Closing the Medicare Part D Coverage Gap:
Effects on Drug Utilization, Expenditures, and Access to Drugs

By

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ABSTRACT

The standard Medicare Part D benefit structure contains a gap in coverage (or so-called "doughnut hole") which requires beneficiaries to pay 100% of the cost for prescription drugs until they reach the catastrophic coverage phase. This coverage gap has been linked to a financial burden for beneficiaries resulting in poor medication adherence and other cost-related access problems. Under the 2010 Affordable Care Act (ACA) reform, the coverage gap has been gradually phasing out since 2011 such that beneficiaries will only pay 25% of drug costs by 2020. This study evaluated the impact of closing the coverage gap under the ACA by conducting three separate studies using data from the 2008-2015 Medicare Current Beneficiary Survey. Outcomes assessed included the utilization of and expenditures for prescription drugs, as well as cost-related access problems.

Chapter 3 (Manuscript #1) analyzes trends in the distribution of beneficiaries in each benefit phase, prescription drug utilization, and expenditures among Part D beneficiaries not receiving the Low-Income Subsidy (LIS). After the ACA, the proportion of beneficiaries reaching the catastrophic coverage threshold increased (from 4% in 2010 to 6% in 2015), and they reached the threshold earlier in the year. The overall number of 30-day drug fills also increased after the ACA, although no significant changes in the number of 30-day drug fills were seen among those reaching the catastrophic coverage threshold. Total drug spending steadily increased after the ACA, with the largest increase seen in those reaching the catastrophic threshold; however, out-of-pocket spending significantly decreased among all beneficiaries (17% decrease in 2015 compared to 2009).

Chapter 4 (Manuscript #2) evaluates the effects of the ACA coverage gap reform on drug utilization and expenditures using a difference-in-differences study design. Over the first five years after implementation of the ACA, out-of-pocket drug spending significantly decreased among non-LIS beneficiaries (treatment) relative to LIS beneficiaries (control), with growing decreases over time (average decreases of $41 in 2011 versus $135 in 2015). This was particularly noticeable among those who reached the coverage gap but not the catastrophic threshold. Despite seemingly large reductions in cost-sharing in the coverage gap, there were no significant changes in the number of 30-day drug fills and total drug spending after the ACA reform between non-LIS and LIS beneficiaries.

Chapter 5 (Manuscript #3) evaluates the effects of the ACA coverage gap reform on cost-related access problems among beneficiaries using a difference-in-differences study design. Cost-related access problems were estimated by the likelihood of having cost-related nonadherence (CRN) or the adoption of drug cost-reduction strategies (CRS) by beneficiaries. Compared to LIS beneficiaries, no significant changes in CRN were seen among non-LIS beneficiaries after the ACA; furthermore, the likelihood of adopting CRS increased by 4 percentage points for non-LIS beneficiaries relative to LIS beneficiaries.

Although the ACA reform has helped reduce out-of-pocket drug costs for beneficiaries by gradually reducing the beneficiary cost-sharing rate in the Part D coverage gap, the significant reduction in cost-sharing rate did not translate into an increased use of prescription drugs or resolved cost-related access problems for beneficiaries. Additionally, this study provides evidence of increased Part D spending, which has been a growing concern for the Medicare program. The findings of this study provide empirical evidence on the effects of closing the Part D coverage gap and address gaps in the limited existing literature. Overall, although the ACA

decreased out-of-pocket drug costs, this study suggests additional initiatives will be needed to provide better protection against the cost of prescription drugs for Part D beneficiaries.

DOCUMENT ORGANIZATION

This dissertation consists of eight chapters which organize the evaluation of the impact of the ACA Medicare Part D coverage gap reform. Chapter 1 provides the background and significance of this study with gaps in the existing literature. Chapter 2 describes the objectives, study questions, and hypotheses. Chapters 3, 4, and 5 contain three separate manuscripts to address the three objectives of this dissertation, following the format of journals targeted for submission. Chapter 3 addresses trends in the distribution of beneficiaries entering each benefit phase and the utilization of and expenditures for prescription drugs from 2008 to 2015. Chapter 4 focuses on changes in the use of and expenditures for prescription drugs before and after the ACA between non-LIS and LIS beneficiaries. Chapter 5 addresses changes in the likelihood of having cost-related medication nonadherence and adopting drug cost-reduction strategies among Part D beneficiaries before and after the ACA. Finally, Chapter 6 provides a summary of all findings of the three studies and presents policy implications and conclusions, followed by references in Chapter 7 and appendices in Chapter 8.

I. INTRODUCTION

Medicare Part D is a voluntary outpatient prescription drug benefit program Medicare beneficiaries that went into effect in 2006 under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA).[1] Since 2006, all Medicare beneficiaries have had access to prescription drug coverage though Part D plans offered by private companies approved by the federal government. This coverage is provided either through stand-alone prescription drug plans (PDPs) or Medicare Advantage prescription drug plans (MA-PDs).[2] In 2017, 59% of Part D enrollees were in PDPs, and 41% were in MA-PDs.[3] These Part D plans are required to offer a defined standard benefit or an alternative benefit deemed equal in value ("actuarially equivalent").[4] Additionally, a Low-Income Subsidy (LIS) program is available for beneficiaries with limited income and assets, which provides support for Part D plan premium and cost-sharing.[5] In 2017, 42.5 million (72.5%) Medicare beneficiaries were enrolled in Part D plans, of which 12.2 million (29%) received the LIS.[3]

The standard Medicare Part D benefit includes four coverage phases: the deductible, initial coverage period, coverage gap, and catastrophic phases. The cost of enrollees and plans depends on which coverage phase the beneficiary is in. A unique feature of the Part D benefit is the coverage gap (also known as the "doughnut hole"), where enrollees are required to pay 100% of their drug costs until they incur spending high enough to reach the catastrophic threshold. In 2015, 10.7 million (26%) Part D enrollees had spending high enough to reach the coverage gap; of those, 3.6 million (9%) incurred additional spending high enough to reach the catastrophic coverage threshold.[3]

Although the coverage gap in the Part D plan has resulted in lower total drug costs among Part D beneficiaries, it has unfavorably impacted beneficiaries' out-of-pocket drug costs, drug use, and medication adherence.[6,7] The entry of Part D beneficiaries into the coverage gap has been associated with substantially increased out-of-pocket drug costs by as much as 89%, decreases in drug use, and cost-related medication nonadherence (CRN) such as discontinuing a medication, delaying prescription filling, skipping doses, or switching to a different medication with lower cost.[6,7] This CRN can negatively affect beneficiaries' health outcomes and increase the risk of more serious health consequences over time. Ultimately, it could result in higher costs for other parts of the Medicare program due to beneficiaries' use of comparatively more expensive medical services such as hospitalizations or emergency room visits.[8–10]

In response to these concerns, the Patient Protection and Affordable Care Act (ACA) of 2010 included a provision that initiated a ten-year process to close the Part D coverage gap, by gradually phasing down the coinsurance rate in the gap from 100% in 2010 to 25% by 2020.[11] The law provided a one-time tax-free rebate of $250 to Part D enrollees who reached the coverage gap in 2010. Beginning in 2011, manufacturers have been required to provide a 50% discount on the price of brand-name drugs in the gap; starting in 2013, insurers have been required to bear 2.5% of drug costs in the gap, which will gradually increase to 25% by 2020. For generic drugs, insurers have been responsible for paying 7% of drug costs in the gap starting in 2011, increasing gradually every year up to 75% by 2020. As a result, Part D beneficiaries will be responsible for only 25% of the costs of their drugs in the coverage gap in 2020 after full implementation of the ACA reform.

While there is a fair amount of previous study on the effects of the Part D coverage gap,[6,7] relatively few studies have evaluated the effects of ACA provision of closing the Part D

coverage gap.[12–17] These studies have indicated that beneficiaries' out-of-pocket costs in the coverage gap have decreased after the implementation of the ACA provision. However, there are still several limitations of the existing studies that indicate research gaps. Limitations include that they (1) only included specific populations such as those taking specialty drugs[16] or those with certain conditions such as diabetes[13] or cancer[14,15,17]; (2) conducted descriptive analyses without a rigorous study design;[15–17] (3) used survey data with limited drug claims,[12] and (4) have not evaluated the effects on beneficiaries' cost-related access problems for prescription drugs.

By addressing these gaps in the existing literature, this study evaluates the key provision of the ACA designed to reduce beneficiaries' cost-sharing in the Part D coverage gap. Using recent nationwide data on the Medicare population, this study examines the effects of the ACA coverage gap reform on prescription drug use, expenditures, and cost-related access problems through three separate studies.

The following sections provide the background of this study. Section 1.1 offers a general overview of the Medicare Part D program. Section 1.2 discusses the impact of the Part D coverage gap, with a focus on studies prior to the ACA of 2010. Section 1.3 provides an overview of the ACA provisions intended to close the coverage gap in Part D plans, which is the main policy change that this study focuses on. Section 1.4 discusses the impact of closing the coverage gap under the ACA by summarizing the limited existing literature. Finally, the research gaps to be addressed in this study are presented in Section 1.5.

1.1. Medicare Part D Prescription Drug Benefit

Medicare is the federal health insurance program for people ages 65 and older or people under age 65 with permanent disabilities or end-stage renal disease.[18] There are two main ways

to get Medicare coverage: Original Medicare (Part A and Part B) or a Medicare Advantage Plan (MA Plan or Part C).[19] Under Original Medicare, most people ages 65 and older are entitled to Part A, which covers inpatient hospital stays, care in a skilled nursing facility, hospice care, and some home health care. Most of the Part A enrollees elected to enroll in Part B to get coverage for doctors' services, outpatient care, medical supplies, and preventive services. In contrast, Part C plans provide all of the Part A and Part B benefits with reduced cost sharing and/or additional benefits, and are administered by private companies that contract with Medicare.

Medicare also provides prescription drug coverage through the Part D program.[19] On December 8, 2003, President George W. Bush (R) signed the Medicare Prescription Drug, Improvement, and Modernization Act (P.L. 108-173), which amends Title XVIII (Health Insurance for the Aged and Disabled) of the Social Security Act to authorize Medicare coverage of outpatient prescription drugs under Medicare Part D, starting in 2006.[2] Part D drug benefits are offered through private insurers approved by the federal government.[20] The private insurers administer drug benefits either through stand-alone prescription drug plans (PDPs) or Medicare Advantage-Prescription Drug plans (MA-PDs).[20] PDPs add prescription drug coverage to Original Medicare, some Medicare Cost Plans, some Medicare Private-Fee-for-Service Plans, and Medicare Medical Savings Account Plans.[20] MA-PDs provide all of the Part A and Part B benefits with added prescription drug coverage.[20]

All Part D Medicare PDPs and MA-PD plans must offer qualified prescription drug coverage, which is defined as either (1) standard prescription drug coverage or (2) alternative prescription drug coverage (Table I-1).[4,21] The Centers for Medicare and Medicaid Services (CMS) has defined two types of coverage for plans that follow the standard prescription drug coverage approach: (1a) defined standard coverage; and (1b) actuarially equivalent standard

coverage.[21] Defined standard coverage refers to the standard benefit structure with (1) an annual deductible; (2) 25% coinsurance for actual costs above the annual deductible but at or below an initial coverage limit; (3) gap coinsurance percentages for brand-name and generic drugs during the coverage gap; and (4) catastrophic coverage with nominal cost-sharing for the remainder of the coverage year once an beneficiary's costs exceed the annual catastrophic threshold. Secondly, actuarially equivalent standard coverage allows Part D plans to substitute certain cost-sharing requirements in defined standard coverage, as long as the cost-sharing structure is actuarially equivalent to an average expected coinsurance in the defined standard coverage.

Table I-1. Medicare qualified prescription drug coverage.[21]

	Types of coverage that are included
1. Standard Prescription Drug Coverage	(1a) Defined standard coverage
	(1b) Actuarially equivalent standard coverage
2. Alternative Prescription Drug Coverage	(2a) Basic alternative coverage
	(2b) Enhanced alternative coverage

Alternative prescription drug coverage refers to coverage that modifies the defined standard coverage and includes the following two types: (2a) basic alternative coverage and (2b) enhanced alternative coverage.[21] Basic alternative coverage is actuarially equivalent to defined standard prescription drug coverage combined with features such as a reduction in the deductible, changes in cost-sharing (e.g., benefit designs using tiered copayments or coinsurance), or a modification of the initial coverage limit. Enhanced alternative coverage refers to the alternative coverage whose value exceeds that of defined standard coverage, which is only possible if a Part D sponsor offers supplemental benefits in addition to its basic coverage.

Supplemental benefits include a reduction in the cost-sharing in the coverage gap or coverage for supplemental drugs.

Although Medicare offers prescription drug coverage to all Medicare beneficiaries, beneficiaries can choose whether or not to get drug coverage through Medicare when they are first eligible.[20] In 2017, 42.5 million individuals (72.5% of all Medicare beneficiaries) were enrolled in Part D plans, where 59% were in PDPs and 41% were in MA-PDs.[3] Beneficiaries may owe a late enrollment penalty if they do not have either creditable prescription drug coverage (i.e., prescription drug coverage from an alternative source such as an employer or union that is at least as generous as Medicare's standard prescription drug coverage) or Low-Income Subsidy for any continuous period of 63 days or more after their initial enrollment period is over.[20] The cost of the penalty depends on how long the beneficiary went without Part D or creditable prescription drug coverage.[22]

Medicare Part D has a monthly premium, which varies across plans, regions, and enrollees' income (e.g., higher-income beneficiaries may pay more).[23] The 2018 Part D national base beneficiary premium is $35.02 per month.[24] The average monthly premium remained relatively flat over time, where it has been near $30 per month since 2010 (

Figure ***I-1***).[3] On average, premiums were higher for beneficiaries enrolled in PDPs than those enrolled in MA-PDs. If beneficiaries are subject to the late enrollment penalty, it will be added to the premium.[23] The penalty will be calculated by multiplying 1% of the national base beneficiary premium times the number of uncovered months that the beneficiary did not have Part D or creditable prescription drug coverage.[22]

Figure I-1. Changes in average Part D premiums (weighted by enrollment), 2007-2017.[3]

	Average monthly premium weighted by enrollment (in dollars)						Average annual growth rate 2010–2017
	2007	2010	2014	2015	2016	2017	
All plans (any coverage)	$23	$30	$29	$30	$31	$32	1.0%
PDPs							
Basic coverage	24	34	30	28	29	31	–1.1
Enhanced coverage	40	50	49	48	53	54	1.2
All types of coverage	27	37	38	37	39	41	1.2
MA–PDs, including SNPs*							
Basic coverage	17	26	25	21	22	26	0.3
Enhanced coverage	9	13	13	16	17	18	4.6
All types of coverage	10	14	16	18	18	19	4.3

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), SNP (special needs plan). The premium amounts do not include monthly adjustment amounts paid by beneficiaries who are subject to income-related premiums or the late enrollment penalty. Figures exclude employer-only plans, plans offered in U.S. territories, 1876 cost plans, demonstrations, and Part B–only plans. The average premium for any PDP coverage increased, on average, between 2010 and 2017 despite a decrease in the average for basic PDPs because, over time, more beneficiaries enrolled in PDPs with enhanced coverage.
*Reflects the portion of Medicare Advantage plans' total monthly premium attributable to Part D benefits for plans that offer Part D coverage. MA–PD premiums reflect Part C rebate dollars that were used to offset Part D premium costs.

Source: MedPAC analysis of CMS landscape, plan report, and enrollment data.

Standard Benefit Structure of Medicare Part D

In this section, a standard drug benefit refers to a Part D plan that follows the "Defined Standard Coverage", which has been used as a fixed point of comparison for all Part D sponsors when developing their own drug benefits such as actuarially equivalent standard coverage or basic/enhanced alternative coverage.[21] The standard drug benefit structure consists of four coverage phases: the annual deductible, initial coverage period, coverage gap, and catastrophic phases. The costs to enrollees and plans depend on which coverage phase the beneficiary is in. Each new phase begins once the enrollee's spending for prescription drugs has reached a certain threshold. The amounts of the annual deductible, initial coverage limit, out-of-pocket threshold,

and beneficiary cost-sharing after the annual out-of-pocket threshold is met have been adjusted annually by the rate of Part D per capita spending growth (Figure I-2).[25]

In 2006, the Part D standard benefit had a $250 annual deductible, where enrollees need to pay 100% of the drug costs (Figure I-2).[26] Next, in the initial coverage period the coinsurance rate was 25% up to an initial coverage limit of $2,250 in total drug costs, followed by a coverage gap (also known as the "doughnut hole"). During the coverage gap, enrollees paid 100% of drug costs until their out-of-pocket spending reached $3,600 or the total drug costs reached $5,100 (i.e., the catastrophic coverage threshold). After enrollees reached the catastrophic coverage threshold, enrollees paid either 5% of drug costs or $2 for generic and $5 for brand-name drugs. Medicare paid the remaining 95% of the drug costs.

Figure I-2. Medicare Part D Standard Benefit Parameters, 2006-2018.[25]

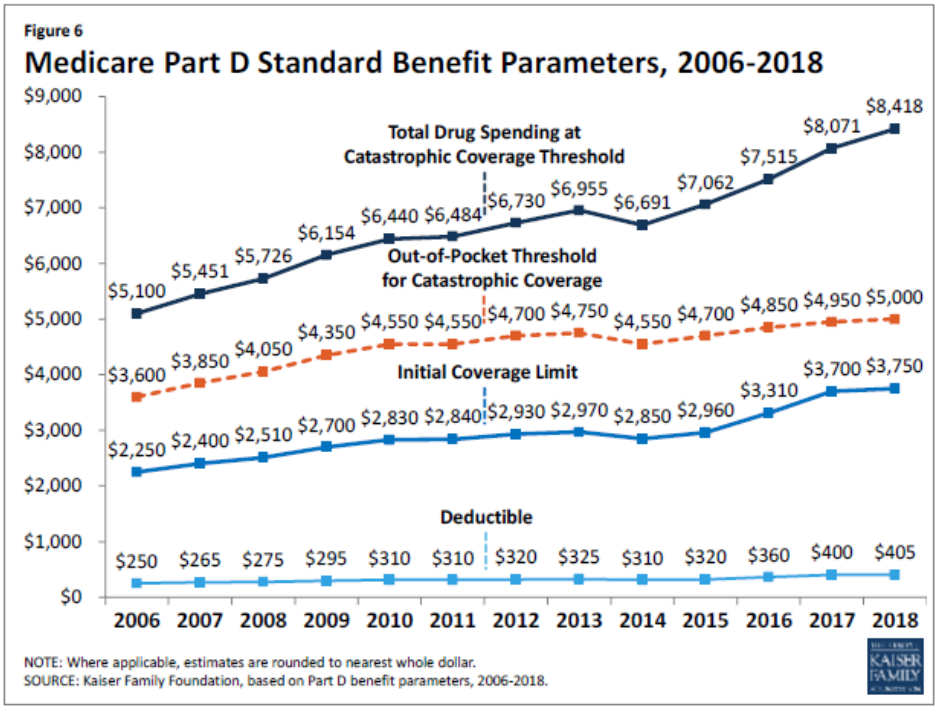
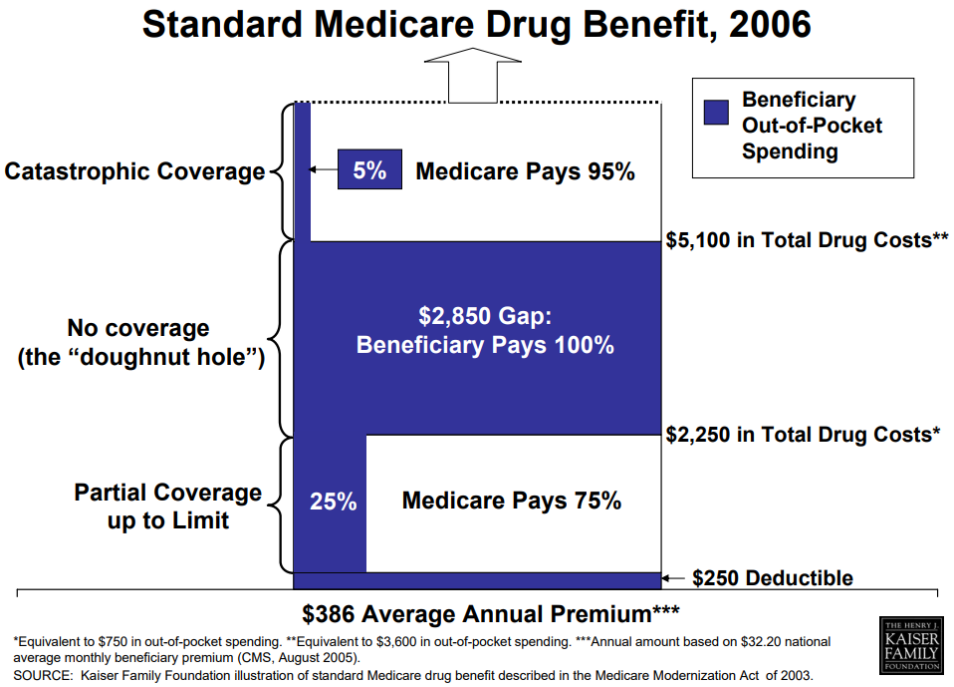


Figure I-3. Standard Medicare Prescription Drug Benefit, 2006.[26]



As described earlier, all Part D plans must offer either the standard drug benefit or an alternative drug benefit that is at least as generous as that provided under the standard drug benefit, such that plans can vary in terms of specific benefit design, formularies, cost-sharing amounts, and cost-containment strategies (e.g., prior authorization, quantity limits, or step therapy).[25] Although no plans in 2018 follow the standard benefit structure, 46% of plans offer equivalent benefits and 54% offer more generous benefits. [25] In 2018, 63% of all PDPs charged a deductible, with 52% charging the full amount ($405).[25] In the initial coverage period, most plans have shifted to varying coinsurance amounts or charging tiered copayments rather than a uniform 25% coinsurance rate.[25] Most PDPs (65%) do not offer additional gap coverage in 2018 beyond the standard benefit; when such coverage was offered, it has typically been limited to generic drugs only.[25] Additionally, many PDPs use specialty tiers for high-cost medications, which have higher out-of-pocket costs.[25]

Low-Income Subsidy (LIS) in Medicare Part D

Eligible beneficiaries who have limited income and assets may qualify for the Medicare Low-Income Subsidy (LIS) program, which provides assistance in paying for their Medicare Part D monthly premium, annual deductible, coinsurance, and copayments. The LIS pays the full cost of the Part D premium and reduces cost sharing for eligible beneficiaries as long as they enroll in PDPs designated as "benchmark" plans with a premium below the specified amount for the beneficiary's state.[5] However, more than 1 million LIS beneficiaries (10% of all LIS beneficiaries in 2018) pay Part D premiums because they don't enroll in the right plans.

Those eligible for both Medicare and full Medicaid benefits (full-benefit dual eligible or dual eligible), those receiving Supplemental Security Income (SSI), and those enrolled in the Medicare Savings Programs (MSP) are deemed eligible for the LIS (also called "deemed eligible"); they automatically qualify and do not have to apply separately.[27] Other beneficiaries must apply for the LIS and they may qualify for full or partial subsidies by the Social Security Administration (SSA) or their State Medicaid office if their income and assets are below specified levels.[27]

Detailed information on income and asset eligibility thresholds for 2018 are described in **Figure *I-4*** (adapted from the National Council on Aging, 2018).[28] Full benefit dual eligibles who reside in an institution pay no premiums, deductible, copayments, or coinsurance; those who do not reside in an institution with income less than 100% of the federal poverty level (FPL) have copayments up to $1.25 for generics and $3.70 for brand-name drugs in 2018. Medicare beneficiaries with income below 135% of FPL and resources of $7,560 for an individual or $11,340 for a couple will pay no premium, no deductible, and copayments up to $3.35 for

generics and $8.35 for brand-name drugs Once beneficiaries who are qualified for the full LIS reach the catastrophic phase, they pay nothing for their prescriptions.

Beneficiaries with income below 135% of FPL and resources between $7,560 to $12,600 for an individual and $11,340 to $25,150 for a couple have no premium, but have deductibles of up to $83 and cost-sharing of up to 15% coinsurance. Those with income between 135% and 150% of FPL and resources of up to $12,600 individual or $25,150 for a couple have a sliding-scale premium based on income, and deductibles and cost-sharing is the same with those with income below 135% of FPL. Once they reach the catastrophic phase, they have copayments of up to $3.35 for generics and $8.35 for brand-name drugs.

