



Published in final edited form as:

*J Am Geriatr Soc.* 2010 May ; 58(5): 822–828. doi:10.1111/j.1532-5415.2010.02813.x.

## Generic-only Drug Coverage in the Medicare Part D Gap and Effect on Medication Cost-Cutting Behaviors for Patients with Diabetes: The Translating Research into Action for Diabetes (TRIAD) Study

O. Kenrik Duru, M.D., M.S.<sup>1</sup>, Carol M. Mangione, M.D, M.S.P.H.<sup>1,2</sup>, John Hsu, M.D., M.B.A., M.S.C.E.<sup>3</sup>, W. Neil Steers, Ph.D.<sup>1</sup>, Elaine Quiter, M.S.<sup>1</sup>, Norman Turk, M.S.<sup>1</sup>, Susan L. Ettner, Ph.D.<sup>1</sup>, Julie A. Schmittdiel, Ph.D.<sup>3</sup>, and Chien-Wen Tseng, M.D., M.P.H.<sup>4,5</sup>

<sup>1</sup> David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, CA

<sup>2</sup> School of Public Health, University of California, Los Angeles, Los Angeles, CA

<sup>3</sup> Center for Health Policy Studies and the Division of Research, Kaiser Permanente Northern California

<sup>4</sup> Pacific Health Research Institute, Honolulu, HI

<sup>5</sup> University of Hawaii Department of Family Medicine and Community Health, Honolulu, HI

### Abstract

**Background**—Medicare Part D beneficiaries with diabetes are at risk of medication non-adherence and forgoing necessities due to cost pressures. Generic drug coverage during the Part D gap may attenuate these potentially adverse behaviors.

**Objective**—To examine the association between drug coverage during the gap and medication cost-cutting behaviors among insulin users and non-users.

**Participants and Setting**—2007 survey of Medicare Advantage Part D (MAPD) and Prescription Drug Plan (PDP) beneficiaries within a network-model health system who entered the gap by October 2006 (N=1,468, 57% response rate).

**Design**—The study was cross-sectional.

**Measurements**—The primary predictor variable was no gap coverage versus generic-only gap coverage. We examined seven cost-cutting behaviors as dependent variables, including cost-related non-adherence (CRN) to any medication. Covariates included race/ethnicity, education, health status, income, and comorbidities, as well as generic medication use in the first quarter. We

---

Address for correspondence and reprints: Obidiugwu Kenrik Duru, M.D. Division of General Internal Medicine, University of California, Los Angeles, 911 Broxton Plaza, Los Angeles, CA 90024. kduru@mednet.ucla.edu, tel# (310) 794-8138, fax# (310) 794-0732.

Conflict of Interest: The study authors have no financial or personal conflicts of interest related to this manuscript. This includes no employment or affiliations, grants, honoraria, consultancies, stocks, royalties, prior expert testimony, board memberships, patents, or personal relationships that would constitute a conflict.

Author Contributions:

Study Concept and Design: Drs. Duru, Mangione, Hsu, Tseng

Acquisition of Data: Drs. Mangione, Hsu, Steers; Ms. Quiter, Mr. Turk

Analysis and Interpretation of Data: Drs. Duru, Mangione, Hsu, Steers, Ettner, Schmittdiel, Tseng; Mr. Turk

Preparation of Manuscript: Drs. Duru, Mangione, Hsu, Steers, Ettner, Schmittdiel, Tseng

Significant contributions to this study were made by members of the Translating Research into Action for Diabetes (TRIAD) Study Group

constructed logistic regression models using non-response weights, to generate predicted percentages.

**Results**—In multivariate analyses, beneficiaries taking insulin were less likely to report CRN if they had generic-only gap coverage compared to no gap coverage (16% vs. 29%,  $p=0.03$ ). No differences in CRN by type of gap coverage were seen among beneficiaries not taking insulin.

**Conclusions**—Medicare beneficiaries using insulin are at high risk of CRN. Generic-only coverage during the gap is associated with an attenuated risk of CRN among insulin users, possibly due to savings on other, generic medications. Future research should evaluate CRN within alternative benefit designs covering selected brand name medications, such as insulin, during the gap.

