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RESEARCH ARTICLE

How Medicare Part D Benefit Phases Affect Adherence with Evidence-Based Medications Following Acute Myocardial Infarction

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Objective. Assess impact of Medicare Part D benefit phases on adherence with evidence-based medications after hospitalization for an acute myocardial infarction.

Data Source. Random 5 percent sample of Medicare beneficiaries.

Study Design. Difference-in-difference analysis of drug adherence by AMI patients stratified by low-income subsidy (LIS) status and benefit phase.

Data Collection/Extraction Methods. Subjects were identified with an AMI diagnosis in Medicare Part A files between April 2006 and December 2007 and followed until December 2008 or death ($N = 8{,}900$). Adherence was measured as percent of days covered (PDC) per month with four drug classes used in AMI treatment: angiotensin-converting enzyme (ACE) inhibitors/angiotensin II receptor blockers (ARBs), beta-blockers, statins, and clopidogrel. Monthly exposure to Part D benefit phases was calculated from flags on each Part D claim.

Principal Findings. For non-LIS enrollees, transitioning from the initial coverage phase into the Part D coverage gap was associated with statistically significant reductions in mean PDC for all four drug classes: statins (−7.8 percent), clopidogrel (−7.0 percent), beta-blockers (−5.9 percent), and ACE inhibitor/ARBs (−5.1 percent). There were no significant changes in adherence associated with transitioning from the gap to the catastrophic coverage phase.

Conclusions. As the Part D doughnut hole is gradually filled in by 2020, Medicare Part D enrollees with critical diseases such as AMI who rely heavily on brand name drugs are likely to exhibit modest increases in adherence. Those reliant on generic drugs are less likely to be affected.

Key Words. Medicare Part D, benefit design, AMI, evidence-based drugs

The advent of the Medicare Part D drug benefit presents an opportunity to explore the impact of cost sharing on patients' use of and adherence with evidence-based medications following an acute myocardial infarction (AMI). Although there have been numerous studies of how Part D changed the drug utilization behavior of Medicare beneficiaries with various diseases, including AMI (Yin et al. 2008; Zhang et al. 2008; Lau et al. 2011), none has systematically examined the impact of the unique benefit phase structure of Part D coverage.

Differences in cost sharing under Part D derive from three sources: subsidized versus nonsubsidized enrollment status, Part D plan type and cost sharing schedules, and benefit phase. In 2012, beneficiaries with dual Medicare/Medicaid eligibility who enrolled in the low-income subsidy (LIS) program[1] faced nominal out-of-pocket (OOP) copays of $1.15 for generics and $3.30 for brands. Nonsubsidized enrollees in so-called defined standard benefit plans in 2012 were responsible for an annual deductible of $320, 25 percent coinsurance up to the initial coverage limit or ICL ($2,930), coinsurance of 50 percent for brand drugs and 86 percent for generics filled in the coverage gap, and 5 percent coinsurance in the catastrophic phase (>$6,730.39). Other plan types providing actuarially equivalent coverage may waive the annual deductible and charge variable copayments or coinsurance rates based on drug type, formulary status, and copay tier. Some plans have up to six tiers. Four-tier plans are the most common with copays ranging from $0 to $85 or more. Finally, plans designated as "enhanced alternative" typically offer better coverage in the coverage gap and somewhat broader formularies in exchange for higher monthly premiums.

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Of all the cost sharing elements in the Part D design, benefit phases—and in particular, the gap known as the doughnut hole—have garnered the most interest in both the popular and academic press. This attention is natural, given the unusual progression of generous coverage followed by nothing, followed by even more generous coverage in a cyclical pattern that repeats year after year. That pattern was broken by the Affordable Care Act (ACA), which will gradually fill the doughnut hole until it disappears altogether in 2020. However, to understand how the ACA provisions will impact future beneficiaries and Part D program costs, it is essential that policy makers have a solid understanding of how the original program design influenced beneficiary behavior.

