Responses to Medicare Drug Costs among Near-Poor versus Subsidized Beneficiaries

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Objective. There is limited information on the protective value of Medicare Part D low-income subsidies (LIS). We compared responses to drug costs for LIS recipients with near-poor (≤ 200 percent of the Federal Poverty Level) and higher income beneficiaries without the LIS.

Data Sources/Study Setting. Medicare Advantage beneficiaries in 2008.

Study Design. We examined three drug cost responses using multivariate logistic regression: cost-reducing behaviors (e.g., switching to generics), nonadherence (e.g., not refilling prescriptions), and financial stress (e.g., going without necessities).

Data Collection. Telephone interviews in a stratified random sample ($N = 1,201$, 70 percent response rate).

Principal Findings. After adjustment, a comparable percentage of unsubsidized near-poor (26 percent) and higher income beneficiaries reported cost-reducing behaviors (23 percent, $p = .63$); fewer LIS beneficiaries reported cost-reducing behaviors (15 percent, $p = .019$ vs near-poor). Unsubsidized near-poor beneficiaries were more likely to reduce adherence (8.2 percent) than higher income (3.5 percent, $p = .049$) and LIS beneficiaries (3.1 percent, $p = .027$). Near-poor beneficiaries also more frequently experienced financial stress due to drug costs (20 percent) than higher income beneficiaries (11 percent, $p = .050$) and LIS beneficiaries (11 percent, $p = .015$).

Conclusions. Low-income subsidies provide protection from drug cost-related nonadherence and financial stress. Beneficiaries just above the LIS income threshold are most at risk for these potentially adverse behaviors.

Key Words. Medicare, low-income subsidies, drug cost-sharing

The Medicare Part D outpatient prescription drug program includes substantial amounts of patient cost-sharing, but it also provides premium and cost-sharing subsidies for low-income beneficiaries with incomes below 150 percent of the federal poverty level (FPL) and limited assets. This broadened eligibility for subsidized drug benefits among Medicare beneficiaries, since

the 150 percent FPL limit included a number of individuals whose income level was previously above the level of Medicaid eligibility; however, near-poor beneficiaries with incomes just above this level face the same cost-sharing levels as higher income beneficiaries. There is limited empirical information to inform policy decisions including subsidy levels or qualification thresholds. Few studies have assessed variation in beneficiaries' responses to drug costs by income level and subsidy availability, or from extending protections for low-income patients further up the income scale.

The low-income subsidies (LIS) are intended to reduce cost-related barriers to drug use as well as financial stress. Indeed, unsubsidized (i.e., non-LIS) Part D benefits have been associated with reductions in necessary drug use and reports of financial burdens, such as going without necessities due to drug costs (Hsu et al. 2008; Fung et al. 2009; Zhang et al. 2009). The 2010 Patient Protection and Affordable Care Act (ACA) phases out the coverage gap, the most notorious form of Part D cost-sharing, for non-LIS beneficiaries over the next 10 years. The coverage gap requires that patients pay the full cost for their drugs after their total drug spending reaches an annual threshold (\$2,510 in 2008, the year of our study, higher in subsequent years), until their cumulative annual out-of-pocket spending reaches another threshold (\$4,050 in 2008, higher in subsequent years).

Nonetheless, even after 2020, unsubsidized beneficiaries will continue to face substantial cost-sharing from co-payments and co-insurance. Near-poor beneficiaries—those just above the income cut-off for the LIS—may be especially vulnerable to the adverse effects of cost-sharing (Chernew et al. 2008); however, there is limited information on how Part D cost-sharing effects vary by income level. If clinically undesirable cost-sharing effects occur with frequency among near-poor beneficiaries, expanding current subsidies with a more gradual set of thresholds may reduce adverse effects and potentially save money in Parts A (inpatient) and B (outpatient). An estimated 13

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percent of Medicare beneficiaries have incomes between 151 and 200 percent FPL (AARP Public Policy Institute 2009).

