

HEALTH POLICY

Drug Benefit Changes Under Medicare Advantage Part D: Heterogeneous Effects on Pharmaceutical Use and Expenditures

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BACKGROUND: Although Medicare Part D improved drug benefits for many beneficiaries, its impact on the coverage of Medicare Advantage Part D (MAPD) enrollees depended on their pre-existing benefits and whether they had gap coverage under Part D.

OBJECTIVE: To examine changes in prescription drug utilization and expenditures associated with drug benefit changes resulting from the implementation of Part D.

PATIENTS: We studied 248,773 continuously enrolled MAPD patients in eight states. Patients whose insurance product or Census block could not be identified or who had atypical benefits, low-income subsidies or Medicaid coverage were excluded.

MAIN MEASURES: The main outcomes were changes in prescription drug days supply and expenditures from 2005 to 2006 and 2005 to 2007.

DESIGN: We linked Census data with 2005–7 MAPD claims, encounter, enrollment, and benefits data and estimated associations of the outcomes with changes in drug benefits, controlling for 2005 comorbidities, demographics, and Census population characteristics.

KEY RESULTS: MAPD enrollees whose drug benefits became potentially less generous after Part D had the smallest increases in drug utilization and expenditures (e.g., drug expenditures increased by \$130 between 2005 and 2006), while those who potentially gained the most from Part D experienced the largest increases (\$302). The differences in benefit design changes had a stronger association with drug utilization and outcomes among patients at high risk of gap entry than among the entire sample.

CONCLUSIONS: Although Medicare Part D unambiguously improved drug coverage for many elderly, it led to heterogeneous changes in drug benefits among MAPD enrollees, who already had generic and sometimes branded drug benefits. After 2006, benefits were worse for individuals who had branded drug coverage in 2005

but now had a coverage gap, but benefits may have improved for individuals who acquired branded drug coverage. Commensurate with these differential changes in benefits following Part D, changes in drug utilization and expenditures varied substantially as well.

KEY WORDS: medicare part D; benefit design; drug and medical expenditures.

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INTRODUCTION

The Part D Prescription Benefit took effect January 2006, providing voluntary drug coverage to Medicare beneficiaries through private plans contracting with Medicare^{1,2}. Part D coverage is offered through stand-alone prescription drug plans (PDPs) and Medicare Advantage Part D plans (MAPDs)^{3,4}. One-quarter of Medicare patients who lacked drug coverage in 2005 signed up for a Part D plan in 2006⁶. Pharmacy-based studies comparing drug use and spending before and after Part D among elderly Part D enrollees vs. non-elderly customers concluded that Part D increased drug utilization and reduced out-of-pocket costs^{7–9}.

However, studies of the average impact of Part D among all elderly beneficiaries (including beneficiaries with no, poor, and generous prior drug coverage) may mask important heterogeneity in the effects. Using pharmacy, enrollment, and benefits data on MAPD enrollees, Zhang and colleagues compared changes in drug utilization and spending before and after Part D among enrollees whose coverage did not change, enrollees who newly acquired drug coverage, enrollees whose drug benefits improved slightly, and enrollees whose benefits improved substantially^{10–12}. They concluded that Part D increased drug utilization and adherence and decreased out-of-pocket spending, but changes were smaller for beneficiaries with more generous prior drug coverage.

However, not all MAPD enrollees necessarily benefited from Part D¹³. Many already had generic and often branded drug benefits before the introduction of Part D. Moreover, the standard Part D benefit included a coverage gap (the so-called “doughnut hole”), triggered annually with a threshold level of total participant and health plan costs¹⁴. While in the gap, beneficiaries were respon-

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sible for the full cost of prescription medications until a patient out-of-pocket expenditure threshold was reached and “catastrophic coverage” began. Although some plans offered gap coverage, by 2009 75% of PDP and 49% of MAPD plans had none¹⁵.

For MAPD enrollees who already had branded drug coverage, Part D might have actually increased financial risk if their plan did not offer supplemental gap coverage. For others who initially had generic-only drug benefits, the changes brought about by Medicare Part D were mixed, as their benefits were expanded to include certain branded drugs, but they were newly exposed to 100% financial risk after hitting the gap threshold. The effects of the coverage gap are of particular interest in light of the changes to Medicare Part D effected by the Affordable Care Act (ACA) of 2010. The Part D coverage gap will be phased out over time, so evidence regarding the likely impact of eliminating the gap is needed to inform the forthcoming regulations.

