

# Effects of Medicare Part D Coverage Gap on Medication Adherence

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**Objectives:** To evaluate the effects of the Medicare Part D coverage gap on pharmacy use among a national sample of Medicare beneficiaries and on medication adherence among 2 subsamples with heart failure and/or diabetes.

**Study Design:** Pre-post design, with comparison group and propensity score weighting.

**Methods:** We used a 5% random sample of elderly Medicare beneficiaries enrolled in stand-alone Part D plans in 2007. The comparison group had full coverage in the gap, whereas the 2 study groups had either no coverage or generic-only coverage in the gap. Main outcomes included probability of filling a prescription, monthly pharmacy spending and number of prescriptions filled, and adherence measured by medication possession ratios.

**Results:** Relative to the comparison group, beneficiaries without drug coverage in the gap reduced the number of prescriptions filled per month by 16.0% (95% confidence interval [CI], 15.5%-16.5%); those with generic drug coverage in the gap reduced it by 10.8% (95% CI, 10.3%-11.4%). Most of the reduction was attributable to reduced use of brand-name drugs. Beneficiaries with heart failure reduced adherence to heart failure drugs by 3.6% (95% CI, 2.9%-4.2%) and beneficiaries with diabetes reduced antidiabetic medication adherence by 10.3% (95% CI, 9.4%-11.3%).

**Conclusions:** Medicare beneficiaries reduced medication use (mainly brand-name drugs) after entering the coverage gap. This result suggests that while beneficiaries' financial burden would continue because of the coverage gap, the gap would not result in a large reduction in medication adherence for essential drugs for diabetes and heart failure.

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For author information and disclosures, see end of text.

Medicare Part D offers prescription drug coverage for Medicare beneficiaries. Since the program's inception in 2006, many beneficiaries have obtained improved drug coverage and increased their use of medications.<sup>1-3</sup> The standard Part D benefit in 2007 included an initial \$265 deductible, a period in which beneficiaries paid 25% of drug costs between \$265 and \$2400, a coverage gap in which they paid 100% of costs until their total out-of-pocket spending reached a catastrophic limit of \$3850, and a catastrophic coverage period in which they paid 5%.<sup>4</sup>

A major concern is the large coverage gap in the standard Part D design. About one-third of all Medicare beneficiaries enter this coverage gap each year.<sup>5</sup> Faced with a sudden increase in medication costs, beneficiaries might cut back on their medication use and reduce medication adherence for the essential drugs.<sup>6-8</sup> That, in turn, might put their health at risk, leading to subsequent increases in hospitalizations and medical spending.<sup>9</sup> Because of the high cost of Medicare and the potential implications for health outcomes, it is important to determine whether the coverage gap leads to reduction in medication adherence for essential drugs.

A few studies have examined the effects of the coverage gap on medication use, but the majority of these studies used pharmacy data either from 1 local Medicare-Advantage Part D plan<sup>7,10,11</sup> or for 1 specific condition—diabetes.<sup>6,10,12-14</sup> One recent study used Medicare Part D data to examine the effects of the coverage gap among 2 subsamples with hypertension and hyperlipidemia.<sup>15</sup> They found that the coverage gap was associated with reduction in use of and adherence to medications for hypertension and hyperlipidemia. Another recent study looked at aged Medicare beneficiaries with cardiovascular disease enrolled in a stand-alone Part D plan (PDP) or a retiree drug plan that was administered by CVS Caremark.<sup>16</sup> They found that beneficiaries with no financial assistance during the coverage gap were more likely to discontinue their cardiovascular drugs.

In this study, we evaluated the effects of the coverage gap on medication spending and use among aged Medicare beneficiaries (those 65 years or older) in the national Part D data. In addition, we selected 2 subsamples of those with heart failure and/or diabetes to evaluate the gap effect on medication spending and adherence. We selected these 2 conditions because they are common in Medicare beneficiaries and because the

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medication treatment is very important—premature discontinuation may lead to increases in subsequent spending on medical care.<sup>17,18</sup> We determined how beneficiaries with these chronic conditions responded to the coverage gap compared with the general Medicare population.

