© Health Research and Educational Trust
DOI: 10.1111/1475-6773.12145
RESEARCH ARTICLE

Nonlinear Pricing in Drug Benefits and Medication Use: The Case of Statin Compliance in Medicare Part D

Kyoungrae Jung, Roger Feldman, and A. Marshall McBean

Objective. To examine how enrollees' statin compliance responds to expected prices in Medicare Part D, which features a nonlinear price schedule due to a coverage gap.

Data Sources/Study Setting. Prescription Drug Event data for a 5 percent random sample of Medicare Advantage Prescription Drug Plan enrollees in 2008 who did not receive a low-income subsidy.

Study Design. We analyze statin compliance *prior to the coverage gap*, where the "effective price" is higher than the actual copayment for drugs because consumers anticipate that more spending will make them more likely to reach the gap. We construct each enrollee's effective price as her expected price at the end of the year, which is the weighted average between pre-gap and in-gap copayments with the weight being the predicted probability of hitting the gap. Compliance is defined as at least 80 percent of days covered.

Principal Findings. Part D enrollees' pre-gap statin compliance decreases by 3.7–4.7 percentage points for a \$10 increase in the effective price.

Conclusion. The presence of a coverage gap decreases statin compliance prior to the gap, suggesting that incorporating expected future prices is important to assess the full impact of cost sharing on drug compliance under nonlinear price schedules.

Key Words. Nonlinear pricing, statin compliance, Medicare part D

Pharmacy coverage is an essential benefit in health insurance programs because prescription drugs are cost-effective treatments for many health conditions. However, like other health benefits, drug benefits include consumer cost-sharing mechanisms to control moral hazard. Cost-sharing can be designed in various ways, but it often involves a nonlinear price schedule in which the drug price varies depending on consumers' accumulated drug expenditures. With a deductible, consumers experience a decrease in price once reaching a spending threshold. A coverage gap is another example on nonlinear pricing; consumers experience a steep increase in price once

entering the gap. The coverage gap in Medicare Part D is followed by catastrophic coverage, but some pharmacy benefits may have a hard cap with no coverage once the cap is reached.

Economic models suggest that under a varying price schedule, consumers anticipate that their current consumption will increase the likelihood of reaching the spending threshold, after which price decreases or increases; they will incorporate that future price change in their current consumption decisions (Keeler, Newhouse, and Phelps 1977; Ellis 1986). With a coverage gap, the “effective” price is higher than the actual copayments before the gap.

While an extensive literature shows that cost-sharing decreases the demand for prescription drugs (Goldman, Joyce, and Zheng 2007), consumers’ responses to the effective price under nonlinear pricing have not been widely examined. Studies assessing drug benefits with a gap or cap are limited to examining whether overall drug use or compliance with certain drugs falls when consumers enter the gap or reach the cap (Joyce et al. 2002; Zhang et al. 2009a; Fung et al. 2010). These analyses implicitly assume that the presence of a gap or cap does not affect drug utilization before the gap or cap. However, as discussed above, if consumers anticipate that any spending makes them more likely to hit the gap, they may reduce their drug use even before the gap. Without accounting for this possibility, the effect of varying price schedules on drug utilization is likely to be underestimated.

We examine how consumers’ drug use responds to expected prices in Medicare Part D, which features nonlinear pricing due to a coverage gap. We focus on enrollees’ compliance with statins—the dominant lipid-lowering agents and the drug class with the highest reimbursement in Part D (\$6.0 billion or 9.7 percent of Part D spending in 2007; Medicare Payment Advisory Commission 2010a). Statins are an important treatment to prevent and manage coronary heart disease, whose annual cost estimate is about \$165.4 billion (Lloyd-Jones et al. 2009). Goldman, Joyce, and Karaca-Mandic (2006) and Gibson et al. (2006) reported that increased statin compliance decreases cardiovascular hospitalizations and emergency room visits.

We analyze statin compliance *prior to the coverage gap*, where the effective price is higher than the actual copayment. To our knowledge, we are the first

Address correspondence to Kyoungrae Jung, Ph.D., Department of Health Policy and Administration, College of Health and Human Development, The Pennsylvania State University, 604 Ford Building, University Park, PA 16802; e-mail: kuj11@psu.edu. Roger Feldman, Ph.D., and A. Marshall McBean, M.D., M.Sc., are with the Division of Health Policy and Management, School of Public Health, University of Minnesota, Minneapolis, MN.

to examine the impact of the presence of a coverage gap on *pre-gap* drug compliance. Our study thus provides information that could be useful in refining drug benefit designs, particularly for drugs with high clinical values, which reduce adverse health outcomes (Chernew, Rosen, and Fendrick 2007). The findings also provide implications of the Part D benefit change mandated by the 2010 Affordable Care Act (ACA)—filling in the coverage gap—for drug compliance among Medicare beneficiaries. The potential impact of this ACA expansion on *pre-gap* drug compliance has not been recognized by policy makers.

We construct each enrollee's effective price as her expected price at the end of the year, and we examine how *pre-gap* statin compliance responds to that price. Using records from a random sample of Part D enrollees in 2008, we find that enrollees' statin compliance is sensitive to their effective prices. The presence of a gap decreases statin compliance even prior to the gap, suggesting that this impact should be considered in designing drug benefits and that closing the gap in Part D will improve pre-gap statin compliance.