In 2011, one-third of Part D beneficiaries (10 of 29.5 million) received the LIS. Dual-eligible beneficiaries and Medicare Savings Program and Supplemental Security Income recipients automatically receive the LIS and comprise over 80 percent of LIS beneficiaries (The Kaiser Family Foundation 2010). Other beneficiaries must apply for the subsidy and have incomes less than 150 percent FPL and limited assets (in 2008, the asset limit was \$11,990 for an individual). Not surprisingly, existing studies suggest that out-of-pocket costs for many drug classes did not change or decreased slightly, on average, for dual-eligible beneficiaries after Part D introduction since Medicaid had mostly covered their drug cost prior to Part D (Shrank et al. 2008; Donohue, Huskamp, and Zuvekas 2009; Basu, Yin, and Alexander 2010).

In this cross-sectional telephone interview study, we examined a range of behavioral responses to drug costs, including both potentially cost-saving behaviors, such as switching to generic medications, and potentially adverse behaviors, including cost-related nonadherence and financial stress. This study compares Part D beneficiaries receiving the LIS, those with employer-supplemented insurance (ESI), and those with no subsidies (LIS or ESI), within a large Medicare Advantage (MA) Prescription Drug plan. We use individual-level income information collected in the telephone surveys to compare behaviors across lower and higher income beneficiaries, with and without subsidies. We hypothesized that the low-income subsidies would provide some protection from adverse consequences associated with Part D cost-sharing, and that these effects would be concentrated among near-poor beneficiaries without subsidies that offset standard Part D cost-sharing levels.

METHODS

Setting and Study Population

Kaiser Permanente-Northern California (KPNC) is an integrated delivery system with approximately 300,000 MA beneficiaries. This study included beneficiaries with three coverage levels: (1) LIS recipients; (2) beneficiaries with ESI; and (3) beneficiaries without either LIS or employer subsidies. Within this setting, we were able to link individual-level survey responses with administrative pharmacy data, membership records, and detailed plan cost-sharing levels for all subjects. All subjects were continuously enrolled in the KPNC MA plan with the same subsidy status throughout 2008; all subjects also had the same

Table 1: Coverage Levels in 2008

<i>Coverage Level</i>	<i>Initial Coverage Period \$0 to \$2,510 in TDC*</i>	<i>Coverage Gap \$2,510 in TDC to \$4,050 in TrOOP</i>	<i>Catastrophic Coverage \$4,050+ in TrOOP</i>
Low-income subsidy (LIS) beneficiaries			
Full subsidy ($<135\%$ FPL)	$<\$2.25$ Generic; $<\$5.60$ Brand	$<\$2.25$ Generic; $<\$5.60$ Brand	\$0 Generic/Brand
Partial subsidy ($<150\%$ FPL)	15% coinsurance	15% coinsurance	\$2.25 Generic; \$5.60 Brand
Individual beneficiaries with no low income or employer subsidies (No Subsidy)	\$12 Generic; \$45 Brand; 25% Specialty	\$12 Generic; 100% (full cost) Brand/Specialty	\$5 Generic; \$12 Brand/Specialty
Employer-supplemented insurance (ESI) beneficiaries	1 or 2 tier copay: \$0–10 Generic (mean \$6); \$0–35 Brand (mean \$11)	1 or 2 tier copay: \$0–10 Generic (mean \$6); \$0–35 Brand (mean \$11)	1 or 2 tier copay: \$0–10 Generic (mean \$6); \$0–35 Brand (mean \$11)

Note. Total Drug Costs (TDC); True Out-of-Pocket Costs (TrOOP). Cost-sharing levels for ESI beneficiaries vary by employer group. The asset limits in 2008 for the Full subsidy were \$7,790 for an individual and \$12,440 for a couple; the Partial subsidy asset limits were \$11,990 for an individual and \$23,970 for a couple (The Government Accountability Office 2008a).