That is a surprisingly difficult task. The complexity arises from two sources. First is the fact that the transitions between benefit phases are demarked by cumulative annual drug spending ($2,930 and $6,730.39 in 2012). As a result, the OOP prices faced by nonsubsidized Part D enrollees vary by level of drug spending. However, because the level of spending is determined by individual prescription filling behavior, enrollees can, in effect, determine their own prices by how much they choose to spend. The extent to which Part D enrollees actively manipulate their spending to obtain optimal prices is unknown. However, given endogenous prices, it is impossible to obtain unbiased estimates of the impact of phase transitions simply by examining changes in enrollee behavior before and after phase transitions, with or without nonequivalent controls, which is the standard approach followed in the literature on this subject (Pedan, Lu, and Varasteh 2009; Zhang et al. 2009; Gu et al. 2010; Hales and George 2010; Hoadley et al. 2011; Polinski et al. 2011).

The second problem is that phase exposure is deterministically related to the components of drug spending. This creates a form of reverse causality. For example, although we might hypothesize that beneficiaries will cut back on drug adherence after they enter the coverage gap due to high OOP prices, high adherers incur more drug costs and are therefore more likely to reach the gap compared with low adherers.

The aim of this article was to produce estimates of the impact of Part D phase transitions on medication use and adherence that address both sources of bias. We selected AMI for the analysis for three reasons. First, although AMI can be a devastating disease, studies have shown that survivors tend to have suboptimal adherence with standardized protocols for medication management following hospital discharge (Choudhry et al. 2008). Second, AMI patients generally have high levels of chronic comorbid conditions that

lead to high drug costs and increased probability of being caught up the Part D gap and catastrophic coverage phases (Choudhry et al. 2011). Finally, the timing, if not the overall risk of AMIs, is unpredictable, which means that we can rule out self-selection into Part D plans based on coverage for medications used in AMI treatment.[2]

METHODS

Study Sample

Our study cohort was selected from a 5 percent random sample of Medicare beneficiaries diagnosed with an AMI (ICD-9 410.xx) in the primary or secondary position on an inpatient claim between April 1, 2006 and December 31, 2007, and who survived at least 30 days after hospital discharge. To assure complete data capture, we required that all subjects have continuous coverage for Medicare Part A, Part B, and Part D. Individuals with an AMI prior to April 2006 were excluded (our dataset included an AMI indicator flag back to 1999). We also excluded beneficiaries enrolled in capitated Medicare Advantage plans (Part C) as these plans do not submit medical claims data to the Centers for Medicare and Medicare Services. As a result, our analysis was restricted to beneficiaries enrolled in stand-alone, fee-for-service prescription drug plans (PDPs).

Drug Utilization Measures

Subjects were tracked from 3 months prior to their index AMI hospitalization through December 31, 2008 or death. Our focus was on four drug classes recommended in AMI treatment guidelines (Anderson et al. 2007; Antman et al. 2008): renin–angiotensin–aldosterone system inhibitors including angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs), beta blockers, HMG-CoA reductase inhibitors (statins), and clopidogrel. Drug use data were obtained from the prescription drug event (PDE) files for study subjects. Our primary utilization measure was the percent of days covered (PDC). The PDC measures were calculated monthly based on total days supply for all drugs in each class divided by days observed in the month multiplied by 100. Inpatient days were removed from the denominator to reflect the fact that facilities provide patients with all needed drug products. We also identified months in which there was no evidence of drug use as well as the proportion of users in each month with PDC

values ≥80 percent—a common threshold for good adherence (Osterberg and Blaschle 2005). Drugs were identified by National Drug Codes in the Part D PDE file using the FirstDataBank drug dictionary (Medical Economics 2009).