Figure I-4. Part D Low-Income Subsidy Eligibility and Coverage Chart, 2018.[28]

Full Low-Income Subsidy (LIS)/Extra Help (2018) - 48 STATES + DC							
Beneficiary Group	**Annual Income Eligibility Requirement**	**Monthly Income Eligibility Requirement**	**Asset Eligibility Requirement**	**Need to apply for LIS?**	**Monthly Premium**	**Annual Deductible**	**Copay/Coinsurance Plan's Formulary Drugs**
Full-Benefits Duals: Institutionalized or receiving Home and Community-based Services	Meet State Medicaid financial eligibility	Meet State Medicaid financial eligibility	Meet State Medicaid financial eligibility	No, receive it automatically	No	No	None
Full-Benefit Duals: income ≤ 100% FPL	Meet State Medicaid/MSP financial eligibility	Meet State Medicaid/MSP financial eligibility	Meet State Medicaid/MSP financial eligibility	No, receive it automatically	No	No	*Copay:* $1.25 generic /$3.70 brand *Catastrophic Copay:* $0
Full-Benefit Duals: income > 100% FPL	Meet State Medicaid/MSP financial eligibility	Meet State Medicaid/MSP financial eligibility	Meet State Medicaid/MSP financial eligibility	No, receive it automatically	No	No	*Copay:* $3.35 generic/$8.35 brand *Catastrophic Copay:* $0
Non-duals: income ≤ 135% FPL AND lower asset levels	Single: $16,389/$16,629* Couple: $22,221/$22,461*	Single: $1,366/$1,386* Couple: $1,852/$1,872*	Single: $7,560/$9,060** Couple: $11,340/$14,340**	No, if receiving SSI; otherwise, yes	No	No	*Copay:* $3.35 generic/$8.35 brand *Catastrophic Copay:* $0
Partial Low-Income Subsidy (LIS)/Extra Help (2018) - 48 STATES + DC							
Beneficiary Group	**Income Eligibility Requirement**	**Monthly Income Eligibility Requirement**	**Asset Eligibility Requirement**	**Need to apply for LIS?**	**Monthly Premium**	**Annual Deductible**	**Copay/Coinsurance Plan's Formulary Drugs**
Non duals with income ≤ 135% FPL AND assets between lower and higher limits	Single: $16,389/$16,629* Couple: $22,221/$22,461*	Single: $1,366/$1,386* Couple: $1,852/$1,872*	Single: between $7,560/$9,060 - $12,600/$14,100** Couple: between $11,340/$14,340 - $25,150/$28,150**	Yes	No	$83	*Coinsurance:* 15% *Catastrophic Copay:* $3.35 generic/$8.35 brand
Non duals with income between 135-150% FPL	Single: $18,210/$18,450* Couple: $24,690/$24,930*	Single: $1,518/$1,538* Couple: $2,058/$2,078*	Single: $12,600/$14,100** Couple: $25,150/$28,150**	Yes	Yes, Sliding scale	$83	*Coinsurance:* 15% *Catastrophic Copay:* $3.35 generic/$8.35 brand

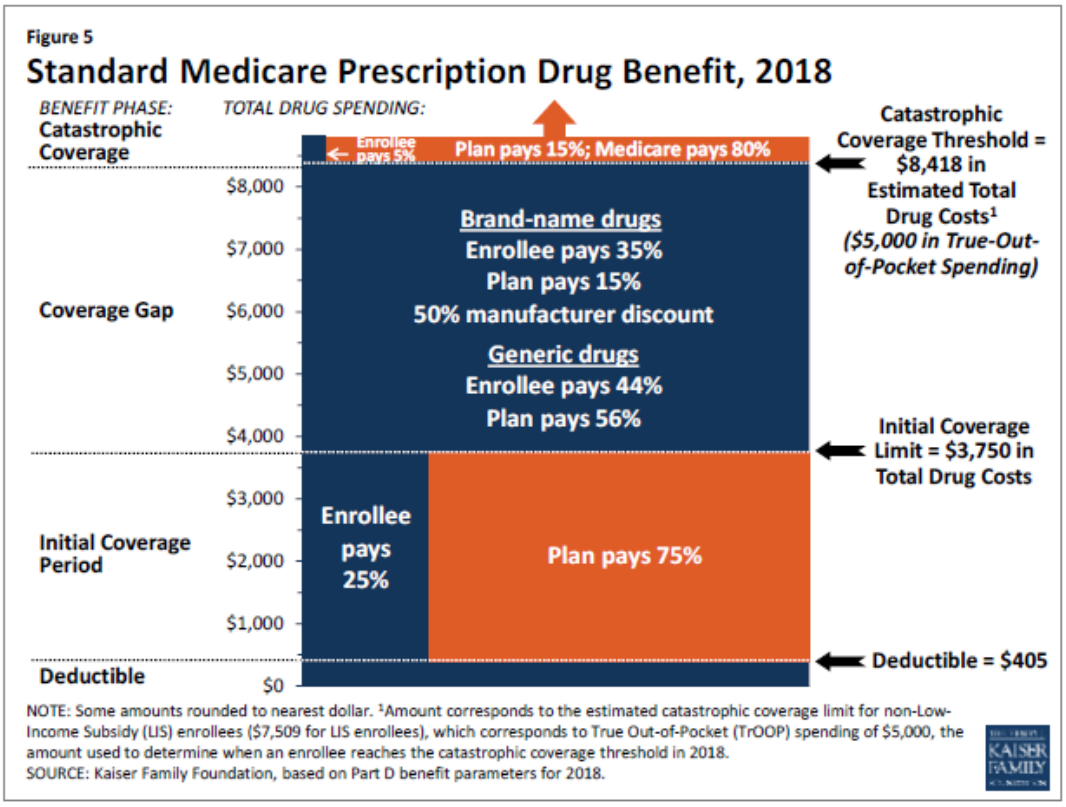
* Income amounts reflect threshold without/with the $20 monthly income disregard (annually = $240); income is rounded to the nearest whole dollar.
** Asset limits include amount without/with $1,500/person burial allowance.

Current Medicare Part D Enrollment, Premiums, and Cost-sharing

Of 60 million people with Medicare in 2018, approximately 43 million (72%) have prescription drug coverage under a Medicare Part D plan; among them, 58% are in PDPs, and the remainder are in MA-PDs.[5] Three firms (United Health, Humana, and CVS Health) account for 55% of all Part D enrollees (both PDPs and MA-PDs) and 67% of all stand-alone PDP enrollees in 2018.[5]

The 2018 Part D standard drug benefit (i.e., defined standard coverage) structure is described in **Figure *I-5*** (adapted from the Kaiser Family Foundation, 2017).[25] The annual deductible is $405. After reaching the deductible, in the initial coverage period the coinsurance rate is 25% up to an initial coverage limit of $3,750 in total drug costs, followed by the coverage gap. During the coverage gap, manufacturers provide 50% discounts on the price of brand-name drugs (which still count towards enrollees' out-of-pocket spending) and enrollees pay 35% of plans' costs. For generic drugs, enrollees pay 44% of plans' costs and plans pay the rest of the costs. After enrollees reach the catastrophic coverage threshold, enrollees pay either 5% of drug costs or $3.35 for generics and $8.35 for brand-name drugs. Medicare pays 80% of the drug costs and plans pay 15%. The coinsurance rate in the coverage gap has decreased after the implementation of the Patient Protection and Affordable Care Act (ACA), which is described in more detail in the following section.

Figure I-5. Standard Medicare Prescription Drug Benefit, 2018.[25]



The average monthly premium for stand-alone PDPs is $41 in 2018, but varies widely across PDPs.[5] Among the most popular PDPs, the premiums range from $20 for Humana Walmart Rx to $84 for AARP Medicare Rx Preferred.[5] The average MA-PD premium is $34 per month, which includes Part D and other benefits; this relatively lower cost reflects the ability of MA-PD sponsors to use rebate dollars from Medicare payments for benefits covered under Part A and B to lower the Part D premiums.[5]

Among all Part D enrollees, nearly half (45%) are in plans with no deductible, 29% are in plans charging the standard deductible amount of $405, and 26% face a partial deductible amount.[5] The weighted average Part D deductible is higher among PDP enrollees than MA-PD enrollees ($213 vs $129).

The vast majority of Part D plans use tiered cost sharing with five tiers, which has been the most common type since 2013.[29] The five-tier design typically includes tiers for preferred generics, non-preferred generics, preferred brands, non-preferred drugs (including a mix of brands and generics), and specialty drugs.[29] For the preferred generics, approximately 20% of Part D enrollees have a $0 copayment; the median copayment is $1 for PDP enrollees and $3 for MA-PD enrollees.[5] For non-preferred generics, the median cost sharing is $6 for PDPs and $12 for MA-PDs.[5] A majority of Part D plans charge copayments for preferred brand-name drugs, where the median copayment is $37 for PDPs and $45 for MA-PDs.[5] For non-preferred drugs, nearly all PDP enrollees pay coinsurance, where half of them pay between 40% and 50%.[5] However, most MA-PD enrollees pay a copayment between $90 and $100.[5] For specialty drugs, more than 4 in 10 Part D enrollees have plans charging the maximum 33% coinsurance rate for 2018, where a specialty drug is defined by CMS as those that cost at least $670 per month (i.e., $670 specialty-tier cost threshold).[5,30]

In 2017, more than 12 million Part D enrollees (29% of Part D enrollees) received low-income subsidies (LIS) for Part D coverage.[3] Of those, nearly 8 million were dual eligibles and the remainders were qualified through the Medicare Savings Program, Supplemental Security Income program, or direct application to the Social Security Administration. Compared to non-LIS enrollees, LIS enrollees were more likely to be female, under age 65, and African American, Hispanic or Asian.

1.2. Impact of Part D Coverage Gap (before the ACA)

After the implementation of Medicare Part D in 2006, enrollees have experienced increased drug utilization and decreased out-of-pocket costs for prescription medications.[31,32]

However, the lack of coverage in the coverage gap (i.e., doughnut hole) has raised concerns that it may have an adverse effect on drug utilization and medication adherence due to the relatively higher cost-sharing.[6,7] An estimated 3.4 million Part D enrollees (about 14% of all Medicare enrollees) enter the coverage gap in any given year, where enrollees with chronic conditions taking multiple medications each day are likely to fall into the doughnut hole at some time during the year.[33] Furthermore, a number of enrollees who entered the coverage gap or anticipate reaching the coverage gap stop taking at least some of their drugs during this period.[33] Previous studies have consistently shown that entry into the coverage gap is been linked to adverse effects on drug utilization and cost-related medication nonadherence (CRN).[6,7] Hence, the Patient Protection and Affordable Care Act (ACA) was enacted in 2010 to gradually reduce beneficiaries' cost-sharing while in the coverage gap by 2020.[11]

This section describes the effects of the Part D coverage gap before the ACA, and then the effects of closing the Part D coverage gap under the ACA will follow in the next section.

Part D Enrollees Reaching the Gap

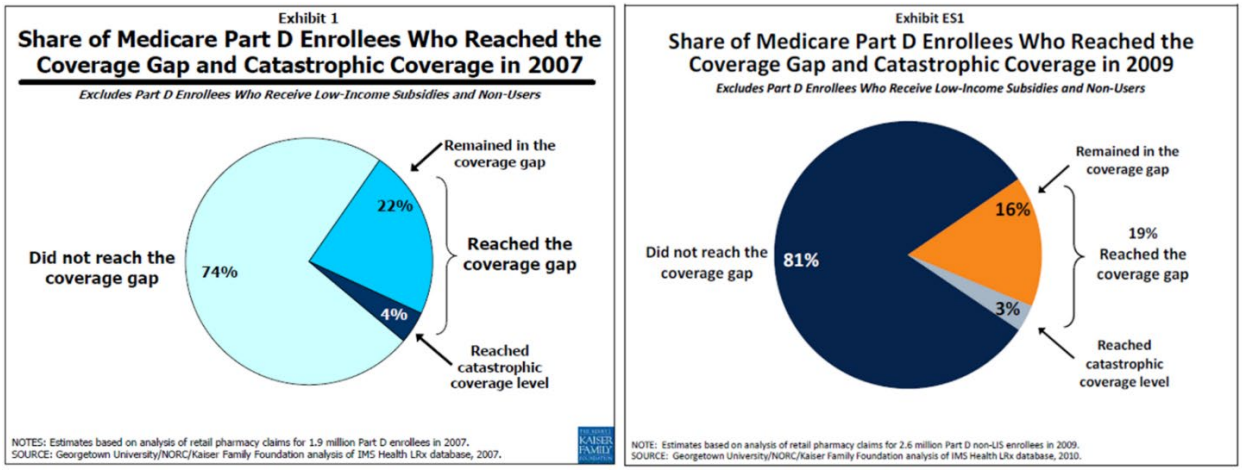
The estimates of the proportion of Part D enrollees reaching the coverage gap widely varies across studies depending on the data sources and study periods used, and range from 6% to 26%.[8,34] Comprehensive information from nationwide patient-level retail pharmacy claims data for Part D enrollees found that among Part D non-LIS enrollees who used prescription drugs in 2007, 26% reached the coverage gap, in which 4% reached catastrophic coverage while 22% remained in the coverage gap (**Figure *I-6***).[8] When applying these estimates to the total population of Part D enrollees and adjusting for several factors such as total LIS enrollment, the number of beneficiaries taking no drugs, and the number of beneficiaries with full gap coverage,

approximately 3.4 million beneficiaries (14% of total Part D enrollees) reached the coverage gap in 2007.[8]

In 2009, nearly one in five (19%) Part D non-LIS enrollees who filled at least one prescription had spending high enough to reach the coverage gap (Figure 6).[11] Among them, only 3% had enough spending to qualify for catastrophic coverage, while 16% remained in the gap for the rest of the year.[11] Among the entire population of Part D enrollees, more than 3.4 million beneficiaries (12%) reached the coverage gap.[11]

When compared to the estimates in 2007, the share of Part D non-LIS enrollees reaching the coverage gap has decreased modestly. This might be because of an increase in the number of Part D enrollees between 2007 and 2009, from 24 million to 27 million, while the absolute number of enrollees reaching the coverage gap remained fairly constant.[8] Additionally, Part D non-LIS enrollees who reached the coverage gap in one year tend to continue reaching the gap again the following year; for example, about 71% of those who reached the gap in 2008 did so again in 2009.[8]

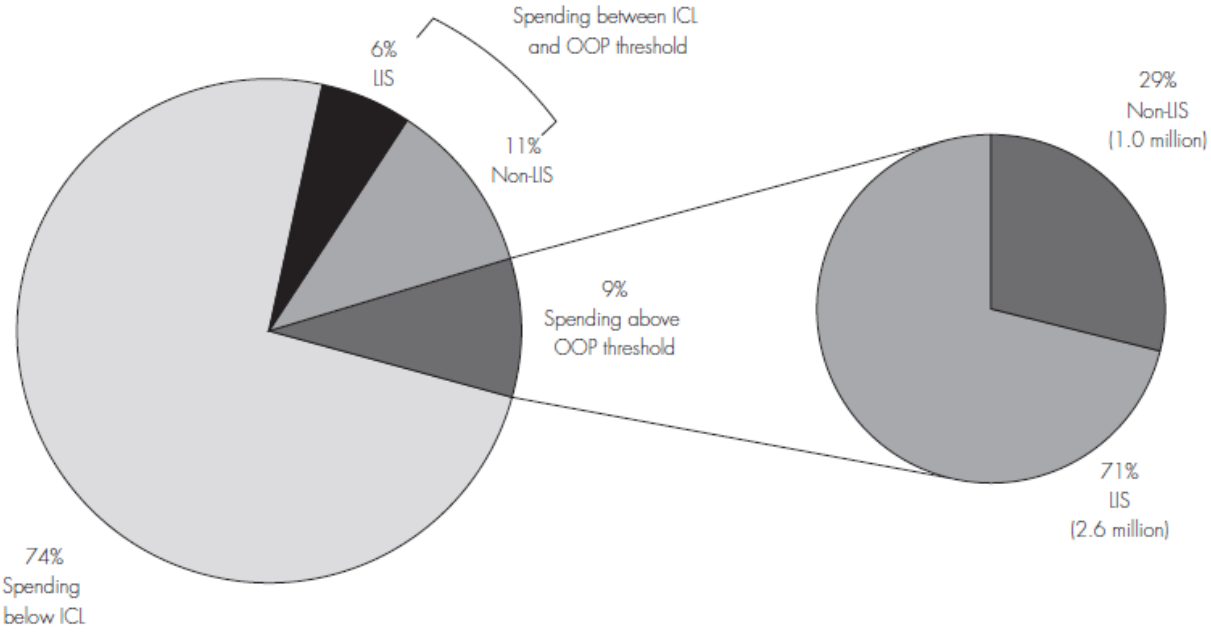
Figure I-6. Part D Enrollees who reached the coverage gap, 2007 and 2009.[8,11]



In 2015, 10.7 million (26%) Part D enrollees had spending high enough to enter the coverage gap, regardless of whether they received the LIS or not.[3] Of those, 3.6 million (9%) incurred additional spending above the catastrophic coverage threshold (**Figure *I-7***). Most of those with spending above the catastrophic coverage threshold (more than 2.6 million individuals, or 71%) received the Part D LIS. Thus, the proportion of enrollees with spending above the catastrophic coverage threshold is higher among LIS enrollees compared to non-LIS enrollees (20% vs. 4%).

Figure I-7. Part D enrollees with spending in the coverage gap and catastrophic phase, 2015.[3]

FIGURE 14–6 **Part D enrollees with spending in the coverage gap and catastrophic phase, 2015**



Note: ICL (initial coverage limit), OOP (out-of-pocket), LIS (low-income subsidy). Enrollees with spending between the ICL and the OOP threshold fall within Part D's coverage gap. LIS enrollees do not face a coverage gap because Medicare's low-income cost-sharing subsidy pays for what otherwise would be enrollee cost sharing. In 2015, Part D enrollees reached the ICL at $2,960 in gross drug spending. With no supplemental coverage, an enrollee reached the threshold at $4,700 of OOP spending or qualifying drug spending made on behalf of the beneficiary, including the 50 percent discount paid for by pharmaceutical manufacturers for brand-name drugs. Some non-LIS enrollees who reached the catastrophic phase of the benefit may have had some gap coverage.

Source: MedPAC analysis of Part D prescription drug event data and Part D denominator file from CMS.

Additionally, Part D beneficiaries with certain conditions were more likely to be affected by the coverage gap than Medicare patients in general or those with other conditions.[35] Approximately 43% of Part D enrollees with depression, 44% of those with heart failure, and 58% of those with both conditions entered the coverage gap in 2007, whereas 24% of all Part D enrollees reached the gap.[35] Also, more than half of Part D non-LIS enrollees taking drugs for treatment of breast cancer (56%) and Alzheimer's disease (54%) had spending high enough to reach the coverage gap in 2009, which is much higher than the overall average and higher than the share of those taking other drugs (e.g., 40% for anti-diabetes drugs, 39% for proton pump inhibitors, and 39% for angiotensin receptor blockers).[11]

Impact on Drug Expenditures

Several studies on the effect of the Part D coverage gap on drug expenditures have consistently shown that having the coverage gap resulted in lower total drug costs but higher out-of-pocket spending on drugs, although the magnitude of the impact varies across studies depending on data sources and study population.[6,7]

In a study using nationwide patient-level pharmacy claims data for 2007, average monthly out-of-pocket drug costs among Part D non-LIS enrollees during the coverage gap were nearly twice as much as in the months prior to reaching the gap.[8] For those reaching the coverage gap but not reaching the catastrophic coverage, monthly out-of-pocket spending increased from $104 prior to the coverage gap to $196 during the gap.[8] For those with spending high enough to qualify for catastrophic coverage, monthly out-of-pocket spending nearly doubled from $207 in the months prior to the coverage gap to $408 per month during the gap, and then dropped down to $285 per month during the catastrophic coverage phase.[8]

According to a study using data from 2009, average annual total drug spending and out-of-pocket costs among Part D non-LIS enrollees were $1,525 (about $127 per month) and $588 (about $49 per month), respectively.[11] As would be expected, when compared to enrollees who did not reach the coverage gap, average total and out-of-pocket drug spending was much higher among those who reached the coverage gap but not catastrophic coverage, and even much higher among those who reached catastrophic coverage.[11]

When compared to Part D enrollees with gap coverage (i.e., beneficiaries eligible for partial or full drug coverage while in the coverage gap such as LIS or other supplemental plans), Part D enrollees with no gap coverage who entered the doughnut hole had lower total drug costs and higher out-of-pocket expenditures. For example, enrollees with no gap coverage decreased their monthly pharmacy spending by 11.4% in 2007 relative to those receiving LIS.[35] Among the beneficiaries with integrated Medicare Advantage Prescription Drug (MA-PD) plans who reached the coverage gap in 2006, those with no gap coverage had 2% lower annual total drug costs and 284% higher annual out-of-pocket costs compared with those with gap coverage.[36]

The findings of decreased total costs and increased out-of-pocket medication costs in the gap is consistent for beneficiaries with certain conditions. Among MA-PD beneficiaries with diabetes, those with a gap had 3% and 4% lower total drug spending compared to those with no-gap and generic-only gap coverage, respectively.[36] Annual out-of-pocket expenditures for all drugs were 189% and 14% higher for those with a gap versus no-gap beneficiaries and generic-only gap coverage, respectively.[36] Among the MA-PD beneficiaries with osteoporosis enrolled in partial or full-gap exposure plans, out-of-pocket costs rose as high as 186% when they reached the coverage gap, but it fell for those enrolled in no-gap exposure plans.[37] Part D enrollees taking drugs for breast cancer reduced their average total drug spending by 25%, which is the most

reduction among the nine drug classes assessed (Alzheimer's disease, breast cancer, high cholesterol, depression, diabetes, gastroesophageal reflux disease, heart failure, hypertension, and osteoporosis), while Part D enrollees in general reduced their spending by 15%.[11] In another study, out-of-pocket costs increased from the months before the coverage gap to the months after it, ranging from $12 for warfarin to $65 for clopidogrel per 30 defined daily doses.[38]

Impact on Drug Utilization and Adherence

The Part D coverage gap has also had an unfavorable impact on drug utilization and medication adherence. Previous studies have consistently found that the entry of Part D beneficiaries into the coverage gap has been associated with less use of drugs or an increase in cost-related nonadherence such as drug discontinuation, delaying prescription filling, or skipping doses of prescriptions due to costs.[6,7,11,35,39–41]

Zhang et al. (2013) studied the effects of the coverage gap on drug utilization and medication adherence using a 5% random sample of Medicare beneficiaries who were continuously enrolled in PDPs in 2007.[39] They found that Part D beneficiaries without gap coverage who entered the coverage gap but did not reach the catastrophic coverage phase reduced their monthly prescription fills by 16% (0.85 prescriptions per month), while those with generic drug coverage in the gap reduced their use by 10.8% (0.66 prescriptions per month), compared with those receiving LIS.[39] Similar decreases in utilization of 14% (0.7 prescriptions per month) were found in the coverage gap for Medicare Advantage Prescription Drug plan enrollees, compared with those who had coverage of both brand-name and generic drugs.[40] In another study using data from 2 large retail pharmacy chains, 9.5% fewer prescription were filled

per month after reaching the coverage gap among beneficiaries who reached the coverage gap but did not reach the catastrophic coverage phase.[41]

Among Part D non-LIS enrollees using one of nine selected classes of drugs in 2009, an average of 11% fewer prescriptions were filled after reaching the coverage gap threshold, while 3% and 4% reductions were seen in Part D LIS enrollees and those enrolled in employer sponsored insurance (i.e., beneficiaries in employer plans receiving the Medicare Retiree Drug Subsidy, retirees whose employers offer drug coverage but did not participate in the subsidy program, and beneficiaries still insured as active employees), respectively.[11] Among the nine drug classes, the highest reduction was seen for breast cancer drugs (17%), followed by osteoporosis drugs (14%), angiotensin receptor blockers (12%), proton pump inhibitors (11%), oral anti-diabetics (10%), statins (9%), ACE inhibitors (8%), Alzheimer's drugs (7%), and antidepressants (6%).[11] Although the magnitude of effect of reaching the coverage gap on drug consumption varies across studies depending on the study population, research has consistently shown that the coverage gap significantly limits drug use among beneficiaries with diabetes, cardiovascular disease, osteoporosis and arthritis, mental health, and kidney disease.[6,7]

After entering the coverage gap, Part D enrollees with a gap are more likely to reduce their use of brand-name drugs than generic drugs, which may imply some substitution of generics for brand-name drugs, such that overall decreases in medication use and spending on drugs is primarily due to decreases in the use of brand name drugs.[6,39] For example, when Part D enrollees without drug coverage in the gap reduced their overall medication use by 0.85 medications per month, 75% of the reduction was accounted for by brand-name drugs and 25% by generic drugs.[39] In another study, Part D enrollees without drug coverage in the gap reduced

their number of monthly prescriptions for brand-name and generic drugs by 10.8% and 4.7%, respectively, relative to those receiving LIS.[35]