Our analyses were guided by a number of hypotheses: (1) Medicare beneficiaries will decrease all their medication use regardless of drug classes once they enter the gap—and that the decrease will be higher for those with no drug coverage in the gap than for those with generic coverage in the gap.<sup>19,20</sup> However, those who anticipate going through the gap and entering the catastrophic period will not reduce their medication use in the gap.<sup>7</sup> (2) Beneficiaries will decrease their use of all brand-name drugs more than generic drugs, and if beneficiaries have generic drug coverage they will shift from brand-name to generic drugs.<sup>19</sup> (3) Among those with heart failure and/or diabetes, adherence to cardiovascular and diabetic drugs will decrease in the coverage gap.<sup>10</sup>

## METHODS

### Data and Study Population

We obtained beneficiary demographic and enrollment information, plan benefits, prescription drug events, and medical claims for a 5% random sample of all aged Medicare beneficiaries who were continuously enrolled in PDPs in 2007. We identified 2 subpopulations of beneficiaries: those with heart failure and/or diabetes. Each subpopulation was identified by 2 criteria: (1) having a diagnosis for the condition before January 1, 2007, defined by 2006 Centers for Medicare & Medicaid Services Chronic Condition Warehouse indicators (**Appendix A**); and (2) use of at least 1 medication for the condition in the initial coverage period so we could ensure that beneficiaries were on medications of interest before entering the coverage gap (**Appendix B** provides the list of medications). The study design was approved by the institutional review board at the University of Pittsburgh.

### Study Design

Although the standard Part D benefit includes the 4 phases described in the first paragraph of this study, some companies offering PDPs modified the design and offered either “actuarially equivalent” or enhanced plans. In 2007, 72% of stand-alone PDPs had the standard coverage gap, 27% of PDPs had some generic coverage in the gap, and fewer

### Take-Away Points

We examined the effect of the coverage gap on a national sample of Medicare beneficiaries as well as those with heart failure and/or diabetes. Although beneficiaries’ financial burden in the coverage gap will continue until 2020, the gap will not result in a large reduction in medication adherence for essential drugs.

- Medicare beneficiaries reduced medication use (mainly brand-name drugs) after entering the coverage gap.
- Beneficiaries with generic drug coverage in the gap reduced their drug use less.
- However, medication adherence was reduced to a much smaller degree for essential drugs used to treat heart failure and diabetes.

than 1% offered coverage for both brand-name and generic drugs.<sup>21</sup> In addition, beneficiaries with low incomes who are eligible for subsidies had a lower copayment throughout the year and did not face a coverage gap.<sup>4</sup>

Using this variation in drug coverage, we identified 2 study groups based on the type of coverage they had in the gap (no coverage, generic only) and 1 comparison group. The comparison group consisted of beneficiaries who had either 12-month Medicaid coverage or 12-month low-income subsidies (LIS group). Thus, the drug coverage for the comparison group did not change throughout the year; that is, they did not face the gap in coverage. Even though the LIS group was different from the 2 study groups in socioeconomic characteristics, they could still serve the purpose of controlling for the underlying time trends in medication use, because their drug coverage did not change while the study groups had a sudden increase in drug costs once entering the coverage gap.

We used a pre-post study design with a comparison group to assess the impact of the coverage gap on medication and medical care use. This approach uses a difference-in-difference estimate, comparing the pregap and within-gap change for each study group with the pregap and within-gap change in the comparison group. This design does not require that study and comparison groups have the same baseline characteristics. As long as different groups have similar baseline trends, we could get unbiased results.<sup>22</sup> We tested the baseline pregap trends in overall medication use across 3 groups, and they were similar.

We hypothesized that beneficiaries who went through the coverage gap and entered the catastrophic coverage period would not reduce their medication use in the gap.<sup>7</sup> We ran regressions to test this hypothesis and found that those entering the catastrophic period did not change their medication use in the gap (**Appendix C**). Thus, for this study we primarily focused on beneficiaries who entered the gap but did not go through it. That is, each individual in our study sample had a pregap and a within-gap period.

To define pregap and within-gap periods, we first identified the index date as the first day that the beneficiary’s to-

tal drug spending reached the coverage gap threshold. The pregap period was defined as January 1, 2007, to the index date. The within-gap period was defined as the time from the first day after the index date until December 31, 2007. The index date was included in the pregap period because almost all prescriptions filled by beneficiaries on that day were subject to copayment levels in the initial coverage period. We compared the change in each outcome in the pregap and within-gap periods between each study group and the comparison group: no coverage versus LIS and generic only versus LIS. We used a propensity score weighting mechanism to balance each study group with the comparison group. The propensity score weighting was conducted separately for each group: the general population and each subgroup of those with heart failure and/or diabetes.

### Outcomes of Interest

For the pregap and within-gap periods separately, we defined 4 outcomes to measure medication use: (1) probability of using a medication (1 = used a medication; 0 = did not use a medication in the study period); (2) the mean number of monthly prescriptions filled per month, defined as the total number of prescriptions standardized by 30-day supply (ie, a prescription with a 90-day supply would count as 3 monthly drugs) divided by the number of months in the study period; (3) mean monthly pharmacy spending per month; and (4) medication adherence measured by medication possession ratio (MPR). For the general population, we focused on the first 3 outcomes. We measured these outcomes for all medications and then for brand-name and generic drugs separately.

