown in this study, an increased number of high-cost beneficiaries has led to increases in total drug spending.<sup>26</sup> Second, the increasing use of high-priced brand-name and specialty drugs has contributed to the growth in drug spending and has helped more beneficiaries reach the catastrophic threshold.<sup>26,28</sup> In this study, the findings of increases in total drug spending from 2013 to 2015 despite slight decreases in drug use support the trend of rising drug prices. Lastly, the innate and complex Part D structure provides an incentive for insurers to cover more expensive medications in the catastrophic phase even if lower-cost options are available, which has contributed to increases in Part D drug spending.<sup>26,28</sup>

The growth in Part D spending for high-cost beneficiaries has led to a growing cost burden on the Medicare program because Medicare pays the majority of the drug costs in the catastrophic coverage phase (ie, reinsurance), which is expected to continue to grow in the future.<sup>25,26,30,31</sup> Medicare payments for individual reinsurance have grown faster than other components of Part D spending, with

an annual average of more than 24% between 2010 and 2015, and became the largest component of Part D spending starting in 2014.<sup>26</sup> Additionally, the annual growth in Part D spending per beneficiary is expected to be higher than growth in other categories of Medicare spending over the next decade.<sup>25,26</sup> Thus, comprehensive efforts are needed to reduce the growth in Part D spending.<sup>31</sup>

### Limitations

This study has several limitations. First, this study is descriptive in nature without a comparison group. The findings in this study may not provide as compelling empirical evidence on the impact of the ACA reform as those employing a quasi-experimental design. Our study design may not have adequately controlled for changes in confounding factors that might have been occurring at the same time as the ACA reform. Future research with a more rigorous study design is required for a better estimation of the policy impact. Second, this study did not examine the trends in drug utilization and expenditures by drug type because information on whether beneficiaries filled the brand-name or generic drug was not available in the MCBS data. The trends could have varied by drug type given the stepwise structure of the cost-sharing reductions. Additionally, the trends could have been better explained; for example, increased drug use and decreased out-of-pocket costs could be partly explained by the increased use of generic drugs as best-selling brand-name drugs lost patent protection.<sup>32</sup> Third, Medicare beneficiaries can have drug coverage through Part D prescription drug plans or Medicare Advantage Prescription Drug plans, which could have a different impact on drug use and expenditures. However, we were not able to differentiate between these plans using the MCBS data. Fourth, Part D plans could have a variety of drug benefit structures, including different cost-sharing requirements in the coverage gap or even removal of the gap in some plans.<sup>33</sup> We were not able to identify each plan's benefit structure, but consistent with previous literature we estimated the impact using total drug spending under the standard Part D benefit structure.<sup>14</sup> Lastly, like previous research, drug prices in this study did not include manufacturer rebates due to a lack of information in the data.<sup>3,10,14,34</sup>

## CONCLUSIONS

Following changes to the structure of the Medicare Part D coverage gap under the ACA, beneficiary out-of-pocket drug spending significantly decreased despite increases in drug utilization and total drug costs. In addition, a substantial increase was seen in the proportion of high-cost beneficiaries reaching the catastrophic threshold. Although the trends shown in this study suggest that the ACA reform has helped to reduce financial barriers to prescription drugs for Part D beneficiaries, substantial increases in total drug spending over time, especially among high-cost beneficiaries, indicate a growing burden of Part D spending on the Medicare program. As Medicare's share of drug costs increases considerably in the catastrophic coverage phase, potential changes to the Part D

program and alternative drug pricing models are needed to reduce the growing number of high-cost beneficiaries and associated Part D spending, while still ensuring that beneficiaries have affordable access to prescription drugs. ■

**Author Affiliations:** Social and Administrative Sciences Division, University of Wisconsin–Madison School of Pharmacy (JP, KAL), Madison, WI.

**Source of Funding:** None.

**Author Disclosures:** The authors report no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this article.

**Authorship Information:** Concept and design (JP, KAL); analysis and interpretation of data (JP, KAL); drafting of the manuscript (JP, KAL); critical revision of the manuscript for important intellectual content (JP, KAL); statistical analysis (JP); administrative, technical, or logistic support (JP); and supervision (KAL).