To address variation in the benefit changes resulting from Part D and the commensurate heterogeneity in the program’s early effects, we linked drug benefit design to administrative records for elderly adults continuously enrolled in a large, national for-profit MAPD. Part D regulations required MAPD plans to provide the same “qualified prescription drug benefits” as PDP plans; as a result, the MAPD plan changed drug benefit design for its beneficiaries, although the changes were heterogeneous, depending on the individual’s pre-Part D benefits and whether there was gap coverage.

We used 2005–2007 data to examine the association of this heterogeneity in drug benefit changes with pre/post Part D changes in drug utilization and expenditures. We tested the hypothesis that individuals whose drug benefits became relatively less generous after Part D would have smaller increases in drug utilization and expenditures over time than those whose coverage became more generous.

Our study extends that of Zhang et al.^{10–12} in three ways. Their intervention groups were defined by the pre-Part D cap on drug benefits, and they did not seek to distinguish between enrollees with and without gap coverage after Part D, as we do. We enhance the external validity of the findings by studying 248,773 MAPD patients in eight states, including two highly populous states, vs. the Pennsylvania MAPD studied by Zhang et al. (N=36,176). Finally, we compared the effects of benefit design changes among all patients vs. those at high risk of gap entry.

METHODS

Sources of Data and Sample

Enrollment and benefits files, medical encounters and inpatient, outpatient and pharmacy claims (both mail order and retail) for 2005–2007 were geocoded and linked to 2000 Census block data. The main sample (N=248,773) was MAPD beneficiaries 65 and older whose Census block could be identified and who were continuously enrolled in identifiable insurance products in all 3 years; did not have Medicaid, a federal low-income subsidy, supplemental retirement benefits, deductible or atypical gap threshold; and were in one of the four major benefit design groups described below (see eTable 1, available online).

Beneficiaries may modify their pharmaceutical spending based on their perceived risk of hitting the gap threshold. As

the impact of benefit design changes may also depend on whether beneficiaries believe they are at risk of gap entry, we re-estimated the models using individuals predicted to be in the top quintile of the distribution of predicted risk of gap entry, using methodology developed by Ettner et al.¹⁶.

Outcome Measures

Drug expenditures were constructed by adding up patient out-of-pocket costs and health plan reimbursements across all pharmacy claims filled by an individual during the year separately for 2005, 2006, and 2007. Drug days supply was similarly aggregated across claims and refers to the number of days of pill-taking the prescription would cover at the prescribed dose, i.e., 30 days means that the patient receives enough pills to adhere to a single medication for 30 days (or two medications for 15 days each, etc). We also examined days supply and expenditures separately for branded vs. generic drugs.

All outcomes were expressed as 2005–2006 changes and 2005–2007 changes after adjusting prices for inflation using the medical Consumer Price Index. Changes between 2005 and 2006 reflect the short-term impact of benefit design changes, while 2005–2007 changes more likely reflect a stable response to these incentives after individuals have experienced a “learning curve” with regard to understanding the new benefit design.

Main Predictors

The main predictors were indicators for the following benefit design changes: (1) capped branded drug coverage in 2005 and the standard Part D benefit in 2006–2007; (2) non-capped branded drug coverage in 2005 and a Part D benefit with generic-only gap coverage in 2006–2007; and (3) generic-only drug coverage in 2005 and the standard Part D benefit in 2006–2007. The reference category was non-capped branded drug coverage in 2005 and the standard Part D benefit (including a coverage gap) in 2006–2007. All groups also had generic drug coverage in 2005. Empirically, the “capped” plans all had branded drug benefit caps of \$2,000 or less. Individuals whose benefits did not fall into any of these categories (four percent of the sample) were excluded from analysis.

Individuals in the reference group may have experienced a reduction in the generosity of their drug benefits after Part D was introduced (eTable 2, available online); Part D did not necessarily provide them with new branded drug benefits, but it did introduce financial risk in the form of the coverage gap. Individuals in category (2) could have also experienced a reduction in the generosity of their drug benefits, but since they continued to have generic drug coverage in the gap, the financial risk was less than for the reference group. Individuals in categories (1) and (3) were more likely than those in the reference group to experience improved drug benefits under Part D, despite the coverage gap, since Part D provided significant benefits for branded drugs.