Part D Benefit Phase Measures

Each PDE contains a flag indicating the benefit phase applicable to that particular prescription fill. Rolling up PDEs by month enabled us to identify all months spent in each of three benefit phases: the initial coverage phase (we included deductible months in this phase), the coverage gap or doughnut hole phase, and the catastrophic coverage phase. In cases where two phases were identified in a given month, we assigned the month to the higher phase. Although LIS enrollees do not face the coverage gap, the PDE files provide benefit phase flags for these individuals that reflect the phase they would have faced had they enrolled in a defined standard benefit plan without the subsidy.

Subject Characteristics

Other variables included demographic characteristics from Medicare enrollment files (age, sex, race, census region), a zip-code level measure of average income for elderly headed households based on 2000 Census data, selected comorbidities likely to impact use and adherence (see list in Table 1), treatment characteristics during the index AMI hospitalization (drug eluting coronary artery stent, nondrug eluting stent, transfer/readmission with 1 day, and length of stay including transfers), count of unique chronic care drugs taken in 2006, and death during the follow-up period.

Statistical Analysis

The key to our analytic strategy lies in the fact that non-LIS enrollees face OOP price changes at benefit phase transitions that differ systematically from those who receive LIS subsidies. Enrollees with LIS subsidies pay the same nominal copays whether they are in the spending range defined by the initial coverage phase or the coverage gap. Once an LIS enrollee transitions into the catastrophic coverage zone, all covered drugs are free. By contrast, nonsubsidized enrollees face a steep increase in OOP charges after they enter the doughnut hole and an equally steep reduction in OOP after transitioning into

Table 1: Sample Characteristics by Low-Income Subsidy (LIS) Status

Characteristics	*Full Study Sample*	*Low-Income Subsidy (LIS) Status*	
		Non-LIS	*LIS*
Sample size	8,900	4,204	4,696
Age (%)			
<65–SSDI	13.1	3.9	21.4
65–74	30.3	33.0	27.9
75–84	35.4	39.9	31.3
85+	21.2	23.2	19.4
Race (%)			
White	83.7	95.4	73.2
Black	10.5	3.2	17.1
Hispanic	2.5	0.4	4.4
Other	1.7	0.7	2.6
Sex (%)			
Female	65.3	63.2	67.1
Male	34.7	36.8	32.9
Income (zip code-based)			
% Population 65+ w/income<15 K	29.7	26.6	32.6
% Population 65+ w/income 15–30 K	28.3	28.5	28.1
% Population 65+ w/income 30–50 K	20.8	21.8	19.9
% Population 65+ w/income 50–100 K	15.6	16.8	14.4
% Population 65+ w/income >100 K	5.6	6.4	5.0
Region (%)			
Northeast	18.1	17.6	18.6
North Central	27.6	33.2	22.6
South	41.4	37.0	45.4
West	12.8	12.2	13.4
Disease burden (%)			
Atrial fibrillation	20.8	21.2	20.4
Alzheimer's or related dementia	21.7	15.3	27.3
Congestive heart failure	55.4	47.0	62.9
Chronic kidney disease	32.5	26.7	37.6
COPD	35.7	29.0	41.7
Diabetes	47.6	40.3	54.1
Ischemic heart disease	78.8	76.4	81.0
Stroke/TIA	22.8	19.9	25.4
Idiopathic cardiomyopathy	12.1	10.7	13.4
Hypertension	86.9	85.3	88.2
Hyperlipidemia	66.4	71.3	62.0
Peripheral vascular disease	32.2	28.3	35.6
Valvular heart disease	29.1	28.8	29.3

continued

Table 1. *Continued*

Characteristics	*Full Study Sample*	*Low-Income Subsidy (LIS) Status*	
		Non-LIS	*LIS*
Treatment characteristics (from index AMI hospital claim) (%)			
Drug eluting coronary artery stent	8.8	10.0	7.7
Nondrug eluting coronary artery stent	17.0	20.2	14.2
Subendocardial infarction	68.4	67.0	69.7
Transfer/readmission within 1 day	11.6	11.7	11.5
Length of hospital stay including transfers	9.0 (7.0)	8.6 (6.6)	9.3 (7.4)
Maintenance drug count (mean/SD)	5.5 (3.7)	4.7 (3.2)	6.2 (4.0)
Follow-up months (mean/SD)	17.6 (9.2)	18.2 (8.9)	17.0 (9.4)
Died after 30 days post-AMI (%)	33.6	28.0	38.5