BACKGROUND

Medicare Part D Benefits

The Medicare Part D program, which began in 2006, is delivered through private plans, primarily Medicare Advantage Prescription Drug Plans (MA-PDs) and stand-alone PDPs. The standard Part D benefit has three phases: pre-gap (initial coverage), coverage gap, and catastrophic coverage. The pre-gap benefit includes an annual deductible (\$310 in 2010) and 25 percent coinsurance after the deductible is met. Once a beneficiary's total drug spending reaches an Initial Coverage Limit (ICL, \$2,830 in 2010), she enters the gap and pays the full cost of drugs. The final phase, catastrophic coverage, kicks in after total drug spending reaches \$6,440 in 2010 (or \$4,550 of total out-of-pocket spending). In this phase, beneficiaries pay the greater of 5 percent coinsurance or \$2.50 per generic prescription and \$6.30 per branded prescription. The 2010 ACA stipulates that the gap will be gradually filled in: after 2020, the standard benefit will include a deductible and 25 percent coinsurance before catastrophic coverage.

Part D plans can modify the benefits as long as their schemes are equal in value to the standard package. Plans can also offer more generous benefits than the standard coverage for higher premiums. In fact, many plans have developed their own schemes. For example, more than 90 percent of MA-PDs

eliminate deductibles and coinsurance before the gap but use tiered copayments (Medicare Payment Advisory Commission 2012). Generic drugs are placed in a tier with the lowest copayment and branded drugs are placed in tiers with higher copayments. Some MA-PDs offer coverage for generic drugs in the gap. Little variation exists in the catastrophic benefit, where Medicare reimburses plans for 80 percent of drug costs.

We utilize data from *enrollees in MA-PDs*, where we can exploit variation in drug benefit generosity created by *external factors*. MA-PDs cover inpatient and outpatient services of Medicare Part A and Part B in addition to prescription drug coverage. While MA-PDs receive per-beneficiary payments from Medicare separately for Part D and A/B, they are allowed to subsidize Part D using revenue from the Part A/B payment. During the study period, the A/B payment was generous enough to exceed what was needed to cover an average Medicare beneficiary (Medicare Payment Advisory Commission 2010b). This “overpayment,” along with plans’ ability to cross-subsidize Part D, enabled many MA-PDs to offer enhanced Part D benefits, and geographical differences in the A/B payment created variation in drug benefits across MA-PDs. We use this variation in drug benefits to identify the effective price.

Literature Review

A few studies used the effective price approach to examine the demand for health care under a coverage ceiling (Ellis and McGuire 1986) or a deductible (Aron-Dine et al. 2012). These studies measured expected future prices by the probability of reaching the cap or deductible before the end of the policy year. Consumers who expect to exceed the cap (deductible) by the end of the year face high (low) future prices. Aron-Dine et al. (2012) empirically tested and supported the key assumption behind the effective price approach—consumers are forward-looking and use expected future prices in making current consumption decisions. They also reported that price elasticity estimated with the expected future price was greater than the estimate that did not incorporate this price, suggesting the importance of accounting for consumers’ responses to the future price.

Recently, Jung, Feldman, and McBean (2013) estimated the price elasticity of prescription drug spending in Part D accounting for nonlinear pricing. They reported that *total pre-gap drug spending* of elderly Medicare beneficiaries was sensitive to the effective price, measured by the expected end-of-year price. However, they did not examine where the decrease in pre-gap spending comes from. It is not clear whether beneficiaries facing high expected future

prices reduce their use of *essential* drugs for treatment of chronic conditions. Because elderly Medicare beneficiaries often develop multiple chronic conditions, it is critical to comply with medications to manage chronic conditions. Facing a coverage gap, they may turn to less costly drugs without reducing compliance (e.g. they may switch from branded to generic drugs in the same therapeutic class), or they may reduce use of essential drugs. Our study examines how elderly Medicare beneficiaries' compliance with statins, which are cost-effective treatments for cardiovascular diseases, responds to the effective price.

Several studies have assessed the price responsiveness of statin compliance—defined as at least 80 percent days covered—but their estimates vary. Schultz et al. (2005) found that a \$10 increase in statin copayment decreases the probability of compliance by 2.4 percentage points among enrollees in employer-sponsored plans. Goldman, Joyce, and Karaca-Mandic (2006) calculated a 6–10 percentage point decrease in compliance for a \$10 increase in copayment. For the elderly (age >65), Schneeweiss et al. (2007) found a 5.6 percentage point decrease in compliance for about \$20 increase in copayment. Karaca-Mandic et al. (2013) reported that statin compliance decreased as cost-sharing increased among Part D enrollees; however, they did not account for nonlinear pricing in Part D. Our study differs from prior work in that we examine statin compliance as a function of an expected future price.

DATA AND STUDY SAMPLE

The primary data source was the 2008 Medicare Prescription Drug Event file, which contains information about each prescription fill by Part D enrollees, including the National Drug Code of the drug, fill date, days supplied, and benefit phase (pre-gap, gap, or catastrophic coverage). We constructed pre-gap statin compliance using this file. We used the 2007 Prescription Drug Event file to create one covariate—the number of therapeutic classes of drugs used by a beneficiary in the previous year. The 2008 Beneficiary Summary File and Part D Plan Characteristics File provided beneficiary characteristics and plan attributes respectively. Each beneficiary's health-risk (Prescription Drug Hierarchical Condition Category [RxHCC]) score was supplied by the Centers for Medicare and Medicaid Services (CMS). We obtained ZIP code income and education from the 2000 Census file and payment rates for MA plans from the CMS rate book.