However, patients whose clinical profile puts them at high risk of gap entry may be less likely to view this tradeoff favorably, since the potential improvement in branded drug coverage may not offset the increase in financial risk they now bear as a result of the Part D coverage gap. If so, one might expect that they would increase their drug utilization and expenditures by less than the general patient

population in response to the benefit changes resulting from Part D. On the other hand, the patients at highest risk of gap entry are also those who are sickest and likely to increase their use of drugs the most rapidly over time, with or without benefit changes; therefore, they may also be more responsive to improvements in branded drug coverage because they can make greater use of new drug benefits than somebody who is healthier. Thus, competing theoretical arguments imply that patients at high risk of gap entry might demonstrate either more or less sensitivity to changes in drug benefits resulting from Part D.

Other Covariates

All models controlled for patient sex, age group, comorbidities, urban residence (as a proxy for proximity to care), and the socioeconomic characteristics of the population in the beneficiary’s Census block. Comorbidity indicators were based on ICD-9-CM diagnoses from 2005 medical claims and encounters, categorized using the Clinical Classifications Software¹⁷.

Statistical Analysis

Linear regression was used to estimate each change score. The estimates were used to predict the value of the outcome under each of the four benefit design scenarios described above (e.g., first setting the benefit design indicators to zero to obtain the predicted outcomes for the reference category, then in turn setting each of the benefit design indicators to one in order to obtain the predicted outcomes for that benefit design), holding all other covariate values constant. These predictions were then averaged across the sample. “Difference-in-difference” estimates reflect the difference in these mean predicted changes over time between each benefit design group and the reference category.

RESULTS

Population Characteristics (Table 1)

Study patients were primarily female (59%), urban residents (94%), and lived in economically and ethnically diverse areas. All age groups were well represented, and comorbidities were common.

Almost half of the MAPD study population had capped branded drug coverage in 2005 and no gap coverage in 2006–2007. Less than one-tenth had the most generous benefits in all years (non-capped branded drug coverage in 2005 and generic gap coverage in 2006–2007). The remaining individuals were split about equally between patients with non-capped branded drugs in 2005 and no gap coverage in 2006–2007 and patients with generic-only coverage in 2005.

Adjusted Associations of Drug Benefit Changes with Changes in Days Supply (Table 2)

Consistent with expectations, patients most likely to experience a decline in benefits (those with non-capped branded coverage in

Table 1. Characteristics of the Study Cohort (N=248,773)

Variable	Percent (%) or mean (SD)
Changes in coverage 2005–2007*	
Non-capped branded coverage in 2005, no gap coverage in 2006–2007	21.0
Capped branded coverage in 2005, no gap coverage in 2006–2007	45.8
Non-capped branded coverage in 2005, generic-only gap coverage in 2006–2007	8.7
Generic-only coverage in 2005, no gap coverage in 2006–2007	24.4
Age group	
65 to 69	18.0
70 to 74	27.4
75 to 79	26.2
80 to 84	17.9
85 and over	10.5
Female	59.2
Urban residence	94.4
Health problem	
Hypertension	60.2
Hyperlipidemia	44.5
Non-skin cancer	21.5
Osteoarthritis	20.3
Diabetes	19.4
Coronary artery disease	16.9
Atrial fibrillation	15.6
Chronic obstructive pulmonary disease	14.7
Stroke	9.1
Mental health condition	7.9
Congestive heart failure	6.8
Peripheral vascular disease	6.9
Dementia	3.2
Rheumatologic arthritis	1.8
End-stage renal disease	1.2
% living in a Census block where >50% of residents have less than a high school education	22.6
Median household income in Census block (\$)	51,736 (SD=22,142)
Mean % (SD) of Census block residents who are...	
Caucasian	80.8% (SD=20.2%)
African-American	4.7% (SD=11.6%)
Asian/Pacific Islander	6.1% (SD=10.2%)
Native American	1.9% (SD=3.1%)
Other race	9.8% (SD=13.6%)
Mean % (SD) of Census block residents who are Latino	19.6% (SD=23.1%)
Mean % (SD) of Census block residents who were not born in the US	15.0% (SD=12.4%)
Mean % (SD) of Census block residents who:	
Speak no English	1.6% (SD=3.1%)
Speak English poorly	3.8% (SD=4.7%)
Speak English well	94.6% (SD=7.3%)

*All beneficiaries had generic drug benefits in 2005, so the variation is limited to whether they had branded drug benefits and, if so, whether they were capped or non-capped

2005, who had a coverage gap starting in 2006) had the smallest increase over time in drug days supply. Increases were largest among groups relatively most likely to perceive an improvement in their drug benefits. The increase in days supply among individuals who had non-capped branded coverage in 2005 and generic-only gap coverage in 2006–2007 was similar but somewhat higher than the increase among those with capped branded coverage in 2005 but no gap coverage in 2006–2007.