the catastrophic coverage phase. However, do LIS recipients represent a reasonable counter-factual to non-LIS enrollees? If the two groups were identical on all factors hypothesized to influence drug use and adherence, one could simply subtract the experience of LIS recipients from that of non-LIS enrollees to obtain measures of price responsiveness. However, the two groups vary widely in their observable characteristics and presumably differ in unobserved predictors of drug use as well.

The solution was to make each study subject his or her own control through differencing. We began by identifying all beneficiaries who experienced at least two different benefit phases post-AMI discharge: (1) initial coverage phase and coverage gap; and (2) gap and catastrophic coverage phase. For each individual, we computed mean monthly PDC values during months spent in the three Part D benefit phases. We then subtracted the mean value observed in one phase from that observed in the next. These within-individual differences net out the impact on drug use of all fixed characteristics that distinguish LIS from non-LIS enrollees whether these factors are observed or not. Moreover, because the average time spent in a given benefit phase segment was relatively short (7.7 months on average), we would not expect the results to be confounded by systematic dynamic changes that differentially affected the two groups except, of course, those associated with differences in OOP prices.

With these results, it was a simple matter to calculate the impact of each benefit phase on non-LIS enrollees using LIS enrollee behavior as the control. We calculated the impact of the doughnut hole with the following ordinary least squares regression:

$$Y(G - I)_i = \alpha + \beta_1 E_i + \mu \quad (1)$$

where Y is the dependent drug utilization variable; G and I are mean monthly Y values in the gap and initial coverage phases, respectively, for each individual i; E represents enrollee group where non-LIS = 1 and LIS = 0; α and β_1 are coefficients to be estimated; and u is the error term. Because the dependent variable is a difference, this formulation is a fixed-effects, difference-in-difference (DID) equation. That is also the reason there are no covariates in the model because all fixed-effects are differenced out. And because LIS enrollees face the same nominal copays in both phases, we hypothesize that β_1 will be negative, given the higher OOP prices faced by nonsubsidized enrollees who transition into the coverage gap.

We compute the impact of being in the catastrophic phase (C) in a similar fashion:

$$Y(C - G)_i = \alpha + \beta_1 E_i + \mu \quad (2)$$

In this case, OOP prices for non-LIS enrollees are either full list prices or close to that amount in the gap and approximately 5 percent of list in the catastrophic phase. However, they also drop slightly for LIS enrollees as well (from nominal copays to no copays). The DID estimator thus captures the impact of the relative price differences faced by the two groups. In this case, we do not have a strong hypothesis regarding the sign on β_1. The reason is that if nonsubsidized beneficiaries anticipate entry into the catastrophic phase, the relevant marginal price is the 5 percent coinsurance (or equivalent copay) in that phase, not the intramarginal prices faced in prior benefit phases (Ellis 1986).

Because DID estimators control for all individual-level fixed-effects, including stable psychological factors relating to drug utilization behavior, these models protect against confounding associated with selection bias and response to endogenous prices. By requiring that all subjects in each model be exposed to the same pair of benefit phases, we also remove the deterministic element of benefit phase progression. However, it is possible that individuals with disparate baseline characteristics could have different dynamic behavioral trajectories that might influence the study findings. To test for that possibility, we conducted a sensitivity analysis using propensity score matching to

construct a sample of subjects closely matched on all of the characteristics listed in Table 1. We used the Stata 12 psmatch2 command to implement one-to-one matching with a 0.0001 caliper using common support (Leuven and Sianesi 2003). We then replicated the DID models for these matched pairs of LIS and non-LIS enrollees.