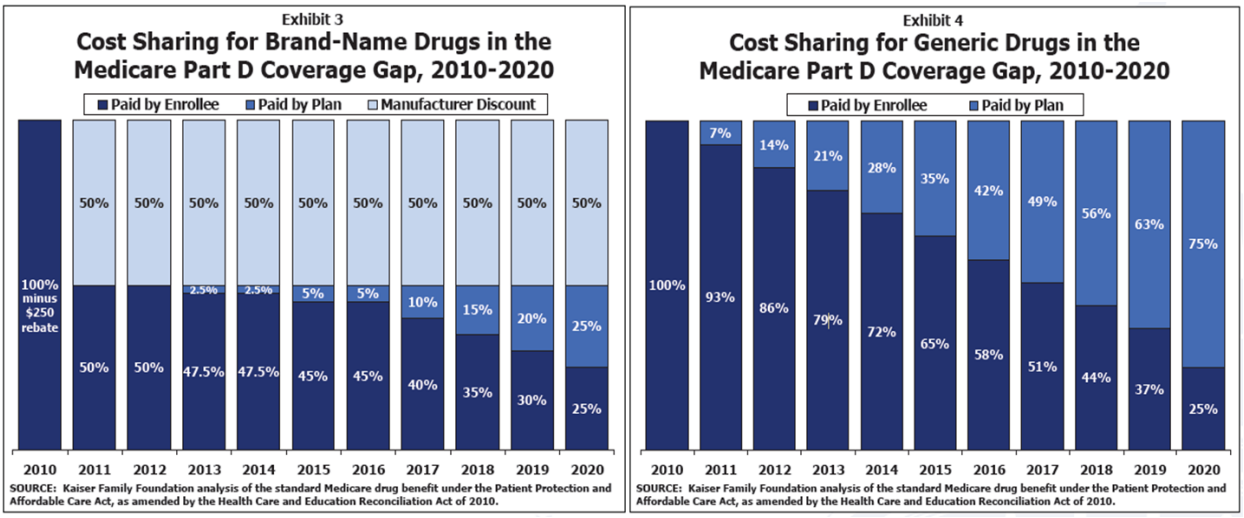
Overall, the Part D coverage gap is associated with a greater likelihood of having CRN and lower medication adherence. Polinski et al. (2011) found that Part D enrollees with a gap who entered the coverage gap were two times more likely to discontinue their drug and 18% more likely to reduce their drug adherence compared to those with financial assistance.[42] Compared to those with drug coverage in the gap, beneficiaries without drug coverage in the gap had higher CRN regardless of whether they reached the coverage gap (OR = 5.75) or not (OR = 2.46).[43] Among MA-PD beneficiaries taking oral diabetes, hypertension, and lipid drugs, those with a gap had lower odds of adherence to each of these drugs than those with no gap (OR = 0.83, 0.78, and 0.69 for oral diabetes, hypertension, and lipid drugs).[36] Among Part D non-LIS enrollees diagnosed with chronic obstructive pulmonary disease, those who reached the coverage gap had lower likelihood of being adherent compared with those who were not exposed to the gap.[44] Meanwhile, medication adherence did not significantly decrease for antidepressants among Part D non-LIS enrollees, compared with those receiving LIS, while adherence for hypertension drugs dropped slightly.[35] When compared across certain conditions, female beneficiaries with osteoporosis discontinued or skipped medications more often than those with other chronic conditions such as hypertension, high cholesterol, gastrointestinal disease, thyroid disease, or depression, regardless of plans or benefit design.[37]

1.3. Closing the Coverage Gap in Part D under the ACA

As discussed so far, the Medicare Part D coverage gap has caused a large and unexpected financial burden for Medicare beneficiaries, resulting in adverse effect on drug utilization and

medication adherence.[45–47] In response to these concerns, the Patient Protection and Affordable Care Act (ACA), as amended by the Health Care and Education Reconciliation Act of 2010, was signed by President Obama on March 23, 2010, which initiated a ten-year process of closing this coverage gap that gradually phased down the beneficiary coinsurance rate in the gap from 100% to 25% by 2020.[11] In 2010, Medicare Part D enrollees who reached the coverage gap received a one-time tax-free $250 rebate check.[48] Beginning in 2011, manufacturers are required to provide a 50% discount on the cost of brand name drugs (although the full cost still count towards reaching catastrophic coverage), and beginning in 2013 insurers are required to bear 2.5% of drugs costs for those that fall into the coverage gap, increasing to 25% by 2020 (**Figure *I-8***).[48] Insurers are required to bear 7% of the costs for generic drugs, increasing to 75% by 2020 (**Figure *I-8***).[48] As a result, by 2020 Part D enrollees will be responsible for only 25% of the total costs of their brand-name and generic drugs.[48]

Figure I-8. Phase-in schedule for brand-name and generic drugs, 2010-2020.[48]



1.4. Impact of the ACA Coverage Gap Reform

Unlike studies evaluating the effect of the Part D coverage gap before the ACA,[6,7] there are few empirical studies evaluating the impact of closing the gap in Part D coverage after the ACA. To date, six studies have specifically looked at the impact of closing the Part D coverage gap on drug utilization, out-of-pocket spending, or medication adherence.[12–17] Of the six studies, one study was conducted among Part D beneficiaries in general,[12] while others have studied specific populations such as specialty drug users[16] or beneficiaries with certain conditions such as diabetes[13] or cancer.[14,15,17] Three studies used a quasi-experimental study design,[12–14] while the other two studies used descriptive methods.[15,16] Across all studies, the results provide early evidence that the ACA provisions to close the coverage gap have reduced the out-of-pocket burden beneficiaries incur while in the coverage gap. The three descriptive studies will be described first, followed by the three studies using a difference-in-differences approach.

Trish et al. (2014) evaluated trends in specialty drug spending and out-of-pocket burden among Medicare beneficiaries using 2007-2011 pharmacy claims data from a 20% random sample of Medicare beneficiaries.[16] Annual specialty drug spending increased considerably from $2,641 in 2007 to $8,976 in 2011, where oral anticancer drugs were the primary contributors to overall increases. Out-of-pocket expenditures were considerably higher and increased much more rapidly from 2007 to 2010 for beneficiaries who used specialty drugs compared to those who did not use specialty drugs. However, out-of-pocket spending for specialty drug users significantly decreased by 26% from 2010 to 2011, which was mainly due to the implementation of cost-sharing reductions in the coverage gap under the ACA.

Shih et al. (2017) examined trends in targeted oral anticancer medication (TOAM) and patient out-of-pocket costs between 2007 and 2012 using SEER-Medicare Part D data.[17] They found that mean TOAM prices increased by nearly 12% per year, reaching $7,719 per patient per month in 2012. Mean out-of-pocket costs per patient per month also increased steadily from 2007 to 2010 ($980 to $1,200) but dropped to $832 in 2011 when the coverage gap began to close. This decrease in out-of-pocket costs were larger among patients whose out-of-pocket costs were in the top five percentiles, with more than a 40% drop from 2010 to 2011.

Dusetzina and Keating (2016) used the Medicare July 2014 Prescription Drug Plan Formulary, Pharmacy Network, and Pricing Information Files to evaluate benefit designs and estimate changes in out-of-pocket drug costs in 2010 and 2020 (before and after the closing of the gap) among Part D non-LIS enrollees taking oral anticancer medications.[15] Median out-of-pocket costs for a course of oral anticancer therapies ranged from $6,456 to $12,160 in 2010, and is estimated to range from $3,889 to $9,623 in 2020. Although the out-of-pocket costs decreased compared to those in 2010, the authors emphasized that Part D non-LIS enrollees still have considerable out-of-pocket costs after the doughnut hole is closed in 2020, which will impose a financial burden on Part D enrollees who require oral anticancer therapies.

Zeng et al. (2013) examined the impacts of the 2011 Part D coverage gap reform (i.e., closing the coverage gap) among beneficiaries with diabetes using pharmacy claims data from 2010 (pre-ACA) to 2011 (post-ACA) and employing a difference-in-difference-in-difference method.[13] The changes in diabetic medication adherence before and after reaching the coverage gap in response to the ACA reform were examined between patients with no coverage, partial coverage, and full coverage. They found that the ACA reform had an immediate reduction in copayments for diabetes medications in the coverage gap, regardless of the presence of absence

of drug coverage in the gap. The copayments for beneficiaries with no coverage and those with full coverage in the gap decreased by 36% and 27% in 2011 compared to the copayments in 2010. This decrease was mainly due to the 50% manufacturer discount on brand-name drugs. Corresponding to the copayment decrease, adherence to diabetes medication in the coverage gap improved. Patients with no coverage had improved adherence to diabetes medications in the coverage gap in 2011 compared to 2010, while those with full coverage in both years did not change their adherence.

Tehrani and Cunningham (2017) studied the changes in drug utilization and out-of-pocket spending after closing the coverage gap under the ACA using 2008-2013 Medical Expenditure Panel Survey data with a difference-in-differences approach.[12] The results showed that although total drug utilization did not significantly change after implementation of the ACA, overall out-of-pocket spending significantly decreased by $119 for all Part D beneficiaries and $179 for those who reached the coverage gap but did not reach the catastrophic coverage threshold. Also, drug utilization and out-of-pocket spending on brand-name drugs decreased significantly, and the effect was larger among those who fell into the coverage gap but did not reach the catastrophic coverage threshold. In contrast, utilization of generic drugs significantly increased after the ACA, especially among those who reached the coverage gap.

Jung et al. (2017) studied the early impact of the closing of Part D coverage gap on cancer specialty drug use and out-of-pocket expenditures among patients with 6 relatively uncommon cancer types (leukemia, kidney, pancreatic, skin, sarcoma, and non-Hodgkin lymphoma).[14] For the analysis, they used Part D Prescription Data Event Files and Medicare Master Beneficiary Summary Files from 2009 to 2013 and examined pre-post changes between patients with and without LIS by employing a difference-in-difference method. The results

showed that the closure of the coverage gap decreased beneficiaries' annual out-of-pocket spending for specialty cancer drugs by $1,114 but had no significant effect on the use of specialty cancer drugs in its early years. Additionally, considering the mean annual out-of-pocket spending for beneficiaries taking specialty cancer drugs was $4,494, the authors concluded that the in-gap discount would not be sufficient financial protection without additional subsidies.

Three additional related studies have been conducted on the impacts of the ACA, although they did not specifically evaluate the coverage gap provisions. These studies have focused on different study populations, including beneficiaries with spending above the catastrophic coverage threshold,[49] those taking specialty drugs,[50] and those with newly diagnosed chronic myeloid leukemia.[51]

Cubanski et al. (2017) studied trends in out-of-pocket prescription drug spending from 2007 to 2015 among Part D enrollees who had drug spending above the catastrophic coverage threshold using data from a 5% sample of Medicare Part D prescription drug event claims.[49] They found that average out-of-pocket costs declined substantially among Part D non-LIS enrollees with spending above the catastrophic threshold; between 2007 and 2010, average out-of-pocket spending in this group increased every year from $3,854 to $4,465, and it dropped substantially to $3,004 in 2011 after the ACA provisions to close the coverage gap took effect.[49] However, the trends have reversed since 2013, where average out-of-pocket spending in this group increased by 9% from $2,789 in 2013 to $3,041 in 2015.[49] Additionally, the number of Part D non-LIS enrollees who incurred drug spending above the catastrophic coverage threshold increased from 2.7% in 2007 to 3.6% in 2015.[49] This increase is due in part to the ACA counting the 50% manufacturer discount as out-of-pocket spending, as well as to the growing availability and use of high-costs drugs such as treatments for hepatitis C.[49] In addition, Part D non-LIS

enrollees with drug spending above the catastrophic coverage threshold spent more of their out-of-pocket costs in the catastrophic coverage phase between 2011 and 2015, while spending below the catastrophic phase decreased.[49] Average out-of-pocket spending in the catastrophic coverage phase nearly doubled from 2011 to 2015, while those below the catastrophic coverage threshold decreased every year.[49]

Tish et al. (2016) examined total and out-of-pocket spending for Part D beneficiaries taking at least one of the top eight classes of specialty drugs in terms of spending (oral cancer agents, rheumatoid arthritis agents, blood growth factors, multiple sclerosis agents, antiretrovirals, bone density regulators, immunomodulators, and pulmonary hypertension).[50] Annual total pharmacy spending among this group consistently and considerably increased between 2008 and 2012, with spending incurred while in the catastrophic coverage phase increasing more rapidly than the spending incurred during the coverage gap . Mean annual out-of-pocket costs increased from 2008 to 2010, but decreased in 2011, which was likely attributable to the ACA's cost-sharing reductions. Similar trends were seen in out-of-pocket spending incurred below the catastrophic coverage phase between 2008 and 2011, but there were persistent increases in out-of-pocket spending incurred while in the catastrophic coverage phase. This increase while in the catastrophic coverage phase almost offset the reductions incurred while in the coverage gap.

1.5. Gaps in Literature

The coverage gap in Part D has been considered a key problem that exposes beneficiaries to high out-of-pocket drug costs. In response to this concern, the ACA of 2010 included a provision to gradually reduce cost-sharing from 100% in 2010 to 25% by 2020 for beneficiaries

while in the coverage gap. However, there is limited research on how the ACA Part D coverage gap reform affected the utilization of and expenditures for prescription drugs, and cost-related access problems among beneficiaries. Additionally, as half of the existing studies are descriptive in nature, rigorous study designs are needed to provide more compelling empirical evidence on the effects of the ACA coverage gap reform.

In addition, we found several gaps in knowledge on the effects of the ACA coverage gap reform. First, among six previous studies, only one study examined the impact of the ACA provisions on Part D beneficiaries in general,[12] while other studies focused on beneficiaries with certain conditions such as diabetes[13] or cancer,[14,15,17] or those taking specialty drugs.[16] Although it is important to study the effects of the ACA reform on more vulnerable populations with a greater risk for high out-of-pocket burden, a better understanding of the policy's impact on the general Part D population is important to fully evaluate the impacts of the policy on the Part D program as a whole.

Secondly, previous research on the general Medicare population had limitations due to the use of Medical Expenditure Panel Survey (MEPS) data.[12] Although MEPS data is one of the most detailed nationally representative data sources on health care use and expenditures, it is not the best data source for the Medicare population because MEPS data do not include detailed information about characteristics of the beneficiaries' Medicare insurance coverage. For example, there is no information on (1) what type of Medicare (e.g., Part A, B, C, or D) coverage the beneficiary had; (2) whether or not the beneficiary was receiving the LIS (since those receiving LIS are not affected by coverage gap); and (3) whether the beneficiary received their drug insurance coverage through a stand-alone PDP or MA-PD (since those in a MA-PD will face lower out-of-pocket costs compared to those with a PDP).[12] Furthermore, the information

about drug use and expenditures might be exposed to a greater risk for inaccuracy because MEPS data is primarily based on participants' self-reported responses (i.e., not linked to drug claims), which may be subject to errors in memory and other biases.[52]

Lastly, there is a lack of research that has examined the effects of the ACA coverage gap reform on beneficiaries' cost-related access problems for prescription drugs. As one of the primary goals of the ACA is to make affordable health insurance available to more people,[53] it is crucial to evaluate the effect of closing the coverage gap under the ACA on access to health care, including access to prescription drugs. Although there is one study on the effects of the coverage gap reform on adherence to diabetes medications,[13] no studies have specifically examined the effects of closing the Part D coverage gap on access to prescription drugs for Part D beneficiaries in general.

The present study aims to address these gaps in the existing literature. This study will examine the effects of the ACA Part D coverage gap reform on several outcomes among general Part D beneficiaries, including drug utilization, total and out-of-pocket drug spending, and cost-related access problems for prescription drugs. In order to obtain a representative sample of Part D beneficiaries, this study analyzes Medicare Current Beneficiary Survey data from 2008 to 2015, which covers the first five years of post-ACA data.

II. OBEJCTIVES, RESEARCH QUESTIONS, AND HYPOTHESES

This study aims to evaluate the impact of the ACA Part D coverage gap reform, where impact will be assessed using measures of prescription drugs utilization, cost, and access. As the policy has been effective since January 2011, the pre-period is from 2008 to 2010 and the post-period is from 2011 to 2015. For objective 1, we focused on non-disabled Part D seniors not receiving Low-Income Subsidy (LIS), who were continuously enrolled in Part D plans during the year, with at least one prescription fill. For Objectives 2 and 3, the treatment group consists of Part D beneficiaries not receiving the LIS and the control group is composed of those receiving the LIS, who meet the same criteria applied to the objective 1. The detailed study objectives, research questions, and hypotheses are described in the following sections.

Study Objectives

1. To analyze trends in: (a) the proportion of beneficiaries entering the coverage gap and catastrophic coverage phases; (b) the days taken to entering and the days stayed in each phase; and (c) the utilization of and expenditures for prescription drugs.
2. To evaluate changes in the utilization of and expenditures for prescription drugs between non-LIS and LIS Part D beneficiaries before and after the ACA Part D coverage gap reform.
3. To estimate the effects of the ACA coverage gap reform on beneficiaries' cost-related access barriers to prescription drugs

Research Questions and Hypotheses

Objective 1

1. In response to the ACA reform, how has the proportion of non-LIS beneficiaries reaching the following Part D benefit phases changed over time: (a) the coverage gap, (b) the coverage gap without reaching the catastrophic threshold, and (c) the catastrophic coverage phase?
2. How has the monthly proportion of non-LIS beneficiaries who reached the coverage gap and the catastrophic coverage threshold changed over time?
3. How have the number of days spent to enter the coverage gap and the catastrophic coverage phases changed over time among non-LIS beneficiaries?
4. How has the number of days stayed in the coverage gap changed over time among non-LIS beneficiaries who reached the coverage gap and/or catastrophic coverage threshold?
5. How has the number of 30-day prescription drug fills changed over time among non-LIS beneficiaries?
6. How have the total and out-of-pocket spending changed over time among non-LIS beneficiaries?

Objective 2

1. Was there a significant difference in the number of 30-day prescription drug fills before and after the ACA coverage gap reform between non-LIS and LIS Part D beneficiaries?

   H1: The pre-post change in the number of 30-day prescription drug fills for non-LIS Part D beneficiaries was significantly higher than the change for LIS beneficiaries.
2. Was there a significant difference in the pre-post change in total drug spending between non-LIS and LIS Part D beneficiaries?

   H2: The pre-post change in total drug spending was significantly different between non-LIS and LIS Part D beneficiaries.

3. Was there a significant difference in the pre-post change in out-of-pocket drug spending between non-LIS and LIS Part D beneficiaries?

   H3: The pre-post change in out-of-pocket drug spending for non-LIS Part D beneficiaries was significantly higher than the change for LIS beneficiaries.

Objective 3

1. Were there any significant differences in the pre-post change in cost-related nonadherence before and after the ACA coverage gap reform between LIS and non-LIS beneficiaries?

   H4: The pre-post change in cost-related nonadherence for non-LIS beneficiaries was significantly higher than the change for LIS beneficiaries.

2. Were there any significant differences in the pre-post change of adopting the following cost-reduction strategies between LIS and non-LIS beneficiaries?

   H5: The pre-post change in CRS for non-LIS beneficiaries was significantly higher than the change for LIS beneficiaries.

III. MANUSCRIPT #1

Closing the Medicare Part D Coverage Gap: Trends in the Distribution of Beneficiaries, Drug Utilization, and Expenditures, 2008-2015

Target for submission in: American Journal of Managed Care or Journal of Health Services Research & Policy

Abstract

The Medicare Part D coverage gap (also known as "doughnut hole") has been linked to several adverse effects on beneficiaries. As a result, the Affordable Care Act (ACA) began phasing out the coverage gap, reducing beneficiary cost sharing from 100% in 2010 to 25% by 2020. This study analyzed annual trends in the distribution of beneficiaries entering each benefit phase, drug utilization, and expenditures among Part D beneficiaries not receiving the Low-Income Subsidy from 2008 to 2015 using Medicare Current Beneficiary Survey data. The proportion of beneficiaries reaching the catastrophic coverage phase increased after the ACA (4% in 2010 to 6% in 2015), and they reached the threshold earlier in the year. The overall number of 30-day drug fills increased after the ACA, although no significant changes in utilization were seen among those reaching the catastrophic coverage phase. Total drug spending steadily increased after the ACA, with the largest increase seen in those reaching the catastrophic threshold; however, out-of-pocket spending significantly decreased (17% decrease in 2015 compared to 2009). Although the findings in this study provide evidence that the ACA has helped to reduce financial barriers to prescription drugs for Part D beneficiaries, substantial

increases in total drug spending over time, especially among those reaching the catastrophic threshold, may indicate a growing Part D spending burden on the Medicare program.

Introduction

Medicare beneficiaries have had access to prescription drug coverage through Medicare Part D under the Medicare Modernization Act that went to into effect in 2006.[1] In 2018, 43 million (72%) people with Medicare were enrolled in Part D plans.[5] After the implementation of Part D, beneficiaries have experienced increased drug utilization and decreased out-of-pocket costs for prescription drugs.[7] Additionally, the Part D implementation has had a positive effect on older adults' overall health.[54]

A unique feature of the Part D benefit is the coverage gap (also known as "doughnut hole"), where beneficiaries are required to pay 100% of the costs of their drugs until they incur additional spending high enough to reach the catastrophic threshold. Although the coverage gap in Part D plans has resulted in lower total drug costs, it has unfavorably impacted beneficiaries' out-of-pocket drug costs, drug use, and medication adherence.[6–8,36] The entry of Part D beneficiaries into the coverage gap has been associated with substantially increased out-of-pocket drug costs, reduced use of drugs, and cost-related nonadherence such as discontinuing a medication, delaying prescription filling, skipping doses, or switching to a different medication with lower cost.[6,7] This cost-related nonadherence could increase the risk of more serious health consequences over time, which could not be controlled by medication, and could ultimately, result in higher costs for other parts of the Medicare program.[8]

Responding to these concerns, the Patient Protection and Affordable Care Act (ACA) of 2010 included provisions that initiated a ten-year process of closing the Part D coverage gap

from 100% of beneficiaries' coinsurance rate in 2010 to 25% by 2020.[11] As part of this process, a one-time $250 rebate was provided to Part D enrollees who reached the coverage gap in 2010. Since 2011, manufacturers have been required to provide a 50% discount on the price of brand-name drugs in the gap. Additionally, beneficiaries' coinsurance rates in the coverage gap have gradually decreased, beginning in 2011 for generics and 2013 for brand-name drugs.[48]

While there is a fair amount of previous study on the effects of entering the Part D coverage gap, relatively few studies have evaluated the effects of the ACA's provision of closing the Part D coverage gap.[12–17] Although these previous studies have suggested that beneficiaries' out-of-pocket costs in the coverage gap have decreased after implementation of the ACA provisions, they showed different results on the effects of the ACA on drug utilization depending on study population.[12–17] Also, they have focused on very limited populations, such as those taking specialty drugs,[16] diabetes medications,[13] or anticancer medications[14,15,17] and used survey data with limited information on beneficiaries' eligibility.[12] To better understand the impact of the Part D coverage gap closure on drug use and expenditures, this study examined trends in the distribution of beneficiaries in each benefit phase, utilization of and expenditures for prescription drugs among Part D beneficiaries without Low-Income Subsidy (LIS), using the 2008-2015 Medicare Current Beneficiary Survey (MCBS).

Methods

Study design

A retrospective, repeated cross-sectional study design was used to analyze annual trends of outcome variables in each year. The study period was 2008 to 2015, excluding 2014 for which

no data were available.[55] The seven years of the study period include several years before and after the effective date of the ACA's Part D coverage gap reform. The pre-ACA period was defined as January 2008 to December 2010, and the post-ACA period was defined as January 2011 to December 2015. Trends in outcomes of interest between the pre-and post-ACA periods were analyzed.

Data

This study used data from the MCBS for the years of 2008 to 2013 and 2015. The MCBS is a continuous, in-person, longitudinal survey of a nationally representative sample of the Medicare population, including beneficiaries aged 65 and older and beneficiaries aged 64 and below with disabilities or with end-stage renal disease (ESRD), residing in the US and its territories.[55] The 2014 MCBS data were not released by the Centers for Medicare and Medicaid Services (CMS) due to the implementation of long overdue innovations for accommodating changes in sampling and data collection methodologies.[55] For the analysis, the Cost and Use files from 2008 to 2013 and both the Survey File (formerly Access to Care) and Cost Supplement File (formerly Cost and Use) from 2015 were utilized; the survey population in 2015 are comparable with the past years.[56] The survey reported events on prescription drug use and expenditures were used only if the events were matched to the Part D claims data.[57] More detailed information on the MCBS is described in the Appendix A-1.

Study Population

The study sample included non-LIS Part D beneficiaries who meet the following criteria for each year: (1) age 65 years or older; (2) not disabled or not having end-stage renal disease; (3) continuous enrollment in a Part D plan; and (4) having at least one prescription fill.

The study sample was further categorized into three subgroups (Appendix A-2): (1) beneficiaries who did not enter the coverage gap (i.e., spent less than the initial coverage limit for each year); (2) beneficiaries who entered the coverage gap but did not reach the catastrophic threshold (i.e., spent more than the initial coverage limit but less than catastrophic coverage threshold for each year); and (3) beneficiaries who entered the catastrophic coverage phase (i.e., spent more than the catastrophic threshold for each year). The catastrophic threshold is updated annually by the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary. All analyses were conducted separately for each of the populations.