*Partial LIS beneficiaries in KPNC did not have a deductible; they comprise $<7\%$ of all LIS beneficiaries in 2008 in KPNC. Unsubsidized, individual beneficiaries in KPNC did not have a deductible in 2008.

drug formulary. To improve the comparability of our comparison groups, we excluded beneficiaries younger than 65 years old as of January 1, 2008, since these beneficiaries are concentrated in the LIS population. We selected a stratified random sample, selecting equal numbers of beneficiaries with each of the three coverage levels; subsidy receipt was determined using administrative membership data. We further stratified the sampling based on total drug costs in 2008 to improve our statistical power to detect differences across various levels of drug spending. There were three expenditure strata within each of the coverage groups, two below (\$0–\$1000 and \$1001–\$2,510 in total drug costs) and one above the standard Part D coverage gap threshold ($>\$2,510$ in total drug costs). We obtained 2008 drug costs from the health plan's automated pharmacy databases. Table 1 outlines the cost-sharing levels for each coverage level in 2008.

Recruitment and Interview Protocol

Starting in January 2009, we mailed the subjects a letter introducing the study, the questionnaire, a prepaid reply postcard, and a return envelope.

Subjects could decline participation via postcard or phone, or complete the questionnaire and return it by mail. Otherwise, trained interviewers contacted subjects by telephone, obtained informed verbal consent, and interviewed those interested in participating. The Kaiser Foundation Research Institute approved the study.

We initially contacted 2,650 potential participants. Of these, we excluded institutionalized beneficiaries ($n = 121$), non-English speakers ($n = 278$), those with cognitive impairment or severe illness ($n = 291$), and the deceased ($n = 42$). These exclusions were more common among LIS beneficiaries. We also excluded members who left KPNC in 2009 before the interview, could not be reached after 15 or more telephone attempts, or did not have valid contact information ($n = 204$). Between January and June 2009, 1,201 (70 percent) of 1,714 eligible beneficiaries participated in the study (see supplemental appendix for sample selection and response rates by strata). There were no significant differences between respondents and nonrespondents in terms of gender or drug costs (total and out-of-pocket); however, respondents were younger compared with nonrespondents (difference = 1.31 years, 95 percent CI: 0.65–1.98).

Behavioral Responses to Costs

To assess beneficiaries' responses to their drug costs, we asked whether they engaged in any of 13 behaviors in 2008 because of the cost of their medications. We focused on the subset of behaviors that more clearly represent potentially cost-efficient drug use, that is, cost-reducing behaviors (switched to a cheaper medication such as a generic, or split or skipped pills with their doctor's advice); behaviors more likely to represent adverse cost-sharing outcomes, that is, cost-related nonadherence (split or skipped pills without their doctor's advice, did not fill a new prescription, did not refill an existing prescription); and experiences of financial stress (borrowed money, found a new job or continued to work, or went without some necessity to pay for medications).

Income

To examine variations in beneficiaries' responses across income levels, we stratified non-LIS beneficiaries into two levels based on their 2008 income as a percent of the federal poverty level (FPL): ≤ 200 percent and >200 percent FPL. This stratification allows for comparisons between beneficiaries with the subsidy and near-poor beneficiaries without the subsidy and follows the logic

of regression discontinuity approaches that compare subjects just above and below the threshold to understand policy effects (Thistlewaite and Campbell 1960; Imbens and Lemieux 2008). This stratification also allows for assessment of differences among unsubsidized beneficiaries with higher and lower income levels and resulted in five comparison groups: (1) LIS beneficiaries (<150 percent FPL); (2) near-poor beneficiaries with no subsidies ($\leq$ 200 percent FPL); (3) higher income beneficiaries with no subsidies (>200 percent FPL); (4) near-poor ESI beneficiaries ($\leq$ 200 percent FPL); and (5) higher income ESI beneficiaries (>200 percent FPL).

We determined this classification based on subjects' income category and the number of persons supported by that income as self-reported in the survey. Subjects were asked to report their total household income from all sources before taxes in 2008, and the number of person(s) this income supported, including themselves. There were six income categories (<\$20,000; \$20,000–29,000; \$30,000–39,000; \$40,000–\$59,000; \$60,000–\$100,000; and \$100,000+). We used the midpoint of each category (income >\$100,000 was coded as \$150,000) and 2008 Health and Human Services FPL levels (200 percent FPL was \$20,800 for a one-person household and increased by \$7,200 for each additional person) (U.S. Department of Health and Human Services 2008). Income information was missing for 6 percent of subjects; these subjects were included in the analyses and were coded as having unknown income.