RESULTS

Sample Characteristics

A total of 8,900 Medicare beneficiaries met the study inclusion and exclusion criteria for the main study sample. Their characteristics are shown in the left-hand column of Table 1. The sample was predominately white, female, age 75 or older, with a high concentration residing in the South. Over half lived in zip codes in which elderly households had $30,000 or less in annual income based on the 2000 Census. Common comorbidities included chronic heart failure (55.4 percent), diabetes (47.6 percent), ischemic heart disease (78.8 percent), hypertension (86.9 percent), and hyperlipidemia (66.4 percent). During their index AMI hospitalization, 25.8 percent received a stent, 11.6 percent were transferred to another hospital within a day, and the average length of stay including transfers was 9.0 days. Subjects were followed up for an average of 17.6 months post-AMI and more than a third died during their follow-up periods. The right-hand columns in Table 1 present characteristics of the subsamples with LIS (N = 4,696) and without the subsidy (N = 4,204). The two subpopulations differed on most baseline characteristics. The LIS group was much less likely to receive stents (21.9 percent vs. 30.2 percent), had slightly longer AMI-related hospital stays 9.3 days versus 8.6 days, and had higher postdischarge mortality (38.5 percent vs. 28.0 percent).

Table 2 shows the frequency distribution of phase segments experienced by study subjects. One third had no benefit phase transitions at all. Most of the subjects in this group were exposed only to the initial coverage phase and are thus excluded from our evaluation.[3] The mean number of benefit segments was 3.0, but small numbers of beneficiaries faced seven or more phase segments over the follow-up period.

Table 3 presents our DID model results for mean PDC values for the four drug classes of interest. The table consists of two panels representing the phase-by-phase comparisons described in the statistical analysis section above.

Table 2: Frequency of Part D Benefit Phase Segments Post-AMI Discharge

Number of Benefit Phase Segments Experienced	*Frequency*	*Percent of Subjects*
1	2,963	33.3
2	1,174	13.2
3	1,259	14.2
4	1,641	18.4
5	750	8.4
6	665	7.5
7	274	3.1
8	148	1.7
9	26	0.3
Mean number of segments	3.0	–
Mean duration in months per benefit segment	7.7	–

Panel 1 shows that non-LIS enrollees had consistently lower PDC values after transitioning from the initial coverage phase into the coverage gap, all of which are statistically significant at $p < .05$. The largest differences were for the two drug classes dominated by brands: statins (−4.2) and clopidogrel (−3.2), but there were also somewhat smaller differences in the two classes dominated by generics: ACE inhibitors/ARBs (−2.6) and beta-blockers (−2.6). The first difference comparisons are also interesting. Although non-LIS enrollees had slightly lower PDC levels during gap months, the driver behind the DID findings is the fact that adherence among LIS enrollees was significantly higher during gap months across all drug classes. Also worthy of note is the fact that non-LIS enrollees spent 3.2 more months in the initial coverage phase (13) compared with non-LIS enrollees (9.8). We do not control for these differences in our models because they are in the causal path (i.e., we would expect nonsubsidized enrollees to take longer to transition out of the initial coverage phase because of the higher OOP prices they face in that phase).

Panel 2 shows the effects of transitioning from the gap to the catastrophic phase. Far fewer beneficiaries made this transition compared to gap entry, and LIS enrollees were more than three times as likely to experience this transition than non-LIS enrollees. The DID results indicate that transition to catastrophic coverage had virtually no effect on drug adherence. However, it is interesting to note that average PDC rates for these individuals were uniformly higher than for the cohorts transitioning from the initial coverage phase to the gap. This is an example of the deterministic relationship between components of drug spending and phase exposure. If we just focused on first differences, we would incorrectly conclude that moving into the catastrophic phase led to higher adherence when it does not.