## Keywords

Medicare Part D; pharmaceutical use; diabetes

---

The “standard” Medicare Part D prescription drug benefit has a gap in coverage after total drug costs exceed an annually adjusted threshold, e.g., \$2,510 in 2008.<sup>1</sup> During the coverage gap, beneficiaries with the standard benefit are responsible for 100% of the cost of their medications. Recent studies have found that many Part D beneficiaries with a coverage gap use less medication than prescribed due to cost and go without necessities such as food or rent in order to afford medications.<sup>2–6</sup> Beneficiaries with diabetes and other chronic diseases may be at particular risk, given a high likelihood of entering the coverage gap due to their multi-drug regimens.<sup>7–11</sup> High cost sharing among chronically ill beneficiaries has also been associated in pre-Part D studies with a decline in health and an increase in emergency department visits and hospitalizations.<sup>7, 12–14</sup>

While the majority of Part D plans provide no drug coverage during the gap, several plans have tried to bridge the gap with coverage for generic medications only (generic-only gap coverage).<sup>15</sup> These plans discontinue coverage for brand name medications, such as insulin, once patients enter the gap. To date, only one study has focused on whether providing generic-only drug benefits during the gap significantly lowers cost-related nonadherence (CRN). Zhang et al. used Medicare Advantage Part D (MAPD) data and found that after entering the coverage gap, beneficiaries who retain coverage for generic medications fill only 3% fewer prescriptions each month while beneficiaries without any coverage fill 14% fewer prescriptions each month.<sup>6</sup> Describing the ability of generic-only coverage to reduce CRN is crucial since the downside of more generous drug coverage for beneficiaries, includes higher monthly premiums.<sup>16</sup> There are no published studies to date examining CRN by type of gap coverage among Medicare beneficiaries with diabetes, including those taking insulin.

As part of the Translating Research into Action for Diabetes (TRIAD) study, we conducted a cross-sectional survey of beneficiaries with diabetes enrolled in Part D in 2006 who exceeded the cost threshold for gap entry by the end of the third quarter. We hypothesized that beneficiaries with diabetes (both insulin users and non-insulin users) and generic-only gap coverage would be less likely to report cost-related nonadherence, report forgoing necessities due to financial hardship, and report treatment substitutions compared to beneficiaries with a standard Part D coverage gap.

## Methods

### Setting

We sampled beneficiaries from a multi-state network-model system that offered two different Part D benefit designs. One design had a standard coverage gap between \$2,250 in total drug costs and \$3,600 in out-of-pocket drug costs, and the other provided generic-only medication coverage during this gap. Beneficiaries could have either of the cost-sharing designs through an MAPD plan or through a stand-alone PDP plan. Neither design included a deductible, and both had four copayment tiers: \$8.50 for generics, \$26–27 for preferred brands, 50% coinsurance for non-preferred brands, and 33% coinsurance for specialty drugs. During the coverage gap, beneficiaries that were enrolled in a plan with generic-only coverage continued to have an \$8.50 generic copayment but no coverage for brand name drugs, while those with a complete gap in coverage paid full cost for all drugs including generics. The health plans did not operate their own pharmacies, and both MAPD and PDP beneficiaries filled all of their prescriptions at outside pharmacies.

All MAPD plans had the same formulary, while 2 slightly different formularies were available to PDP beneficiaries. The 3 formularies provided identical drug coverage for almost all diabetes-related (anti-glycemic, anti-hypertensive, and lipid-lowering) medications, including generic metformin, four generic sulfonylureas, two generic HMG Co-A reductase inhibitors/"statins," and two angiotensin-receptor blockers as preferred brands. However, there were two major differences between the MAPD formulary and the PDP formularies: 1) the PDP formularies did not cover insulin analogs (other than NPH insulin) as preferred brands and 2) the PDP formularies did not include a third-option statin as a preferred brand.

### Study Design/Participants

TRIAD is a multi-center study of diabetes care in managed care settings,<sup>17</sup> and this analysis is drawn from a TRIAD survey specifically examining the impact of Medicare Part D. The research protocol was approved by the Institutional Review Board at the University of California, Los Angeles. For the current study, data were drawn from a cross-sectional survey of Part D beneficiaries with diabetes. To be eligible for the survey, beneficiaries had to be 1) continuously enrolled in a Medicare Advantage plan from January 1, 2005 to December 31, 2005 and an MAPD plan from January 1, 2006 to December 31, 2006, or 2) newly enrolled in a PDP plan between November 15, 2005 and March 1, 2006. PDP enrollees were also required to have been continuously enrolled through December 31, 2006. Because specific dates of Part D enrollment were not available for PDP members at the time of sampling, we did not exclude participants who enrolled after January 1, 2006.