Table 2. Adjusted Impact of Changes in Prescription Drug Benefits on Changes in Total Days Supply of Pills

Drug benefit changes		Entire study cohort (N=248,773)				High risk of gap entry (N=49,988)			
2005 (pre-Part D)	2006–2007 (post-Part D)	2005 to 2006		2005 to 2007		2005 to 2006		2005 to 2007	
		Change no. days (SE)	Δ^*	Change no. days (SE)	Δ^*	Change no. days (SE)	Δ^*	Change no. days (SE)	Δ^*
Branded medication coverage, no caps	No gap coverage	73.4 (1.9)	Ref.	227.2 (2.5)	Ref.	78.6 (5.0)	Ref.	268.5 (6.4)	Ref.
Branded medication coverage, with caps	No gap coverage	100.3 (1.2)	26.9 (2.3)	255.5 (1.6)	28.3 (3.0)	120.7 (3.9)	42.1 (6.5)	321.8 (5.8)	53.3 (8.3)
Branded medication coverage, no caps	Generic-only gap coverage	127.1 (2.8)	53.7 (3.4)	271.3 (3.6)	44.1 (4.5)	152.4 (8.1)	73.8 (9.74)	329.1 (10.4)	60.6 (12.4)
Generics-only coverage, no caps	No gap coverage	179.8 (1.7)	106.4 (2.6)	342.8 (2.2)	115.6 (3.4)	256.8 (5.0)	178.2 (7.4)	461.6 (6.4)	193.1 (9.5)

*Denotes difference-in-difference results

Notes: Estimates presented are mean predictions under each benefits scenario. All difference-in-differences were significant at $p < 0.0001$. Linear regression models also controlled for a constant term and the other covariates in Table 1. Sample sizes in each of the four coverage groups in the order listed above are 52,330, 114,049, 21,694, and 60,700 (entire study cohort) and 13,636, 19,447, 4,482, and 12,423 (cohort at high risk of gap entry). All coverage groups had generic drug coverage in 2005–2007.

As an example, on average the group experiencing likely declines in coverage increased their days supply over time by about 106 fewer days than the group that went from generic-only coverage in 2005 to branded coverage under Part D. This is equivalent to the latter group having enough pills to take a single prescription at the recommended dosage about 3½ months longer than the former group.

The changes between 2005 and 2007 look similar to the 2005–2006 changes in terms of the relative ranking of each benefit design group. Differences between coverage groups are larger among the subsample at high risk of gap entry than among the entire population, but again the relative rankings remain the same.

Adjusted Associations of Drug Benefit Changes with Changes in Drug Expenditures

Results for total drug expenditures were generally similar to those for days supply, except that among the reference group, the increases in drug expenditures over time are slightly smaller for the cohort at high risk of gap entry than for the overall population (Table 3). The pattern of findings was the same when limiting to the

portion of drug expenditures paid by the health plan (i.e., excluding the patient cost-sharing portion), but the estimates were higher because of shifting of costs from patients to health plans (Table 4). In results not shown here, we found that changes in out-of-pocket costs were of mixed signs and trivial magnitudes for the reference group (whose drug coverage may have actually worsened as a result of Part D); in contrast, the other three benefit design groups experienced significant reductions in out-of-pocket expenditures, with the largest reductions (around \$200–\$300) among the group that newly acquired branded drug coverage as a result of Part D.

Branded Drug Days Supply and Expenditures (eTables 3 and 4, available online)

Estimates for branded drugs show the same patterns as for all drugs, with the three groups with no gap coverage in 2006–2007 showing increases in drug utilization and expenditures over time that are increasingly larger among groups with increasingly less generous branded drug benefits prior to Part D. As before, the group that started with non-capped branded drug coverage but had generic drug coverage in the gap showed effects that were somewhere between the other groups.