The study population was statin users among the 5 percent random sample of elderly *MA-PD enrollees* in 2008. We excluded beneficiaries who received a low-income subsidy (LIS), and non-LIS enrollees with gap coverage for both generic and brand-name drugs. These beneficiaries were excluded because they do not face the coverage gap. We also excluded enrollees who had a deductible, and those who reached catastrophic coverage. This excluded group may have different characteristics than the study population; however, this exclusion renders the analysis tractable by removing other potential kinks (stemming from deductibles and catastrophic coverage) in the budget constraint. About 5.5 percent of MA-PD non-LIS enrollees were in plans with a deductible, and 1.5 percent reached catastrophic coverage in 2008.

MA-PD enrollees may present different demand for prescription drugs than stand-alone PDP enrollees, but we limit the analysis to MA-PDs because we can exploit variation across MA-PDs in drug benefit generosity created by external factors. Thus, the study *includes* non-LIS elderly beneficiaries not reaching catastrophic coverage in MA-PD plans without deductibles or gap coverage for brand-name drugs.

ANALYSIS

Our analysis has three steps: first, estimating a sample selection model; second, constructing each beneficiary's effective price; third, examining beneficiaries' responsiveness to that price in statin compliance.

Sample Selection Model

The coverage gap in the standard Part D benefit can have potentially significant financial implications. Enrollees with coverage for generic drugs in the gap may have different patterns of drug compliance than those with no gap coverage. Because highly compliant drug users may select plans with gap coverage, we estimated a sample selection model for the choice of gap coverage and conducted the subsequent analyses separately for those with and without gap coverage.

Following Heckman (1979), we estimated gap-coverage choice as a function of demand factors influencing drug compliance and identifying variables that affect plan choice but not drug compliance. We used the following demand factors: demographics (age, gender, and race); health-risk measures

(RxHCC score, indicators of diabetes, depression, pulmonary disease, and heart illness, the number of therapeutic classes of drugs used by an enrollee in the previous year to capture other health conditions); socioeconomic status (ZIP-level median household income, percent college educated); local health care use patterns (per-capita hospital expenditures, numbers of hospital beds and admissions, population density, census region indicators); providers' influence on drug use (percent fills prescribed by primary care providers, who may spend time with patients in emphasizing the importance of drug compliance); plan type (Health Maintenance Organization, Preferred Provider Organization, Private Fee-For-Service); plan size; and state mandates on generic substitution that may affect medication compliance (Briesacher et al. 2009).

As identifying variables, we used the average premiums of MA-PDs with and without gap coverage in the market area (county). The premium is an important determinant of plan choice but it does not directly influence drug compliance: beneficiaries are more likely to choose plans with gap coverage when those plans are available for relatively low premiums. The average premium of plans without gap coverage controls for market-level factors influencing plan costs. Market-level premiums might partially reflect enrollees' drug compliance; however, this will not bias our analysis because unlike the two-stage least squares procedure, Heckman's approach to correct sample-selection does not require orthogonality of identifying variables and error terms in the equation of interest (Heckman 1979). The two premium variables had significant and expected effects on gap-coverage choice (*Z*-statistics = -32.9 and 5.2; Appendix Table S1).

We constructed the Inverse of Mill's Ratio (IMR) for each enrollee from the estimated gap-coverage equation. Separate IMRs for those with and without gap coverage were included in the effective prices and compliance estimation that followed.

Measuring the Effective Price

To construct each enrollee's effective price, we followed Ellis (1986), who showed that when future price depends on accumulated spending, the effective price can be measured by the expected end-of-year price, defined as:

$$\text{Effective price}_{ij} \equiv (1 - P(\widehat{\text{Gap}}))_{ij} * (COP \widehat{AY}_{\text{pre-gap}})_j + P(\widehat{\text{Gap}})_{ij} * (COPAY_{\text{gap}})_j \quad (1)$$

Subscripts *i* and *j* are enrollee and plan, respectively. $P(\widehat{\text{Gap}})$ is the predicted probability of hitting the gap at the end of the year, and $COP \widehat{AY}_{\text{pre-gap}}$

is the estimated pre-gap statin copayment. $COPAY_{\text{gap}}$ is the statin copayment in the gap. We explain each of these three elements in detail below. Note that the effective price captures variation in pre-gap and in-gap copayments across Part D plans, as well as differences in the individual's probability of hitting the gap. The price is close to pre-gap copayments when the probability of hitting the gap is low, suggesting that it captures enrollees' responsiveness to the current price (pre-gap copayments), not just to the probability of hitting the gap.

Predicted Probability of Hitting the Gap. We obtained this probability from a probit model:

$$GAP_{ij} = f(X_{ij}, S_{ij}) \quad (2)$$

GAP is an indicator that equals 1 if the enrollee hit the gap in 2008 and 0 otherwise. X is a vector of demand factors described above. S represents variables that *shift* the effective price and thereby affect pre-gap drug compliance for enrollees with *the same demand* for prescription drugs. The probit model was estimated separately for those with and without gap coverage, and IMRs were included in each model to correct for gap-coverage selection.