Analysis

We used multivariate logistic regression (svy: logistic in Stata/MP 12.0) to assess the associations between coverage and income level and behavioral responses to costs. We controlled for measures obtained from health plan databases, including age, gender, drug costs in 2008, and an indicator for reaching the gap threshold of \$2,510. Because reaching the gap threshold could be endogenous to responses to costs, we conducted sensitivity analyses that omitted this indicator; results were similar. We also adjusted for measures obtained in the questionnaire, including marital status (married or living with partner vs. other), race/ethnicity (non-white vs. white), education (less than high school graduate vs. some college or more), general health status in 2008 (excellent/very good vs. good/fair/poor/very poor), and functional status (0, 1, or 2+ activities of daily living or activities of daily living limitations). To examine differences in the frequency of behaviors between unsubsidized beneficiaries who reached and did not reach the gap, we also included an interaction between reaching the gap and coverage and income levels. Based on

the model results, we calculated adjusted percentages for each outcome by coverage level and income level. The standard population used in the direct adjustment procedure was the mix of co-variable values in the overall target population of KPNC MA beneficiaries. We weighted all analyses by the inverse of the sampling fraction to represent the target population of Medicare beneficiaries, those aged 65+ years who were continuously enrolled in 2008. Standard errors were estimated using Taylor linearization.

RESULTS

Patient Characteristics

Compared with higher income non-LIS and ESI beneficiaries, LIS beneficiaries were more likely to be older, female, live alone, have less education, and be of nonwhite race/ethnicity and more likely to have poorer self-reported health (Table 2). For example, 33 percent of LIS beneficiaries reported excellent or very good health, compared with 51 percent of unsubsidized, higher income beneficiaries and 45 percent of higher income ESI beneficiaries ($p = .045$). Differences between LIS beneficiaries and near-poor beneficiaries were smaller: 37 percent of near-poor beneficiaries without subsidies and 33 percent of near-poor ESI beneficiaries reported excellent or very good health ($p = .74$ for difference with LIS). Consistent with differences in cost-sharing and comorbidity levels, mean total drug costs were highest for LIS beneficiaries (\$1,767) and lowest among unsubsidized, higher income beneficiaries (\$839). In contrast, mean out-of-pocket spending was lowest for LIS beneficiaries (\$82) and highest among unsubsidized, near-poor beneficiaries (\$595).

Cost-Reducing Behaviors

Overall, 18.4 percent of respondents reported at least one cost-reducing behavior. Adjusted for patient characteristics and stratified by coverage and income level, the likelihood of any cost-reducing behaviors was greatest among unsubsidized beneficiaries (Table 3): an estimated 26.0 percent of near-poor and 23.0 percent of higher income beneficiaries reported these behaviors in 2008 ($p = .63$ vs the unsubsidized, near-poor group). By comparison, the likelihood of cost-reducing behaviors was significantly lower among LIS beneficiaries (14.8 percent, OR = 0.48, 95 percent CI: 0.26–0.89) and higher income ESI beneficiaries (13.6 percent, OR = 0.44, 95 percent CI: 0.23–0.83) compared with unsubsidized, near-poor beneficiaries.