Table 3: Estimates of Post-AMI Drug Adherence by LIS Status and Benefit Phase

			Drug Class			
Benefit Phase and LIS Status	*N*	*Mean Months in Phase*	*ACE-inhibitors/ ARBs Mean PDC*	*Beta-blockers Mean PDC*	*Statins Mean PDC*	*Clopidogrel Mean PDC*
Panel 1: Enrollees with exposure to both the initial coverage and gap phases						
Non-LIS						
Gap phase months	2,601	7	50.9	43.3	52.9	45.9
Initial coverage phase months	2,601	13	50.9	43.9	53.8	46
1st difference		−6.1*	0	−0.6	−0.9	−0.1
LIS						
Gap phase months	3,201	7.4	50.9	45.4	53.1	43.4
Initial coverage phase months	3,201	9.8	48.4	43.4	49.8	40.4
1st difference		−2.5*	2.5*	2.0*	3.3*	3.0*
DID results		−3.6*	−2.6*	−2.6*	−4.2*	−3.2*
Panel 2: Enrollees with exposure to both the gap and catastrophic phases						
Non-LIS						
Catastrophic phase months	466	4.6	56.7	45.4	61.6	53.7
Gap phase months	466	9.5	53.9	45	59.5	51.5
1st difference		−4.9*	2.8	0.4	2.2	2.1
LIS						
Catastrophic phase months	1,564	6.2	53.2	48.7	57.7	48.6
Gap phase months	1,564	8.4	51.9	47.1	54.7	46.9
1st difference		−2.2*	1.3	1.6	3.0*	1.7
DID results		−2.7*	1.5	−1.2	−0.8	0.4

*Difference significant at $p < .05$.

We drill down further into the relationship between OOP prices and drug utilization patterns in Table 4. The structure of the table is the same as the previous one except that mean monthly PDC values are separated into two components: the percent of beneficiaries using the drug in each phase and the percent of users with high adherence (PDC ≥80 percent). This decomposition helps explain the source of phase-related changes in drug adherence presented in Table 3. For example, among non-LIS enrollees observed in both the initial coverage and gap phases (Panel 1), we see large, statistically significant declines in user rates across all four drug classes. User rates also declined for LIS enrollees, but the reductions were smaller. Although LIS enrollees

Table 4: Estimates of Post-AMI Drug Use and PDC ≥80% by LIS Status and Benefit Phase

			Drug Class							
			ACE-inhibitors/ ARBs		*Beta-blockers*		*Statins*		*Clopidogrel*	
Benefit Phase and LIS Status	*N*	*Mean Months in Phase*	*% User*	*% PDC≥ 80%**	*% User*	*% PDC≥ 80%*	*% User*	*% PDC≥ 80%*	*% User*	*% PDC≥ 80%*
Panel 1: Enrollees with exposure to both the initial coverage and gap phases										
Non-LIS										
Gap phase months	2,601	7	71.6	52.8	62.3	52.2	74.4	50.9	63.7	54.7
Initial coverage phase months	2,601	13	78.7	50.1	69.4	48.6	79.7	48.4	68.4	53.7
1st difference		−6.1†	−7.0†	2.6	−7.1†	3.6†	−5.3†	2.4	−4.7†	1.0
LIS										
Gap phase months	3,201	7.4	72.5	54.7	67.1	49.1	72.8	54.2	59.6	57.9
Initial coverage phase months	3,201	9.8	75.1	47.1	69.7	41.1	74.9	44.3	60.9	48.6
1st difference		−2.5†	−2.6†	7.6†	−2.6†	8.0†	−2.1	9.9†	−1.3	9.3†
DID results		−3.6†	−4.4†	−5.0†	−4.5†	−4.4†	−3.1†	−7.5†	−3.4†	−8.3†
Panel 2: Enrollees with exposure to both the gap and catastrophic phases										
Non-LIS										
Catastrophic phase months	466	4.6	70.6	69.4	60.3	61.7	74.9	73.9	65	76.0
Gap phase months	466	9.5	77.3	55.2	68	53.9	81.1	62.2	69.3	61.5
1st difference		−4.9†	−6.7†	14.2†	−7.7†	7.8	−6.2†	11.7†	−4.3	14.5†
LIS										
Catastrophic phase months	1,564	6.2	70.1	64.9	65.5	59.9	73	65.3	62.1	67.5
Gap phase months	1,564	8.4	75.5	55.3	70.3	50.7	75.5	54.2	64.8	58.2
1st difference		−2.2†	−5.4†	9.6†	−4.8†	9.2†	−2.5	11.1†	−2.7	9.3†
DID results		−2.7†	−1.2	4.6	−2.9	−1.4	−3.7†	0.7	−1.6	5.2