Inclusion of S in equation (2) is critical to identify how statin compliance responds to price. Without those shifters, the effective price would depend on pre-gap drug use and pre-gap drug compliance would depend on the effective price. To break this simultaneity, we used variation in drug benefit schemes, such as a high ICL and coverage for drugs that are not covered by Part D (e.g., benzodiazepines). Consider two enrollees with the same demand factors, but one has the standard ICL and the other has a higher ICL. The enrollee with the higher ICL has a lower expected price because she is less likely to reach the limit and experience a price hike. Enrollees with coverage for non-Part D drugs, whose costs do not count toward the ICL, also are less likely to hit the gap if they tend to use those non-Part D drugs.

However, the benefit variables (the ICL and coverage of non-Part D drugs) in S are endogenous because Part D plan choice is voluntary. We thus replaced them with an exogenous variable that influences drug benefits but does not directly influence drug compliance: Part A/B payments. Beneficiaries in market areas with higher A/B payments have choices of MA-PDs with more generous benefits because MA plans can use the extra revenue from the A/B payment to subsidize Part D coverage. Specifically, enrollees in areas with higher payments are more likely to have a high ICL, which decreases the

probability of reaching the limit, or coverage for non-Part D drugs, and thus, they are less likely to reach the gap.

During the study period, MA plans were paid legislatively determined rates independent of the cost of treating beneficiaries in the plan: the highest of a floor rate, a blend of local and national rates, minimum 2 percentage point increase, and expected FFS spending. These administrative rules weakened the link between payment rates and local costs and resulted in payments being higher than the cost of serving similar patients in the FFS sector (Department of Health and Human Services 2009). We used the payment rate for a beneficiary of average risk to measure payment generosity that is unaffected by differences in beneficiaries' health risk across counties.

Some may be concerned that A/B rates capture local practice patterns in inpatient and outpatient (A/B) services; however, it is not clear whether/how those rates are related to local *drug* use. A recent study indicated only a weak correlation between Part D and Part A/B spending (Zhang, Baicker, and Newhouse 2010). Medicare Payment Advisory Commission (2013) also reported no systematic relation between A/B spending and Part D costs in metropolitan areas. Furthermore, we empirically explored whether A/B rates reflect local drug utilization patterns. For A/B rates to be a valid instrument, they should not influence drug use in a model controlling for drug benefits. We thus regressed enrollees' Part D spending on A/B rates controlling for drug benefits and demand factors, and found the rates had no significant effect on Part D spending (Appendix Table S2). To explore whether regional practice patterns lead to more or fewer diagnoses and thus related medication use, we also used the number of therapeutic classes of drugs used by enrollees as the dependent variable. We found the same result as the spending analysis (Appendix Table S3). In both models, the payments had significant coefficients when drug benefits were excluded (results not shown). These results were consistent in both analyses of statin users and 5 percent MA-PD enrollees. They suggest that A/B rates influence drug use through drug benefits but do not reflect unobserved local variations in drug use.

Pre-Gap Statin Copayment. To control for the plan's tier structure before the gap, we calculated the weighted average of all pre-gap statin copayments in each plan, where the weight was the share of the statin's fills in the total fills of the entire study sample. Because pre-gap copayments may be endogenous (beneficiaries may choose plans offering low copayments for statins they use), we used two instruments to predict pre-gap copayments: MA payments and

the county-level average premium of MA-PDs offering enhanced benefits *besides* gap coverage. We obtained this premium separately for plans with and without gap coverage to capture enhanced benefits other than gap coverage, such as low pre-gap copayments. The premium is a determinant of plan choice: beneficiaries are more likely to choose plans with generous benefits when premiums of those plans are lower. Using market-level premiums might not be completely exogenous to individuals' plan choice and drug compliance; however, this is unlikely to bias our analysis because we have another instrument to estimate pre-gap copayments. Both instruments had significant effects on pre-gap copayments (Appendix Table S4).

In-Gap Statin Copayment. We used a similar method for the in-gap copayment but accounted for the fact that enrollees with gap coverage have the same pre-gap and in-gap copayment for generic drugs. First, we created the "full" price index based on the average gross cost instead of copayments, separately for generic and brand-name statins of the plan. Second, we replaced the full price of generic statins with the predicted pre-gap copayment for generic statins for enrollees with gap coverage. We then obtained the weighted average of generic and brand-name statin copayments, where the weight was the share of each type of statin.

Analysis of Statin Compliance

We estimated the model of pre-gap statin compliance as a function of the effective price constructed from equation (2). Compliance was measured by the proportion of days covered between the date of the enrollee's first statin use in 2008 and the last day of her pre-gap phase in 2008. For enrollees who did not hit the gap, this last day was December 31, 2008. We defined "compliant" statin users by setting an indicator equal to 1.0 if proportion of days covered was 80 percent or more and 0 otherwise. The model included the same demand-shifters as above and IMRs for enrollees with and without gap coverage.

We used logistic regression and obtained standard errors from bootstrapping because predicted values were used as an explanatory variable.