For the patients with chronic conditions, we focused on the mean number of monthly prescriptions filled and the MPR. We examined the mean number of monthly prescriptions filled overall as well as the number of monthly prescriptions for disease-specific drugs. We defined the MPR as the proportion of days during a given period (eg, either the pregap or the within-gap period) that a subject had possession of any drugs used to treat the chronic illness. The prescriptions filled on the day the patient entered the coverage gap were included in calculating the within-gap MPRs for 2 reasons: (1) because these drugs were used in the within-gap period and (2) because inclusion of these drugs was consistent with the pregap MPR definition where drugs filled on the first day (January 1, 2007) were included in the calculation. Similarly, to be consistent with the MPR calculation in the pregap period where prescriptions filled before January 1, 2007, were not included, prescriptions filled before entering the gap were not included in the calculation for the within-gap adherence. However, the definitions for MPRs should

not change the difference-in-difference results because we applied the same rules for the study and comparison groups.

### Statistical Analysis

To implement the propensity score weighting mechanisms, we conducted a 2-stage analysis. In the first stage, we ran 2 logistic regression models to predict the probability of being in a study group relative to the comparison group, controlling for age, sex, race, number of Elixhauser comorbidities,<sup>23</sup> and Prescription Drug Hierarchical Condition Category, the beneficiary risk adjuster used by Centers for Medicare & Medicaid Services to adjust payment to plans for pharmacy costs.<sup>24</sup>

In the second stage, we ran a difference-in-difference model with the inverse of the propensity score as a weight. This effectively assigned a higher weight to individuals in the comparison group who had characteristics similar to those of individuals in the study group. In this model, the dependent variable was the difference between within-gap and pregap periods for each previously defined outcome. Because pregap and within-gap measures were likely to be correlated, the advantage of this approach versus using 2 interrelated outcomes is that we could simply eliminate the correlated structure in 2 outcomes. The key independent variable was the indicator for being in the study group relative to the comparison group. All the covariates used in calculating propensity scores were included in the model.

In addition, we controlled for duration of time spent in the coverage gap (Figure) in the model because the longer beneficiaries stayed in the gap, the more likely it was that they would change their medication use and medical spending. All analyses were conducted using SAS software, version 9.2 (SAS Institute Inc, Cary, North Carolina) and R: A Language and Environment for Statistical Computing, version 2.12 (<http://www.r-project.org>).

## RESULTS

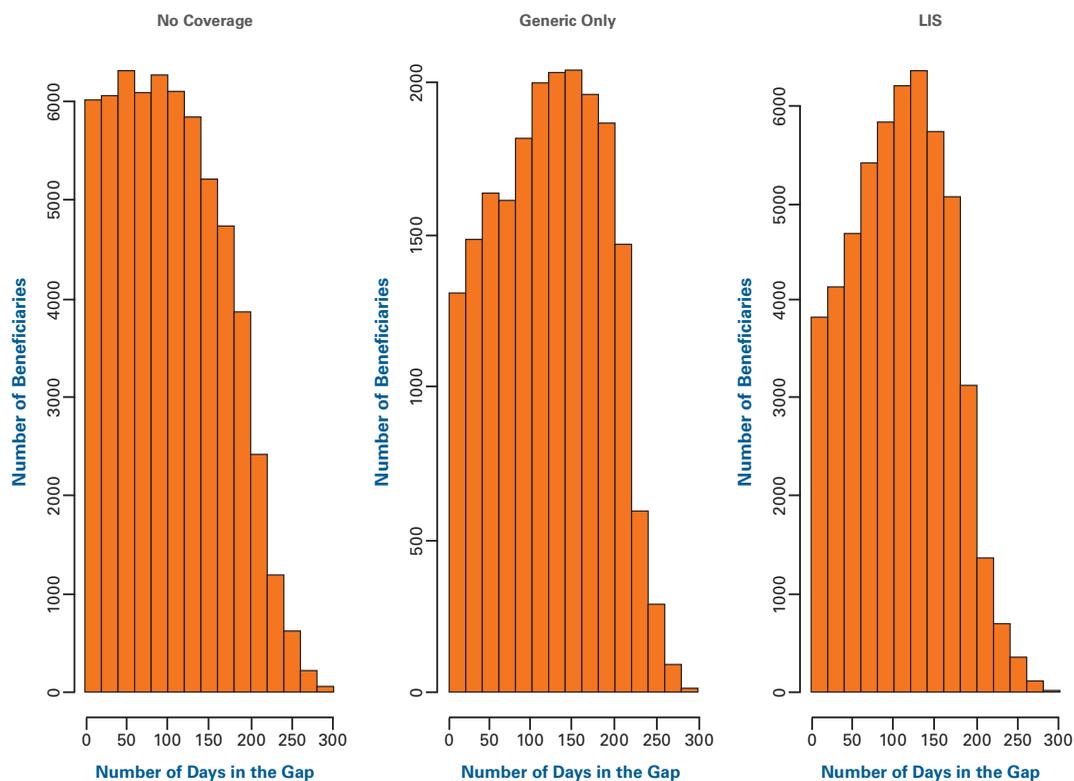
Table 1 compares the characteristics between each study group and comparison group for beneficiaries whose pharmacy spending exceeded the coverage gap threshold but did not exceed the catastrophic coverage threshold. All the numbers are after adjustment with propensity score weights. After adjustment, all characteristics were comparable (ie, there was no statistically significant difference at  $P > .05$ ) between each study group and the comparison group.