Table 2: Study Population Characteristics

Characteristics	Total N = 1,201	Low-Income Subsidy		No Subsidy		Employer-Supplemented Insurance (ESI)		p-Value
		N = 278	≤ 200% FPL N = 135	> 200% FPL N = 271	≤ 200% FPL N = 77	> 200% FPL N = 375		
Age 65–74	50.5%	39.3%	39.2%	54.1%	43.5%	54.7%	.012	
75–84	40.9%	48.3%	50.0%	40.1%	40.0%	37.2%		
85+	8.6%	12.4%	10.8%	5.8%	16.6%	8.2%		
Female	60.6%	76.5%	75.7%	53.1%	66.8%	58.3%	.001	
Nonwhite race/ethnicity	23.0%	49.6%	38.5%	12.3%	43.5%	19.1%	.001	
Living w/a partner or spouse	61.0%	20.7%	51.1%	65.5%	48.0%	69.0%	.001	
High school graduate or less	33.1%	58.8%	59.7%	26.6%	46.6%	22.8%	.001	
Self-reported health: Excellent or very good	44.4%	32.6%	36.9%	50.8%	33.4%	45.3%	.019	
Functional limitations: 1+	42.9%	67.3%	44.1%	37.5%	72.4%	37.8%	.001	
No. medications in 2008: 5+	42.0%	52.1%	50.9%	33.9%	50.5%	42.9%	.0055	
Drug costs in 2008								
Total drug costs, mean (SD)	\$1,219 (\$51)	\$1,767 (\$118)	\$1,138 (\$95)	\$839 (\$56)	\$1,401 (\$175)	\$1,504 (\$116)	.010	
Out-of-pocket costs, mean (SD)	\$346 (\$11)	\$82 (\$6)	\$595 (\$41)	\$449 (\$24)	\$255 (\$25)	\$207 (\$10)	.001	

Note. All percentages weighted for sampling proportions. To qualify for the LIS, beneficiaries were required to have incomes <150% FPL and limited assets. Beneficiaries with No Subsidy receive no low-income or employer subsidies for Part D benefits. Functional limitations include instrumental activities of daily living (IADL) and activities of daily living (ADL). IADLs include using telephone, doing light/heavy housework, preparing meals, shopping, managing money; ADLs include bathing, dressing, eating, getting in/out bed or chairs, walking, and using toilet.

Table 3: Frequency of Cost-Reducing Behaviors by Subsidy Status and Income Level

	<i>Adjusted %</i>	<i>OR</i>	<i>95% CI</i>		<i>p-Value</i>
Any cost-reducing behavior					
LIS	14.8	0.48	0.26	0.89	0.019
No subsidy: Near-poor ($\leq 200\%$ FPL)	26.0	1.0	—	—	—
No subsidy: Higher income ($>200\%$ FPL)	23.0	0.85	0.43	1.68	0.631
ESI: Near-poor ($\leq 200\%$ FPL)	15.8	0.52	0.23	1.19	0.124
ESI: Higher income ($>200\%$ FPL)	13.6	0.44	0.23	0.83	0.011
Switch to a cheaper medication					
LIS	10.7	0.67	0.33	1.39	0.287
No subsidy: Near-poor ($\leq 200\%$ FPL)	15.0	1.0	—	—	—
No subsidy: Higher income ($>200\%$ FPL)	13.1	0.85	0.37	1.93	0.692
ESI: Near-poor ($\leq 200\%$ FPL)	13.1	0.85	0.33	2.18	0.736
ESI: Higher income ($>200\%$ FPL)	6.6	0.39	0.18	0.85	0.018
Split/skip pills with doctor's advice					
LIS	6.6	0.40	0.18	0.87	0.021
No subsidy: Near-poor ($\leq 200\%$ FPL)	14.7	1.0	—	—	—
No subsidy: Higher income ($>200\%$ FPL)	12.9	0.85	0.35	2.08	0.728
ESI: Near-poor ($\leq 200\%$ FPL)	4.0	0.23	0.08	0.69	0.008
ESI: Higher income ($>200\%$ FPL)	8.8	0.55	0.25	1.23	0.144

Note. Logistic regression weighted for sampling proportions and adjusted for age, gender, income*coverage group, race/ethnicity, education, marital status, self-reported health status, and functional status, reaching the gap threshold, and 2008 drug costs. Near-poor beneficiaries with no low-income or employer subsidies were the reference group.

Cost-Related Nonadherence and Financial Stress

Overall, 2.9 and 9.6 percent of beneficiaries reported cost-related nonadherence or financial stress, respectively; however, there was substantial variation by income and coverage level. Cost-related nonadherence was significantly more likely among unsubsidized, near-poor beneficiaries (8.2 percent) compared with all other groups: unsubsidized, higher income non-LIS (3.5 percent, OR = 0.37, 95 percent CI: 0.14–0.996), LIS (3.1 percent, OR = 0.32, 95 percent CI: 0.12–0.88), near-poor ESI (1.3 percent, OR = 0.13, 95 percent CI: 0.02–0.83), and higher income ESI (1.2 percent, OR = 0.12, 95 percent CI: 0.03–0.48) beneficiaries (Table 4).