We randomly sampled plan members who were at least 65 years of age by January 1, 2005, could complete the survey in either English or Spanish, and had total drug costs in 2006 that exceeded the \$2250 gap threshold by October 1, 2006. Beneficiaries who could not provide informed consent, were enrolled in Medicare solely due to their end-stage renal disease status, or were too ill to participate were excluded. Because Medicare Part D does not include a coverage gap for beneficiaries with the low-income subsidy, they were also excluded. The survey was fielded between April and October 2007. Potential participants were offered the option of completing either a computer-assisted telephone interview (CATI) or a self-administered written survey to report their experiences in 2006. The coverage gap may influence medication-taking behavior both prior to the gap, since beneficiaries may preemptively reduce or alter medication use to avoid gap entry, as well as during the gap itself. Therefore, the survey focused on identifying medication cost-cutting behaviors during the entire 2006 calendar year.

## Variables/Measurement

Dependent variables included seven separate medication cost-cutting behaviors during 2006: 1) skipped doses, delayed or stopped refills altogether, or otherwise used any medication less often than prescribed (i.e., cost-related nonadherence, or CRN), 2) went without food, rent, or other essentials in order to afford medication (i.e., forgoing necessities due to financial hardship), 3) switched to a cheaper medication such as a generic (i.e., generic substitution), 4) split pills according to their doctor's advice, 5) used an over-the-counter substitute instead of their prescribed medication, 6) used a mail-order pharmacy to fill prescriptions, and 7) called different pharmacies to find the lowest price for a given medication. The last five strategies were classified as "substitution" strategies, in which beneficiaries either sought to change the medication they used or where they purchased the medication but were not necessarily less adherent. These items have been used previously in analyses examining the financial burden of prescription drugs.<sup>18</sup> Among the subset of CATI respondents who reported any CRN during 2006, we asked a follow-up question to determine the specific medication/s which were used less often than prescribed due to cost.

We measured several survey-based covariates, specifically race/ethnicity, education, income, self-rated health status (excellent, very good, good, fair, poor), and a claims-based summed comorbidity score. The comorbidity score included six chronic conditions from the survey: congestive heart failure, chronic obstructive pulmonary disease, depression, non-skin cancer, a history of either a myocardial infarction, or a history of a cerebrovascular accident. We also measured annual income at the residential census tract level, and used this variable as a proxy to represent individual income for those participants with missing income data. We included as a covariate the percentage of all unique medications the patient was taking in the first quarter of 2006 that were generic. This variable was derived from administrative claims. For the 66 (3.1%) of participants who did not fill prescriptions in the first quarter of 2006, we calculated the percentage of generic medications using data from the second quarter. Two participants did not fill any prescriptions until the third quarter of 2006, and were excluded from all analyses.

We also used claims data to measure the number of unique medications each patient was taking, the percentage of patients who were taking a single-source brand name medication without a generic equivalent, and the total medication cost for each participant in 2006. However, we did not include these variables as covariates in the multivariate models because the interpretation of statistical relationships is not entirely straightforward (e.g., higher medication costs may result in lower adherence while lower adherence and less medication use may result in lower costs). We also used administrative claims data to determine the Part D enrollment date for each participant, as well as identify those participants who exited the coverage gap and received "catastrophic coverage" to assist with their prescription drug costs.

## Statistical Analyses

We used age and gender data from the administrative claims to construct non-response weights, using raking techniques with multiple iterations.<sup>19</sup> We constructed multivariate logistic regression analyses using SAS PROC LOGISTIC to examine the association between the use of medication cost-cutting behaviors and either no gap coverage or generic-only coverage, in separate analyses among insulin users and insulin non-users. The percentage of missing data was less than 10% for all covariates. Seventeen percent of beneficiaries were missing individual data for income, and we "backfilled" this variable using the median income of their residential census tract. Participants with missing data other than income were excluded from the multivariate analyses. To increase interpretability

of the results, we converted odds ratios into predicted percentages, and calculated 95% confidence intervals for each result.