Table 3. Adjusted Impact of Changes in Prescription Drug Benefits on Changes in Total Drug Expenditures

Drug benefit changes		Entire study cohort (N=248,773)				High risk of gap entry (N=49,988)			
2005 (pre-Part D)	2006–2007 (post-Part D)	2005 to 2006		2005 to 2007		2005 to 2006		2005 to 2007	
		Change In \$ (SE)	Δ^*	Change In \$ (SE)	Δ^*	Change In \$ (SE)	Δ^*	Change In \$ (SE)	Δ^*
Branded medication coverage, no caps	No gap coverage	\$130 (\$5)	Ref.	\$230 (\$8)	Ref.	\$129 (\$13)	Ref.	\$218 (\$18)	Ref.
Branded medication coverage, with caps	No gap coverage	\$200 (\$3)	\$70 (\$6)	\$325 (\$5)	\$95 (\$9)	\$286 (\$10)	\$157 (\$16)	\$433 (\$14)	\$215 (\$24)
Branded medication coverage, no caps	Generic-only gap coverage	\$270 (\$7)	\$140 (\$9)	\$378 (\$11)	\$148 (\$14)	\$369 (\$20)	\$240 (\$24)	\$440 (\$30)	\$222 (\$35)
Generics-only coverage, no caps	No gap coverage	\$302 (\$4)	\$172 (\$7)	\$434 (\$7)	\$204 (\$11)	\$471 (\$13)	\$342 (\$19)	\$619 (\$18)	\$401 (\$27)

*Denotes difference-in-difference results

Notes: Estimates presented are mean predictions under each benefits scenario. All difference-in-differences were significant at $p < 0.0001$. Linear regression models also controlled for a constant term and the other covariates in Table 1. Sample sizes in each of the four coverage groups in the order listed above are 52,330, 114,049, 21,694, and 60,700 (entire study cohort) and 13,636, 19,447, 4,482, and 12,423 (cohort at high risk of gap entry). All coverage groups had generic drug coverage 2005–2007.

Table 4. Adjusted Impact of Changes in Prescription Drug Benefits on Changes in Drug Expenditures Paid by Health Plan

Drug benefit changes		Entire study cohort (N=248,773)				High risk of gap entry (N=49,988)			
2005 (pre- Part D)	2006–2007 (post-Part D)	2005 to 2006		2005 to 2007		2005 to 2006		2005 to 2007	
		Change In \$ (SE)	Δ*	Change In \$ (SE)	Δ*	Change In \$ (SE)	Δ*	Change In \$ (SE)	Δ*
Branded medication coverage, no caps	No gap coverage	\$154 (\$4)	Ref.	\$216 (\$6)	Ref.	\$152 (\$9)	Ref.	\$225 (\$14)	Ref.
Branded medication coverage, with caps	No gap coverage	\$317 (\$2)	\$163 (\$4)	\$414 (\$4)	\$198 (\$7)	\$464 (\$7)	\$312 (\$12)	\$607 (\$11)	\$382 (\$18)
Branded medication coverage, no caps	Generic-only gap coverage	\$429 (\$5)	\$275 (\$7)	\$504 (\$9)	\$288 (\$11)	\$602 (\$15)	\$450 (\$18)	\$651 (\$22)	\$426 (\$27)
Generics-only coverage, no caps	No gap coverage	\$502 (\$3)	\$348 (\$5)	\$599 (\$5)	\$383 (\$8)	\$766 (\$9)	\$614 (\$18)	\$894 (\$14)	\$669 (\$20)

*Denotes difference-in-difference results

Notes: Estimates presented are mean predictions under each benefits scenario. All difference-in-differences were significant at $p < 0.0001$. Linear regression models also controlled for a constant term and the other covariates in Table 1. Sample sizes in each of the four coverage groups in the order listed above are 52,330, 114,049, 21,694, and 60,700 (entire study cohort) and 13,636, 19,447, 4,482, and 12,423 (cohort at high risk of gap entry). All coverage groups had generic drug coverage in 2005–2007.

Changes over time again tended to be larger among the (sicker) subgroup at high risk of gap entry.

Generic Drug Days Supply and Expenditures (eTables 5 and 6, available online)

The rank ordering of the estimated changes over time is different when examining generic drugs, and in some cases, expenditures decline over time. The entire study cohort had generic drug coverage both before and after Part D, so use of generics would be affected by the changes in benefit design only indirectly, either by substitution of newly covered branded drugs for generics¹⁸ or by cutting back on generics because of fear of gap entry. However, declines were not seen among the group most likely to substitute branded drugs (those with generic-only coverage in 2005, who acquired branded drug coverage following implementation of Part D).