Outcome Variables

We assessed three outcomes for annual trends from 2008 to 2015 in non-LIS Part D beneficiaries. The first outcome was the proportion of beneficiaries entering the coverage gap and catastrophic coverage phases. Total drug spending was used to determine whether a person reached the coverage gap and/or the catastrophic coverage threshold during the year. For each person, total drug spending was tracked from January 1st to identify when in the year they reach the coverage gap or catastrophic coverage threshold. For the calculation, total drug spending was sorted by person and date, and then cumulatively added. The date on which the person's cumulative total spending was exceeded the threshold of either the coverage gap or catastrophic coverage phase was identified. This calculation was reset on January 1 of each year. A person with a date of entry into either the coverage gap or catastrophic coverage phases was defined as reaching the coverage gap or catastrophic coverage phase, respectively. The dates of entry into coverage gap and catastrophic phase were used to measure the number of days taken to enter the coverage gap and catastrophic coverage phases and the number of days stayed in each phase.

The second outcome was the utilization of prescription drugs measured as the annual number of 30-day prescription drug fills per person. Each record in the Prescribed Medicine Events is an individual outpatient prescribed medicine event, which is a single purchase/fill of a single drug in a single container.[57] Since each fill has a different number of tablets or patches in the container, each drug fill was normalized to 30-day fills using the days of supply to account for the variability in the number of days dispensed across fills.

The final outcome was expenditures for prescription drugs and was measured at two levels: 1) mean annual total spending per person paid by all payment sources and 2) mean annual out-of-pocket spending per person.

Statistical Analysis

Descriptive statistics were calculated to describe the characteristics of the study population for each year and to demonstrate annual trends in the outcome variables. Statistical comparisons across every year, 2008-2015, were evaluated using Chi-squared test for categorical variables and ANOVA for continuous variables.

In order to obtain nationally representative estimates for non-LIS Medicare Part D population and to account for the complex sampling design of the MCBS (e.g., the rotating-panel and multistage-sampling design of the MCBS data), the Balanced Repeated Replication (i.e., Fay's method) of variance estimation was used to adjust both serial and intra-cluster correlation in the data, using replicate cross-sectional weights for each year.[58] All statistical analyses were conducted using Stata 15.1 (StataCorp, College Station, Texas) and statistical significance was determined by an α level of 0.05. All estimates of spending and income were converted to inflation-adjusted 2015 dollars using the all-items Consumer Price Index.[59]

Results

Study Sample Characteristics

The weighted characteristics of the study samples are presented in Table III-1 from 2008 to 2015. The weighted counts of non-LIS Part D beneficiaries steadily increased over time with substantial increases in the post-ACA period. Compared to those in the pre-ACA period, beneficiaries in the post-ACA period were more likely to be younger, non-Hispanic blacks or other racial group, educated, employed, having higher income, and living in a metropolitan area. The average number of chronic conditions was not changed over the years.

Distribution of Beneficiaries Entering Each Benefit Phase

More non-LIS Part D beneficiaries were reaching the catastrophic coverage threshold in the post-ACA period than in the pre-ACA period, and fewer beneficiaries fell into the coverage gap without reaching the catastrophic threshold (Table III-2). In 2008, 471,529 (4% of total non-LIS Part D beneficiaries) reached the catastrophic coverage threshold, compared to about 1.5 million beneficiaries (6% of total non-LIS Part D beneficiaries) in 2015. Although the absolute number of beneficiaries entering the coverage gap without reaching the catastrophic threshold also increased in the post-ACA period, the percentage of beneficiaries to total non-LIS Part D beneficiaries decreased (23% in 2008 vs 17% in 2015). Correspondingly, for those not reaching the coverage gap, both increased in the post-ACA period (2,322 and 74% in 2008 vs 3,173 and 76% in 2015).

Table III-2 shows trends in how soon beneficiaries reached the coverage gap and the catastrophic coverage threshold and how long they stayed in each benefit phase. In the post-ACA period, beneficiaries reached the coverage gap and the catastrophic coverage threshold more

quickly (i.e., earlier in the year) than in the pre-ACA period. Accordingly, beneficiaries entering the coverage gap without reaching the catastrophic coverage threshold were more likely to stay in the coverage gap longer (101 days in 2008 vs 122 days in 2015), while those entering the catastrophic coverage phase spent less time in the coverage gap but longer in the catastrophic coverage phase (100 days in 2008 vs 139 days in 2015). Figure III-1 also highlight how quickly beneficiaries reached the coverage gap and the catastrophic coverage threshold during the year over the study period. In 2008, 3% of beneficiaries reached the coverage gap by May, while 7% reached the coverage gap by May in 2015. For those reaching the catastrophic coverage threshold, 0.1% of beneficiaries reached the threshold by May in 2008, while 1.3% reached the threshold by then in 2015.

Drug Utilization

For all non-LIS beneficiaries, the mean annual number of 30-day drug fills increased after the ACA, which increased by 7% in 2015 compared to 2009 (Table III-3). When comparing the changes from year to year after the ACA, the number of drug fills remained relatively unchanged between 2010 and 2011, and then increased considerably in 2012 and 2013 but slightly decreased in 2015.

Similar trends were seen in the number of drug fills for two subgroups: those not reaching the coverage gap and those entering the coverage gap without reaching the catastrophic threshold. The mean annual number of 30-day drug fills increased by 8% and 6% in 2015 compared to 2009, among those not reaching the coverage gap and those entering the coverage gap without reaching the catastrophic threshold, respectively. However, for those reaching the

catastrophic threshold, there was no significant change in the mean annual number of 30-day drug fills after the ACA.

Drug Expenditures

For all non-LIS beneficiaries, mean annual total drug spending steadily increased after the ACA, while mean annual out-of-pocket spending decreased (Table III-3). Total spending increased by 12% in 2015 compared to 2009, while out-of-pocket spending decreased by 17%. For those not reaching the coverage gap, both total and out-of-pocket spending decreased in the post-ACA period; both decreased by more than 30% in 2015 compared to 2009.

Like all non-LIS beneficiaries there were significant increases in the total drug spending and decreases in the out-of-pocket spending after the ACA, both among those entering the coverage gap without reaching the catastrophic threshold and those reaching the catastrophic threshold. For those entering the coverage gap without reaching the catastrophic threshold, the total spending increased by 7% in 2015 compared to 2009 and the out-of-pocket spending decreased 14%. For those reaching the catastrophic threshold, the total spending increased by 43% in 2015 compared to 2009, while the out-of-pocket spending decreased by 15%.

Table III-1. Characteristics of Study Population, non-LIS Part D beneficiaries, Medicare Current Beneficiary Survey (MCBS), 2008-2015 †

	2008		2009		2010		2011		2012		2013		2015		
Sample size (n)	3,260		3,076		3,084		3,317		3,736		4,126		4,320		
Population size (N)	12,400,843		13,123,739		13,599,760		14,563,427		16,304,256		19,376,540		24,751,318		
	Mean or %	SE	Mean or %	SE	Mean or %	SE	Mean or %	SE	Mean or %	SE	Mean or %	SE	Mean or %	SE	*p*-value [b]
Age *	76.4	0.1	76.3	0.1	76.1	0.1	76.2	0.1	76.1	0.1	75.9	0.1	75.2	0.1	0.00
Female (%)	59.3	0.8	60.4	0.8	60.4	0.8	59.8	0.8	58.1	0.7	58.3	0.8	57.6	0.8	0.05
Race/Ethnicity (%) *															0.00
White, non-His	91.8	0.5	91.3	0.5	91.7	0.5	91.1	0.5	91.6	0.5	90.3	0.5	88.5	0.6	
Black, non-His	5.1	0.4	5.1	0.4	5.3	0.4	5.4	0.4	4.6	0.3	5.7	0.3	6.5	0.4	
Hispanic	1.2	0.2	1.3	0.2	1.8	0.2	1.2	0.1	1.1	0.2	1.1	0.2	1.1	0.2	
Other, non-His	1.9	0.3	2.3	0.3	2.3	0.3	2.3	0.3	2.7	0.4	3.0	0.4	3.9	0.5	
Married (%)	56.7	0.9	56.6	0.9	56.8	0.8	57.7	0.9	57.5	0.8	57.9	0.8	59.5	0.9	0.10
Education *															0.00
Less than high school	20.5	0.8	19.2	0.8	19.2	0.9	18.2	0.7	17.0	0.8	15.7	0.7	12.8	0.5	
High school graduate	32.9	1.0	32.8	1.1	32.4	0.9	30.5	0.9	28.4	0.8	28.4	1.0	26.2	0.9	
Some college or more	46.6	1.2	48.0	1.2	48.3	1.2	51.3	0.9	54.6	0.9	55.9	1.0	61.1	1.0	
Job status (Having a job) *	12.7	0.6	12.9	0.7	12.5	0.7	12.8	0.6	14.3	0.7	14.3	0.7	15.0	0.9	
Household income ($) [a]	45,524	1,133	42,725	712	42,871	817	43,631	844	46,290	870	51,132	2,374	59,534	2,025	0.00
Census region (%)															0.19
Northeast	18.5	0.7	18.6	0.7	18.5	0.7	16.7	0.8	17.6	0.8	18.5	0.6	19.0	0.8	
Midwest	23.9	0.7	24.6	0.8	22.6	0.8	23.9	0.7	24.4	0.8	24.4	0.7	24.9	0.8	
South	33.0	0.8	33.0	0.9	34.7	1.1	34.8	1.1	32.9	1.0	33.6	0.8	33.7	0.8	
West	24.7	0.7	23.8	0.8	24.2	1.0	24.6	1.0	25.2	0.8	23.5	0.8	22.5	0.8	
Living in Metro area *	79.6	0.7	80.3	0.8	80.1	0.8	78.8	0.7	78.2	0.6	78.4	0.6	81.4	1.0	0.01
Chronic conditions															
Number of chronic conditions	3.0	0.0	3.0	0.0	3.0	0.0	3.0	0.0	3.1	0.0	3.1	0.0	3.0	0.0	0.38

† No MCBS data released in 2014.
[a] All amounts are in 2015 US dollars and rounded off to the nearest whole number.
[b] *p*-values reflect ANOVA or chi-squared tests for comparisons across the years.
* Significant at $p<0.05$

Table III-1. Distribution of non-LIS Part D beneficiaries entering each benefit phase, MCBS 2008-2015

	2008		2009		2010		2011		2012		2013		2015		
Sample size (n)	3,260		3,076		3,084		3,317		3,736		4,126		4,320		
Population size (N)	12,400,843		13,123,739		13,599,760		14,563,427		16,304,256		19,376,540		24,751,318		
	Mean or %	SE	Mean or %	SE	Mean or %	SE	Mean or %	SE	Mean or %	SE	Mean or %	SE	Mean or %	SE	*p*-value‡
All Beneficiaries															
Days to reach coverage gap*	241	2.0	240	2.8	237	2.4	233	3.3	224	3.8	221	2.9	206	2.6	0.00
Days stayed in coverage gap	108	2.6	109	2.6	113	2.1	112	2.4	113	2.7	116	2.3	123	2.7	0.01
Days to reach catastrophic coverage*	267	6.4	263	8.5	262	10.3	264	7.1	249	6.7	239	6.8	226	7.3	0.00
Not Reaching Coverage Gap															
Sample size (n)	2,348		2,259		2,346		2,489		2,887		3,169		3,242		
Population size (N)	9,012,863		9,685,520		10,394,938		11,086,617		12,675,994		14,964,161		18,831,931		
Total as % of all non-LIS enrollees*	73%		74%		76%		76%		78%		77%		76%		
Reaching the Gap, Not Catastrophic															
Sample size (n)	764		696		628		681		662		751		786		
Population size (N)	2,840,962		2,908,349		2,733,057		2,855,364		2,822,810		3,432,878		4,326,968		
Total as % of all non-LIS enrollees*	23%		22%		20%		20%		17%		18%		18%		
Days to reach coverage gap*	264	2.8	261	2.8	257	2.3	259	2.7	257	3.1	254	2.5	242	3.0	0.00
Days stayed in coverage gap*	101	2.9	104	2.8	108	2.3	106	2.7	108	3.1	111	2.5	123	3.0	0.00
Reaching Catastrophic Coverage															
Sample size (n)	148		121		110		147		187		206		292		
Population size (N)	547,018		529,870		471,765		621,445		805,452		979,501		1,592,419		
Total as % of all non-LIS enrollees*	4%		4%		3%		4%		5%		5%		6%		
Days to reach coverage gap*	124	4.5	121	5.7	119	5.1	119	4.1	106	4.3	105	3.9	102	3.7	0.00
Days stayed in coverage gap	141	4.6	138	5.5	143	6.4	140	4.7	130	4.8	131	4.9	123	4.5	0.06
Days to reach catastrophic coverage*	267	6.4	263	8.5	262	10.3	264	7.1	249	6.7	239	6.8	226	7.4	0.00
Days stayed in catastrophic coverage*	98	6.4	102	8.5	101	10.3	101	6.7	116	6.7	126	6.8	139	7.3	0.00

‡ *p*-values reflect ANOVA or chi-squared tests for comparisons across the years.

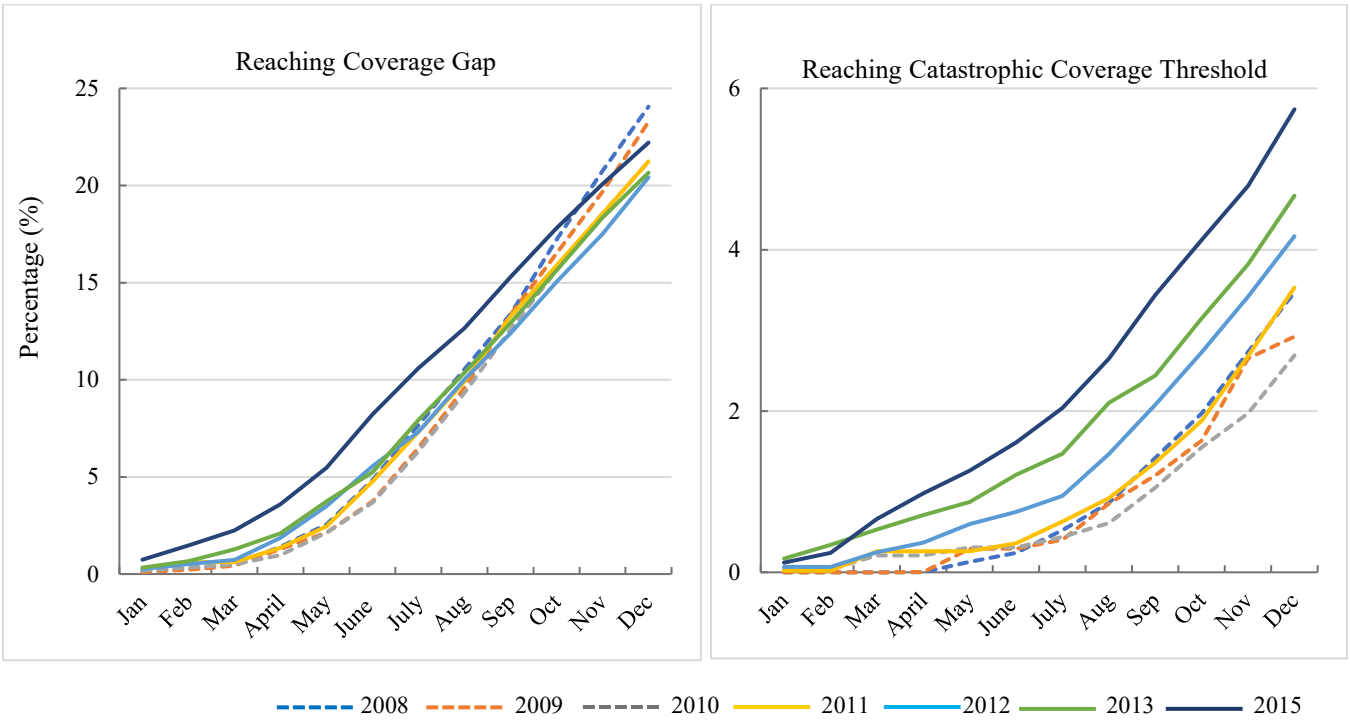
* Significant at $p < 0.05$.

Table III-2. Drug utilization and expenditures among non-LIS Part D beneficiaries, MCBS 2008-2015

	2008		2009		2010		2011		2012		2013		2015		
	Mean	SE	Mean	SE	Mean	SE	Mean	SE	Mean	SE	Mean	SE	Mean	SE	*p*-value‡
All Beneficiaries															
Annual number of 30-day Rx fills	43.1	0.8	44.5	0.5	45.2	0.6	45.3	0.6	47.4	0.6	48.7	0.5	47.6	0.7	0.00
Total drug spending ($)	2,167	51	2,248	67	2,201	67	2,164	80	2,252	93	2,354	89	2,518	119	0.03
Total OOP spending ($)	760	21	751	18	717	17	701	20	680	18	634	17	621	17	0.00
Not Reaching the gap															
Annual number of 30-day Rx fills	33.9	0.6	35.3	0.5	37.3	0.6	37.1	0.6	39.1	0.5	39.4	0.5	38.2	0.6	0.00
Total drug spending ($)	1,183	21	1,203	19	1,187	21	1,051	21	1,004	18	927	17	810	18	0.00
Total OOP spending ($)	383	8	389	8	400	9	349	7	329	6	299	6	270	5	0.00
Reaching the gap, But Not Catastrophic															
Annual number of 30-day Rx fills	63.9	0.8	67.0	1.0	67.3	1.0	67.0	1.0	71.3	1.2	74.8	1.2	70.9	1.5	0.00
Total drug spending ($)	3,904	36	4,093	44	4,245	41	4,211	40	4,274	53	4,384	39	4,383	52	0.00
Total OOP spending ($)	1,543	43	1,552	43	1,566	39	1,567	40	1,490	53	1,371	38	1,337	40	0.00
Reaching Catastrophic Coverage															
Annual number of 30-day Rx fills	96.0	3.0	97.3	4.4	101.5	3.3	100.3	2.9	97.8	3.1	102.7	3.8	97.0	2.7	0.65
Total drug spending ($)	10,738	609	12,501	1,532	14,063	1,899	13,925	1,412	15,493	1,534	17,515	1,508	17,843	1,484	0.00
Total OOP spending ($)	3,348	175	3,355	228	3,148	228	3,378	198	3,534	158	3,289	163	2,860	127	0.01

OOP: Out-of-pocket
‡ *p*-values reflect ANOVA test for comparisons across the years.

Figure III-1. Cumulative percentage of beneficiaries reaching the coverage gap and catastrophic coverage threshold, 2008-2015.



Discussion

This study analyzed Part D claims in the 2008 to 2015 MCBS data to examine the trends in the distribution of beneficiaries entering each benefit phase, as well as beneficiary drug utilization and expenditures after the ACA's coverage gap reform beginning in 2010. We found that the number of non-LIS Part D beneficiaries who reached the catastrophic coverage threshold substantially increased after the ACA, and they reached the threshold earlier in the year. Additionally, although total drug spending increased, beneficiary out-of-pocket drug spending decreased, and prescription drug utilization increased.

Overall, the trends in out-of-pocket costs and drug utilization reported in this study provide evidence suggesting phasing out the Part D coverage gap has helped to improve the affordability of prescription drugs for beneficiaries. The findings of significant decreases in out-

of-pocket drug costs may indicate financial relief for beneficiaries, due to reductions in beneficiaries' cost-sharing in the coverage gap and the 50% manufacturer discount on the price of brand-name drugs. In addition, beneficiaries significantly increased their prescription drug use after the ACA, which was mainly due to the increases seen among those who did not enter the coverage gap, and those who entered the coverage gap without reaching the catastrophic threshold. As many previous studies found an inverse association between cost-sharing and drug utilization, the increased drug utilization in this study may be due in part to the reduction in cost-sharing in the coverage gap after the ACA.[9,10,13,60,61] These positive effects of the ACA on out-of-pocket burden for beneficiaries were consistent with a previous study in patients with diabetes.[13]

Although our findings provide support for improved financial protection and drug affordability for beneficiaries under the ACA, it is important to note that the trends in drug utilization and out-of-pocket costs remained relatively unchanged among beneficiaries reaching the catastrophic coverage threshold (i.e., high-cost beneficiaries). This implies the high-cost beneficiaries were mainly unaffected by the closure of the Part D coverage gap, which might be due to the characteristics of the beneficiaries. The high-cost beneficiaries were more likely to have severe, complex, or life-threatening diseases such as HIV/AIDS, multiple sclerosis, viral hepatitis, leukemia/lymphoma, and schizophrenia, resulting in high drug use including high-priced drugs such as specialty drugs.[49] Therefore, the high-cost beneficiaries might be more likely to pass through the initial coverage and the coverage gap quickly (i.e., spent less time in the coverage gap where the policy effect occurred), and this might be accelerated in the post-ACA period due to drug price inflation as well as the greater availability of high-priced drugs.[3] Furthermore, as the high-cost beneficiaries without receiving LIS are still responsible for up to

5% of their drug costs in the catastrophic coverage phase, they could be exposed to out-of-pocket drug cost burden for very high-priced drugs such as specialty drugs.[49]

This study also provides evidence supporting the recent attention focused on growth in Part D drug spending with highlighting significant growth in spending for the high-cost beneficiaries reaching the catastrophic threshold.[3,16,62,63] From 2010 to 2015, Part D spending per beneficiary per month has grown with an annual average of 4.6%, and the aggregate spending for the high-cost beneficiaries has grown from about 40% of all Part D spending before 2011 to 57% in 2015.[3] This trend is reflected in this study; overall annual total drug spending steadily increased over the study years, which seems to be mainly due to the increases in total drug spending among beneficiaries reaching the catastrophic threshold. A combination of several factors has contributed to the growth in total drug spending. First, as shown in this study, an increased number of high-cost beneficiaries has led to increases in total drug spending.[3] The ACA's provision of manufacturer discounts in the coverage gap that count as beneficiary out-of-pocket spending has helped beneficiaries move through the coverage gap faster and use more brand-name drugs, resulting in more people reaching the catastrophic threshold quickly.[3,64] Also, the provision of slowing the growth rate of the annual out-of-pocket spending threshold between 2014 and 2019 made more beneficiaries qualified for the catastrophic coverage phase with less out-of-pocket spending.[49] Second, a greater availability of high-priced drugs and biologics including specialty drugs has contributed to the growth in drug spending, as well as it has helped more beneficiaries to reach the catastrophic threshold.[3,63] In this study, the findings of increases in total drug spending from 2013 to 2015 despite slight decreases in drug use support the trend of rising drug prices. Lastly, the innate and complex Part D structure that allows insurers have incentives to cover more expensive medications in the catastrophic coverage phase has helped to

increases in Part D drug spending.[3,63] To get more incentives, insurers would pay higher prices for the medications even if lower-cost ones would available.

Since Medicare pays the majority of the drug costs in the catastrophic coverage phase (i.e., reinsurance), the growth in Part D spending mainly due to the increased spending for high-cost beneficiaries has led the growing cost burden on Medicare program, which is expected to grow in the future[3,49,65,66] Medicare payments for individual reinsurance have grown faster than other components of Part D spending, with an annual average of over 24% between 2010 and 2015, and became the largest component of Part D spending in 2014.[3] Additionally, the annual growth in Part D spending per beneficiary is expected to be higher than growth in other spending categories of Medicare spending over the next decade.[3,49] Total Part D spending increased $62.5 billion in 2010 to $89.7 billion in 2015, accounting for about 12% and 14% of total Medicare spending, respectively.[67,68] Furthermore, total Medicare spending is projected to increase from $700 billion in 2016 to $1 trillion by 2022 because of the aging of the baby-boom generation and the rising health care costs.[3,66] As Medicare accounts for a growing share of the total US prescription drug spending along with the growing Part D spending, comprehensive efforts might be needed to reduce the growing Part D spending.[66]

This study has limitations to note. First, Medicare beneficiaries can have drug coverage through Part D prescription drug plans (PDPs) or Medicare Advantage Prescription Drug plans (MA-PDs) and these two different plans could have different impact on beneficiaries' drug use and expenditures. However, this study was not able to differentiate the impact using the MCBS data since the MCBS data do not contain drug claims data from MA-PDs. Second, although there is a standard drug benefit structure that Part D plans should follow, Part D plans have a discretion to develop their own drug benefits such as actuarially equivalent standard coverage or

basic/enhanced alternative coverage, as long as the cost-sharing structure is actuarially equivalent to an average expected coinsurance in the standard benefit structure.[57] Therefore, Part D plans could have a variety of drug benefit structure, which would have different structure of coverage gap, or some plans does not even have the coverage gap. This study was not able to identify each plan's benefit structure using the MCBS data but estimated the benefit structure using total drug spending under the Part D standard benefit structure.