Responses to the Effective Price over Time

Next, we examined how enrollees' responsiveness to the effective price changes as the year progresses. Beneficiaries may not strongly respond to their

future price (i.e., their expectations about reaching the gap at the end of the year) at the start of a coverage year, but they may increasingly incorporate their expected future price in pre-gap consumption decisions over time. Toward the very end of the year, enrollees who are certain they will not hit the gap during the coverage year may become less responsive to the effective price. We thus constructed pre-gap statin compliance by quarter and analyzed enrollees' responsiveness to the effective price in each quarter. To check whether changes in price responsiveness over time are driven by changes in enrollees' expectations about future prices, we also examined the responsiveness of compliance to the probability of hitting the gap in each quarter.

RESULTS

Table 1 shows descriptive statistics. Beneficiaries with gap coverage had slightly better pre-gap statin compliance and lived in areas with lower average premiums for MA-PDs offering gap coverage, compared with those without gap coverage. The probability of reaching the gap is similar between the two groups, but the effective price is lower among those with gap coverage due to lower in-gap copayments.

The MA payment rate was a strong predictor of the probability of hitting the gap in both groups (Appendix Table A5). The payment variable had significant negative coefficients, suggesting that enrollees in areas with higher payments are less likely to reach the gap. Having a high ICL or coverage for additional drugs decreases the probability of hitting the gap.

Table 2 presents the results from the analysis of pre-gap statin compliance. The results indicate that Part D enrollees' pre-gap statin compliance was sensitive to the effective price. The marginal effect for enrollees with gap coverage was -0.37 : the probability of being compliant prior the gap decreases by 3.7 percentage points for a \$10 increase in the effective price. Enrollees without gap coverage were more price-sensitive: pre-gap statin compliance decreased by 4.7 percentage points for a \$10 increase in the effective price. This difference between the two groups was statistically significant: $\chi^2 = 98.87$ from test based on seemingly unrelated estimation; and $F = 15.96$ from a Chow test based on linear probability models.

The results on other covariates were similar between the two groups. Enrollees who used more therapeutic classes of drugs were more likely to comply with statins, suggesting that enrollees with higher risk have better statin compliance. Having a large share of fills prescribed by primary care

Table 1: Descriptive Statistics

<i>Variable</i>	<i>Enrollees with Gap Coverage (N = 27,643)</i>		<i>Enrollees without Gap Coverage (N = 19,776)</i>	
	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>
Proportion of days covered (PDC; %)	81.85	23.09	80.66	23.75
Statin compliance (PDC $\geq$ 80%)	69.28	46.13	66.90	47.06
Effective price (\$)*	14.72	3.35	16.81	4.82
Probability of reaching the gap	0.22	0.42	0.21	0.41
Pre-gap copayment (\$)	11.23	3.27	10.49	2.44
In-gap copayment (\$)	28.22	2.04	37.78	4.27
Average premium of plans with gap coverage in a market area (\$)	24.51	9.38	27.27	8.62
Average premium of plans without gap coverage in a market area (\$)	16.90	3.68	17.37	3.93
Part A/B benchmark rates (\$)	868.90	121.80	837.70	94.19
Average premium of plans with enhanced benefits besides gap coverage (\$)	21.55	10.21	16.64	4.20
Age	77.09	6.02	77.43	6.10
Female	0.62	0.49	0.63	0.48
White	0.89	0.32	0.89	0.31
Prescription drug hierarchical chronic condition (RxHCC) score	1.27	0.33	1.10	0.32
Number of therapeutic classes of drugs taken in the previous year	8.04	4.27	7.71	4.10
Chronic obstructive pulmonary disease	0.11	0.31	0.11	0.31
Diabetes	0.30	0.46	0.28	0.45
Major depression	0.03	0.16	0.02	0.14
Cardiovascular disease	0.13	0.34	0.13	0.34
% fills prescribed by primary care providers	0.74	0.34	0.75	0.34
Health maintenance organization (HMO)	0.90	0.29	0.88	0.33
Preferred provider organization (PPO)	0.06	0.24	0.06	0.23
Number of enrollees in a plan	33,452	25,189	23,537	22,572
Percent college educated	25.68	14.30	25.25	14.13
Median household income \$35,000–\$50,000	0.42	0.49	0.44	0.50
Median household income more than \$50,000	0.38	0.49	0.35	0.48
Population density	1839.8	4863.2	2393.6	6794.4
Hospital expenditures per capita (\$)	883.69	458.79	853.35	563.62
Number of admissions/1,000	127.16	57.13	127.60	74.18
Number of hospital beds/1,000	3.12	1.65	3.08	2.05
Midwest	0.15	0.36	0.16	0.37
South	0.22	0.41	0.19	0.39
West	0.39	0.49	0.39	0.49
State mandate on generic substitution	0.29	0.45	0.27	0.44

*Effective price is the weighted average between in-gap and pre-gap copayments; weights are the predicted probability of hitting the gap and (1-that probability), respectively.