“Ceiling” and “Floor” Effects

The magnitude of utilization changes may depend on the level at which the patient started, so we re-estimated each model controlling for the baseline value of the outcome. The estimates were almost identical to the originals. Calculating changes in drug expenditures as a percentage of the 2005 level showed similar patterns as well. For example, compared with the reference group, the other three benefit design groups had 2005–2006 increases in drug expenditures that were respectively 9, 15, and 20 percentage points higher (e.g., if the increase in drug expenditures was X% for reference patients, it was (X+20)% for those with no 2005 branded drug coverage).

DISCUSSION

Using longitudinal data for a large population of MAPD enrollees, we found that all beneficiaries increased their prescription drug use after Medicare Part D was implemented. This result was not surprising, since we analyzed continuously

enrolled patients who were getting older and sicker over time. However, the changes in utilization varied substantially, depending on how the individual’s drug benefits changed. Beneficiaries whose drug benefits may have actually become less generous after Part D had the smallest increases in drug utilization and expenditures, e.g., an increase of 73 days of drug supply between 2005 and 2006. For comparison, beneficiaries who acquired new branded drug coverage increased their drug supply by 180 days over the same time period. The differences in benefit design had an even stronger impact on patients at high risk of gap entry, who are the sickest and highest utilizers.

Our conclusions should be interpreted in light of several study limitations. We have data from only eight states, predominantly in the western half of the country, and formularies may vary across MAPD plans. Therefore, our findings may not be nationally generalizable. Nonetheless, the majority of MAPD enrollees are in for-profit plans,¹⁹ and the for-profit MAPD plan we studied was among the largest in the country.

We minimized bias from potential self-selection into benefit design by limiting the sample to the continuously enrolled, controlling for comorbidities based on medical claims and encounters, and defining our outcomes as changes over time, thereby implicitly controlling for differences in baseline levels of utilization and expenditures. We also performed sensitivity analyses allowing the trajectories of change over time to depend on the level of utilization at which the individual started. However, restricting the sample to those continuously enrolled may have limited the generalizability of the findings, as discontinuously enrolled patients were somewhat younger and healthier.

Although the four benefit design groups roughly follow an ordering in terms of changes in the generosity of coverage over time, this monotonicity does not necessarily hold in terms of all benefit design features, e.g., there are small differences in copayments that may partially offset other features, thereby biasing against finding the hypothesized effects. We also have no information on who participated in State Pharmaceutical Assistance Programs, although given the states and years we studied, we do not believe this was a notable issue for our sample.

It is conceivable that we have incomplete information on branded drugs in 2005 for individuals without branded drug

benefits. However, the MAPD provided strong financial incentives for patients to use their insurance cards when filling prescriptions for non-covered drugs, by allowing them to purchase the drugs at the discounted health plan price with a 100% coinsurance rate instead of paying the retail price. Extensive examination of the data suggested that branded drug claims were being submitted routinely (and paid 100% out of pocket) by patients without branded drug coverage.

CONCLUSIONS

Analysis of the impact of Medicare Part D should account for the heterogeneity in changes in benefit design that resulted from its implementation, including the possibility that an individual's coverage declined. Our study found significant differences in the associated changes in drug utilization and expenditures, depending on the extent to which beneficiaries had branded drug benefits before Part D, and whether they had gap coverage after Part D, an issue that was not examined in earlier studies of the effects of Part D¹⁰⁻¹².

Our findings suggest that patients whose 2005-2007 drug benefits were identical except for generic drug coverage in the gap had significantly different increases in drug utilization and expenditures over time. For example, between 2005 and 2006, those with gap coverage increased their drug utilization by about 54 more days supply, and their drug expenditures by about \$140 more, than those without gap coverage. These differences were even larger among the subset of patients at high risk of gap entry (74 days and \$240 respectively), a population of strong policy interest that was not examined in the earlier studies¹⁰⁻¹². Eliminating the Part D coverage gap for branded drugs would have increased these differences even more, so these estimates represent a lower bound on the likely effects of eliminating the gap under the ACA.

Future studies will examine how changes in drug benefit design resulting from Part D affected medication adherence⁵, medical utilization and expenditures, and avoidable hospitalizations.