Conclusions

Following changes to the structure of the Medicare Part D benefit under the ACA, a substantial increase was seen in the proportion of Medicare Part D enrollees reaching the catastrophic coverage phase, and out-of-pocket drug spending significantly decreased, despite increases in drug utilization and total drug costs. Although the findings in this study provide evidence that the ACA's coverage gap reform has helped to reduce financial barriers to prescription drugs for Part D beneficiaries, substantial increases in total drug spending over time, especially among those reaching the catastrophic threshold, may indicate a growing Part D spending, ultimately resulting in burden on the Medicare program. As Medicare's share of drug costs increases considerably in the catastrophic coverage phase, potential changes to the Part D program and drug pricing models may be needed to reduce the growing high-cost beneficiaries and Part D spending, while ensuring broad provisions of benefits.

IV. MANUSCRIPT #2

Five-Year Impact of Medicare Part D Coverage Gap Reform on Drug Utilization and Expenditures

Target for submission in: Health Affairs

Abstract

Under Affordable Care Act (ACA) reforms, the Medicare Part D coverage gap has been gradually phasing out since 2011. We examined the impact of the ACA reform on the utilization of and expenditures for prescription drugs within the first five years of the policy. We employed a difference-in-differences model using 2008-2015 Medicare Current Beneficiary Survey data. After implementation of the ACA reform, out-of-pocket drug spending significantly decreased among beneficiaries not receiving the Low-Income Subsidy (non-LIS) compared to those receiving the LIS, with growing decreases over time (average decreases of $41 in 2011 and $135 in 2015). Despite significantly reduced out-of-pocket spending, there were no significant changes in the number of 30-day drug fills and total drug spending after the ACA reform. Our study demonstrates that the ACA reform has helped to reduce out-of-pocket drug costs burden for beneficiaries, although it had no significant impacts on drug use or total drug spending.

Introduction

The implementation of Medicare Part D in 2006 has brought several positive impacts, such as increased prescription drug use, decreased out-of-pocket costs, and decreased cost-related medication nonadherence.[6,7] Furthermore, Part D enrollment is associated with an improved health status of elderly beneficiaries.[54] Despite these favorable impacts, the coverage gap in the Part D benefit structure (also known as the "doughnut hole"), during which beneficiaries are required to pay 100% of their drug costs, has been criticized as a financial barrier to prescription drug access for beneficiaries.[6,7] In 2015, an estimated 10.7 million Part D beneficiaries or about 26% fell into the coverage gap,[3] with those with chronic conditions at greater risk.[69]

Substantial evidence indicates that the coverage gap in Part D negatively impacts out-of-pocket costs, drug utilization, and medication adherence for beneficiaries.[6–8,36] Part D beneficiary entry into the coverage gap has been associated with increased out-of-pocket drug costs by as much as 89%, decreases in drug use, and cost-related medication nonadherence (such as medication cessation, skipping doses, or delaying or foregoing prescriptions due to the drug costs).[6,7,40] Medication nonadherence can negatively affect beneficiaries' health outcomes and result in increased health care expenditures, which increase the financial burden to other parts of the Medicare program due to beneficiaries' use of comparatively more expensive medical services, such as emergency room visits.[8–10]

In response to these concerns, the Patient Protection and Affordable Care Act (ACA) of 2010 implemented provisions that initiated a ten-year process to close the Part D coverage gap, by gradually phasing down the coinsurance rate in the gap from 100% in 2011 to 25% by 2020.[11] As part of this process, Part D beneficiaries who reached the coverage gap in 2010 received a

one-time tax-free rebate of $250. Beginning in 2011, manufacturers have been required to provide a 50% discount on the price of brand-name drugs in the coverage gap; since 2013 insurers have been required to bear 2.5% of brand-name drug costs in the coverage gap, increasing to 25% by 2020. For generic drugs, insurers have been responsible for paying 7% of drug costs in the coverage gap since 2011, increasing gradually every year up to 75% by 2020. Under this policy, in 2020 Part D beneficiaries will be responsible for only 25% of the costs of their drugs in the coverage gap. Recent changes made by the Bipartisan Budget Act of 2018 closed the coverage cap early for brand-name drugs (i.e., 25% of the coinsurance rate in the gap) in 2019, with generic drugs on schedule for 2020.[70,71]

Although previous studies have evaluated the effects of the ACA coverage gap reform on drug utilization and expenditures, they have focused on specific populations such as those with uncommon cancers[14] or diabetes,[13] or used survey data with limited drug claims.[12] Using nationally representative data from 2008 to 2015, this study examines the annual changes in drug utilization and expenditures after implementation of the ACA Part D coverage gap reform following its implementation in 2011. We hypothesized that the ACA coverage gap reform would be associated with increased prescription drug use and decreased out-of-pocket costs, with a larger effect among those who fell into the coverage gap, compared to those who did not enter the coverage gap or who reached the catastrophic threshold. To our knowledge, this study is the first to examine the year-by-year changes in drug utilization and in total and out-of-pocket drug spending among general Part D beneficiaries after the 2011 implementation of the ACA's provision to close the coverage gap.

Study Data and Methods

Design and population

This study adopted a difference-in-differences approach to estimate the effects of the ACA coverage gap reform on drug use and expenditures. The treatment group was Part D beneficiaries not receiving the LIS (i.e., non-LIS beneficiaries) who may have been exposed to the coverage gap. Part D beneficiaries who received the LIS were selected as the control group.[14,51] LIS beneficiaries were not affected by the ACA coverage gap reform because they already had little or no cost-sharing in the coverage gap before the ACA.[72(p13)] The following inclusion criteria were used to identify the study sample: (1) age 65 years or older; (2) not disabled or having end-stage renal disease; (3) continuous enrollment in a Part D plan; and (4) having at least one prescription fill.

The study period was 2008 to 2015, where the pre-ACA period was defined as January 1st, 2008 to December 31st, 2010, and the post-ACA period was defined as January 1st, 2011 to December 31st, 2015. Since the coverage gap has been phasing out gradually since 2011, we identified the policy effects separately for each year of the post-ACA period (2011, 2012, 2013, and 2015) to the pooled years of the pre-ACA period, 2008-2010 (i.e., year-by-year changes difference-in-differences model). This approach has been used to trace out differential changes over time after the ACA policy changes.[73]

Data

This study used data from the Medicare Current Beneficiary Survey (MCBS) for the years of 2008 to 2013 and 2015. MCBS data for 2014 were not released by the Centers for Medicare & Medicaid Services.[55,56] The MCBS is a continuous, in-person, longitudinal survey of

a nationally representative sample of the Medicare population that is linked to administrative claims data, and provides more comprehensive information on the health care utilization and expenditures of beneficiaries.[55] We used the Cost and Use files from 2008 to 2013 and both the Survey File (formerly Access to Care) and Cost Supplement File (formerly Cost and Use) from 2015.[58] Among these files, we used survey-reported data to define the study cohorts and obtain sociodemographic data, and administrative Part D events data in the Prescribed Medicine Events file to estimate drug use and expenditures.

Outcome variables

We constructed two outcome measures: utilization of and expenditures for prescription drugs. Prescription drug use was measured as the mean annual number of 30-day drug fills per person. Each record in the Prescribed Medicine Events is an individual outpatient prescribed medicine event, which is a single fill of a single drug in a single container. In order to account for the variability in the number of days supplied across fills, each drug fill was normalized to 30-day fills.[3] Prescription drug expenditures were measured at two levels: mean annual total drug spending per person paid by all payment sources and mean annual out-of-pocket spending per person.

Statistical analysis

We used chi-square tests to compare the equivalence of beneficiaries' characteristics by year within each study group.

We performed difference-in-differences regressions to compare the changes in drug use and expenditures among non-LIS beneficiaries (treatment) and LIS beneficiaries (control) over the pre-ACA (2008-2010) and post-ACA periods (2011-2015). One key assumption for a

difference-in-differences analysis is that the treatment and control groups have pre-policy parallel trends in the outcome measures. We tested this pre-policy parallel trend assumption through visual analysis (Figure IV-1 and Appendix B-2) and regression models (Appendix B-1, Appendix B-3 and Appendix B-4), where the assumption is valid.

First, year-by-year changes difference-in-differences models were estimated for each outcome using linear regression models with interaction terms between treatment group and year, which captured the changes attributable to the ACA coverage gap reform in each year of the post-ACA period, compared to the pooled pre-ACA period.[73] Second, we estimated difference-in-differences models that pooled the pre-ACA and post-ACA periods to see the overall effects of the policy changes. Both regression equations are described in the Appendix B-1. Lastly, we repeated our difference-in-differences analyses for several subgroups of interest: (1) beneficiaries who did not enter the coverage gap (i.e., spent less than the initial coverage limit for each year); (2) beneficiaries who entered the coverage gap but did not reach the catastrophic threshold and (3) beneficiaries who entered the catastrophic coverage phase (Appendix B-5). The primary population targeted by the policy would be the second subgroup that reached the coverage gap but not the catastrophic threshold. The criteria for each subgroup are described in the Appendix B-6.

All regression models were adjusted for beneficiary demographics (age, sex, race/ethnicity), socioeconomic characteristics (attained education level, family income as percentage of poverty level, urban versus rural residence), health status measured by the number of chronic conditions, and enrollment in a Medicare Advantage plan. In order to obtain nationally representative estimates for the non-LIS Medicare Part D population and to account for the complex sampling design of the MCBS, the Balanced Repeated Replication (i.e., Fay's

method) of variance estimation was used to adjust both serial and intra-cluster correlation in the data, using replicate cross-sectional weights for each year.[58] All statistical analyses were conducted using Stata 15.1 (StataCorp, College Station, Texas). All estimates of drug spending were converted to inflation-adjusted 2015 dollars using the all-items Consumer Price Index.[59]

Sensitivity analyses were conducted using each year of the pre-ACA period (i.e., 2008, 2009, and 2010) in place of the pooled pre-ACA years to check if the policy effect would differ by the selection of baseline year in the pre-ACA period. Our findings were robust to the selection of the year in the pre-ACA period and all regression results are in Appendix B-15.

Limitations

This study has several limitations to note. First, the effects of the policy may differ for brand and generic drugs due to differences in the stepwise structure of the cost-sharing reductions for each type of drug. However, information on whether beneficiaries filled the brand-name or generic version of a drug was not available in the MCBS data.

Second, because the coverage gap is gradually closing from 2011 through 2020, the policy effect is expected to increase over time. Additional reductions in cost-sharing for brand-name drugs were scheduled since 2016, and the cost-sharing reductions for generic drugs gradually increased over time. Therefore, the later years of the policy may better reflect the impact of the policy on generic drugs.

Lastly, our study sample included beneficiaries who have Medicare Advantage Prescription Drug plans (MA-PDs), which could have had a differential impact on beneficiaries' drug use and expenditures, as those with MA-PDs are likely to face lower out-of-pocket costs than those with a stand-alone prescription drug plan (PDP).[12] Although our models were adjusted

for beneficiary enrollment in an MA-PD, the information whether the beneficiary was enrolled in an MA-PD is collected from beneficiaries' self-reported responses, which may be subject to errors in memory with a greater risk for inaccuracy.

Study Results

Table ***IV-1*** presents the characteristics of the study sample by group and by year. Table IV-2 presents the unadjusted estimates of outcome variables after the ACA coverage gap reform for non-LIS and LIS beneficiaries, by year and by subgroup, where the pooled estimates for the pre- and post-ACA period were described first, followed by the estimates for each year of the post-ACA period. Table IV-3 shows the difference-in-differences estimates of outcome variables for non-LIS beneficiaries after the ACA coverage gap reform, compared with LIS beneficiaries. The estimates were drawn from two difference-in-differences regression models: 1) the pooled pre- and post-ACA period model, where the differences were measured between the pooled years 2008-2010 and the pooled years 2011-2015 and 2) the year-by-year changes model, where the differences were measured between the pooled years 2008-2010 and each year of the post-ACA period (2011, 2012, 2013, and 2015), separately. The full regression results are reported in Appendix B-7 and Appendix B-11.

Study population

The study population consisted of 24,919 non-LIS Part D beneficiaries in the treatment group and 9,835 LIS beneficiaries in the control group.

Table ***IV-1*** presents the weighted characteristics of the two groups, which were systemically different from one another. Compared to the LIS beneficiaries, non-LIS

beneficiaries were more likely to be male, younger, non-Hispanic white, more educated, higher income, living in an urban area, have fewer chronic conditions, and enrolled in an MA-PD.

Effects on drug utilization

Overall, the ACA coverage gap reform did not have significant impact on the number of 30-day drug fills. Although the unadjusted number of 30-day drug fills slightly increased in both groups in the post-ACA period (**Table IV-2**), the fully adjusted difference-in-differences estimates from the both models (pooled and year-by-year changes) showed decreases in the use of prescription drugs among non-LIS beneficiaries relative to LIS beneficiaries after the ACA, but no statistical difference (**Table IV-3**).

The results from the subgroup analyses were consistent with the primary analyses conducted among all beneficiaries. In all three subgroups, although the unadjusted number of 30-day drug fills increased in the post-ACA period, the adjusted difference-in-differences analyses results showed no significant effect of the ACA reform on the use of prescription drugs for beneficiaries.

Effects on total drug spending

Overall, there was no significant effect on total drug spending after the ACA coverage gap reform. Unadjusted mean annual total drug spending increased after the ACA, with larger increases seen in the control group (**Table IV-2**). The fully adjusted difference-in-differences analyses show a decrease of $335 among non-LIS beneficiaries relative to LIS beneficiaries, but it was not statistically significant (**Table IV-3**). However, the year-by-year changes difference-in-differences analysis showed a significant decrease of $944 for non-LIS beneficiaries in 2015

relative to LIS beneficiaries (**Table IV-3**), which seems to be mainly due to the considerable increases in total spending for LIS beneficiaries in 2015 (**Table IV-2**).

For those beneficiaries that did not reach the coverage gap, the ACA coverage gap reform was associated with decreases in total drug spending of $107 in 2012, $106 in 2013, and $122 in 2015, for non-LIS beneficiaries compared to LIS beneficiaries (all $p < 0.05$). However, there were no significant changes in mean annual total drug spending after the ACA for the other two subgroups (**Table IV-3**).

Effects on out-of-pocket drug spending

The ACA coverage gap reform significantly decreased out-of-pocket spending among non-LIS beneficiaries relative to LIS beneficiaries. Unadjusted mean annual out-of-pocket spending decreased in the post-ACA period relative to the pre-ACA period in both groups, from $768 to $664 in the treatment group and $135 to $108 in the control group, respectively (**Table IV-2**). The fully adjusted pooled difference-in-differences analyses showed that the out-of-pocket costs significantly decreased by $88 in the treatment group relative to the control group (**Table IV-3**). The average marginal effect estimated from the year-by-year changes difference-in-differences model were significant in all years ($p < 0.05$), with decreases of $41 in 2011, $49 in 2012, $105 in 2013, and $135 in 2015. This corresponds to decreases of 5%, 6%, 14%, and 18% from the baseline of $768, which shows the growing effects of the policy on out-of-pocket spending over time.

The subgroup analyses showed significant and growing reductions in out-of-pocket spending for non-LIS beneficiaries after the ACA among those not reaching the coverage gap and those entering the coverage gap without reaching the catastrophic threshold (**Table IV-3**).

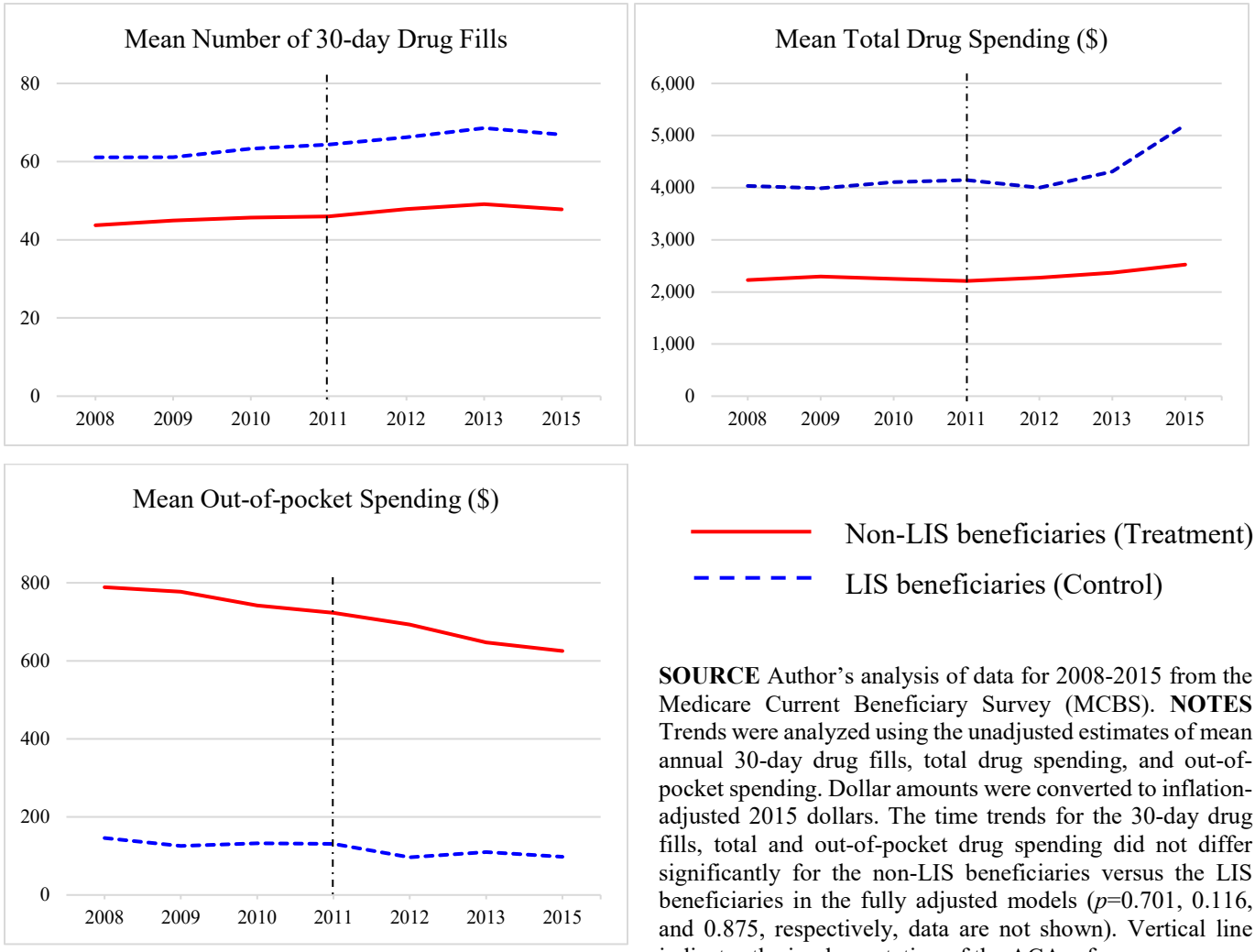
For those not reaching the gap, both unadjusted estimates (**Table IV-2**) and adjusted difference-in-differences estimates (**Table IV-3**) showed significant decreases of out-of-pocket spending in the treatment group after the ACA, with growing decreases over time (a $41 decrease in 2011 to $135 in 2015). Similar trends were seen among those entering the gap but not reaching the catastrophic threshold, although the decrease was more gradual. Mean annual out-of-pocket spending decreased slightly in 2011 and 2012, with larger decreases seen in 2013 and 2015 among non-LIS beneficiaries (**Table IV-2**). These results were reflected in the fully adjusted difference-in-differences analyses, where significant decreases of $179 and $254 were seen in 2013 and 2015, respectively (**Table IV-3**). Average marginal effects estimated from the difference-in-differences analysis were a decrease of $179 in 2013 and $254 in 2015 in the treatment group after the ACA relative to the control group (all $p < 0.01$), which corresponded to 11% and 16% decrease from the $1,576 at the baseline. For those reaching the catastrophic threshold, overall, there were no significant and meaningful trends in mean annual out-of-pocket spending in both unadjusted and adjusted analyses.

Table IV-1. Characteristics of non-LIS and LIS Part D beneficiaries by year, 2008-2015

	Non-LIS Part D beneficiaries (Treatment)					LIS Part D beneficiaries (Control)				
	Pre-ACA[a]	**2011**	**2012**	**2013**	**2015**	**Pre-ACA[a]**	**2011**	**2012**	**2013**	**2015**
Sample size (n)	9,420	3,317	3,736	4,126	4,320	4,150	1,339	1,393	1,416	1,537
Population size (N)	39,124,342	14,563,427	16,304,256	19,376,540	24,751,318	14,844,481	5,283,088	5,504,294	5,761,143	7,453,439
Female (%)	60	60	58	58	58	72	71	69	70	68
Age (%)										
65-74	47	49	49	50	54	41	44	44	44	48
75-84	37	36	36	31	35	39	36	35	34	33
85+	15	15	15	14	15	20	20	21	22	19
Race/ethnicity (%)										
White, non-His	92	91	92	90	89	66	65	64	64	63
Black, non-His	5	5	5	6	7	19	18	20	19	18
Hispanic	1	1	1	1	1	6	8	8	8	9
Other, non-His	2	2	3	3	4	8	9	9	9	10
Education (%)										
Less than high school	20	18	17	16	13	57	56	55	53	50
High school graduate	33	31	28	28	26	24	23	22	23	27
Some college or more	48	51	55	56	61	19	21	23	23	22
Family income (percent of poverty, %)										
< 125%	17	18	17	17	16	74	79	81	83	79
125%-200%	25	25	25	24	22	18	17	15	14	16
200%-400%	41	38	37	38	33	7	4	3	3	4
> 400%	17	19	21	21	30	1	1	0	0	1
Residence in rural area (%)	14	14	15	14	13	16	16	17	16	15
No. of chronic conditions (%)										
0-2	40	38	37	37	28	27	25	24	22	17
3-4	42	44	45	44	49	43	44	44	41	41
> 5	18	18	18	19	23	30	32	33	37	41
Enrolled in MA-PDs (%)	42	46	46	43	41	21	25	28	30	31

SOURCE Author's analysis of data from 2008-2015 Medicare Current Beneficiary Survey (MCBS). No MCBS data released in 2014. **NOTES** [a] The numbers for the pre-ACA reflect pooled estimates for the years 2008-2010. All estimates are rounded off to the nearest whole number. Chi-square tests were used for equality in frequencies across categories within each study group by year. All comparisons were statistically significant ($p < 0.05$), except for rural residence for the treatment group and sex, race/ethnicity, and rural residence for the control group. MA-PDs: Medicare Advantage Prescription Drug plans.

Figure IV-1. Trends of drug utilization and expenditures among non-LIS and LIS Part D beneficiaries, 2008-2015



SOURCE Author's analysis of data for 2008-2015 from the Medicare Current Beneficiary Survey (MCBS). **NOTES** Trends were analyzed using the unadjusted estimates of mean annual 30-day drug fills, total drug spending, and out-of-pocket spending. Dollar amounts were converted to inflation-adjusted 2015 dollars. The time trends for the 30-day drug fills, total and out-of-pocket drug spending did not differ significantly for the non-LIS beneficiaries versus the LIS beneficiaries in the fully adjusted models (p=0.701, 0.116, and 0.875, respectively, data are not shown). Vertical line indicates the implementation of the ACA reform.

Table IV-2. Unadjusted estimates of drug utilization and expenditures before and after the ACA's Part D coverage gap reform, by year and by subgroup

	Non-LIS Beneficiaries (Treatment)						LIS Beneficiaries (Control)					
	Pre-ACA	Post-ACA					Pre-ACA	Post-ACA				
	Pooled	Pooled	2011	2012	2013	2015	Pooled	Pooled	2011	2012	2013	2015
All Beneficiaries												
Sample size (n)	9,420	15,499	3,317	3,736	4,126	4,320	4,150	5,685	1,339	1,393	1,416	1,537
30-day drug fills	44.8	47.8	46.0	47.9	49.1	47.8	61.8	66.6	64.4	66.3	68.6	66.9
Total spending ($)	2,257	2,370	2,210	2,275	2,371	2,524	4,045	4,480	4,144	4,000	4,310	5,204
OOP spending ($)	768	664	723	693	647	625	135	108	131	97	110	98
By Subgroup:												
I. Those not reaching the gap												
Sample size (%)	74%	76%	75%	77%	77%	75%	50%	53%	50%	55%	55%	54%
30-day drug fills	35.7	38.7	37.3	39.3	39.5	38.3	37.6	43.1	40.2	43.7	45.8	42.6
Total spending ($)	1,195	933	1,056	1,008	930	812	1,275	1,122	1,204	1,198	1,123	1,013
OOP spending ($)	393	308	352	331	301	272	81	67	76	62	70	62
II. Those entering the gap but not the catastrophic threshold												
Sample size (%)	22%	19%	21%	18%	18%	18%	32%	28%	32%	27%	27%	26%
30-day drug fills	66.2	71.5	67.3	71.8	75.4	70.9	74.8	80.4	75.8	80.9	83.2	81.8
Total spending ($)	4,097	4,333	4,225	4,287	4,390	4,388	4,579	4,727	4,634	4,699	4,760	4,805
OOP spending ($)	1,576	1,441	1,594	1,500	1,396	1,339	191	156	182	146	150	146
III. Those reaching the catastrophic threshold												
Sample size (%)	4%	5%	4%	5%	5%	7%	18%	19%	18%	18%	18%	20%
30-day drug fills	98.6	99.8	102.5	99.1	103.2	97.1	112.0	118.8	114.2	118.5	121.8	118.2
Total spending ($)	12,140	16,456	13,552	15,162	17,317	17,713	11,439	14,407	11,776	12,140	14,281	17,642
OOP spending ($)	3,393	3,186	3,345	3,551	3,313	2,862	197	163	200	137	182	143

SOURCE Author's analysis of data for 2008-2015 from the Medicare Current Beneficiary Survey (MCBS). **NOTES** Characteristics of non-LIS and LIS beneficiaries are described in the Table 1. Dollar amounts were converted to inflation-adjusted 2015 dollars. All estimates indicate the mean annual estimates per beneficiary. ACA, Affordable Care Act; OOP, out-of-pocket.