Table 2: Marginal Effects of Selected Variables on Statin Compliance (PDC $\geq 80\%$)

Variable	Marginal Effect (Standard Error)	
	Enrollees with Gap Coverage	Enrollees without Gap Coverage
Effective price (\$)	−0.367 (0.197)*	−0.469 (0.218)**
Age	−0.032 (0.047)	0.128 (0.056)**
Female	−3.008 (0.557)***	−1.819 (0.736)**
White	6.464 (0.903)***	9.560 (1.001)***
Prescription drug hierarchical chronic condition (RxHCC) score	−2.039 (1.126)*	−3.247 (1.430)**
Number of therapeutic classes of drugs taken in the prior year	0.857 (0.130)***	0.918 (0.218)***
Chronic obstructive pulmonary disease	−0.643 (0.957)	−1.142 (1.188)
Diabetes	2.196 (0.671)***	1.950 (0.903)**
Major depression	−2.728 (1.732)	−0.327 (2.337)
Cardiovascular disease	0.181 (0.844)	0.153 (1.006)
% of fills prescribed by primary care providers	1.929 (0.827)**	1.807 (0.998)*
Plan type		
Private fee-for-service (ref.)		
Health maintenance organization	−1.079 (1.603)	1.202 (1.623)
Preferred provider organization	5.945 (1.895)***	2.622 (2.201)
Number of enrollees of a plan	0.000 (0.000)***	0.000 (0.000)
Percent college educated	0.071 (0.024)***	0.082 (0.033)**
Median household income		
Less than \$35,000 (ref.)		
\$35,000 to \$50,000	2.486 (0.795)***	1.562 (0.928)*
More than \$50,000	5.605 (1.078)***	3.33 (1.231)**

Corrected for sample-selectivity associated with choosing gap coverage.
The difference between the two groups was statistically significant: $\chi^2 = 98.87$ based on a test from seemingly unrelated estimation; $F = 15.96$ from a Chow test based on linear probability models.
* $p < .1$; ** $p < .05$, *** $p < .01$.
PDC, proportion of days covered.

providers and being a male or white were also positively associated with pre-gap statin compliance.

Table 3 reports the results from the quarterly analysis. In both groups, the responsiveness to the effective price in pre-gap statin compliance increased over time until the third quarter of the year but fell slightly during the fourth quarter. Only enrollees without gap coverage showed significant responses to the effective price during the first and second quarters. These time-varying changes in price responsiveness appear to reflect changes in enrollees' responses to the probability of hitting the gap (their expectations about future prices): the lower panel of Table 3 indicates increasing responses to the

Table 3: Price Responsiveness of Pre-Gap Statin Compliance (PDC $\geq 80\%$) by Quarter

Time Period	Marginal Effect (SE)	
	Enrollees with Gap Coverage	Enrollees without Gap Coverage
Effective price (\$)		
1st quarter	0.033 (0.142)	-0.408 (0.166)**
2nd quarter	-0.325 (0.214)	-0.910 (0.226)***
3rd quarter	-0.101 (0.220)***	-1.088 (0.234)***
4th quarter	-0.857 (0.236)***	-0.996 (0.261)***
Predicted probability of hitting the gap		
1st quarter	-0.007 (0.051)	-0.261 (0.081)***
2nd quarter	-0.268 (0.068)***	-0.559 (0.106)***
3rd quarter	-0.583 (0.069)***	-0.762 (0.108)***
4th quarter	-0.459 (0.075)***	-0.513 (0.117)***

Corrected for sample-selectivity associated with choosing gap coverage.

** $p < .05$, *** $p < .01$.

PDC, proportion of days covered.

probability of hitting the gap until the third quarter and then a slight decrease in the response during the last quarter.

DISCUSSION

We found that Part D enrollees' pre-gap statin compliance responded to the effective price. Enrollees without gap coverage, who face a greater price increase in the gap, were more sensitive to the effective price than those with gap coverage for generic drugs. These findings support the prediction of economic models that consumers use expected end-of-year prices in making current consumption decisions. They are also consistent with prior empirical work on deductibles and coverage ceilings, suggesting the importance of accounting for expected future prices in examining medication use.

We also found that enrollees' pre-gap statin compliance becomes more responsive to the effective price as the year progresses, which reflects increasing responses to the probability of hitting the gap. This suggests that beneficiaries' reliance on the future price is small in early periods of the year; however, as the remaining time in the coverage year decreases, they become more sensitive to a possible future price hike.

The analysis indicated that pre-gap statin compliance decreased by 3.7–4.7 percentage points for a \$10 increase in the effective price. This is within the range of estimates reported in the literature, which varied from a

2.4 to 10 percentage point decrease in compliance for a \$10 increase in copayments.

Our results suggest that filling the coverage gap in Part D by ACA will increase statin compliance *prior to the gap*. This effect has not been recognized previously. This finding adds a rationale for the ACA expansion of Part D coverage because statins are one of the most cost-effective therapies to treat hyperlipidemia and reduce cardiovascular hospitalizations. While it also implies additional Part D costs, several studies showed that generous drug benefits decrease inpatient spending in the elderly (Zhang et al. 2009b; Chandra, Gruber, and McKnight 2010; Afendulis et al. 2011; McWilliams, Zaslavsky, and Huskamp 2011), suggesting that the increase in Part D spending may be offset by a decrease in Medicare Part A costs. The impact of improved Part D benefits on other medical cost is an important topic to pursue in future research.