In sensitivity analyses, results did not differ between participants who completed computer-assisted telephone interviews or written surveys. Using inpatient and outpatient claims data for the MAPD sample, we substituted a claims-based comorbidity score including 15 conditions for the self-reported comorbidity measure, and did not observe major differences as compared to the results of the main model. In addition, the results did not change appreciably after exclusion of either the 16% of participants who enrolled in Part D after January 1, 2006 or of the 11% of participants who entered catastrophic coverage during 2006. Therefore, we report only the results from the main analyses examining the full sample.

## Results

The analytic sample included 1,468 participants with diabetes who completed the survey (crude response rate of 57.3%). The approximate distribution of benefit designs was 65% standard coverage (n=928) and 35% generic-only gap coverage (n=540). In unadjusted analyses, demographic and clinical characteristics including age, education, income, self-rated health and comorbidity scores were similar between participants without gap coverage and those with generic-only coverage (Table 1). Participants without gap coverage were more likely to be enrolled in an MAPD plan (81%) compared to those with generic-only gap coverage (52%,  $p<0.001$ ). Participants without gap coverage were also more likely to be taking insulin compared to patients with generic-only gap coverage (34% vs. 28%,  $p=0.02$ ). In additional unadjusted analyses, no differences between the two groups were seen in the number of medications, or total medication costs in either the first quarter of 2006 or the entire year (Table 1). Compared to participants with generic-only gap coverage, participants without gap coverage had higher out-of-pocket costs in the first quarter of 2006 (\$313 vs. \$278,  $p=0.002$ ) and were more likely to exit the gap (12% vs. 8%,  $p=0.01$ ).

After non-response weighting and multivariate adjustment, generic-only gap coverage was associated with lower rates of reported CRN compared to no gap coverage among participants using insulin (16% vs. 29%,  $p=0.03$ , Table 2). No differences by type of gap coverage were seen for other cost-cutting behaviors among insulin users. Among participants not using insulin, no differences in rates of CRN were seen by type of gap coverage (Table 3). However, participants not using insulin who had generic-only gap coverage were less likely than others with no gap coverage to switch any medication to a cheaper alternative (36% vs. 46%,  $p=0.01$ ) or call different pharmacies to find the lowest price for their medication (22% vs. 36%,  $p<0.001$ ).

Among all CATI respondents who reported any CRN (both insulin users and insulin non-users), 59% reported using at least one anti-glycemic, anti-hypertensive, or lipid lowering medication less often than prescribed due to cost (data not shown). Among CATI respondents using insulin who reported any CRN, 13% reported using less insulin than prescribed, while 87% reported cutting down on another medication due to cost (data not shown).

## Discussion

This is the first study in the peer-reviewed literature to report the use of medication cost-cutting behaviors specifically among Medicare Part D beneficiaries with diabetes, and to what extent these behaviors are associated with drug benefits of varying generosity during the coverage gap. Our data indicate that generic-only coverage significantly attenuates the

reduction in filled prescriptions after reaching the gap among all Part D beneficiaries, but this finding is limited to the subgroup of participants who use insulin. Although generic-only coverage is associated with a lower likelihood of CRN among insulin users, approximately 15% of all beneficiaries with generic-only coverage still report CRN. Generic-only coverage during the gap did not change the proportion of beneficiaries who reported having to go without basic necessities to pay for their medications.

Our finding of frequent CRN among insulin users with a coverage gap likely reflects the lack of alternative therapeutic options for these patients, who have likely already failed oral anti-glycemic therapy. There are no generic, less expensive versions of any biologic agents including insulin, so insulin users face a steep increase in out-of-pocket medication costs during the gap. If they are unable to afford all of their medications during the gap, these patients may use less of their other medications than prescribed, or in some cases even cut down on the amount of insulin they use. While there are no published papers examining this issue, our findings are consistent with a recent abstract showing that 24% of insulin users who had a coverage gap discontinued at least one medication during the gap.<sup>20</sup> The somewhat lower rates of CRN that we observed among insulin users with generic-only coverage in the gap may be due to an indirect benefit from savings on other, generic medications resulting in lower total out-of-pocket costs.