Table IV-3. Difference-in-differences estimates of the effects of the ACA Part D coverage gap reform on drug utilization and expenditures for non-LIS beneficiaries, by year and by subgroup.

	Pre vs. Post [a]	Year-by-Year Changes [b]			
	Post-ACA	2011	2012	2013	2015
All Beneficiaries					
30-day drug fills	-1.3	-0.9	-1.1	-1.1	-1.8
Total costs ($)	-334.5	-113.9	54.7	-117.6	-943.8**
OOP costs ($)	-88.1**	-41.4*	-48.7*	-104.8**	-135.2**
By Subgroup:					
I. Those not reaching the gap					
30-day drug fills	-1.9	-1.4	-2.0	-3.3	-1.3
Total costs ($)	-106.2**	-81.7	-107.2*	-105.5*	-121.6*
OOP costs ($)	-74.6**	-43.0**	-46.0**	-84.9**	-109.0**
II. Those entering the gap but not the catastrophic threshold					
30-day drug fills	-0.1	1.3	-0.5	1.7	-2.2
Total costs ($)	67.9	81.9	69.9	111.3	35.5
OOP costs ($)	-123.0**	23.9	-49.9	-179.2**	-253.6**
III. Those reaching the catastrophic threshold					
30-day drug fills	-5.5	0.6	-6.7	-4.3	-8.9
Total costs ($)	920.8	1,135.8	2,421.9	1,861.3	-602.6
OOP costs ($)	-179.8	-32.2	189.1	-119.5	-503.1*

SOURCE Author's analysis of data from 2008-2015 Medicare Current Beneficiary Survey (MCBS). **NOTES** The sample size and characteristics are explained in Table 1. Results show difference-in-differences estimates for the non-LIS beneficiaries versus the LIS beneficiaries, by year and by subgroup. [a] Pooled difference-in-differences estimates for the years 2011-2015 (post-ACA period), compared with the pooled estimates for the years 2008-2010 (pre-ACA). [b] Year-by-year changes difference-in-differences estimates, compared with the pooled estimates for the years 2008-2010 (pre-ACA period). All analyses were adjusted for sex, age, race/ethnicity, education, family income as a percentage of poverty, urban versus rural residence, number of chronic conditions, and Medicare Advantage Prescription Drug plan status. ACA, Affordable Care Act; OOP, out-of-pocket. *$p < .0.05$, **$p < 0.01$

Discussion

This study evaluated the effects of the ACA Part D coverage gap reform on drug utilization and expenditures among non-LIS beneficiaries. We found that the ACA Part D coverage gap reform significantly decreased out-of-pocket spending for prescription drugs among non-LIS beneficiaries, with no major effects on the use of prescription drugs and total drug spending without statistical significance. The reduction in out-of-pocket spending grew over time after implementation of the reform, with larger effects among beneficiaries that entered the coverage gap without reaching the catastrophic coverage threshold. The finding of a significant decrease of out-of-pocket spending indicates that the ACA Part D coverage gap reform has helped to reduce financial barriers to the use of prescription drugs for beneficiaries, supporting the intent of the policy. This finding was consistent with the limited previous literature that has focused on specific populations of Part D beneficiaries.[12–14]

Gradual and statistically significant decreases in out-of-pocket spending occurred after implementation of the ACA coverage gap reform, with the largest reduction seen in 2015. This may be due to the unique characteristics of the gradual phase-in schedule of the reform under the ACA.[48] The immediate decreases in out-of-pocket spending in 2011 may be mainly due to the mandated 50% manufacturer discount on the price of brand-name drugs.[48] Although the 50% discount for brand-name drugs was large enough to see an immediate impact of the policy, it might have affected a relatively small proportion of beneficiaries as the majority of drugs used by Part D beneficiaries are generic drugs, with an average generic dispensing rate of 87% in 2015.[3] On the other hand, the significant reductions in out-of-pocket spending in the later years of the post-ACA period may reflect the delayed effects of the policy, which seems largely due to the gradual reduction in cost-sharing for generic drugs that experienced continuous decreases by

7% per year from 2011 to 2015.[48] Further study is needed to better identify how the different phase-in schedules for brand-name and generic drugs contributed to the reductions in out-of-pocket spending after the ACA.

The effects of the coverage gap reform on the primary population targeted by the policy – those entering the coverage gap without reaching the catastrophic threshold – had little immediate impact on out-of-pocket spending but grew over time by 2015 (11% decrease in 2013 and 16% decrease in 2015). Significant reductions in out-of-pocket spending were also seen among those not reaching the coverage gap. This effect might be due in part to the fact that the annual deductible remained relatively unchanged in the post-ACA period, and even decreased once adjusted for inflation from $334 in 2010 to $320 in 2015.[48]

Although the ACA's provisions of closing the Part D coverage gap helped beneficiaries reduce their out-of-pocket spending for prescription drugs, it did not lead to an increase in the use of prescription drugs, such that the mean number of 30-day drug fills did not significantly change after the ACA. Previous studies have shown different results on the effects of the coverage gap reform on drug utilization depending on the study population,[12–14] such that the effects on drug utilization might differ by beneficiaries' disease conditions. In this regard, the effects on drug utilization may be canceled out in this study since this study targeted general Part D beneficiaries using a population-level approach that assessed changes regardless of disease states. More research is needed as to which subpopulations of Part D beneficiaries were most impacted by this reform in terms of drug utilization.

No significant changes in total drug spending were seen after the ACA. Although mean annual total drug spending remained relatively unchanged after the ACA among non-LIS

beneficiaries, it increased considerably among LIS beneficiaries, resulting in a significant negative effect of the ACA on total drug spending for non-LIS beneficiaries in 2015 (a decrease of $944). The increase in total spending among LIS beneficiaries may be due in part to the higher proportion of people reaching the catastrophic coverage threshold relative to non-LIS beneficiaries, which reflects the fact that the majority of high-cost Part D enrollees are likely to receive the LIS.[3] Our subgroup analyses also reflect this trend: although average total spending by subgroup was relatively similar between non-LIS and LIS beneficiaries, the average total spending for all beneficiaries was higher among LIS beneficiaries, and they were more likely to reach the catastrophic threshold. The growth in Part D spending, mainly due to the increased spending for high-cost beneficiaries, has been a growing concern for the Medicare program.[3,49,66] Policy makers should consider changes to the Part D program to promote more cost-effective and high quality medication use by Part D beneficiaries, especially by high-cost beneficiaries.

We note three key contributions to the limited existing literature on the effects of the ACA Medicare Part D coverage gap reform. First, we provide the first estimates of the year-by-year changes of the policy change on drug use and expenditures through the law's first five years of implementation. Second, our subgroup analyses allowed us to examine the effects of the ACA Part D coverage gap reform on the target population (i.e., those entering the coverage gap without reaching the catastrophic threshold) and untargeted populations (i.e., those not entering the coverage gap or those reaching the catastrophic threshold) individually. Third, using a leading source of information on the Medicare population, we document the effects of the ACA coverage gap reform in the general Medicare Part D population, not limited to a specific population such as beneficiaries with certain conditions.

Conclusion

Over the first five years after implementation of the ACA reforms to close the Part D coverage gap for non-LIS beneficiaries, significant reductions were seen in out-of-pocket spending for prescription drugs that continued to decrease over time. This was particularly noticeably among the population targeted by the policy: those who reached the coverage gap but not the catastrophic threshold. However, despite seemingly large reductions in cost-sharing to Part D beneficiaries while in the coverage gap, the ACA had no significant effect on the use of prescription drugs or on total drug spending. This study demonstrates that the ACA reform has helped to reduce out-of-pocket drug costs burden for Part D beneficiaries, which is expected to increase in the later years of the policy as more generous coinsurance rate phased in.

V. MANUSCRIPT #3

Five-Year Impact of Closing the Medicare Part D Coverage Gap on Affordability and Access to Prescription Drugs

Target for submission in: Health Services Research or Health Affairs

Abstract

The affordability and access of prescription drugs have been persistent problems among Medicare beneficiaries, leading to cost-related medication nonadherence (CRN) or the adoption of cost-reduction strategies (CRS). The Affordable Care Act (ACA) initiated provisions to gradually phase out the Medicare Part D coverage gap beginning in 2011 to alleviate these cost-related access problems. We examined the changes in CRN and adoption of drug cost-reduction strategies within the first five years of the policy's implementation. We used a difference-in-differences approach using data from the 2008-2015 Medicare Current Beneficiary Survey. Compared to beneficiaries receiving the Low-Income Subsidy (LIS) who were not affected by the ACA, there was no significant change in CRN among non-LIS beneficiaries after the ACA. Furthermore, the probability of adopting CRS increased by 4 percentage points for non-LIS beneficiaries relative to LIS beneficiaries. Our findings demonstrate that the ACA reform reducing cost-sharing in the coverage gap did not lead to a reduction in cost-related access problems for Medicare Part D beneficiaries.

Introduction

Prior to implementation of the Medicare Part D program in 2006, cost-related medication nonadherence (CRN) such as not filling, stopping, or skipping doses of a prescription drug due to cost, was a persistent problem among Medicare beneficiaries, particularly among disabled beneficiaries or those with poor health, multiple morbidities, or limited drug coverage.[74] Drug costs represent financial barriers that contribute to more than 55% of participants with chronic conditions not filling a new prescription and 40% of stopping a medication.[75] Such CRN has been negatively associated with health status and outcomes, such as health declines, decreased quality of life, and increased use of emergency or institutional sevices.[76–78]

Evidence shows that Medicare contributed to a reduction in cost-related access problems by offering prescription drug coverage for beneficiaries under the Part D program.[79–81] However, Part D did not fully resolved these cost-related access problems, particularly among the sickest beneficiaries or those with certain conditions like depression or stroke.[82,83] Additionally, the Part D benefit structure has a coverage gap (also known as the "doughnut hole") during which beneficiaries are required to pay 100% of their drug costs, which can inhibit access to medications. There is clear evidence that the coverage gap has unfavorably impacted beneficiaries' out-of-pocket drug costs,[6,7] resulting in an increase in cost-related medication access problems.[8,42,43] Beneficiaries with a coverage gap in their drug plans were up to 5 times more likely to have CRN than those without the coverage gap.[42,43] Furthermore, beneficiaries with the coverage gap were more likely to adopt drug cost-reduction strategies (CRS) after reaching the gap, with an even greater likelihood for beneficiaries with lower income and poorer health status.[43] Among those with the coverage gap, beneficiaries who reached the gap were twice as likely to discontinue their medication after reaching the coverage gap.[8]

Responding to these adverse effects of the coverage gap on beneficiaries, the Patient Protection and Affordable Care Act (ACA) of 2010 has been gradually phasing in strategies to reduce cost sharing in the coverage gap from 100% coinsurance in 2010 to 25% by 2020.[33,48] Since 2011, manufacturers have been required to provide a 50% discount on the price of brand-name drugs in the gap. Additionally, beneficiaries' coinsurance rates in the coverage gap have gradually decreased, beginning in 2011 for generics and 2013 for brand-name drugs.[48]

To date, little is known about how the ACA Part D coverage gap reform has affected cost-related access problems. In this study, we assessed the prevalence of having CRN and adopting CRS among a nationally representative sample of Medicare Part D beneficiaries before and after the 2011 implementation of the ACA coverage gap reform (2008-2015). Additionally, we evaluated whether the ACA decreased rates of CRN and CRS using a quasi-experimental study design. To our knowledge, this is the first study to examine the effects of the ACA coverage gap reform on CRN and cost-reduction strategies using a nationally representative sample of Medicare beneficiaries.

Methods

Data source

The data for this study were extracted from the Medicare Current Beneficiary Survey (MCBS) for the years of 2008 to 2013 and 2015. MCBS data for 2014 were not released by the Centers for the Medicare & Medicaid Services.[55,56] The MCBS is a continuous, in-person, longitudinal survey of a nationally representative sample of the Medicare population that is linked to administrative claims data, and provides comprehensive information on health care

utilization and expenditures, as well as beneficiaries' access to health care, satisfaction with care, and usual source of care.[55] We used the Cost and Use Files from 2008 to 2013 and the Cost Supplement File from 2015 to identify study cohorts and obtain sociodemographic data, and the Access to Care files from 2008 to 2013 and Survey File from 2015 to assess CRN or adoption of CRS among beneficiaries.[58]

Study population

This study used a difference-in-differences approach to compare the pre-post change of the outcome variables between the treatment and control groups. The study period was from January 2008 to December 2015, where the pre-ACA period was defined as January 2008 to December 2010, and the post-period was defined as January 2011 to December 2015.

The treatment group was Part D beneficiaries who did not receive the LIS (i.e., non-LIS beneficiaries) who may have been exposed to the coverage gap. The inclusion criteria for the treatment group were: (1) age 65 years or older; (2) not disabled or not having end-stage renal disease; (3) continuous enrollment in a Part D plan; and (4) having at least one prescription fill. Like other studies, part D beneficiaries who received the LIS (i.e., LIS beneficiaries) were selected as the control group, because they were not affected by the ACA's coverage gap reform since they already had little or no cost-sharing in the coverage gap before the ACA reform.[14,51] The study sample of the control group was identified using the same inclusion criteria used in the treatment group.

Outcome variables

CRN and CRS were our two primary outcome measures of interest, which were evaluated using self-reported responses to survey questions in the MCBS.[84] First, CRN was measured by

the following 4 validated survey questions: 1) has the beneficiary often, sometimes, or never decided not to fill a prescription because it cost too much, 2) skipped doses to make the medicine last longer, 3) taken smaller doses than prescribed of a medicine to make the medicine last longer, or 4) delayed getting a prescription filled because it cost too much.[85–87] As in the previous studies, we constructed a summary indicator of CRN that took the value "yes" if a respondent indicated often or sometimes and "no" if never.[79,82,88] We classified those respondents who answered "yes" to any of the 4 questions as having CRN.

Second, CRS were measured by the following 4 questions: 1) has the beneficiary often, sometimes, or never asked for generics instead of brand-name drugs, 2) asked for or received free samples from doctor or health provider, 3) compared drug prices or shopped around for the best price, or 4) spent less money on food, heat, or other basic needs so that he/she would have money for medicine.[79,87] Like for CRN, responses were categorized as "yes" if a respondent indicated often or sometimes and "no" if never, then a binary aggregate measure was constructed by classifying individuals as adopting CRS if the answer was "yes" to any of the 4 CRS during the survey year.

Statistical analyses

First, we used descriptive statistics to describe the sociodemographic characteristics of the treatment and control groups in the pooled pre-ACA period (2008-2010) and for each post-ACA year (2011, 2012, 2013, and 2015). Next, we measured the unadjusted annual prevalence of CRN and adoption of CRS in the treatment and control groups from 2008 to 2015.

We estimated an adjusted logistic regression model to assess the changes in odds of engaging in CRN or CRS after the ACA for non-LIS beneficiaries (treatment). We then

estimated difference-in-difference (DD) logistic regression models to estimate changes in the likelihood of having CRN and adopting CRS for non-LIS beneficiaries relative to LIS beneficiaries (control) after the ACA reform.[89] While the coefficient of the interaction term in a linear DD regression directly represents the impact of policy on the outcomes of interest, in a logistic DD regression the estimated coefficient of the interaction term is the ratio of the two odds ratios (ORs): OR for the treatment group/OR for the control group.[89] This ratio-of-odds ratios (ROR) DD estimate thus captures the extent to which the increase in odds of engaging in CRN or CRS (from the pre- to the post-ACA) is higher for the treatment group relative to the control group.[89] We also estimated average marginal effect of the interaction term to help interpretation of the DD estimates. One key assumption for a difference-in-differences analysis is that the treatment and control groups have pre-policy parallel trends in the outcome measures. We tested this pre-policy parallel trend and verified the assumption is valid through visual analysis (Figure V-1) and regression models (Appendix C-3).

For each outcome (a binary indicator of CRN and CRS) we estimated two DD logistic regression models: 1) pooled DD logistic regression model that pooled the pre-ACA and post-ACA years to see the overall effects of the policy changes, and 2) year-by-year changes DD logistic regression model with interactions between treatment group and year, which captured the changes attributable to the ACA reform in each year of the post-ACA period compared to the pooled pre-ACA period.[73] All regression models were adjusted for beneficiary demographics (age, sex, race/ethnicity), socioeconomic characteristics (attained education level, family income as percentage of poverty level), health status measured by the number of chronic conditions, and enrollment in a Medicare Advantage plan. Regression equations are described in Appendix C-1.

In order to obtain nationally representative estimates for the Medicare Part D population and to account for the complex sampling design of the MCBS (e.g., the rotating-panel and multistage-sampling design), the Balanced Repeated Replication (i.e., Fay's method) of variance estimation was used to adjust both serial and intra-cluster correlation in the data using replicate cross-sectional weights for each year.[58] All statistical analyses were conducted using Stata 15.1 (StataCorp, College Station, Texas).

Sensitivity Analysis

Our sensitivity analyses using two different measures of CRN and CRS showed similar results with the primary analysis using the binary indicators. More detailed information on study method is described in the Appendix C-2.

Study Results

Characteristics of study population

The study population defined by the inclusion criteria were 24,919 non-LIS Part D beneficiaries in the treatment group and 9,835 LIS Part D beneficiaries in the control group for the study period, 2008-2015.

Table ***V-1*** provides the weighted demographic and socioeconomic characteristics of the non-LIS (treatment) and LIS beneficiaries (control), which were systemically different from one another. Compared to the LIS beneficiaries, non-LIS beneficiaries were more likely to be males, younger, non-Hispanic whites, educated, have higher family income levels, have fewer chronic conditions, and be enrolled in a MA-PD.

Table V-1. Characteristics of non-LIS and LIS Part D beneficiaries by year, 2008-2015

	Non-LIS Part D beneficiaries (Treatment)					LIS Part D beneficiaries (Control)				
	Pre-ACA[a]	**2011**	**2012**	**2013**	**2015**	**Pre-ACA[a]**	**2011**	**2012**	**2013**	**2015**
Sample size (n)	9,420	3,317	3,736	4,126	4,320	4,150	1,339	1,393	1,416	1,537
Population size (N)	39,124,342	14,563,427	16,304,256	19,376,540	24,751,318	14,844,481	5,283,088	5,504,294	5,761,143	7,453,439
Female (%)	60	60	58	58	58	72	71	69	70	68
Age (%)										
65-74	47	49	49	50	54	41	44	44	44	48
75-84	37	36	36	31	35	39	36	35	34	33
85+	15	15	15	14	15	20	20	21	22	19
Race/ethnicity (%)										
White, non-His	92	91	92	90	89	66	65	64	64	63
Black, non-His	5	5	5	6	7	19	18	20	19	18
Hispanic	1	1	1	1	1	6	8	8	8	9
Other, non-His	2	2	3	3	4	8	9	9	9	10
Education (%)										
Less than high school	20	18	17	16	13	57	56	55	53	50
High school graduate	33	31	28	28	26	24	23	22	23	27
Some college or more	48	51	55	56	61	19	21	23	23	22
Family income (percent of poverty, %)										
< 125%	17	18	17	17	16	74	79	81	83	79
125%-200%	25	25	25	24	22	18	17	15	14	16
200%-400%	41	38	37	38	33	7	4	3	3	4
> 400%	17	19	21	21	30	1	1	0	0	1
No. of chronic conditions (%)										
0-2	40	38	37	37	28	27	25	24	22	17
3-4	42	44	45	44	49	43	44	44	41	41
> 5	18	18	18	19	23	30	32	33	37	41
Enrolled in MA-PDs (%)	42	46	46	43	41	21	25	28	30	31

SOURCE Author's analysis of data from 2008-2015 Medicare Current Beneficiary Survey (MCBS). No MCBS data released in 2014. **NOTES** [a] The numbers for the pre-ACA reflect pooled estimates for the years 2008-2010. All estimates are rounded off to the nearest whole number. Chi-square tests were used for equality in frequencies across categories within each study group by year. All comparisons were statistically significant ($p < 0.05$), except for rural residence for the treatment group and sex, race/ethnicity, and rural residence for the control group. MA-PDs: Medicare Advantage Prescription Drug plans.

Effects on cost-related nonadherence (CRN)

There was no significant effect of the ACA's coverage gap reform on CRN. The unadjusted year-to-year changes in the prevalence of the CRN slightly increased among both groups from 2008 to 2015 (Figure V-1). The fully adjusted difference-in-differences logistic regression estimates from both models (pooled and year-by-year changes) show that the ACA's coverage gap reform had no significant effect on CRN (Table V-3).

From the adjusted logistic regression, the odds of having CRN increased by a factor of 1.37 among non-LIS beneficiaries after the ACA (Table V-2). When we compared this estimate to changes in CRN among LIS beneficiaries, the DD estimate (ratio of the non-LIS beneficiary OR to the LIS beneficiary OR) remained greater than 1 but not statistically significant (ROR = 1.19, Table V-3). This DD estimate indicates that the increase in the odds of having CRN was higher for the non-LIS beneficiaries relative to the LIS beneficiaries, although this difference was not statistically significant. Similar trends were seen in the year-by-year changes DD logistic model, with statistically significance seen only in 2015 (ROR = 1.37, $p = 0.04$). The detailed results from the regressions are reported in Appendix C-6 and Appendix C-7.

Effects on cost-reduction strategies (CRS)

Overall, we found that non-LIS beneficiaries were more likely to engage in CRS both before and after the ACA reform compared to LIS beneficiaries. The unadjusted prevalence rate of adopting CRS decreased in both groups after the ACA, with a larger decrease seen among LIS beneficiaries than non-LIS beneficiaries (i.e., decreased by 22% and 39% from 2010 to 2015 for non-LIS and LIS beneficiaries, respectively; Figure V-1).

This trend was reflected in the fully adjusted difference-in-difference logistic regression analyses. From the adjusted logistic regression, the odds of adopting CRS after the ACA were reduced by 56% for non-LIS beneficiaries (OR = 0.44; p = 0.00; Table V-2), which indicates that non-LIS beneficiaries were less likely to experience CRS after the ACA. However, the corresponding pooled DD estimate shows that the decrease in the odds of adopting CRS was significantly lower for the non-LIS beneficiaries relative to the LIS beneficiaries (ROR = 1.19; p = 0.03; Table V-3). The average marginal effect showed that the probability of adopting CRS for non-LIS beneficiaries increased by 4 percentage points relative to LIS beneficiaries after the ACA. Similar trends were seen in the year-by-year changes DD logistic regression, with slightly increasing average marginal effects over time indicating the growing effects of the policy in the later years. Full regression results are described in Appendix C-6 and Appendix C-7.