**Address Correspondence to:** Joohyun Park, PhD, University of Wisconsin–Madison School of Pharmacy, 777 Highland Ave, Madison, WI 53705-2222. Email: park399@wisc.edu.

## REFERENCES

- Cubanski J, Damico A, Neuman T. Medicare Part D in 2018: the latest on enrollment, premiums, and cost sharing. Kaiser Family Foundation. May 17, 2018. Accessed June 28, 2018. <https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/>
- Polinski JM, Kilabuk E, Schneeweiss S, Brennan T, Shrank WH. Changes in drug use and out-of-pocket costs associated with Medicare Part D implementation: a systematic review. *J Am Geriatr Soc*. 2010;58(9):1764-1779. doi:10.1111/j.1532-5415.2010.03025.x
- Park YJ, Martin EG. Medicare Part D's effects on drug utilization and out-of-pocket costs: a systematic review. *Health Serv Res*. 2017;52(5):1685-1728. doi:10.1111/1475-6773.12534
- Hoadley J, Hargrave E, Cubanski J, Neuman T. The Medicare Part D coverage gap: costs and consequences in 2007. Kaiser Family Foundation. August 1, 2008. Accessed July 11, 2018. <https://www.kff.org/medicare/report/the-medicare-part-d-coverage-gap-costs-and-consequences-in-2007/>
- Fung V, Mangione CM, Huang J, et al. Falling into the coverage gap: Part D drug costs and adherence for Medicare Advantage prescription drug plan beneficiaries with diabetes. *Health Serv Res*. 2010;45(2):355-375. doi:10.1111/j.1475-6773.2009.01071.x
- Hoadley J, Sumner L, Hargrave E, Cubanski J. Understanding the effects of the Medicare Part D coverage gap in 2008 and 2009. Kaiser Family Foundation. August 30, 2011. Accessed July 6, 2018. <https://www.kff.org/medicare/report/understanding-the-effects-of-the-medicare-part-d-coverage-gap-in-2008-and-2009/>
- Moon M. Medicare and the Affordable Care Act. *J Aging Soc Policy*. 2012;24(2):233-247. doi:10.1080/08959420.2012.659111
- Explaining health care reform: key changes to the Medicare Part D drug benefit coverage gap. Kaiser Family Foundation. March 1, 2010. Accessed July 6, 2018. <https://www.kff.org/health-reform/issue-brief/explaining-health-care-reform-key-changes-to/>
- Trish E, Joyce G, Goldman DP. Specialty drug spending trends among Medicare and Medicare Advantage enrollees, 2007-11. *Health Aff (Millwood)*. 2014;33(11):2018-2024. doi:10.1377/hlthaff.2014.0538
- Zeng F, Patel BV, Brunetti L. Effects of coverage gap reform on adherence to diabetes medications. *Am J Manag Care*. 2013;19(4):308-316.
- Shih YCT, Xu Y, Liu L, Smieliauskas F. Rising prices of targeted oral anticancer medications and associated financial burden on Medicare beneficiaries. *J Clin Oncol*. 2017;35(22):2482-2489. doi:10.1200/JCO.2017.72.3742
- Jung J, Xu WY, Cheong C. In-gap discounts in Medicare Part D and specialty drug use. *Am J Manag Care*. 2017;23(9):553-559.
- Dusetzina SB, Keating NL. Mind the gap: why closing the doughnut hole is insufficient for increasing Medicare beneficiary access to oral chemotherapy. *J Clin Oncol*. 2016;34(4):375-380. doi:10.1200/JCO.2015.63.7736
- Tehrani AB, Cunningham PJ. Closing the Medicare doughnut hole: changes in prescription drug utilization and out-of-pocket spending among Medicare beneficiaries with Part D coverage after the Affordable Care Act. *Med Care*. 2017;55(1):43-49. doi:10.1097/MLR.0000000000000613
- Medicare Current Beneficiary Survey (MCBS). CMS. Accessed July 30, 2018. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/MCBS.html>
- 2015 MCBS cost supplement file. CMS. May 2018. Accessed July 31, 2018. [https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/Codebooks-Items/2015\\_Cost\\_Supplement](https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/Codebooks-Items/2015_Cost_Supplement)
- 2019-2006 Medicare Part D standard benefit model plan parameters. Q1 Medicare. Accessed October 29, 2018. <https://q1medicare.com/PartD-The-MedicarePartDOutlookAllYears.php>