The number of Medicare Part D plans providing generic-only gap coverage has increased in recent years, from 13% of PDPs and 23% of MAPD plans in 2006 to 25% and 34% respectively in 2009.<sup>15</sup> The value of this coverage has been debated, since the higher premiums charged to patients, particularly by PDP plans that serve the majority of Medicare beneficiaries, may outweigh the financial benefits expected during the coverage gap.<sup>16,21</sup> Premiums for generic-only coverage are generally lower in MAPD plans, since the plans are able to subsidize the cost of providing generic-only gap coverage with revenues they receive for providing other Medicare services within an integrated system. Insulin users, who have high out-of-pocket medication costs during the gap, represent a group of patients for whom higher premiums associated with generic-only coverage may be worthwhile, in terms of providing savings on other medications and reducing overall costs. Additional studies are needed to evaluate these findings in other settings, including the specific cost savings to the patient with different monthly Part D premiums and different types of medication regimens.

Other, more direct options to address the issue of CRN among older adults with diabetes include either providing generic insulin or covering brand name medications during the gap. Existing laws prohibit generic drug manufacturers from marketing biologic agents such as insulin in the United States. Even if pending legislation that would enable the production of generic insulin were to pass,<sup>22,23</sup> the medications would not be available to consumers for several years. On the other hand, providing gap coverage for generics as well as some “essential” brand name medications for compounds without generic equivalents would also be effective in minimizing CRN and financial hardship strategies. This type of benefit design, a variant of “reference pricing” used in many other countries,<sup>24,25</sup> provides a financial incentive for patients in the gap to choose a cheaper generic over a more expensive, “non-preferred” brand name equivalent, while still covering other brand name prescriptions. While no plans offered this type of gap coverage in 2006, 4% of MAPD plans are providing it during 2009.<sup>15</sup> Future studies should investigate the effectiveness of this design as it relates to medication-taking decisions and behaviors.

Our study has several limitations. First, as with several prior studies that surveyed Medicare beneficiaries, we relied solely on patients’ self report of medication cost-cutting behaviors. These patient reports may have been influenced by recall bias. Second, we cannot determine whether cost-cutting behaviors took place before, during, and/or after the coverage gap.

However, since some patients may have preemptively decreased their medication use in an attempt to delay or avoid the gap altogether, cost-cutting behaviors reported gap entry may have been attributable to the coverage gap. Our results were also similar after excluding patients who exited the gap and entered catastrophic coverage. Third, our results reflect patients enrolled in one health system and may not be generalizable to other systems with different formularies, deductibles, or other design features. Fourth, we used census-tract level income data as a proxy for individual income in a small minority of cases. Fifth, patients who did not fill any prescriptions in 2006 were excluded from the sampling frame. Finally, this was a non-randomized study and there may be unmeasured group differences between beneficiaries who selected the standard gap plan and those who selected the generic-only plan. We did not see significant differences between the groups in terms of observable clinical characteristics such as self-rated health, number of comorbidities, and number of medications. To mitigate potential selection bias, we controlled for these characteristics and also focused on comparisons within a single health system. To the extent that patients with greater medication needs and costs chose more generous plans, unmeasured selection may remain but would likely exaggerate group differences and would suggest even less of an advantage for beneficiaries to have the generic-only plan.

In conclusion, our results suggest that generic-only coverage during the Part D gap is associated with protection against cost pressures with respect to any CRN, for patients with diabetes who are taking insulin. This may be due to savings on other, generic medications that reduce the total out-of-pocket medication costs faced by insulin users during the gap. Generic-only coverage is not associated with protection against forgoing necessities, compared to the standard coverage gap. Future research should investigate the effectiveness of health plan efforts to educate beneficiaries with diabetes about their prescription drug options, as well as the effects of alternative designs such as covering both generics and essential brand-name medications such as insulin in the coverage gap.

## Acknowledgments

This project was funded by Centers for Disease Control, Cooperative Agreement U58/CCU923527-04-1: The Translating Research into Action for Diabetes (TRIAD) Study.