*PDC ≥80% calculated for continuous users in both phases.
†Difference significant at $p < .05$.

faced no change in OOP prices over the transition, it is normal to observe some drug discontinuance over time among all population groups. Perhaps the most interesting finding here is that among remaining users during gap months, we observe much higher proportions with PDC ≥80 percent. This would appear to imply that transitioning to the gap increases adherence, but a more plausible explanation is that discontinuers had poor adherence during the initial coverage phase and their absence in the gap phase serves to raise the mean adherence among continuing users. Results in Panel 2 of Table 4 show further consolidation of drug regimens during months spent in the catastrophic coverage phase.

Our propensity score matching algorithm identified 1,525 matched pairs of LIS and non-LIS enrollees with very similar baseline characteristics (Table S1). Because of smaller sample sizes, we found fewer statistically significant results in the DID models (Tables S2 and S3), but the patterns of differences between LIS and non-LIS enrollees were very similar to those observed in the main analysis, particularly regarding the estimated impact of the coverage gap on PDC values among nonsubsidized enrollees.

DISCUSSION

Our results show that overall adherence with evidence-based medications following hospital discharge for AMI is suboptimal with percent of days covered ranging from 48.4 to 56.7 percent for ACEIs/ARBs, 43.3 to 48.7 percent for beta-blockers, 52.9 to 61.6 percent for statins, and 40.4 to 53.7 percent for clopidogrel depending on LIS status and Part D benefit phase. Post-AMI adherence rates among LIS recipients for ACEIs/ARBs and statins were comparable to those reported by Choudhry et al. (2008) for low-income Medicare beneficiaries in 2003 (52 and 56.2 percent, respectively). Beta-blocker adherence was 60.5 percent in that study, much higher than what we found. However, a later Choudhry study (2011) reported beta-blocker adherence at 45 percent, which is similar to our findings.

More than 60 percent of all Medicare Part D enrollees without LIS subsidies who suffered an AMI between April 2006 and December 2007 had some exposure to the Part D doughnut hole following their hospital discharge. We found that the doughnut hole depressed adherence with all four drug classes recommended in AMI treatment guidelines. The biggest differences were for statins where adherence dropped by 7.8 percent ($p < .05$) and clopidogrel where adherence fell by 7 percent ($p < .05$). Adherence in drug classes with

many generic drugs fell by between 5.1 percent (ACE-inhibitors/ARBs) and 5.9 percent (beta-blockers). The effect sizes for statins and beta-blockers are higher than those reported in a recent randomized controlled trial in which these drugs were provided free of charge to a sample of patients discharged with AMI (Choudhry et al. 2011). Compared with subjects with usual insurance coverage, those receiving free medications had 6.2 percent better adherence with statins and 4.4 percent better adherence with beta-blockers. Unfortunately, Choudhry et al. do not report net differences in drug prices faced by the two groups, so we cannot make a direct comparison of price responsiveness between our results and theirs; nonetheless, it is reasonable to assume that in relative terms, offering free drugs to individuals with employer-sponsored drug coverage represents a smaller price differential than that faced by non-LIS Part D enrollees compared with LIS recipients in the Part D doughnut hole. For this reason, we would expect our effect sizes to exceed those reported by Choudhry et al. This relationship did not hold for ACEIs/ARBs where AMI patients receiving free drugs experienced adherence rates 5.6 percent higher than those with usual drug coverage, which represents a marginally higher price response than the 5.1 percent difference we found. Overall, however, these results confirm our findings that drug adherence is inversely related to price even for serious life-threatening conditions like AMI.