Cost-sharing is commonly used to control drug spending in commercial populations. Recently, commercial plans and self-insured employers have implemented value-based insurance designs with lower copayments for drugs to treat chronic conditions. Chernew et al. (2008) and Gibson et al. (2011) found those initiatives improve drug compliance. Although our result is based on Medicare beneficiaries, it suggests that if drug coverage includes a spending gap or cap, excluding the cost of important drugs from counting toward the gap or cap will improve drug compliance.

Several limitations of the study should be noted. First, we constructed the effective price from variables known to beneficiaries at the beginning of the year and applied that price to overall pre-gap drug compliance. This allowed us to estimate the price responsiveness during the entire pre-gap phase. However, beneficiaries may update their effective prices depending on the remaining time in the coverage year. We did not fully incorporate this time component because that task would involve additional assumptions and computational complications, which may not be tractable. However, we partially addressed the issue by assessing the changes in price responsiveness by quarter.

Second, we excluded enrollees who reached catastrophic coverage. While this removed a second kink in the budget constraint, these enrollees' drug compliance may not be sensitive to price. Our analysis might then overestimate the price responsiveness for all non-LIS enrollees. However, only 1.5 percent of the sample reached catastrophic coverage, and their price responsiveness in pre-gap drug compliance is not as informative because they passed through the gap phase.

Our results are based on data from elderly enrollees in MA-PDs without deductibles. Their generalizability may be limited to populations with similar health risks and in similar types of plans. Enrollees with different characteristics (LIS or non-elderly populations) or in different types of plans (stand-alone PDPs or deductible plans) may respond differently to expected prices. Furthermore, our estimates are based on 1-year statin compliance. The longer term response may be different as beneficiaries learn more about their drug utilization patterns and expected future prices. Finally, our results may not be generalizable to other therapeutic classes. Enrollees' responsiveness to the effective price may differ depending on the effectiveness or costs of therapeutic classes.

Despite these limitations, our study is the first to examine how medication compliance responds to the effective price in Part D. The findings suggest that incorporating an expected future price is important to assess the impact of cost-sharing on medication compliance under nonlinear pricing.

ACKNOWLEDGMENTS

Joint Acknowledgment/Disclosure Statement: This project was supported by the Centers for Medicare and Medicaid Services contract HHSM-500-2005-00271.

Disclosure: None.

Disclaimer: None.

REFERENCES

- Afendulis, C. C., Y. He, A. M. Zaslavsky, and M. E. Chernew. 2011. "The Impact of Medicare Part D on Hospitalization Rates." *Health Services Research* 46 (4): 1022–38.
- Aron-Dine, A., L. Einav, A. Finkelstein, and M.R. Cullen. 2012. *Moral Hazard in Health Insurance: How Important Is Forward Looking Behavior?* NBER Working Paper #17802. Cambridge, MA: National Bureau of Economic Research.
- Briesacher, B. A., S. E. Andrade, H. Fouayzi, and K. A. Chan. 2009. "Medication Adherence and Use of Generic Drug Therapies." *American Journal Managed Care* 15 (7): 450–6.
- Chandra, A., J. Gruber, and R. McKnight. 2010. "Patient Cost Sharing and Hospitalization Offsets in the Elderly." *American Economic Review* 100 (1): 193–213.
- Chernew, M. E., A. B. Rosen, and A. M. Fendrick. 2007. "Value-Based Insurance Design." *Health Affairs* 26 (2): w195–203.

- Chernew, M. E., M. R. Shah, A. Wegh, S. N. Rosenberg, I. A. Juster, A. B. Rosen, M. C. Sokol, K. Yu-Isenberg, and A. M. Fendrick. 2008. "Impact of Decreasing Copayments on Medication Adherence within a Disease Management Environment." *Health Affairs* 27: 103–12.
- Department of Health and Human Services. 2009. "Payment for Medicare Advantage Plans: Policy Issues and Options" [accessed on March 25, 2013]. Available at <http://aspe.hhs.gov/health/reports/09/medicareadvantage/index.shtml>
- Ellis, R. P. 1986. "Rational Behavior in the Presence of Coverage Ceilings and Deductibles." *RAND Journal of Economics* 17 (2): 158–75.
- Ellis, R. P., and T. G. McGuire. 1986. "Cost Sharing and Patterns of Mental Health Care Utilization." *Journal of Human Resources* 21 (3): 359–79.
- Fung, V., C. M. Mangione, J. Huang, N. Turk, E. S. Quiter, J. A. Schmittiel, and J. Hsu. 2010. "Falling into the Coverage Gap: Part D Drug Costs and Adherence for Medicare Advantage Prescription Drug Plan Beneficiaries with Diabetes." *Health Services Research* 45 (2): 355–75.
- Gibson, T. B., T. L. Mark, K. A. McGuigan, K. Axelsen, O. Baser, and D. A. Rublee. 2006. "Impact of Statin Copayments on Adherence and Medical Care Utilization and Expenditures." *American Journal of Managed Care* 12: SP11–SP19.
- Gibson, T. B., S. Wang, E. Kelly, C. Brown, C. Turner, F. Frech-Tamas, J. Doyle, and E. Mauceri. 2011. "A Value-Based Insurance Design Program at a Large Company Boosted Medication Adherence for Employees with Chronic Illnesses." *Health Affairs* 30 (1): 109–17.
- Goldman, D. P., G. F. Joyce, and P. Karaca-Mandic. 2006. "Varying Pharmacy Benefits with Clinical Status: The Case of Cholesterol-Lowering Therapy." *American Journal of Managed Care* 12: 21–8.
- Goldman, D. P., G. F. Joyce, and Y. Zheng. 2007. "Prescription Drug Spending: Associations with Medication and Medical Utilization and Spending and Health." *Journal of the American Medical Association* 298 (1): 61–9.
- Heckman, J. J. 1979. "Sample Selection Bias as Specification Error." *Econometrica* 47 (1): 153–61.
- Joyce, G. F., J. J. Escarce, M. D. Solomon, and G. P. Goldman. 2002. "Employer Drug Benefit Plans and Spending on Prescription Drugs." *Journal of the American Medical Association* 288 (14): 1733–9.
- Jung, K., R. Feldman, and A. M. McBean. 2013. "Demand for Prescription Drugs under Nonlinear Pricing in Medicare Part D." *International Journal of Health Care Finance and Economics* Epub doi:10.1007/s10754-013-9137-2.
- Karaca-Mandic, P., T. Swenson, J. M. Abraham, and R. L. Kane. 2013. "Association of Medicare Part D Medication Out-of-Pocket Costs with Utilization of Statin Medications." *Health Services Research* 48 (4): 1311–33.
- Keeler, E. B., J. P. Newhouse, and C. E. Phelps. 1977. "Deductibles and the Demand for Medical Care Services: Theory of a Consumer Facing a Variable Price Schedule under Uncertainty." *Econometrica* 45 (3): 641–55.
- Lloyd-Jones, D., R. Adams, M. Carnethon, G. D. Simone, T. B. Ferguson, K. Flegal, E. Ford, K. Furie, A. Go, K. Greenlund, N. Haase, S. Hailpern, M. Ho, V. Howard, B. Kissela, S. Kittner, D. Lackland, L. Lisabeth, A. Marelli, M. McDermott, J.