Dr. Duru is supported by the Harold Amos Medical Faculty Development Award from the Robert Wood Johnson Foundation. Dr. Mangione received support from the UCLA Center for Health Improvement of Minority Elderly/ Resources Centers for Minority Aging Research under the NIH/NIA grant P30AG021684 and the Drew/UCLA Project EXPORT Center under the NIH/NCMHHD grant P20MD000182. Dr. Schmittiel is supported by the Office of Research in Women's Health Building Interdisciplinary Careers in Women's Health K12 Career Development Award (K12HD052163).

The authors acknowledge the participation of our health plan partners.

Sponsor's Role: The organizations funding this study had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript.

## References

1. The Medicare Prescription Drug Benefit Fact Sheet. The Henry J. Kaiser Family Foundation (online); Available at:[http://www.kff.org/medicare/upload/7044\\_08.pdf](http://www.kff.org/medicare/upload/7044_08.pdf)
2. Raebel MA, Delate T, Ellis JL, et al. Effects of reaching the drug benefit threshold on Medicare members' healthcare utilization during the first year of Medicare Part D. *Med Care*. 2008; 46:1116–1122. [PubMed: 18815534]
3. Hsu J, Fung V, Price M, et al. Medicare beneficiaries' knowledge of Part D prescription drug program benefits and responses to drug costs. *JAMA*. 2008; 299:1929–1936. [PubMed: 18430912]

4. Madden JM, Graves AJ, Zhang F, et al. Cost-related medication nonadherence and spending on basic needs following implementation of Medicare Part D. *JAMA*. 2008; 299:1922–1928. [PubMed: 18430911]
5. Schneeweiss S, Patrick AR, Pedan A, et al. The effect of Medicare Part D coverage on drug use and cost sharing among seniors without prior drug benefits. *Health Aff (Millwood)*. 2009; 28:w305–316. [PubMed: 19189990]
6. Zhang Y, Donohue JM, Newhouse JP, et al. The effects of the coverage gap on drug spending: a closer look at Medicare Part D. *Health Aff (Millwood)*. 2009; 28:w317–325. [PubMed: 19189991]
7. Hsu J, Price M, Huang J, et al. Unintended consequences of caps on Medicare drug benefits. *N Engl J Med*. 2006; 354:2349–2359. [PubMed: 16738271]
8. Hwang W, Weller W, Ireys H, et al. Out-of-pocket medical spending for care of chronic conditions. *Health Aff (Millwood)*. 2001; 20:267–278. [PubMed: 11816667]
9. Piette JD, Heisler M, Wagner TH. Problems paying out-of-pocket medication costs among older adults with diabetes. *Diabetes Care*. 2004; 27:384–391. [PubMed: 14747218]
10. Steinberg EP, Gutierrez B, Momani A, et al. Beyond survey data: a claims-based analysis of drug use and spending by the elderly. *Health Aff (Millwood)*. 2000; 19:198–211. [PubMed: 10718034]
11. Schmittiel JA, Ettner SL, Fung V, et al. Medicare Part D coverage gap and diabetes beneficiaries. *Am J Manag Care*. 2009; 15:189–193. [PubMed: 19298100]
12. Cole JA, Norman H, Weatherby LB, et al. Drug copayment and adherence in chronic heart failure: effect on cost and outcomes. *Pharmacotherapy*. 2006; 26:1157–1164. [PubMed: 16863491]
13. Heisler M, Langa KM, Eby EL, et al. The health effects of restricting prescription medication use because of cost. *Med Care*. 2004; 42:626–634. [PubMed: 15213486]
14. Piette JD, Wagner TH, Potter MB, et al. Health insurance status, cost-related medication underuse, and outcomes among diabetes patients in three systems of care. *Med Care*. 2004; 42:102–109. [PubMed: 14734946]
15. Medicare Part D. 2009 Data Spotlight: the Coverage Gap. The Henry J. Kaiser Family Foundation (online); Available at: <http://www.kff.org/medicare/upload/7834.pdf>
16. The Henry J. Kaiser Family Foundation. Medicare Part D 2008 Data Spotlight: Premiums. Medicare Part D 2008 Data Spotlight: Premiums (online). Available at: <http://www.kff.org/medicare/7706.cfm>
17. The TRIAD Study Group. The Translating Research into Action for Diabetes (TRIAD) study: a multicenter study of diabetes in managed care. *Diabetes Care*. 2002; 25:386–389. [PubMed: 11815515]
18. Reed M, Brand R, Newhouse JP, et al. Coping with prescription drug cost sharing: knowledge, adherence, and financial burden. *Health Serv Res*. 2008; 43:785–97. [PubMed: 18370979]
19. Izrael, D.; Hoaglin, DC.; Battaglia, MP. To rake or not to rake is not the question anymore with the enhanced raking macro (online). Available at: <http://www2.sas.com/proceedings/sugi29/toc.html>
20. Skrepnek, GH.; DeNarie, M.; Conner, C.; Forma, FA. Treatment pattern changes observed with the Medicare Part D coverage gap in patients utilizing insulin (Abstract 1225-P). Presented at the 2008 meeting of the American Diabetes Association;
21. Balfour DC III, Evans S, Januska J, et al. Medicare Part D: A roundtable discussion of current issues and trends. *J Manag Care Pharm*. 2009; 15(1 Suppl A):3–9. [PubMed: 19125555]
22. Promoting Innovation and Access to Life-Saving Medicine Act, HR 1427, 111<sup>th</sup> Congress (2009).
23. Promoting Innovation and Access to Life-Saving Medicine Act, S 726, 111<sup>th</sup> Congress (2009).
24. Danzon PM, Ketcham JD. Reference pricing of pharmaceuticals for Medicare: evidence from Germany, The Netherlands, and New Zealand. *Front Health Policy Res*. 2004; 7:1–54. [PubMed: 15612334]
25. Searles A, Jefferys S, Doran E, et al. Reference pricing, generic drugs and proposed changes to the Pharmaceutical Benefits Scheme. *Med J Aust*. 2007; 187:236–239. [PubMed: 17564580]