### Effects of the Coverage Gap on Medication Use and Spending Among the General Population

Table 2 presents the effects of the coverage gap on the probability of using a drug, the mean number of monthly pre-

## Effects of Medicare Part D Coverage Gap

■ **Figure.** Histograms of the Time Spent in the Gap by Group



LIS indicates low-income subsidies (this is the comparison group).

■ **Table 1.** Characteristics of the Study Population in 2007 After Propensity Score Weighting<sup>a</sup>

Variable	No Coverage vs LIS			Generic Only vs LIS		
	No Coverage (n = 61,040)	LIS (n = 57,699)	P	Generic Only (n = 21,219)	LIS (n = 57,699)	P
<b>Female sex, %</b>	64.4	64.6	.54	62.2	62.3	.87
<b>Race, %</b>						
Non-Hispanic white	93.5	93.6	.88	94.4	94.5	.99
African American	3.0	3.0	.67	2.3	2.4	.51
Hispanic	2.1	2.2	.67	1.9	2.0	.51
Asian	0.8	0.8	.62	0.8	0.9	.34
<b>Age, y, %</b>						
65-74	40.8	40.9	.92	46.1	46.2	.94
75-84	40.1	40.1	.90	37.8	37.7	.85
≥85	19.1	19.1	.97	16.1	16.1	.88
<b>Prescription drug risk score, mean ± SE</b>	0.96 ± 0	0.96 ± 0	.97	0.99 ± 0	0.99 ± 0	.66
<b>Elixhauser comorbidities, n, mean ± SE</b>	2.83 ± 0.01	2.83 ± 0.01	.87	3.03 ± 0.02	3.02 ± 0.01	.71
<b>Diagnosed chronic conditions, %</b>						
Hypertension	59.8	56.5	<.001	59.9	57.8	<.001
Hyperlipidemia	43.8	32.2	<.001	44.3	33.7	<.001
AMI	1.2	1.2	.49	1.0	1.3	.01
COPD	14.2	20.7	<.001	14.9	22.5	<.001
Heart failure	22.6	29.9	<.001	25.1	30.9	<.001
Diabetes	33.6	38.5	<.001	39.6	40.6	.03
RA/OA	26.9	30.3	<.001	28.2	30.5	<.001

AMI indicates acute myocardial infarction; COPD, chronic obstructive pulmonary disease; LIS, low-income subsidies (this group includes dual eligibles and non-dual eligibles with LIS for Part D); RA/OA, rheumatoid arthritis/osteoarthritis; SE, standard error.

<sup>a</sup>All numbers in the table were adjusted using inverse propensity score weights. Propensity scores were calculated using logistic regression models that predicted the probability of being in a study group (no coverage, generic only) relative to the comparison group (LIS group), controlling for age, sex, race, number of Elixhauser comorbidities, and prescription drug hierarchical condition.

■ **Table 2.** Effect of the Coverage Gap on Medication Use Among All Aged Beneficiaries Who Reached the Coverage Gap Threshold but Did Not Reach the Catastrophic Coverage Threshold in 2007<sup>a</sup>