Figure V-1. Unadjusted prevalence of cost-related medication nonadherence and drug cost-reduction strategies among non-LIS and LIS Part D beneficiaries, 2008-2015

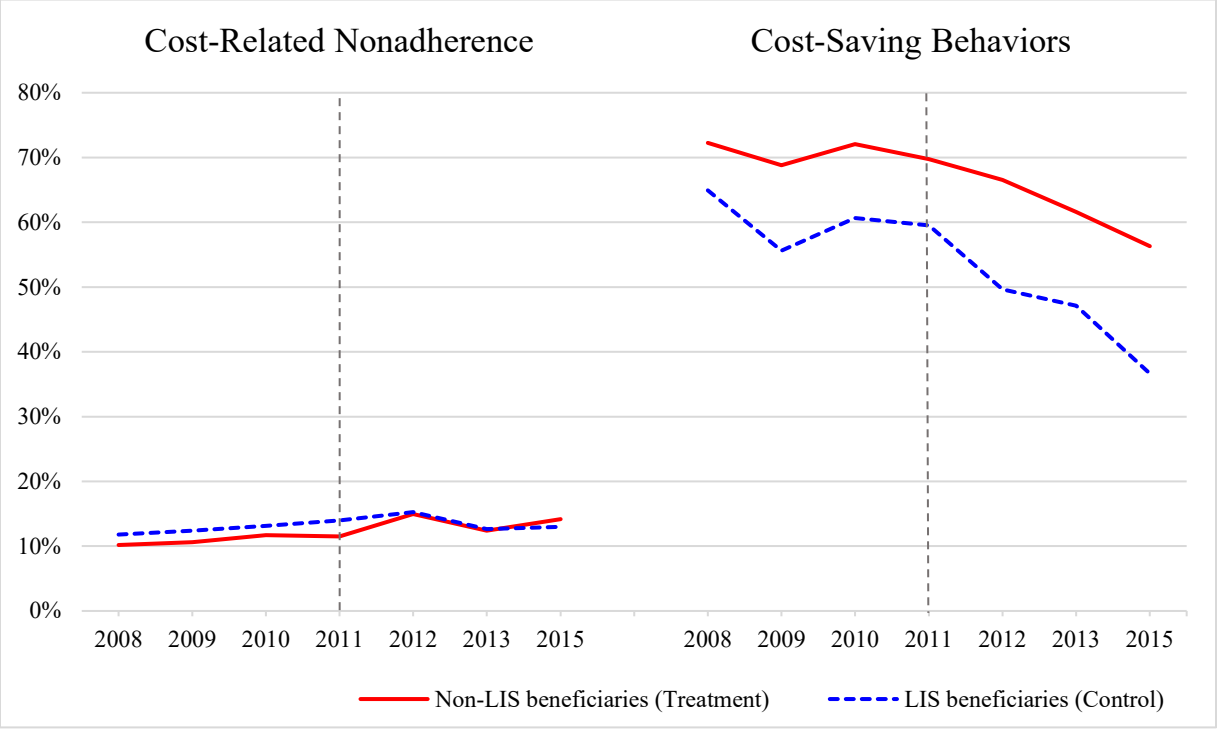


Table V-2. Changes in cost-related medication nonadherence (CRN) and drug cost-reduction strategies (CRS) among non-LIS beneficiaries after the ACA reform

	Pre vs. Post [a]		Year-by-Year Changes [b]							
	Post-ACA		2011		2012		2013		2015	
	OR	SE	OR	SE	OR	SE	OR	SE	OR	SE
CRN										
Post [c]	1.37**	0.12	1.06	0.09	1.45**	0.09	1.15	0.08	1.29**	0.10
CRS										
Post [c]	0.44**	0.03	0.94	0.06	0.79**	0.04	0.63**	0.03	0.47**	0.03

NOTES ACA = Affordable Care Act; OR = odds ratio; SE = standard error. [a] Pooled estimate from simple adjusted logistic regression for the years 2011-2015 (post-ACA period), compared with the pooled estimates for the years 2008-2010 (pre-ACA). [b] Year-by-year changes estimates from simple adjusted logistic regression, compared with the pooled estimates for the years 2008-2010 (pre-ACA period). [c] The Post OR reflects the simple adjusted odds of having cost-related nonadherence or adopting cost-reduction strategies for non-LIS beneficiaries after the ACA. *$p < .0.05$, **$p < 0.01$

Table V-3. Effect of ACA reform on cost-related medication nonadherence (CRN) and drug cost-reduction strategies (CRS) for non-LIS beneficiaries after the ACA reform

	Pre vs. Post [a]		Year-by-Year Changes [b]							
	Post-ACA		2011		2012		2013		2015	
	OR	SE	OR	SE	OR	SE	OR	SE	OR	SE
CRN										
Post × Treated	1.19	0.13	0.96	0.15	1.21	0.17	1.19	0.19	1.37*	0.21
Average Marginal Effect	0.02	0.012	-0.01	0.02	0.02	0.02	0.02	0.02	0.03*	0.02
CRS										
Post × Treated	1.19*	0.09	0.98	0.09	1.26*	0.13	1.12	0.11	1.38*	0.17
Average Marginal Effect	0.04*	0.02	-0.01	0.02	0.05*	0.02	0.03	0.02	0.07*	0.03

NOTES ACA = Affordable Care Act; OR = odds ratio; SE = standard error. [a] Pooled difference-in-difference estimate for the years 2011-2015 (post-ACA period), compared with the pooled estimate for the years 2008-2010 (pre-ACA). [b] Year-by-year changes difference-in-differences estimates, compared with the pooled estimates for the years 2008-2010 (pre-ACA period). [c] Post × Treated OR reflects DD estimate, which is the ratio of the OR of having CRN or adopting cost-reduction strategies for non-LIS beneficiaries to that for LIS beneficiaries. *$p < .0.05$, **$p < 0.01$

Sensitivity analysis

Our sensitivity analyses using two different measures of CRN and CRS showed similar results with the primary analysis using the binary indicators.

The unadjusted prevalence of each individual measure of the CRN and CRS are presented in Appendix C-8 and Appendix C-9. Among the 8 measures, two CRS (asked for generics and price shopped) violated the parallel trends assumption, which is the key assumption for a difference-in-difference analysis. Non-LIS beneficiaries had higher odds of having CRN across the 4 measures, with the measures of "did not fill" and "delayed filling" being statistically significant. The DD estimates indicate that the increase in the odds of CRN were higher for non-LIS beneficiaries relative to LIS beneficiaries, although the difference is statistically significant only in the measure of "did not fill" (Appendix C-10). For CRS, non-LIS beneficiaries had lower odds of receiving free samples and spending less on basic needs, but statistical significance was seen only for receiving free samples (Appendix C-10). The corresponding DD estimates were not statistically significant. Full regression results are reported in Appendix C-11 and Appendix C-12.

Secondly, we used 5-point ordinal scales to construct the measures of CRN and CRS, with the unadjusted prevalence by year presented in Appendix C-13. The prevalence rate of no CRN (CRN = 0) for non-LIS beneficiaries decreased slightly in the post-ACA period, while those for LIS beneficiaries remained stable (88% in 2010 to 86% in 2015 for the non-LIS beneficiaries vs. 87% in 2010 to 87% in 2015 for the LIS beneficiaries). For CRS, the non-LIS and LIS beneficiaries were both more likely to not experience any CRS (CRS = 0) after the ACA, with a larger increase seen among LIS beneficiaries (increased by 57% and 80% for non-

LIS and LIS beneficiaries, respectively). The difference-in-differences OLS regression presents no significant effect on CRN and CRS for the non-LIS beneficiaries relative to the LIS beneficiaries (Appendix C-14). The difference-in-differences ordinal logistic regression showed similar results to our primary analysis model (Appendix C-14). There was no significant effect on CRN, but the decrease in the odds of CRS was significantly smaller for non-LIS beneficiaries relative to LIS beneficiaries (ROR = 1.16; p = 0.04). However, we found that the use of ordinal logistic regression model in this study is not valid because the parallel regression assumption has been violated, which is a key assumption underlying the ordinal logistic regression.[90,91] Full regression results are described in Appendix C-15 and Appendix C-16.

Discussion

This study evaluated how the ACA coverage gap reform affected the likelihood of CRN and CRS for Medicare Part D beneficiaries during the first 5 years of the ACA's implementation. We analyzed the changes in CRN and CRS between non-LIS and LIS beneficiaries before and after the ACA coverage gap reform. No significant change in the rate of CRN was found, but the rate of using CRS increased among non-LIS beneficiaries relative to the LIS beneficiaries. Our findings indicate that the ACA provision to gradually close the coverage gap did not provide significant relief to beneficiaries with cost-related medication access problems within the first 5 years of the policy.

Although there is no previous research specifically on the effect of the ACA coverage gap reform on beneficiaries' cost-related access problems, our results are in line with findings from other related studies. First, several studies found that the implementation of Medicare Part D had no significant impact on cost-related problems to access prescription drugs.[43,74,82,83,89]

After Medicare Part D implementation, CRN was still persistent or slightly increased among beneficiaries, with a greater prevalence among those with certain conditions such as stroke,[83] depression,[82] or glaucoma.[79] Given that we would expect Part D implementation to have a greater positive impact on CRN, because gaining drug coverage would have more impact on CRN than a cost-sharing reduction, it may be a natural consequence that the ACA reform had no impact on CRN.

Additionally, in a study using data from a 2017 survey of older adults in 11 high-income countries, the United States stood out as having the highest rate of older adults with cost-related barriers such as skipping care or drug doses due to cost or not filling a prescription (23% in the US versus 5% or less in other countries).[92] Some studies also shows that the ACA coverage gap reform had no significant effect on the use of prescription drugs, although it significantly decreased out-of-pocket drug costs.[12,14] These findings of no significant changes in the use of prescription drugs may be partly explained by persistent cost-related access problems to drugs even after the ACA, as reported in this study.

As the ACA gradually reduced beneficiaries' cost-sharing in the coverage gap, we hypothesized that the ACA would have decreased the rate of CRN and use of CRS for non-LIS beneficiaries. Our hypothesis relied on previous studies that found an inverse relationship between cost-sharing and medication adherence.[9,60,61,93] However, contrary to our hypothesis, this study demonstrates that the likelihood of having CRN was slightly increased among non-LIS beneficiaries after the ACA, and when compared to LIS beneficiaries, no significant changes were seen in having CRN. For CRS, although the overall prevalence decreased among non-LIS beneficiaries after the ACA, which is consistent with our hypothesis, but compared to LIS beneficiaries, non-LIS beneficiaries were still more likely to use several strategies to reduce drug

costs and/or save money on their medications. These findings indicate that having CRN or CRS for non-LIS beneficiaries was unaffected by the policy.

This unfavorable impact of the ACA on CRN or CRS could be explained by a combination of several factors. First, although the ACA has phased out the coverage gap by reducing the coinsurance rate resulting in decreased out-of-pocket costs,[12] the magnitude of this reduction may not have been sufficient to reduce out-of-pocket drug costs burden for beneficiaries given the high and rising cost of prescription drugs.[3,94] Although annual out-of-pocket drug costs decreased by 29% after the ACA,[12] Part D drug prices increased by an average of 66% cumulatively between 2006 and 2015.[3] Additionally, with the greater availability and use of high-priced drugs, the decreased coinsurance rate by the ACA still could translate into significant out-of-pocket costs for beneficiaries.[3]

Second, the persistence of cost-related access problems after the ACA could be in part due to the absence of an annual out-of-pocket spending limit under Part D, which has been a growing concern for high-cost beneficiaries (i.e., those who incurred out-of-pocket spending above the catastrophic threshold).[49,50] Although high-cost beneficiaries are required to pay for only 5% of their drug costs after reaching the catastrophic threshold, because there is no hard cap on out-of-pocket spending this could translate into a substantial out-of-pocket cost burden for beneficiaries, particularly those with special conditions taking high-priced drugs such as cancer, multiple sclerosis, or viral hepatitis.[15,49,50,95] The average annual out-of-pocket spending for high-cost beneficiaries was over $3,000 in 2015, with an average of $1,215 in out-of-pocket costs above the catastrophic threshold.[49] In this regard, high-cost beneficiaries could have experienced cost-related access problems despite the ACA's cost-sharing reduction in the coverage gap, resulting in the adoption of several CRS. As the number of high-cost beneficiaries has increased

since 2011,[3,49] we believe that cost-related access problems experienced by high-cost beneficiaries might have been reflected in the findings of this study.

Third, Part D premiums and tiered coinsurance rates could be other contributing factors to the out-of-pocket costs for beneficiaries, resulting in cost-related access problems.[5,96] Part D beneficiaries generally pay a monthly premium for prescription drug coverage, which averaged $41 per month in 2018 and ranged from $20 to $84 per month.[5] Additionally, beneficiaries are required to bear much higher cost-sharing rates for brand-name, non-preferred, and specialty tier drugs.[5] In 2018 the median cost sharing for preferred brand-name drugs was $37 with a 40% coinsurance rate for non-preferred drugs, and about half of Part D beneficiaries were in plans that charged the maximum 33% coinsurance rate for specialty drugs.[5] Therefore, even though the coverage gap was gradually closed by the ACA, monthly premium and higher cost sharing under different formulary tiers could continue to be a serious out-of-pocket costs burden for many beneficiaries, resulting in cost-related access problems.

Limitation

Despite these results suggesting the ACA has had little to no impact on CRN and CRS, there are several limitations of this study. First, although the ACA has gradually closed the coverage gap since 2011 through 2020, this study shows only the effects of the ACA within the first five years and did not examine its full effects through 2020, which are likely to have increased since 2016. As cost-sharing reductions for generic drugs have gradually grown in linear fashion over time, the later years of the policy may better reflect the overall impact of the policy. Additionally, as the majority of drugs used by Part D beneficiaries are generic drugs, with

87% of prescriptions filled in 2015,[3] we may find more evidence to support the impact of the policy on cost-related access problems using more recent data .

Second, this study was not able to determine which beneficiaries actually experienced the coverage gap during the year, since the MCBS data did not contain detailed information on each drug plan's benefit structure. Part D plans could have a variety of drug benefit structures, since they have discretion to develop their own drug benefits, as long as the cost-sharing structure is actuarially equivalent to the average expected coinsurance in the standard benefit structure. Therefore, each plan would have different structure for the coverage gap, while some plans do not have a coverage gap. Due to lack of detailed information on plan structures, it was impossible to identify whether or not a given beneficiary entered the coverage gap.

Third, our results are subject to limitations common to other studies using population-based health surveys. Survey respondents may not fully recall all relevant events or be vulnerable to social desirability bias, whereby they may report an overly optimistic estimation of medication adherence or unwilling to admit their medication nonadherence due to cost.[79,89,97] As a result, cost-related access problems may be underreported due to the limitations of self-reporting measures. Despite such underreporting issues, the magnitude of underreporting is consistent across time in the MCBS dataset[79,98] and supports the validity of our study results.

Fourth, our study findings are based on some of the CRN or CRS that we were able to test using the MCBS dataset. There are other CRN behaviors or CRS not collected in the MCBS, such as borrowing money from family members or friends.[79] Additionally, the survey questions asking about CRN and CRS in the MCBS do not provide detailed information on cost-related

access problems for specific medications or classes of drugs. Rather, they indicate overall cost-related access problems for all kinds of prescription drugs.

Lastly, although we used LIS beneficiaries as our control group for difference-in-differences analysis relying on the previous study,[14] LIS beneficiaries may have very different characteristics from non-LIS beneficiaries, which could affect the likelihood of experiencing cost-related access problems. For example, compared to non-LIS beneficiaries, LIS beneficiaries were more likely to be sicker, poorer, and have much more generous drug coverage with out-of-pocket costs up to an $8.35 copayment or 15% coinsurance rate.[28] Additionally, LIS beneficiaries were more likely to be high-cost beneficiaries than non-LIS beneficiaries (nearly 20% versus less than 4%, respectively) and tend to use more brand-name drugs than non-LIS beneficiaries.[3] Despite such systemic differences between non-LIS and LIS beneficiaries, we believe the parallel trends assumption was not violated, which supports the validity of our findings.

Conclusions

While the ACA has initiated policy that aims to provide more affordable prescription drugs by gradually reducing cost-sharing rates in the coverage gap, our findings suggest that such cost-sharing reductions did not translate into actual mitigation effects for beneficiaries in terms of the cost-related barriers to access to prescription drugs. Closing the coverage gap by reducing the coinsurance rate may not be sufficient to fulfill beneficiaries' unmet need for prescription drugs, and additional initiatives might be needed to reduce cost-related barriers to access to prescription drugs for Part D beneficiaries. For example, a substantial reduction in

prescription drug prices or a shift in benefit design (e.g., from coinsurance to copayments) would potentially provide relief to beneficiaries from cost-related access problems.

VI. DISCUSSION AND CONCLUSION

This section summarizes the main findings from the three manuscripts in Chapters 3, 4, and 5, followed by the policy implications of the findings. Next, limitations of the study and conclusions will be discussed along with areas for future research.

Summary of Findings

This study evaluated the impact of the ACA's Medicare Part D coverage gap reform on the utilization of prescription drugs, drug expenditures, and cost-related access problems for prescription drugs among Part D beneficiaries. Under the ACA, the coverage gap in the Part D benefit has been gradually phasing out since 2011 by reducing the beneficiary cost-sharing rate from 100% in 2010 to 25% by 2020. To evaluate the effects of the ACA reform, we first conducted a descriptive study to examine trends in the distribution of non-LIS beneficiaries entering each benefit phase and their drug utilization and expenditures from 2008 to 2015. Second, using a difference-in-differences approach, we assessed the impact of the ACA reform on drug utilization and expenditures among non-LIS beneficiaries, using LIS beneficiaries as a comparison group. Lastly, we estimated the effects of the ACA reform on cost-related access problems to prescription drugs among beneficiaries, such as the rates of cost-related nonadherence (CRN) or the adoption of drug cost-reduction strategies (CRS).

In the first study, a substantial relative increase was seen in the proportion of non-LIS beneficiaries reaching the catastrophic coverage phase (4% in 2010 to 6% in 2015) after the ACA reform, and they reached the threshold more quickly (i.e., earlier in the year) than in the pre-ACA period. Along with this increase, annual total drug spending increased steadily over the

study years, with the largest increase seen among high-cost beneficiaries (i.e., those reaching the catastrophic coverage threshold). Such increases in the number of high-cost beneficiaries and total drug spending provide evidence supporting the recent attention focused on the growth in Part D drug spending, and emphasizes significant growth in spending for high-cost beneficiaries.[3,16,62,63] Since Medicare is the major source of payment for drug costs in the catastrophic coverage phase and the growth in Part D spending was mainly driven by high-cost beneficiaries, this has led to growing costs for the Medicare program that are expected increase in the future.[3,49,65,66]

Our descriptive study also found that out-of-pocket spending significantly decreased by 17% after the ACA, while prescription drug utilization increased by 7%. The ACA provisions requiring cost-sharing reductions and 50% manufacturer discounts on the price of brand-name drugs likely contributed to the significant decreases in out-of-pocket spending. Furthermore, the increases in drug utilization may also be due in part to the reduction in cost-sharing in the coverage gap under the ACA, which is consistent with previous studies that found an inverse relationship between cost-sharing and drug utilization.[9,10,13,60,61] Overall, the trends in out-of-pocket spending and drug utilization reported in this study suggest that the ACA reform has helped to improve the affordability of prescription drugs for beneficiaries.

The significant decreases in out-of-pocket spending for prescription drugs after the ACA was also shown in our second study using a difference-in-differences approach. These findings were generally consistent with the limited evidence from previous literature.[12–14] Additionally, over the first five years following implementation of the ACA reform, out-of-pocket spending decreased gradually over the years. These findings show the growing effects of the policy, which may be due to the gradual phase-in schedule of closing the coverage gap under the ACA.[48] The

significant decreases were particularly noticeable among those who reached the coverage gap but not the catastrophic threshold, which is the primary population targeted by the policy.

Despite significantly reduced out-of-pocket drug spending following the ACA reform, there was no significant change in drug utilization, relative to LIS beneficiaries. This finding of no impact on drug utilization was generally consistent with the limited evidence from the existing literature, although the utilization measures and study populations differed.[12,14] On the other hand, some studies showed significant effects on drug use, such that the ACA reform increased utilization for generics (but decreased for brand-name drugs)[12] and improved adherence to diabetes medications.[13] Given the mixed evidence on drug utilization, the effects of the ACA reform on drug utilization might be different by type of drug or disease conditions. Therefore, more research is needed as to which types of drugs and populations of Part D beneficiaries were most impacted by the ACA reform.

For total drug spending, the difference-in-differences analyses found that there were no significant changes overall for non-LIS beneficiaries relative to LIS beneficiaries after the ACA reform until 2013. However, a significant decrease of $944 in total drug spending was found among non-LIS beneficiaries in 2015 compared to LIS beneficiaries. This decrease was mainly due to a considerable increase in total drug spending among LIS beneficiaries, while spending for non-LIS beneficiaries remained relatively unchanged. The increase in total drug spending among LIS beneficiaries may be due in part to a higher proportion of high-cost beneficiaries relative to non-LIS beneficiaries, which reflects the fact that the majority of high-cost beneficiaries are likely to receive the LIS.[3]

Lastly, this study found that the ACA had no impact on the likelihood of having CRN, but the rate of adopting cost-reduction strategies increased slightly but significantly among non-LIS beneficiaries relative to LIS beneficiaries after the ACA. Our findings indicate that closing the coverage gap under the ACA did not provide relief to beneficiaries with cost-related access problems for prescription drugs over the first 5 years of the policy. Although there is no study specifically on the effects of the ACA reform on cost-related access problems, our findings are in line with other related studies which found that implementation of Part D in 2006 (i.e., providing drug coverage) had no significant impact on resolving cost-related access problems.[43,74,82,83,89] As such, we believe it may be an expected result that the cost-sharing reductions under the ACA reform, which was anticipated to have a lesser impact compared to Part D implementation, would also have no impact on CRN. Additionally, our findings support evidence from a previous study using data from a 2017 survey which shows that the United States had the highest rate of older adults with cost-related barriers to medication among 11 high-income countries.[92] This unfavorable impact of the ACA reform on cost-related access problems for beneficiaries could be partly explained by several factors, such as increased drug prices, the lack of an annual out-of-pocket spending limit under Part D, rising Part D premiums, and tiered coinsurance rate.[3,5,49,94,96]

Discussion

Overall, the findings in this dissertation consistently demonstrate that the ACA coverage gap reform significantly decreased out-of-pocket drug spending for beneficiaries, which is consistent with the results from previous studies.[12,14–17] Additionally, we found a growing effect of the policy, as was intended, on out-of-pocket spending (i.e., further reductions in out-of-pocket spending over time), with a noticeable effect on the population targeted by the policy who

reached the coverage gap, but not the catastrophic threshold. Despite these reductions in out-of-pocket drug spending after the ACA, the utilization of prescription drugs did not significantly change among non-LIS beneficiaries relative to LIS beneficiaries, which is consistent with limited evidence from previous studies.[12,14] Furthermore, non-LIS beneficiaries still experienced cost-related nonadherence and were still more likely to engage in several strategies to reduce drug costs and/or to save money on their medications compared to LIS beneficiaries.

These findings may reflect a combination of several ongoing factors related to the Part D program. First, given continuing skyrocketing prices of prescription drugs, such reductions in out-of-pocket spending might have been insufficient to alleviate beneficiaries' drug cost burden and to mitigate cost-related access problems to prescription drugs. From 2008 to 2016, drug costs increased considerably faster than inflation across all drug classes, where the costs of oral brand-name drugs rose more than 9% per year on average, with an average annual increase of 21% for oral specialty drugs and 4% for oral generic drugs.[99] Part D drug prices also increased by approximately 66% cumulatively between 2006 and 2015.[3] In this regard, the magnitude of the decrease in out-of-pocket spending after the ACA reported in this study were not enough for beneficiaries to cover the considerable increases in drug prices.

Additionally, given the increased proportion of high-cost beneficiaries reported in this study, these beneficiaries could be more affected by these continued rising drug prices. Despite the reductions in the coverage gap coinsurance rate under the ACA, beneficiaries bore more than 40% of drug costs until 2015 (e.g., 45% for brand-name drugs and 65% for generic drugs in 2015). As such, decreased cost-sharing may not have directly translated into cost savings for high-priced drugs for beneficiaries. In general, average annual out-of-pocket spending was over $3,000 for high-cost beneficiaries,[49] and even higher ($4,494) for those taking specialty cancer

drugs.[14] Evidence shows that the ACA coverage gap reform had no significant impact on the use of prescription drugs among Part D beneficiaries with uncommon cancers, for which specialty drugs are used to treat.[14]

The unchanged drug utilization and persistent cost-related access problems, even with significant decreases in out-of-pocket costs, could be a sign of tightening formulary management by Part D plans responding to the high and rising costs of prescription drugs. The majority of Part D plans use tiered cost-sharing, where they have increasingly charged coinsurance in place of copayments for non-preferred drugs at a higher rate than other preferred drugs.[29] As such, beneficiaries might have switched from non-preferred to preferred drugs (or from brand-name to generic drugs) in order to reduce their out-of-pocket drug costs, which resulted in decreases in out-of-pocket drug spending, but no changes in drug use. This hypothesis could be supported by evidence that, although there were no significant changes in overall drug use among Part D beneficiaries after the ACA, the use of generic drugs significantly increased, while the use of brand-name drugs decreased.[12] Due to high cost-sharing rates for non-preferred or brand-name drugs under a tiered formulary, beneficiaries might have increased the use of generic drugs, resulting in decreases in out-of-pocket drug spending. In other words, for non-preferred or brand-name drugs, beneficiaries still experienced cost-related access problems under the tiered formulary.

Furthermore, the findings in this study provide evidence of increased Part D spending, which has been a growing concern for the Medicare program. The proportion of high-cost beneficiaries steadily increased over the study years, and there was a considerable increase in total drug spending due to spending for LIS beneficiaries after the ACA. Growth in Part D spending, with an increasing share spent on high-cost beneficiaries, has been a pressing concern

for the Medicare program.[3,16,62,63] Part D program spending increased by an average of 6% per year, from $46 billion in 2007 to $79 billion in 2016, where Medicare's reinsurance subsidy became the largest and fastest-growing component of the Part D program spending in 2014.[3] As such, high-cost beneficiaries have been driving Part D program costs, accounting for 57% of gross spending in 2015.[3] Therefore, because Medicare is the major source of payment for drug costs in the catastrophic coverage phase and because the growth in Part D spending was mainly driven by high-cost beneficiaries, this has led to growing costs for the Medicare program that are expected to increase in the future.[3,49,65,66]

This study provides several contributions to the limited existing literature on the effects of the ACA's Part D coverage gap reform. This study provides the first empirical evidence of the year-by-year changes in the policy's impact on drug utilization, expenditures, and cost-related access problems through the first five years of implementation. In addition, our subgroup analyses allowed us to examine the effects of the ACA's reform on the targeted and nontargeted populations individually. Finally, using a nationally representative sample, we document the effects of the ACA reform in the general Medicare Part D population, which provides evidence of the policy effect as a whole.