Table 1

## Unadjusted Participant Characteristics by Type of Gap Coverage

	No Gap Coverage (n=928)	Generic-only Gap Coverage (n=540)	P value
<b>BENEFIT DESIGN</b>			
Gap coverage	None	Generic medications only	
Copayments	\$8.50 generic for 30-day supply/ \$26–27 preferred brand for 30-day supply/ 50% coinsurance for other brand/ 33% coinsurance for specialty drugs	\$8.50 generic for 30-day supply/ \$26–27 preferred brand for 30-day supply/ 50% coinsurance for other brand/ 33% coinsurance for specialty drugs	
<b>DEMOGRAPHICS</b>			
Mean age in years (SD)	75.7 (5.7)	75.6 (6.2)	0.76
Race/Ethnicity (%)			0.08
White (n=1050)	75%	78%	
Latino (n=216)	16%	15%	
Asian/Pacific Islander (n=35)	3%	2%	
African American (n=39)	4%	1%	
Other (n=40)	3%	4%	
Female sex (%)	55%	53%	0.41
Education (%)			0.78
<HS (n=291)	21%	20%	
HS graduate (n=439)	31%	31%	
Some college (n=411)	29%	29%	
4+ years college (n=270)	18%	20%	
Median annual income *			0.16
<\$25K (n=516)	37%	32%	
\$25K - \$40K (n=374)	25%	26%	
>\$40K (n=578)	38%	42%	
Health status			0.12
Excellent/Very Good (n=225)	16%	16%	
Good (n=513)	34%	39%	
Fair/Poor (n=684)	50%	45%	
Mean comorbidity score (n=1416)	1.3 (1.1)	1.3 (1.2)	0.70
Using insulin (%)	34%	28%	<b>0.02</b>
Type of Part D Plan			<b>&lt;0.001</b>
Medicare Advantage Prescription Drug plan (MAPD) (n=1034)	81%	52%	
Stand-alone Prescription Drug plan (PDP) (n=434)	19%	48%	
Completed CATI survey (vs. written)	69%	71%	0.44
<b>UTILIZATION MEASURES</b>			

	No Gap Coverage (n=928)	Generic-only Gap Coverage (n=540)	P value
Mean number of medications in 2006 (SD)	13.7 (5.1)	13.4 (4.9)	0.18
Median total medication costs in Quarter 1 2006 <sup>†</sup>	937	892	0.13
Median total medication costs for the entire 2006 year	3343	3508	0.07
Median out-of-pocket medication costs in Quarter 1 2006 <sup>†</sup>	313	278	<b>0.002</b>
Exited the gap (reached catastrophic coverage) in 2006 (%)	12%	8%	<b>0.01</b>
% of generic meds in Quarter 1 2006 <sup>†</sup>	60%	61%	0.43
% taking a single-source brand medication in 2006 (no generic equivalent)	100%	100%	...