A relatively small fraction (11 percent) of our study sample was exposed to the Part D catastrophic coverage phase. We found no evidence of lower adherence in the coverage gap among nonsubsidized enrollees who also experienced the catastrophic coverage phase. This result is not unexpected, given that the price differential between LIS and non-LIS enrollees is much smaller in the catastrophic phase compared with the coverage gap.

These results have important policy implications for the gradual elimination of the Part D doughnut hole under provisions of the Affordable Care Act. For AMI patients in particular, we foresee only small changes in adherence with AMI-related medications as a result of the ACA reform. One reason is that Lipitor (the biggest selling statin during our observation period) and Plavix (clopidogrel) are now both available in generic form, and we found that being in the doughnut hole had less effect on adherence in drug classes dominated by generics compared with brands. Second, we predict that AMI patients with drug spending high enough to reach the catastrophic coverage phase are unlikely to increase their drug use during periods spent in the (former) doughnut hole. We observed this behavior in our analysis, and it is also consistent with standard economic theory.

These results and policy implications have added weight, given the controls for bias and reverse causality inherent in our fixed-effects model specifications. However, several limitations should be noted. Foremost, the study was restricted to Medicare patients hospitalized for a life-threatening disease, which could influence subsequent medication taking behavior differentially from other illnesses commonly treated with chronic medications. Second, lacking Medicare claims data for Part D enrollees in Medicare Advantage plans required that we restrict our study sample to PDP enrollees. Beneficiaries in managed care plans may have different experiences than those observed here.

Third, although the DID models control for all time-invariant differences between LIS and non-LIS enrollees, it is likely that members of the two groups experienced different changes in health status during the post-AMI follow-up period. Such changes could affect the study findings, if they led to systematic differences in Part D benefit phase transitions for one group relative to the other. We cannot rule out this possibility, but the short mean time span per benefit phase segment would tend to minimize the overall effect.

A final limitation relates to our measures of drug adherence. The PDC measure captures drug availability, not necessarily actual drug use, and as average days supply grow longer with 90-day prescriptions now commonplace, the link between availability and use becomes more tenuous. To see whether this phenomenon might influence interpretation of our results, we calculated mean days per fill for our four drug classes. We found that average days supply varied from 36.1 for clopidogrel to 40.4 for statins. In each case, 30-day fills were roughly 5–7 times more common than 90-day+ fills. Regular refills of these short durations give us confidence that we have measured actual use as opposed to stored or wasted pills.

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NOTES

1. The LIS program is available to Medicare beneficiaries with incomes below 135 percent of the federal poverty line and limited assets. Beneficiaries who are enrolled in state Medicaid programs, the Medicare Savings Program, or Supplemental Security Income are deemed eligible for LIS and are automatically enrolled in the program. Other eligible beneficiaries must apply for LIS benefits from the Social Security Administration or state welfare offices. All LIS enrollees are randomly assigned to Part D plans with monthly premiums at or below the regional benchmark.
2. Although it is true that beneficiaries have the option of changing Part D plans during the next open enrollment period, research has shown that Medicare beneficiaries rarely change plans even when there is a financial incentive to do so.
3. Almost all (95.9 percent) subjects had some exposure to the Part D initial coverage phase. The small number, who were not exposed, died between their index AMI hospitalization date and January 1 of the following year. Excluding individuals exposed only to the initial coverage phase from the analysis does not diminish the policy relevance of our findings as these individuals are not affected by provisions of the ACA.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of this article:

Appendix SA1: Author Matrix.

Table S1: Propensity Score Matched Sample Characteristics ($N = 3{,}050$).

Table S2: Estimates of Post-AMI Drug Adherence by LIS Status and Benefit Phase for Matched Sample.

Table S3: Estimates of Post-AMI Drug Use and PDC ≥ 0.80 by LIS Status and Benefit Phase.