Type of Medication and Group	Unadjusted Data <sup>b</sup>		Difference-in-Difference Coverage Gap Effects <sup>c</sup>		Difference-in-Difference Effects/Pregap Values <sup>d</sup>	
	Pregap	Within Gap	Estimate	95% CI	% Change	95% CI
<b>Probability of using a medication</b>						
All medications						
No coverage	1.00	0.88	-0.03	-0.04 to -0.03	-3.3	-3.6 to -3.0
Generic only	1.00	0.94	-0.02	-0.02 to -0.01	-1.6	-1.9 to -1.3
LIS	1.00	0.94	Reference			
Brand name						
No coverage	1.00	0.79	-0.07	-0.07 to -0.06	-6.7	-7.0 to -6.3
Generic only	1.00	0.84	-0.08	-0.09 to -0.08	-8.2	-8.6 to -7.8
LIS	1.00	0.90	Reference			
Generics						
No coverage	0.98	0.81	-0.05	-0.05 to -0.05	-5.2	-5.5 to -4.8
Generic only	0.98	0.90	-0.02	-0.03 to -0.02	-2.4	-2.8 to -2.0
LIS	0.99	0.91	Reference			
<b>Mean number of monthly prescriptions</b>						
All medications						
No coverage	5.30	3.61	-0.85	-0.88 to -0.82	-16.0	-16.5 to -15.5
Generic only	6.14	4.65	-0.66	-0.70 to -0.63	-10.8	-11.4 to -10.3
LIS	5.84	5.02	Reference			
Brand name						
No coverage	2.71	1.51	-0.64	-0.65 to -0.62	-23.5	-23.9 to -23.0
Generic only	2.87	1.66	-0.61	-0.62 to -0.59	-21.1	-21.7 to -20.5
LIS	2.59	1.99	Reference			
Generics						
No coverage	2.57	2.09	-0.21	-0.23 to -0.19	-8.2	-9.0 to -7.4
Generic only	3.23	2.96	-0.06	-0.08 to -0.03	-1.8	-2.6 to -1.0
LIS	3.22	2.99	Reference			
<b>Mean monthly pharmacy spending, \$</b>						
All medications						
No coverage	309	184	-73.15	-74.65 to -71.66	-23.7	-24.2 to -23.2
Generic only	351	224	-66.59	-68.48 to 64.69	-19.0	-19.5 to -18.5
LIS	331	274	Reference			
Brand name						
No coverage	256	143	-66.65	-68.01 to -65.30	-26.1	-26.6 to -25.5
Generic only	277	157	-65.16	-66.88 to -63.45	-23.5	-24.1 to -22.9
LIS	262	209	Reference			
Generics						
No coverage	52	40	-6.40	-6.92 to -5.88	-12.2	-13.2 to -11.2
Generic only	73	66	-1.39	-2.11 to -0.66	-1.9	-2.9 to -0.9
LIS	68	64	Reference			

CI indicates confidence interval; LIS, low-income subsidies (this is the comparison group).

<sup>a</sup>This is the overall population, a national sample of aged beneficiaries regardless of which medical conditions they had. The sample sizes for the no-coverage, generic-only, and LIS groups were 61,040, 21,219, and 57,699, respectively.

<sup>b</sup>These were average numbers in the pregap and within-gap periods, but they represent unadjusted and unweighted raw data.

<sup>c</sup>These effects are adjusted estimates from the difference-in-difference model with the inverse of the propensity score as a weight. The estimates measured changes in outcomes between the within-gap and pregap periods in each study group, relative to the changes in outcomes in the comparison (reference) group.

<sup>d</sup>The percent change was calculated using the difference-in-difference coverage gap effects divided by pregap values.

scriptions filled, and the mean monthly pharmacy spending for all medications for the overall population. There are 3 main findings:

First, relative to the comparison group, there were statistically significant reductions in all of the outcomes (probability of using a drug, mean number of monthly prescriptions filled, and monthly pharmacy spending) in both study groups. However, those with no coverage generally decreased their use of medications more than those with generic drug coverage in the gap.

Second, the overall decrease in monthly medications and spending on drugs was primarily due to the decrease in the use of brand-name drugs. For example, those without drug coverage in the gap reduced their overall medication use by 0.85 medication per month (95% confidence interval [CI], 0.82-0.88); 75% of the reduction was accounted for by brand-name drugs and 25% by generic drugs. This group decreased its monthly pharmacy spending by \$73.15 (95% CI, \$71.66-\$74.65), of which \$66.65 (95% CI, \$65.30-\$68.01) was for brand-name drugs and \$6.40 (95% CI, \$5.88-\$6.92) was for generic drugs.

Third, those with only generic coverage in the gap reduced their use of brand-name drugs but did not increase their use of generic drugs. In fact, they decreased their use of generic drugs slightly but negligibly. Among the general population, relative to the comparison group, the generic-only group reduced the number of monthly prescriptions filled by 0.66 (95% CI, 0.63-0.70); almost all of this decrease was attributable to the reduction in brand-name drugs (0.61 [95% CI, 0.59-0.62]).

### Effects of the Coverage Gap Among Patients With Chronic Conditions

Beneficiaries with heart failure and/or diabetes decreased their overall use of medications, and the overall decrease was similar to that found for the general population (Table 3). They also decreased their use of the drugs specific to their conditions. The relative decreases in the condition-specific drugs were similar to those observed for the drugs overall.