- 2015 MCBS survey file. CMS. January 2018. Accessed December 19, 2018. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/Codebooks-Items/2015SurveyFile>
- CPI inflation calculator. US Bureau of Labor Statistics. Accessed February 9, 2017. [https://www.bls.gov/data/inflation\\_calculator.htm](https://www.bls.gov/data/inflation_calculator.htm)
- Goldman DP, Joyce G, Zheng Y. Prescription drug cost sharing: associations with medication and medical utilization and spending and health. *JAMA*. 2007;298(1):61-69. doi:10.1001/jama.298.1.61
- Eaddy MT, Cook CL, O'Day K, et al. How patient cost-sharing trends affect adherence and outcomes. *P T*. 2012;37(1):45-55.
- Leibowitz A, Manning WG, Newhouse JP. The demand for prescription drugs as a function of cost-sharing. *Soc Sci Med*. 1985;21(10):1063-1069. doi:10.1016/0277-9536(85)90161-3
- Goldman DP, Joyce G, Escarce JJ, et al. Pharmacy benefits and the use of drugs by the chronically ill. *JAMA*. 2004;291(19):2344-2350. doi:10.1001/jama.291.19.2344
- Cubanski J. Summary of recent and proposed changes to Medicare prescription drug coverage and reimbursement. Kaiser Family Foundation. February 15, 2018. Accessed July 6, 2018. <https://www.kff.org/medicare/issue-brief/summary-of-recent-and-proposed-changes-to-medicare-prescription-drug-coverage-and-reimbursement/>
- Cubanski J, Neuman T, Orgera K, Damico A. No limit: Medicare Part D enrollees exposed to high out-of-pocket drug costs without a hard cap on spending. Kaiser Family Foundation. November 7, 2017. Accessed July 6, 2018. <https://www.kff.org/medicare/issue-brief/no-limit-medicare-part-d-enrollees-exposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending/>
- Report to the Congress: Medicare payment policy. Medicare Payment Advisory Commission. March 2018. Accessed July 25, 2018. [http://www.medpac.gov/docs/default-source/reports/mar18\\_medpac\\_entirereport\\_sec.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf?sfvrsn=0)
- Mendelson D, Brantley K. More Medicare Part D enrollees are reaching catastrophic coverage. Avalere. May 10, 2018. Accessed December 10, 2018. <https://avalere.com/press-releases/more-medicare-part-d-enrollees-are-reaching-catastrophic-coverage>
- Frakt A, Miller M. The case for restructuring the Medicare prescription drug benefit. *Health Serv Res*. 2018;53(6):4132-4137. doi:10.1111/1475-6773.13019
- Cubanski J, Neuman T, Damico A. Closing the Medicare Part D coverage gap: trends, recent changes, and what's ahead. Kaiser Family Foundation. August 21, 2018. Accessed October 23, 2018. <https://www.kff.org/medicare/issue-brief/closing-the-medicare-part-d-coverage-gap-trends-recent-changes-and-whats-ahead/>
- Cubanski J, Neuman T. 10 essential facts about Medicare's financial outlook. Kaiser Family Foundation. February 2, 2017. Accessed July 6, 2018. <https://www.kff.org/medicare/issue-brief/10-essential-facts-about-medicares-financial-outlook/>
- 10 essential facts about Medicare and prescription drug spending. Kaiser Family Foundation. November 10, 2017. Accessed July 6, 2018. <https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/>
- Cutler DM, Sahni NR. If slow rate of health care spending growth persists, projections may be off by \$770 billion. *Health Aff (Millwood)*. 2013;32(5):841-850. doi:10.1377/hlthaff.2012.0289
- Prescription drug benefit manual. CMS. April 19, 2018. Accessed August 20, 2018. <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html>
- Trish E, Xu J, Joyce G. Medicare beneficiaries face growing out-of-pocket burden for specialty drugs while in catastrophic coverage phase. *Health Aff (Millwood)*. 2016;35(9):1564-1571. doi:10.1377/hlthaff.2016.0418

Visit [ajmc.com/link/4732](http://ajmc.com/link/4732) to download PDF