- Meigs, D. Mozaffarian, G. Nichol, C. O'Donnell, V. Roger, W. Rosamond, R. Sacco, P. Sorlie, R. Stafford, J. Steinberger, T. Thom, S. Wasserthiel-Smoller, N. Wong, J. Wylie-Rosett, and Y. Hong. 2009. "Heart Disease and Stroke Statistics-2009 Update: A Report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee." *Circulation* 119 (3): 480–6.
- McWilliams, J. M., A. M. Zaslavsky, and H. A. Huskamp. 2011. "Implementation of Medicare Part D and Nondrug Medical Spending for Elderly Adults with Limited Prior Drug Coverage." *Journal of the American Medical Association* 306 (4): 402–9.
- Medicare Payment Advisory Commission. 2010a. "A Data Book: Healthcare Spending and the Medicare Program" [accessed on March 25, 2013]. Available at <http://www.medpac.gov/documents/jun10databookentirereport.pdf>
- Medicare Payment Advisory Commission. 2010b. "A Data Book: Medicare Part D Program" [accessed on March 25, 2013]. Available at http://www.medpac.gov/documents/Mar10_PartDDDataBook.pdf
- Medicare Payment Advisory Commission. 2012. "Reports to Congress: Medicare Payment Policy" [accessed on March 25, 2013]. Available at http://medpac.gov/documents/Mar12_EntireReport.pdf
- Medicare Payment Advisory Commission. 2013. "Reports to Congress: Medicare Payment Policy." p. 359 [accessed on July 26, 2013]. Available at http://www.medpac.gov/documents/Mar13_entirereport.pdf
- Schneeweiss, S., A. R. Patrick, M. Maclure, C. R. Dormuth, and R. J. Glynn. 2007. "Adherence to Statin Therapy under Drug Cost Sharing in Patients with and without Acute Myocardial Infarction: A Population-Based Natural Experiment." *Circulation* 115: 2128–35.
- Schultz, J. S., J. C. O'Donnell, K. L. McDonough, R. Sasane, and J. Meyer. 2005. "Determinants of Compliance with Statin Therapy and Low-Density Lipoprotein Cholesterol Goal Attainment in a Managed Care Population." *American Journal of Managed Care* 11: 306–12.
- Zhang, Y., K. Baicker, and J. P. Newhouse. 2010. "Geographic Variation in Medicare Drug Spending." *New England Journal of Medicine* 363 (5): 405–9.
- Zhang, Y., J. M. Donohue, J. P. Newhouse, and J. R. Lave. 2009a. "The Effects of the Coverage Gap on Drug Spending: A Closer Look at Medicare Part D." *Health Affairs* 28 (2): w317–25.
- Zhang, Y., J. M. Donohue, J. R. Lave, G. O'Donnell, and J. P. Newhouse. 2009b. "The Effect of Medicare Part D on Drug and Medical Spending." *New England Journal of Medicine* 361 (1): 52–61.

SUPPORTING INFORMATION

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

Appendix SA1: Author Matrix.

Table S1: Results from the Selection Equation (Choice of Gap Coverage).

Table S2: Relation between Part A/B Payment Rates and Enrollees' Annual Spending on Part D–Covered Drugs.

Table S3: Relation between Part A/B Payment Rates and the Number of Therapeutic Classes of Drugs Used by Enrollees.

Table S4: Results from Estimation of Pre-Gap Copayments.

Table S5: Marginal Effects for the Probability of Hitting the Gap.