The decrease in medication use was accompanied by a decrease in medication adherence in both groups, but the decrease in adherence was smaller than the reduction in the number of prescriptions filled (Table 4). In addition, relative to the comparison group, the decrease in medication adherence was always larger in the no-coverage group than in the generic-only group. In the heart failure sample, the MPR for heart failure drugs among the no-coverage group dropped from 0.87 in the pregap period to 0.83 in the within-gap period, while the MPR for those with generic-only coverage dropped from 0.87 to 0.86. Although statistically significant, the relative reduction in ad-

herence for heart failure was negligible. The same pattern was observed for those with diabetes, although decrease in medication adherence was larger in this group.

## DISCUSSION

Medicare beneficiaries decreased their medication use once they entered the gap—and the decrease in use was consistently higher for those who had no coverage in the gap than for those with generic drug coverage in the gap. We hypothesized that beneficiaries would reduce their use of brand-name drugs after entering the coverage gap and if they had generic drug coverage, they would shift their brand-name drugs to generic drugs. We did observe that beneficiaries reduced their use of brand-name drugs substantially more than their use of generic drugs, but those with generic drug coverage did not switch from brand-name to generic drugs. This is partially because those in the generic-only group tended to use more generic drugs in the initial coverage gap period.

We adjusted the time spent in the gap in our model so the beneficiaries spending less time in the gap contributed less to the regression results. In addition, we conducted sensitivity analysis by excluding those beneficiaries who stayed in the gap for less than 1 month or less than 2 months. The results were robust.

The overall coverage gap effects in the no-coverage group on medication use were similar to those found in an earlier study examining beneficiaries enrolled in Medicare Advantage prescription drug plans.<sup>7</sup> However, the effects for those with generic drug coverage were different: in the earlier study beneficiaries with generic drug coverage actually increased their use of generic drugs in the gap, whereas in this population no such increase was observed.<sup>7</sup> This difference may be due to different practices between traditional fee-for-service Medicare and Medicare Advantage plans. For example, Medicare Advantage prescription drug plans might have a better medication management program or chronic disease management program.

A major strength of this study is that we had a random sample of aged Medicare beneficiaries enrolled in PDPs. We examined the effect of the coverage gap on a national overall sample of Medicare beneficiaries as well as those with 2 prevalent chronic conditions: heart failure and/or diabetes. We included all qualified Medicare beneficiaries, including those in nursing homes. (We estimated the model excluding nursing home residents, and the results were similar.)

We used the pre-post design with a comparison group, the strongest quasi-experiment observational study design. The key to this approach is that the drug coverage in the comparison group did not change in the pregap and within-

**Table 3.** Association of the Coverage Gap With Mean Number of Monthly Prescriptions Among Aged Beneficiaries Who Reached the Coverage Gap Threshold but Did Not Reach the Catastrophic Coverage Threshold in 2007, by Health Condition<sup>a</sup>

Health Condition and Group	Unadjusted Data <sup>b</sup>		Difference-in-Difference Coverage Gap Effects <sup>c</sup>		Difference-in-Difference Effects/Pregap Value <sup>d</sup>	
	Pregap	Within Gap	Estimate	95% CI	% Change	95% CI
<b>Heart failure</b>						
All medications						
No coverage	6.36	4.70	-0.83	-0.89 to -0.77	-13.1	-14.0 to -12.2
Generic only	7.27	5.78	-0.60	-0.67 to -0.54	-8.3	-9.2 to -7.4
LIS	6.74	5.85	Reference			
Heart failure medications						
No coverage	2.85	2.09	-0.33	-0.36 to -0.3	-11.7	-12.8 to -10.6
Generic only	3.12	2.49	-0.20	-0.24 to -0.16	-6.4	-7.6 to -5.3
LIS	2.77	2.35	Reference			
<b>Diabetes</b>						
All medications						
No coverage	6.21	4.27	-0.95	-1.01 to -0.89	-15.3	-16.3 to -14.4
Generic only	7.07	5.39	-0.67	-0.74 to -0.6	-9.5	-10.4 to -8.5
LIS	6.64	5.64	Reference			
Diabetes medications						
No coverage	1.31	0.83	-0.22	-0.24 to -0.2	-17.2	-18.7 to -15.6
Generic only	1.40	1.00	-0.14	-0.16 to -0.11	-9.8	-11.7 to -7.9
LIS	1.28	1.01	Reference			