Levels of financial stress were also highest among unsubsidized, near-poor beneficiaries (19.5 percent), followed by unsubsidized, higher income beneficiaries (10.8 percent, OR = 0.48, 95 percent CI: 0.23–1.00), LIS (10.6 percent, OR = 0.46, 95 percent CI: 0.25–0.86), near-poor ESI (8.8 percent, OR = 0.37, 95 percent CI: 0.14–0.96), and higher income ESI (5.7 percent, OR = 0.23, 95 percent CI: 0.11–0.48) beneficiaries.

Table 4: Frequency of Cost-Related Nonadherence and Financial Stress by Subsidy Status and Income Level

	<i>Adjusted %</i>	<i>OR</i>	<i>95% CI</i>		<i>p-Value</i>
Any cost-related nonadherence					
LIS	3.1	0.32	0.12	0.88	.027
No subsidy: Near-poor ($\leq 200\%$ FPL)	8.2	1.0	—	—	—
No subsidy: Higher income ($>200\%$ FPL)	3.5	0.37	0.14	1.00	.049
ESI: Near-poor ($\leq 200\%$ FPL)	1.3	0.13	0.02	0.83	.031
ESI: Higher income ($>200\%$ FPL)	1.2	0.12	0.03	0.48	.003
Any financial stress due to drug costs					
LIS	10.6	0.46	0.25	0.86	.015
No subsidy: Near-poor ($\leq 200\%$ FPL)	19.5	1.0	—	—	—
No subsidy: Higher income ($>200\%$ FPL)	10.8	0.48	0.23	1.00	.05
ESI: Near-poor ($\leq 200\%$ FPL)	8.8	0.37	0.14	0.96	.042
ESI: Higher income ($>200\%$ FPL)	5.7	0.23	0.11	0.48	0
Borrow money					
LIS	5.2	0.44	0.21	0.91	.028
No subsidy: Near-poor ($\leq 200\%$ FPL)	10.5	1.0	—	—	—
No subsidy: Higher income ($>200\%$ FPL)	5.0	0.42	0.16	1.09	.075
ESI: Near-poor ($\leq 200\%$ FPL)	4.0	0.33	0.10	1.13	.078
ESI: Higher income ($>200\%$ FPL)	3.7	0.30	0.12	0.74	.009
Find job or continue to work					
LIS	3.8	0.51	0.18	1.42	.197
No subsidy: Near-poor ($\leq 200\%$ FPL)	7.0	1.0	—	—	—
No subsidy: Higher income ($>200\%$ FPL)	4.7	0.64	0.21	1.93	.425
ESI: Near-poor ($\leq 200\%$ FPL)	2.2	0.29	0.03	2.86	.289
ESI: Higher income ($>200\%$ FPL)	3.1	0.41	0.14	1.18	.097
Cut back on necessities					
LIS	6.3	0.45	0.20	1.00	.049
No subsidy: Near-poor ($\leq 200\%$ FPL)	12.5	1.0	—	—	—
No subsidy: Higher income ($>200\%$ FPL)	4.6	0.32	0.12	0.83	.019
ESI: Near-poor ($\leq 200\%$ FPL)	6.0	0.43	0.15	1.25	.12
ESI: Higher income ($>200\%$ FPL)	3.0	0.20	0.08	0.51	.001

Note: Logistic regression weighted for sampling proportions and adjusted for age, gender, income*coverage group, race/ethnicity, education, marital status, self-reported health status, and functional status, reaching the gap threshold, and 2008 drug costs. Near-poor beneficiaries with no low-income or employer subsidies were the reference group.