Statistically significant results in **bold**

\* We used census-tract level income information as a proxy for individual income data

All MAPD and PDP plans (whether offering generic-only gap coverage or no gap coverage) include the same copayment structure: \$8.50 for 30 days' supply of a generic medication, \$26–27 for 30 days' supply of a preferred brand medication, 50% coinsurance for non-preferred brands, and 33% coinsurance for specialty medications.

<sup>†</sup>We calculated these variables from Quarter 2 claims for those 66 patients (3.1%) with no prescription fills in Quarter 1

**Table 2**

Adjusted Predicted Percentages of Medication Cost-Cutting Behaviors by Type of Gap Coverage, among Beneficiaries using Insulin

	No gap coverage (n=314)	Generic-only gap coverage (n=152)	P value
<i>Cost-related nonadherence (CRN)</i>			
During 2006, because of the amount you had to pay, did you <u>use any medication less often than the doctor prescribed</u> , either by skipping doses, stopping the medication altogether, or deciding not to fill a new prescription?	29%	16%	<b>0.03</b>
<i>Forgoing necessities due to financial hardship</i>			
During 2006, did you <u>go without some necessity</u> (such as food, rent or other basics) because of the amount that you would have to pay for a prescription medication?	15%	18%	0.55
<i>Substitution</i>			
During 2006, because of the amount you had to pay for prescription medications, did you <u>use an over-the-counter medication instead</u> ?	11%	11%	0.87
During 2006, because of the amount you had to pay ... did you <u>split pills</u> (for example, break them in half) according to your doctor's advice?	20%	17%	0.47
During 2006, because of the amount you had to pay ... did you <u>switch to a cheaper medication, such as a generic one</u> ?	45%	51%	0.38
During 2006, because of the amount you had to pay ... did you <u>use a mail-order pharmacy</u> to fill your prescriptions?	44%	50%	0.37
During 2006, because of the amount you had to pay ... did you <u>call different pharmacies to find the lowest price</u> for your medications?	38%	40%	0.77

All models incorporate non-response weights, and are adjusted for age, gender, race/ethnicity, education, comorbidity score, median income of residential census tract, , % generic prescriptions in Q1 of 2006, plan type (MAPD/PDP).

All models incorporate non-response weights.

**Table 3**

Adjusted Predicted Percentages of Medication Cost-Cutting Behaviors by Type of Gap Coverage, among Beneficiaries NOT using Insulin

	No gap coverage (n=614)	Generic-only gap coverage (n=388)	P value
<i>Cost-related nonadherence (CRN)</i>			
During 2006, because of the amount you had to pay, did you <u>use any medication less often than the doctor prescribed</u> , either by skipping doses, stopping the medication altogether, or deciding not to fill a new prescription?	18%	14%	0.24
<i>Forgoing necessities due to financial hardship</i>			
During 2006, did you <u>go without some necessity</u> (such as food, rent or other basics) because of the amount that you would have to pay for a prescription medication?	8%	8%	0.91
<i>Substitution</i>			
During 2006, because of the amount you had to pay for prescription medications, did you <u>use an over-the-counter medication instead</u> ?	9%	6%	0.14
During 2006, because of the amount you had to pay ... did you <u>split pills</u> (for example, break them in half) according to your doctor's advice?	22%	18%	0.31
During 2006, because of the amount you had to pay ... did you <u>switch to a cheaper medication, such as a generic one</u> ?	46%	36%	<b>0.01</b>
During 2006, because of the amount you had to pay ... did you <u>use a mail-order pharmacy</u> to fill your prescriptions?	51%	53%	0.67
During 2006, because of the amount you had to pay ... did you <u>call different pharmacies to find the lowest price</u> for your medications?	36%	22%	<b>&lt;0.001</b>

All models incorporate non-response weights, and are adjusted for age, gender, race/ethnicity, education, comorbidity score, median income of residential census tract, , % generic prescriptions in Q1 of 2006, plan type (MAPD/PDP).

All models incorporate non-response weights.