CI indicates confidence interval; LIS, low-income subsidies (this is the comparison group).  
<sup>a</sup>The sample sizes for the beneficiaries with heart failure in the no-coverage, generic-only, and LIS groups were 11,542, 4578, and 16,786, respectively. The sample sizes for the beneficiaries with diabetes in the no-coverage, generic-only, and LIS groups were 12,349, 5308, and 15,797, respectively.  
<sup>b</sup>These were average numbers in the pregap and within-gap periods, but they represent unadjusted and unweighted raw data.  
<sup>c</sup>These effects are adjusted estimates from the difference-in-difference model with the inverse of the propensity score as a weight. The estimates measured changes in outcomes between the within-gap and pregap periods in each study group, relative to the changes in outcomes in the comparison (reference) group. The propensity score model was conducted separately for each subpopulation.  
<sup>d</sup>The percent change was calculated using the difference-in-difference coverage gap effects divided by pregap values.

gap periods, whereas study groups were exposed to a sudden increase in medication price. Even though the comparison group was different in socioeconomic status from the study groups, all groups had similar baseline trends in medication use. Thus, this study design may have led to unbiased results.<sup>22</sup> However, we acknowledge that we cannot eliminate selection bias.

The weakness of our study is that we did not explicitly estimate the anticipatory effects of the coverage gap: namely, that beneficiaries might change their behaviors before they entered the coverage gap. Thus, we might have underestimated the effects of the coverage gap. We did observe the signs of anticipatory effects. For example, beneficiaries with generic coverage were more likely to use generic drugs in the pregap period; and those who went through the coverage gap did not change their drug use in the gap. By focusing on those who did not go through the coverage gap, we mitigated the problem.

Current provisions of the 2010 Affordable Care Act with respect to Part D include the following: (1) starting in 2010, beneficiaries entering the coverage gap receive a \$250 rebate; (2) starting in 2011, beneficiaries pay 50% for brand-name drugs and 93% for generic drugs that are used in the coverage gap; and (3) the gap size will be gradually reduced in order to eliminate it by 2020.<sup>25</sup> In the 2011 standard Part D benefit, the threshold entering the coverage gap is \$2840 in total pharmacy spending and the threshold entering the catastrophic period is \$4550 in total out-of-pocket pharmacy spending.<sup>26</sup> Thus, the coverage gap will continue to be an important issue that deserves close attention from policy makers, providers, and beneficiaries. However, if our results are replicated, they would indicate that while the financial burden on Medicare beneficiaries would continue because of the coverage gap, the gap would not result in a large reduction in medication adherence.

**Table 4.** Association of the Coverage Gap With Medication Adherence Among Aged Beneficiaries With Heart Failure and/or Diabetes<sup>a</sup>

Health Condition and Group	Unadjusted Data <sup>b</sup>		Difference-in-Difference Coverage Gap Effects <sup>c</sup>		Difference-in-Difference Effects/Pregap Values <sup>d</sup>	
	Pregap	Within Gap	Estimate	95% CI	% Change	95% CI
<b>MPR for heart failure drugs</b>						
No coverage	0.868	0.829	-0.03	-0.04 to -0.03	-3.6	-4.2 to -2.9
Generic only	0.873	0.863	-0.01	-0.02 to 0.00	-1.1	-1.8 to -0.4
LIS	0.853	0.850	Reference			
<b>MPR for diabetes drugs</b>						
No coverage	0.763	0.656	-0.08	-0.09 to -0.07	-10.3	-11.3 to -9.4
Generic only	0.770	0.696	-0.05	-0.06 to -0.05	-7.1	-8.2 to -6.1
LIS	0.754	0.729	Reference			

CI indicates confidence interval; LIS, low-income subsidies (this is the comparison group); MPR, medication possession ratio.

<sup>a</sup>The sample sizes for the beneficiaries with heart failure in the no-coverage, generic-only, and LIS groups were 11,542, 4578, and 16,786, respectively. The sample sizes for the beneficiaries with diabetes in the no-coverage, generic-only, and LIS groups were 12,349, 5308, and 15,797, respectively.

<sup>b</sup>These were average numbers in the pregap and within-gap periods, but they represent unadjusted and unweighted raw data.

<sup>c</sup>These effects are adjusted estimates from the difference-in-difference model with the inverse of the propensity score as a weight. The estimates measured changes in outcomes between the within-gap and pregap periods in each study group, relative to the changes in outcomes in the comparison (reference) group. The propensity score model was conducted separately for each subpopulation.

<sup>d</sup>The percent change was calculated using the difference-in-difference coverage gap effects divided by pregap values.