Behavioral Responses before and after Reaching the Coverage Gap

Unsubsidized beneficiaries faced a coverage gap for brand name drugs in 2008 (i.e., generic-only gap coverage). A similar percentage of near-poor beneficiaries without subsidies who reached the gap (26.9 percent) and did not reach the gap (25.8 percent) reported any cost-reducing behavior ($p = .82$), nonadherence (7.1 percent of those who reached vs. 8.4 percent of those who did not reach the gap, $p = .71$), and financial stress (16.1 percent of those who

reached vs. 20.0 percent of those who did not reach the gap, $p = .33$) (data not shown). Conversely, among higher income beneficiaries without subsidies, those who reached versus did not reach the gap were more likely to have cost-related nonadherence (8.6 percent vs. 2.5 percent, respectively, $p = .046$) and financial stress (19.3 percent vs. 9.7 percent, respectively, $p = .015$).

DISCUSSION

The Medicare Part D program provides generous subsidies for the poorest beneficiaries, but it requires substantial cost-sharing for many beneficiaries. We investigated variation in beneficiaries' responses to drug costs, including cost-reducing behaviors, medication nonadherence, and financial stress, by subsidy availability and income level. We focused on the experiences of beneficiaries with incomes ≤ 200 percent FPL who were not receiving subsidies, that is, the near-poor, compared with the experiences of both higher income beneficiaries and those receiving subsidies through either the LIS or from their former employer. We found important variation in beneficiary behavior by income level, including several potentially adverse behaviors, which would be masked by averaged rates across all beneficiaries. To our knowledge, this is the first study to address the protective value of the Part D subsidy program.

As we hypothesized, lower income beneficiaries without subsidies more frequently reported cost-related nonadherence and experiences of financial stress compared with the other groups. In other words, undesirable cost-sharing effects were concentrated among near-poor beneficiaries without subsidies. These beneficiaries, however, were also most likely to report more desirable cost-sharing effects, such as switching to cheaper medications and splitting or skipping pills with their doctor's advice to reduce drug costs, which could represent more cost-effective drug use. Consistent with cost-sharing differences, the frequency of these behaviors among near-poor beneficiaries was closer to that of higher income beneficiaries without subsidies than LIS beneficiaries.

We also found that the Part D low-income subsidy provides protection from some adverse effects associated with cost-sharing for the poorest beneficiaries. After adjusting for patient characteristics, LIS beneficiaries had similar levels of cost-related nonadherence and financial stress as higher income beneficiaries without subsidies. Nevertheless, an estimated one-in-ten LIS beneficiaries faced financial stress due to drug costs. LIS beneficiaries also

reported lower levels of cost-reducing behaviors such as switching to generic medications, which could indicate less efficient drug use, compared with unsubsidized beneficiaries. However, directly assessing the clinical appropriateness of changes in drug use is outside the scope of this study. For example, it is possible that some switches from brand to generic medications might not be medically appropriate, or that patients reduced their use of discretionary medications.

These findings highlight important policy questions about allocating federal subsidies in the Part D program and underscore the challenges associated with balancing coverage adequacy with program affordability, particularly for more vulnerable patients. The current program structure, including the LIS, appears to mitigate adverse effects among the lowest income beneficiaries but concentrates these effects among near-poor beneficiaries not receiving the subsidy. The LIS currently includes four levels of subsidy based on Medicaid and institutionalized status, and income and assets up to 150 percent FPL. Although other forms of assistance are available for some beneficiaries who do not qualify for the LIS, for example, through states or pharmaceutical manufacturers, access to these programs nationally is limited (The Government Accountability Office 2008a), and only 2.1 percent of unsubsidized, near-poor subjects in this setting reported receiving any help paying for prescription drugs through non-Medicare assistance programs. In addition, recent reports indicate that the number of near-poor Americans is increasing rapidly, particularly among the elderly; the Census estimates 34 percent of elderly are poor or near-poor (DeParle, Gebeloff, and Tavernise 2011; Short 2011). Whether expanding existing Medicare subsidies beyond the current group would result in reductions in adverse clinical events or cost offsets in hospitalizations or outpatient costs are critical remaining questions, particularly given the urgent need to reduce Medicare spending.