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Conflict of Interest: In 2006, Dr. Ettner served as a one-time paid consultant for Lilly USA, LLC ("Lilly") to answer questions about the literature on the cost-effectiveness of antipsychotic medications. In 2010, she served as a one-time paid consultant to Lilly to review the initial study protocol and proposed questionnaires for the Multinational Observational Study Advancing an understanding of the factors associated with differential treatment response and the role of Insulin in the care of patients with Type 2 Diabetes: The MOSAIC Type 2 Diabetes Study.

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REFERENCES

1. Federal Register. Medicare Part D Final Rule, Medicare drug benefit effective CY 2006 (Title 1). Jan 28, 2005. 70: 4193-4585. Available at: <http://edocket.access.gpo.gov/2005/pdf/05-1321.pdf>. Accessed June 7, 2011.
2. **Frakt AB, Pizer SD.** A first look at the new Medicare prescription drug plans. *Health Aff (Millwood)*. 2006;25(4):W252-261.
3. **Hoadley J, Hargrave E, Merrell K, Cubanski J, Neuman T.** *Benefit design and formularies of Medicare Drug Plans: a comparison of 2006 and 2007 offerings*. Menlo Park, CA: Henry J. Kaiser Family Foundation. Nov. 2006. Available at: <http://www.kff.org/medicare/upload/7589.pdf>. Accessed: June 7, 2011.
4. **Summer L, Nemore P, Finberg J.** *Improving the Medicare Part D Program for the most vulnerable beneficiaries*. May 2007. Available at: http://www.commonwealthfund.org/publications/publications_show.htm?doc_id=484282. Accessed: June 7, 2011.
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(2):w305-316.
6. IMS. *IMS Special Report, Medicare Part D: The first year*. Plymouth Meeting, PA: IMS Health, Inc; 2008.
7. **Ketcham JD, Simon KI.** Medicare Part D's effects on elderly patients' drug costs and utilization. *Am J Manag Care*. 2008;14(11 Suppl):SP14-22.
8. **Yin W, Basu A, Zhang JX, Rabbani A, Meltzer DO, Alexander GC.** The effect of the Medicare Part D prescription benefit on drug utilization and expenditures. *Ann Intern Med*. 2008;148(3):169-177.
9. **Lichtenberg FR, Sun SX.** The impact of Medicare Part D on prescription drug use by the elderly. *Health Aff (Millwood)*. 2007;26(6):1735-1744.
10. **Zhang Y, Donohue JM, Lave JR, O'Donnell G, Newhouse JP.** The effect of Medicare Part D on drug and medical spending. *N Engl J Med*. 2009;361(1):52-61.
11. **Zhang Y, Lave JR, Newhouse JP, Donohue JM.** How the Medicare Part D Drug Benefit Changed the Distribution of Out-of-Pocket Pharmacy Spending Among Older Beneficiaries. *J Gerontol B Psychol Sci Soc Sci*. Dec 14 2009.
12. **Zhang Y, Lave JR, Donohue JM, Fischer MA, Chernew ME, Newhouse JP.** The impact of Medicare Part D on medication adherence among older adults enrolled in Medicare-Advantage products. *Med Care*. 2010;48(5):409-417.
13. **Doshi JA, Polsky D.** Drug benefit generosity and essential medication use among Medicare-eligible retirees. *Am J Manag Care*. 2007;13(7):425-431.
14. **Pauly MV.** Medicare drug coverage and moral hazard. *Health Aff (Millwood)*. 2004;23(1):113-122.
15. **Neuman P, Cubanski J.** Medicare Part D update—lessons learned and unfinished business. *N Engl J Med*. 2009;361(4):406-414.
16. **Ettner SL, Steers N, Duru OK, et al.** Entering and exiting the Medicare part D coverage gap: role of comorbidities and demographics. *J Gen Intern Med*. 2010;25(6):568-574.
17. HCUP. *Healthcare Cost and Utilization Project. Clinical Classifications Software (CCS) for ICD-9-CM*: Agency for Healthcare Research and Quality. 2008. Available at: <http://hcup-us.ahrq.gov/toolssoftware/ccs/ccs.jsp#download>. Accessed: June 7, 2011.
18. **Zhang JX, Yin W, Sun SX, Alexander GC.** The impact of the Medicare Part D prescription benefit on generic drug use. *J Gen Intern Med*. 2008;23(10):1673-1678.
19. **Schneider EC, Zaslavsky AM, Epstein AM.** Quality of care in for-profit and not-for-profit health plans enrolling Medicare beneficiaries. *Am J Med*. 2005;118(12):1392-1400.