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■ **Appendix A. Definitions for Heart Failure and Diabetes**

Chronic Condition	Reference Time Period	Valid ICD-9 Codes	Number/Type of Claims to Qualify
Heart failure	January 1, 2005–December 31, 2006	DX: 398.91, 402.01, 402.11, 402.91, 404.01, 404.11, 404.91, 404.03, 404.13, 404.93, 428.0X-428.4X, and 428.9X (any DX on the claim)	At least 1 inpatient, outpatient, or physician claim with DX codes during the 2-y period (2005-2006)
Diabetes	January 1, 2005–December 31, 2006	DX 249.xx, 250.xx, 357.2, 362.01, 362.02, and 366.41 (any DX on the claim)	At least 1 inpatient, nursing home, or home care claim or 2 outpatient or physician claims with DX codes during the 2-y period (2005-2006)

DX indicates diagnosis; ICD-9, *International Classification of Diseases, Ninth Revision*.

■ **Appendix B. Drug Classes Used to Treat Heart Failure and Diabetes**

Chronic Condition	Major Drug Classes
Heart failure	Angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, beta-blockers, calcium channel blockers, diuretics, vasodilators, digoxin
Diabetes (oral medications)	Sulfonylurea, thiazolidinediones, alpha-glucosidase inhibitors, biguanides and combinations, meglitinides, amylinomimetic agents, and incretin therapy

■ **Appendix C. Effect of the Coverage Gap on Medication Use Among All Aged Beneficiaries Who Reached the Catastrophic Coverage Threshold in 2007<sup>a</sup>**

Type of Medication and Group	Unadjusted Data <sup>b</sup>		Difference-in-Difference Coverage Gap Effects <sup>c</sup>		Difference-in-Difference Effects/Pregap Values <sup>d</sup>	
	Pregap	Within Gap	Estimate	95% CI	% Change	95% CI
<b>Probability of using a medication</b>						
All medications						
No coverage	0.97	0.98	0.00	0.00-0.00	-0.1	-0.3 to 0.1
Generic only	0.98	0.99	0.00	-0.01 to 0.00	-0.3	-0.5 to -0.1
LIS	0.99	1.00	Reference			
Brand name						
No coverage	0.97	0.98	0.00	0.00-0.00	-0.1	-0.3 to 0.1
Generic only	0.98	0.99	0.00	0.00-0.00	-0.3	-0.5 to -0.1
LIS	0.99	1.00	Reference			
Generics						
No coverage	0.95	0.96	0.00	0.00-0.00	0.1	-0.2 to 0.5
Generic only	0.95	0.97	0.00	0.00-0.01	0.2	-0.2 to 0.6
LIS	0.98	0.99	Reference			
<b>Average number of monthly prescriptions</b>						
All medications						
No coverage	8.22	7.83	0.05	0.00-0.09	0.6	0.0-1.2
Generic only	8.70	8.25	0.07	0.02-0.13	0.8	0.2-1.5
LIS	9.19	8.82	Reference			
Brand name						
No coverage	4.92	4.40	-0.06	-0.09 to -0.03	-1.2	-1.9 to -0.6
Generic only	5.20	4.69	0.02	-0.02 to 0.05	0.4	-0.3 to 1.0
LIS	4.86	4.45	Reference			
Generics						
No coverage	3.24	3.36	0.11	0.08-0.14	3.3	2.3-4.2
Generic only	3.43	3.49	0.05	0.02-0.09	1.5	0.5-2.5
LIS	4.26	4.30	Reference			
<b>Average monthly pharmacy spending, \$</b>						
All medications						
No coverage	695	656	1.23	-3.55 to 6.01	0.2	-0.5 to 0.9
Generic only	749	706	13.04	7.67-18.41	1.7	1.0-2.5
LIS	753	723	Reference			
Brand name						
No coverage	610	570	-0.74	-5.25 to 3.76	-0.1	-0.9 to 0.6
Generic only	661	619	12.15	7.09-17.2	1.8	1.1-2.6
LIS	637	606	Reference			
Generics						
No coverage	84	85	2.08	0.74-3.41	2.5	0.9-4.1
Generic only	85	84	0.99	-0.48 to 2.46	1.2	-0.6 to 2.9
LIS	115	116	Reference			

CI indicates confidence interval; LIS, low-income subsidies (this is the comparison group).

<sup>a</sup>This is the overall population, a national sample of aged beneficiaries who reached the catastrophic coverage threshold, regardless of which medical conditions they had. The sample sizes for the no-coverage, generic-only, and LIS groups were 9399,3454, and 35,868, respectively.

<sup>b</sup>These were average numbers in the pregap and within-gap periods, but they represent unadjusted raw data.

<sup>c</sup>These effects are adjusted estimates from the difference-in-difference model with the inverse of the propensity score as a weight. The estimates measured changes in outcomes between the within-gap and pregap periods in each study group, relative to the changes in outcomes in the comparison (reference) group.

<sup>d</sup>The percent change was calculated using the difference-in-difference coverage gap effects divided by pregap values.