While the ACA phases out the coverage gap by 2020, the future of this provision remains uncertain given continued fiscal pressures (The Kaiser Family Foundation 2011). Nevertheless, even with the elimination of the coverage gap, significant cost-sharing remains for unsubsidized beneficiaries through tiered co-payments and co-insurance. We found that the frequency of nonadherence and financial stress among near-poor beneficiaries was evenly distributed across those who reached and did not reach the gap in 2008. Thus, although the ACA-mandated gap closure could reduce adverse behaviors among higher income beneficiaries, it may not be sufficient to mitigate these effects among the near-poor. These findings could also inform recent ACA provisions for coverage areas other than Medicare. For example, in addition

to Medicaid expansions, the ACA also permits states to create Basic Health Plans that would cover individuals with incomes between 133 and 200 percent FPL with lower premiums and cost-sharing compared with other plans sold within the health insurance exchanges; however, it is unclear how many states will adopt this option or what the take-up will be.

This cross-sectional survey was not designed to assess the effects of Part D drug costs on clinical outcomes. This study was also conducted within a single Medicare Advantage plan offered by an integrated delivery system, and it is not a nationally representative sample. The plan's service area has a relatively high cost of living; thus, the poverty income limit in real terms is lower than the U.S. average, so that the near-poor in this study could have less real income than those in the country at large. On the other hand, the study plan's drug benefit provided generic-only coverage during the standard gap for non-LIS beneficiaries as did 51 percent of MA drug plans in 2008; the majority of PDP plans (71 percent) in 2008, however, provided no coverage during the gap (Medicare Payment Advisory Commission 2008). Hence, our findings could more closely reflect the experiences of beneficiaries enrolled in MA drug plans. Historically, there has been a dearth of information on the financial experiences of beneficiaries within the MA program. In addition, this delivery system historically has had high baseline levels of generic drug use and care management (Cheetham et al. 2005). Average drug spending in other plans is likely to be higher compared with this setting, as well as opportunities to switch to generics to reduce costs and cost-related nonadherence; thus, these findings could represent conservative estimates of the frequency of these drug cost responses. The study excluded institutionalized beneficiaries, severely ill beneficiaries, and non-English speakers who were not able to complete the telephone interview. These exclusions disproportionately affected the LIS beneficiaries included in our sample. However, the telephone interviews also allowed for the capture of numerous measures that cannot be obtained in administrative data, including financial stress, household income, functional status, and whether changes in drug use were due to drug costs.

Collecting detailed individual- and household-level information frequently requires in-depth interviews with beneficiaries. We collected information on household income only, which could be subjected to reporting error, and did not assess assets. The Government Accountability Office found that income is a more common factor for LIS denials than assets, and that those who fail the asset test often exceed the threshold by a small amount (<\$5,000) (The Government Accountability Office 2008a). Nevertheless, we are unable to identify near-poor beneficiaries who were qualified for the LIS but did not

apply versus those with assets above qualification thresholds. An estimated 2.6 million beneficiaries were eligible but did not receive the subsidy in 2008 (The Government Accountability Office 2008b; The Kaiser Family Foundation 2009). In sensitivity analyses, however, we examined other income thresholds to define the near-poor population (e.g., 300 percent FPL) and Census-based measures of poverty (Krieger 1992); results were consistent across approaches. Nevertheless, these findings highlight the need for reliable measures of financial status to examine these questions in broad populations of Medicare beneficiaries (Meijer, Karoly, and Michaud 2010). Analyzing public datasets that link both financial and medical information could help inform future policy.

In conclusion, we found that the LIS provides some protection from cost-related drug nonadherence and financial stress. However, near-poor beneficiaries with incomes just above low-income subsidy qualification thresholds remain vulnerable to adverse cost-sharing effects. Focusing subsidy changes on the near-poor beneficiaries could potentially result in reductions in adverse clinical events or cost offsets in hospitalization or outpatient costs, and thus possibly pay for themselves. These findings highlight the need for ongoing efforts to evaluate the impact of Part D benefits, including the upcoming closing of the coverage gap, particularly for low-income, vulnerable beneficiaries.

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SUPPORTING INFORMATION

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

Appendix SA1: Author Matrix.

Appendix SA2: Sample Selection and Response Rates.