Policy Implications

Although the ACA made some improvements to the Medicare Part D program by gradually phasing cost sharing in the coverage gap, the findings in this study suggest that the ACA did not provide sufficient financial protection for beneficiaries to resolve cost-related access problems for prescription drugs, with no significant changes in the use of prescription drugs.

This insufficient financial protection against prescription drug costs could be more critical for elderly Medicare beneficiaries than the general population, since seniors are more likely to be poorer and sicker than the general population. More than 21 million adults aged 65 and older (42% of total older adults) had income below 200% of federal poverty level, where the poverty rate increases with age and is higher for women, blacks, Hispanics, and those with relatively poor health.[100] In addition, only a fraction of those people received appropriate subsidies such as Part D Low-Income Subsidy (LIS) program (about 12 million, 28% of total Part D enrollees, receive subsidies through the Part D LIS program in 2018).[5] Additionally, approximately 80% of older adults have at least one chronic condition, such as heart disease, cancer, stroke, or diabetes, and 77% have at least two.[101] Evidence shows that Part D beneficiaries who have chronic conditions and take multiple medications are likely to fall into the coverage gap at some time during the year.[33] Furthermore, older adults are more likely to have severe diseases, such as cancer, arthritis, or Alzheimer's disease, which require high-priced medications for treatment.[102–104] Therefore, given that seniors are a more vulnerable population in terms of financial and health status, additional initiatives might be needed to reduce cost-related access barriers for prescription drugs, such as a reduction in drug prices or a shift from coinsurance to copayments in drug formulary design.

These increases in the proportion of beneficiaries reaching the catastrophic coverage threshold and in total drug spending are in line with the recent attention focused on growth in Part D drug spending. Evidence shows that Part D spending has grown at an average of 4.6% annually, mainly driven by the increased number of and resultant spending for high-cost beneficiaries.[3] Additionally, there are other factors that have contributed to the growth in Part D spending, such as a greater availability of high-priced drugs and a complex Part D structure

incentivizing insurers to cover more expensive medications in the catastrophic coverage phase.[3,63] Since Medicare pays the majority of drug costs in the catastrophic coverage phase, this has led to growing costs for the Medicare program that are expected to rise in the future, as the drug pipeline is shifting toward a greater number of expensive biologic products and specialty drugs.[3,49,65,66] Policy makers should consider changes to the Part D program to promote more cost-effective and high-quality medication use by Part D beneficiaries, especially by high-cost beneficiaries.

Although this study addresses the gap in knowledge about the effects of the ACA coverage gap reform by providing empirical evidence using nationwide Medicare population data, there are some areas that should be addressed in future research. First, with the introduction of a more generous coinsurance rate in the coverage gap in the later years of the policy, future study will be needed using data from 2016 to 2020, where the impact of the policy is expected to increase. Second, future study will be needed to determine if there are any differential effects of the ACA for brand-name and generic drugs. Because the stepwise structure of the cost-sharing reductions under the ACA was different for brand-name and generic drugs, there might have been differential effects on drug use and expenditures for beneficiaries by drug type. Lastly, future research will be needed on changes in drug utilization to determine which subpopulations of Part D beneficiaries (e.g., those with certain conditions or sociodemographic characteristics) were most impacted by the policy. For example, since the cost of medications for treatment depends on the disease, beneficiaries could respond differently to cost sharing in terms of drug use, depending on their specific disease conditions.[13,14] For example, cancer patients taking high-priced specialty drugs may be less responsive to reductions in cost-sharing: due to the high costs of the drugs, they would face high cost-sharing in the initial coverage phase, and thus may not

begin the treatment if they cannot afford the cost-sharing to complete the course of treatment.[14] Such decisions may have nothing to do with cost-sharing reductions in the coverage gap. On the other hand, beneficiaries with other chronic conditions, such as hypertension or diabetes, would respond differently to cost-sharing because the drug costs are not as expensive and more cost-effective alternatives may be available. There are limited studies on subpopulations of Part D beneficiaries, including those with uncommon cancers or diabetes. Evidence from future research will be helpful for policy makers to make changes to the Part D program to provide more affordable drug coverage for beneficiaries, as well as to reduce Part D drug spending.

Limitations

Several limitations of this study should be noted. First, since this study used data from the first five years of the policy, we did not examine the full effects of the ACA coverage gap reform, which are expected to increase over time through 2020. Additional reductions in cost-sharing for brand-name drugs were scheduled beginning in 2016, and the cost-sharing reductions for generic drugs have gradually increased over time. Therefore, we may find more evidence to support the impact of the ACA coverage gap reform by including more recent years of the policy from 2016 to 2020.

Second, we could not determine each drug plan's benefit structure solely using the MCBS data in order to identify whether the coverage gap was present in each plan, but instead estimated the benefit structure based on total drug spending. Part D plans could have a variety of drug benefit structures, since they could develop their own drug benefits as long as the cost-sharing structure is actuarially equivalent to the average expected coinsurance rate in the standard benefit structure.[21] As such, our estimates based on the Part D standard benefit structure

may have some discrepancies as compared to the actual drug benefit structure of each plan, resulting in not being able to determine which beneficiaries actually experienced the coverage gap in their drug plans.

Third, our study sample included beneficiaries who have Medicare Advantage Prescription Drug plans (MA-PDs), who are likely to have lower out-of-pocket drug costs than those with a stand-alone prescription drug plan (PDP), and could have had a differential impact on the study outcomes.[12] Although we adjusted for beneficiary enrollment in an MA-PD, the information is based on beneficiaries' self-reported responses, which may be subject to error due to memory limitations, posing a risk for inaccuracy.

More detailed limitations for each study are described in Chapters 3, 4, and 5.

Conclusions

Under the ACA of 2010, the provisions to initiate a ten-year process of closing the coverage gap in the Part D benefit have been implemented since 2011. On the whole, the changes to the structure of Part D benefits under the ACA aimed to provide better protection against the costs of prescription drugs by reducing beneficiaries' cost-sharing in the coverage gap.[33] As the ACA reform included substantial reductions in cost-sharing in the coverage gap, evaluation of the effectiveness of the policy will bring significant implications in managing the Part D program. In this context, this three part study focused on evaluating the impact of the ACA coverage gap reform using data from the first five years of the policy: 1) the trends in distribution of beneficiaries, drug utilization, and expenditures from 2008-2015; 2) the effects of the ACA coverage gap reform on drug utilization and expenditures among non-LIS beneficiaries

relative to LIS beneficiaries; and 3) the effects of the ACA coverage gap reform on beneficiaries' cost-related access problems for prescription drugs.

The results of this study provide evidence suggesting that the ACA coverage gap reform significantly reduced out-of-pocket drug costs for beneficiaries, although such reductions did not lead to an improvement in the cost-related access problems or an increase in prescription drug use. Additionally, this study presents evidence supporting recent concerns about rapid growth in Part D spending: significant increases in total drug spending were seen, which were mainly driven by increased spending on high-cost beneficiaries along with an increased proportion of such beneficiaries. Lastly, non-LIS beneficiaries still experienced cost-related nonadherence and were still more likely to engage in drug cost-reduction strategies compared to LIS beneficiaries. Although the ACA coverage gap reform has brought substantial changes to the Part D benefit structure in order to provide more affordable care to Medicare beneficiaries, policy makers should consider additional initiatives to address several concerns raised by this study, such as persistent cost-related access problems and increased Part D drug spending.

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VIII. APPENDICES

A. Appendices for Manuscript #1

Appendix A-1. Medicare Current Beneficiary Survey (MCBS)

This study used data from the MCBS for the years 2008-2013 and 2015. The 2014 MCBS data were not released by the Centers for Medicare & Medicaid Services (CMS) due to the implementation of long overdue innovations to accommodate changes in sampling and data collection methodologies.[55]

The MCBS is a continuous, in-person, multi-purpose longitudinal survey of a nationally representative sample of the Medicare population residing in the US and its territories, including beneficiaries aged 65 and older and beneficiaries aged 64 and under with disabilities or with end-stage renal disease. Sponsored by the CMS, the MCBS was implemented in 1991 to provide comprehensive information for administering the Medicare program, estimating health care expenditures and use for beneficiaries, and better understanding the health status and well-being of beneficiaries.[55,105] As such, MCBS is the leading source of information on Medicare and its impact on beneficiaries and has been carried out continuously for more than 25 years encompassing more than one million interviews.

The MCBS data have several unique features.[105] First, the MCBS links beneficiaries' self-reported responses to administrative claims data, which provides more accurate and complete estimates of beneficiaries' total health care expenditures and utilization. Second, the MCBS collects data on all sources of payments for health care costs, including those not covered by Medicare, such as co-payments, deductibles, and costs covered by retiree or VA benefits.

Third, the MCBS has a rotating panel design that enables users to conduct longitudinal analysis. Each sampled beneficiary is scientifically selected as part of a panel and is interviewed up to 3 times per year for 4 consecutive years. One panel is retired after each summer round, and a new panel is selected to replace it for each fall round. Fourth, the MCBS includes facility-dwelling beneficiaries, which follows beneficiaries into and out of long-term care facilities. Fifth, the MCBS oversamples for beneficiaries with disabilities and those aged 85 and over due to interest in their special health care needs. Lastly, the MCBS collects survey-reported health care utilization and expenditures data for beneficiaries enrolled in Medicare Advantage, which allows researchers to analyze these beneficiaries' utilization and cost data in the absence of Medicare fee-for-service claims data.

Each year, CMS releases the MCBS data as two Limited Data Sets (LDS), the Survey File and the Cost Supplement File, which contain beneficiary-level health information, but exclude specific direct identifiers. The 2015 MCBS LDS files were renamed and reorganized compared to prior years, where the Survey File was formerly known as the Access to Care file and the Cost Supplement File was formerly known as the Cost and Use file. The MCBS Survey File contains survey data augmented by administrative data, including the following information: beneficiary demographics, household characteristics, access to care, satisfaction with care, usual source of care, health insurance timeline (e.g., types of insurances, Medicare eligibility, and covered services), health status and functioning, and other topical survey sections, such as medical conditions, health behaviors, preventive services, interview characteristics, beneficiary knowledge of the Medicare program, residence timeline, facility characteristics, and beneficiary income and assets.[55] The MCBS Cost Supplement File provides health care costs and utilization data for each beneficiary in the survey, which can be linked to the MCBS Survey File.[55] The

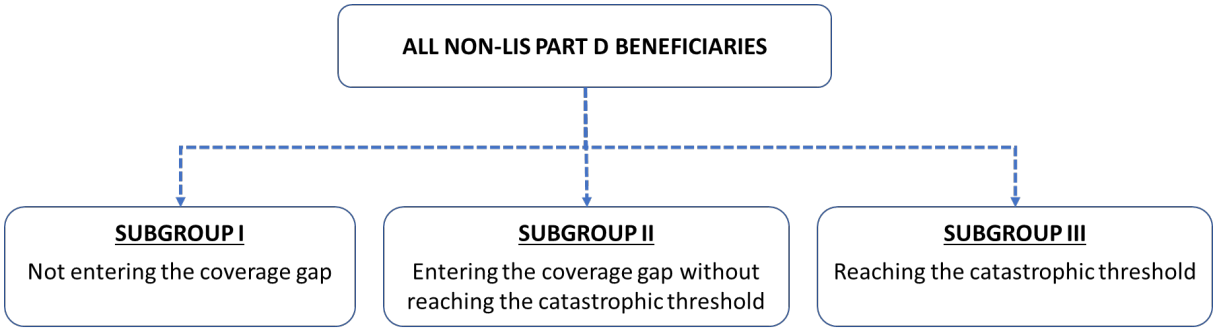
MCBS Cost Supplement File provides complete expenditure and source of payment data on all health care services, including those not covered by Medicare, by linking Medicare claims to survey-reported events. In this regard, it provides a comprehensive picture of health services received, amount paid, and sources of payment for Medicare beneficiaries.

The Prescribed Medicine Events (PME, formerly RIC PME) file contains individual outpatient prescribed medicine events for the MCBS beneficiaries, where the unit of measurement is a single purchase (or fill) of a single drug in a single container.[57] The events in the PME file were collected from two sources: survey-reported responses and Part D Events (PDEs). Each record indicates whether it is a survey-only reported event, a PDE-only event, or a survey reported event matched to PDEs. For survey reported events that were matched to PDEs, information on the PDEs was used to calculate the expenditures. For unmatched events, several adjustments and imputations were made to fill in missing drug payment data, which was similar to those that were used for other missing payment amounts.[57] Beginning in 2006, since PDEs were available for Medicare beneficiaries enrolled in Medicare Advantage Part D Plans (MA-PDs) or stand-alone Part D Plans (PDPs), the PME data that were matched to PDEs include data from Medicare Advantage Prescription drug claims.[4]

This study used the Cost and Use files for the analysis from 2008 to 2013, particularly the RIC 1, RIC 2, RIC 3, RIC 4, RIC A, RIC PME, RIC SS, and RIC X segments of the files. The RIC1, RIC 2, RIC3, RIC 4, RIC A, and RIC SS were used to obtain detailed information on demographics, socioeconomic characteristics, health insurance coverage, and affordability of and access to prescription drugs. The RIC X segment was used to determine the survey weights. The RIC PME was used to obtain information on drug use and expenditures.

For the 2015 analysis, both the Survey File (formerly Access to Care) and the Cost Supplement File (formerly Cost and Use) were utilized, especially the ADMNUTLS, CHRNCOND, DEMO, and HISUMRY segments from the Survey File and the PME and CSEVRWGT segments from the Cost Supplement File. The Survey File was used to obtain detailed information on demographics, socioeconomic characteristics, health insurance coverage, and affordability of and access to prescription drugs. The CSEVRWGT was used to determine the survey weights. The PME segment of the Cost Supplement File was used to obtain information on drug use and expenditures.

Appendix A-2. Subgroups of study sample



Appendix A-3. Total drug spending criteria for subgroups, 2008-2015

	Subgroup I (Not entering the coverage gap)	**Subgroup II** (Entering the coverage gap without reaching the catastrophic threshold)	**Subgroup III** (Reaching the catastrophic threshold)
2008	< $2,510	$2,510 - $5,726	≥ $5,726
2009	< $2,700	$2,700 - $6,154	≥ $6,154
2010	< $ 2,830	$2,830 - $6,440	≥ $6,440
2011	< $ 2,840	$2,840 - $6,484	≥ $6,484
2012	< $ 2,930	$2,930 - $6,730	≥ $6,730
2013	< $2,970	$2,970 - $6,955	≥ $6,955
2015	< $2,960	$2,960 - $7,062	≥ $7,062

B. Appendices for Manuscript #2

Appendix B-1. Technical specification of regression analyses

1) Regression Equation – Parallel Trend Assumption Test

$$Y_{it} = \eta_0 + \eta_1 Time_t + \eta_2 Treat_i + \eta_3 Time_t \times Treated_i + \eta_4 X_i + \epsilon_{it}$$

where *i* indexed individuals and *t* indexed year. Y_{it} represents the dependent variable of interest (e.g., 30-day drug fills, total drug spending, and out-of-pocket spending). *Time* is a time trend variable indicating the years 2008 to 2010. *Treat* is a treatment indicator equal to one for treatment group (non-LIS beneficiaries), and zero for control group (LIS beneficiaries). *Xi* is a vector of sociodemographic control variables for age, sex, race/ethnicity, education level, family income as percentage of poverty level, residence area, number of chronic conditions, and an indicator variable for having Medicare Advantage Prescription Drug plans, for individual *i* in time period *t*, respectively. In **Appendix B-3** and **Appendix B-4**, we see the common trend assumption is valid because the coefficients of the interaction term, η_3, is statistically insignificant.

2) Regression Equation – Difference-in-Differences Model, Pre-ACA vs. Post-ACA

$$Y_{it} = \beta_0 + + \beta_1 Post_t + \beta_2 Treat_i + \beta_3 Post_t \times Treat_i + \beta_4 X_i + e_{it}$$

where *i* indexed individuals and *t* indexed year. Y_{it} represents the dependent variables of interests (e.g., 30-day drug fills, total drug spending, and out-of-pocket spending). *postDummy* is a dummy variable equal to zero for years 2008-2010 and one for years 2011-2015. *Treat* is a treatment indicator equal to one for treatment group (non-LIS beneficiaries), and zero for control group (LIS beneficiaries). β_3 measures the difference-in-differences estimate for the change in

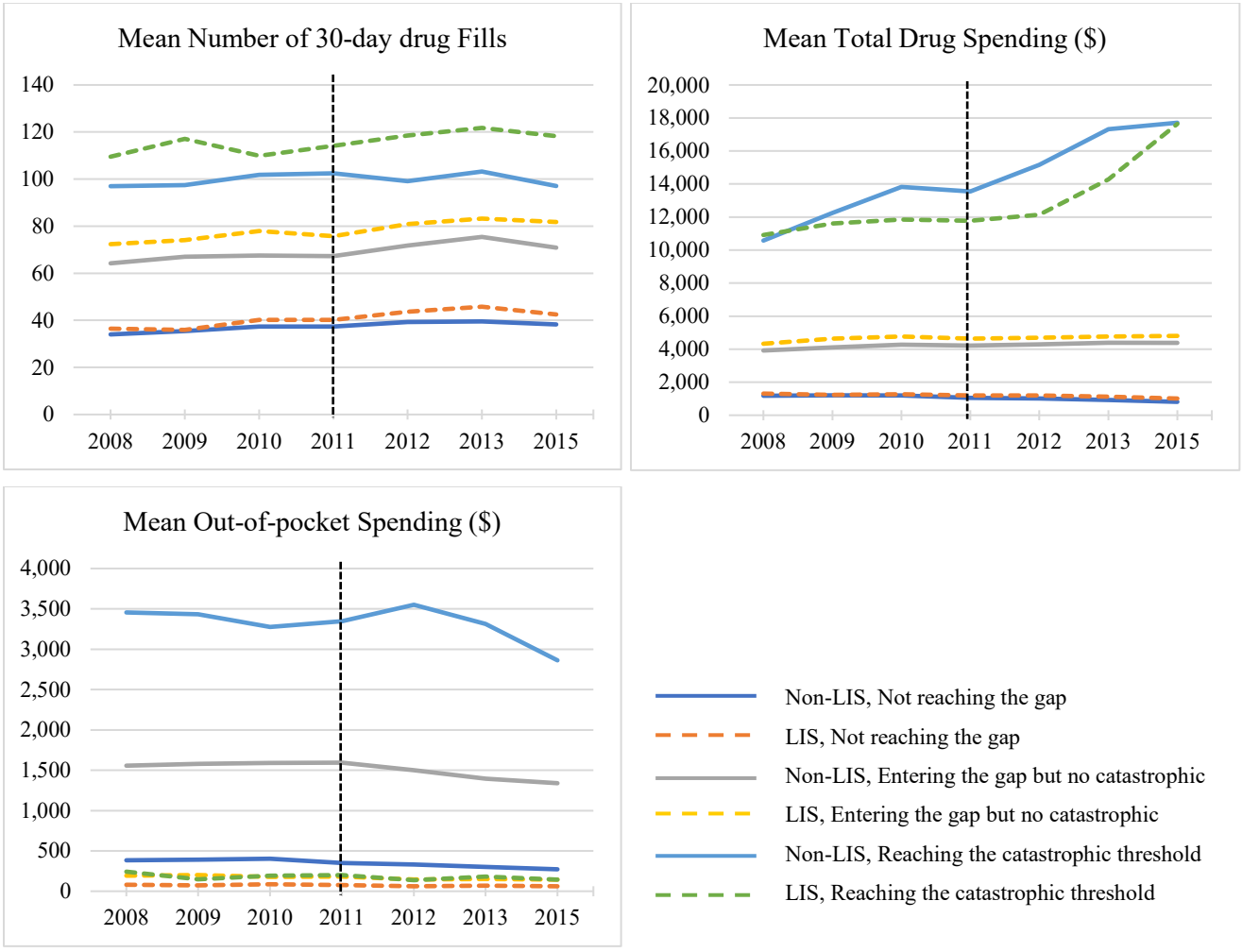
outcome in the treatment group in the post-ACA period, compared to the control group. *Xi* is a vector of sociodemographic control variables for age, sex, race/ethnicity, education level, family income as percentage of poverty level, residence area, number of chronic conditions, and an indicator variable for having Medicare Advantage Prescription Drug plans, for individual *i* in time period *t*, respectively. Full results of the regression models are described in **Appendix B-7**.

3) Regression Equation – Year-by-Year changes Difference-in-Differences Model, Pre-ACA vs. 2011, 2012, 2013, and 2015

$$Y_{it} = \beta_0 + \beta_1 2011_t + \beta_2 2012_t + \beta_3 2013_t + \beta_4 2015_t + \beta_5 Treat + \beta_6 2011_t \times \text{Treat} + \beta_7 2012_t \times \text{Treat} + \beta_8 2013_t \times \text{Treat} + \beta_9 2015_t \times \text{Treat} + \beta_{10} X_i + e_{it}$$

where *i* indexed individuals and *t* indexed year. Y_{it} represents the dependent variables of interests (e.g., 30-day drug fills, total drug spending, and out-of-pocket spending). β_1 captures the direct effect of treatment group (non-LIS beneficiaries) at baseline compared to the control group (LIS beneficiaries), and β_2-β_5 adjust for the year. β_6 measures the difference-in-differences estimate for the change in outcome in the treatment group in 2011, compared to the control group, while β_7, β_8, and β_9 provide the comparable estimates for 2012, 2013, and 2015, respectively. *Xi* is a vector of sociodemographic control variables for age, sex, race/ethnicity, education level, family income as percentage of poverty level, residence area, number of chronic conditions, and an indicator variable for having Medicare Advantage Prescription Drug plans, for individual *i* in time period *t*, respectively. Full results of the regression models are described in **Appendix B-11**.

Appendix B-2 Trends of drug utilization and expenditures among non-LIS and LIS Part D beneficiaries by subgroup, 2008-2015



SOURCE Author's analysis of data for 2008-2015 from the Medicare Current Beneficiary Survey (MCBS).
NOTES Each figure shows the per capita mean annual 30-day prescription drug fills, total drug spending, and out-of-pocket spending by year and study group, respectively. Non-LIS beneficiaries are the treatment group and LIS beneficiaries are the control group. All estimates are adjusted for age, sex, race/ethnicity, education, family income as a percentage of poverty, residence area, number of chronic conditions, and Medicare Advantage Prescription Drug plans status. Dollar amounts were converted to inflation-adjusted 2015 dollars.

Appendix B-3 Full regression results of the parallel trend assumption test for all beneficiaries

	Total spending	**OOP spending**	**30-day fills**
Time (2009)	75.65	7.96	1.16
	(76.67)	(13.36)	(0.75)
Time (2010)	80.92	0.32	2.24
	(141.87)	(13.19)	(1.45)
Treat	-1548.21***	680.30***	-12.75***
	(149.16)	(26.96)	(1.36)
Time × Treat	-28.36	-20.47	-0.15
	(81.86)	(13.16)	(0.80)
Male	50.14	-11.16	0.52
	(88.00)	(19.83)	(0.71)
Age 75-84	-120.63	22.76	2.48***
	(88.92)	(20.24)	(0.66)
Age 85+	3.87	64.13*	3.95***
	(117.11)	(25.36)	(0.89)
Black, non-Hispanic	-455.94*	-55.56*	-3.93*
	(208.89)	(24.97)	(1.56)
Hispanic	-308.92	-32.11	-5.56*
	(202.52)	(42.34)	(2.25)
Other, non-Hispanic	-412.96	-62.37	-4.49
	(226.39)	(39.24)	(2.40)
High school graduate	-121.17	29.02	0.78
	(95.51)	(28.29)	(1.01)
Some college or more	137.92	65.61*	-0.82
	(124.97)	(26.51)	(0.97)
Family income (125-200%)	-110.88	24.31	-1.30
	(114.05)	(19.24)	(0.86)
Family income (200-400%)	100.02	106.13***	0.23
	(110.12)	(25.35)	(0.87)
Family income (>400%)	282.10	172.57***	1.08
	(148.81)	(36.50)	(1.19)
Urban	372.10***	28.20	0.47
	(95.95)	(31.21)	(0.94)
Number of chronic conditions, 3-4	952.85***	271.35***	16.96***
	(102.15)	(19.63)	(0.75)
Number of chronic conditions, 5+	2164.88***	485.71***	34.82***
	(111.46)	(27.33)	(1.01)
Having MA-PDs	-769.30***	-287.55***	-3.71***
	(86.71)	(20.14)	(0.69)
constant	2964.60***	-127.63**	43.00***
	(152.67)	(38.48)	(1.28)
n	41477	41477	41477

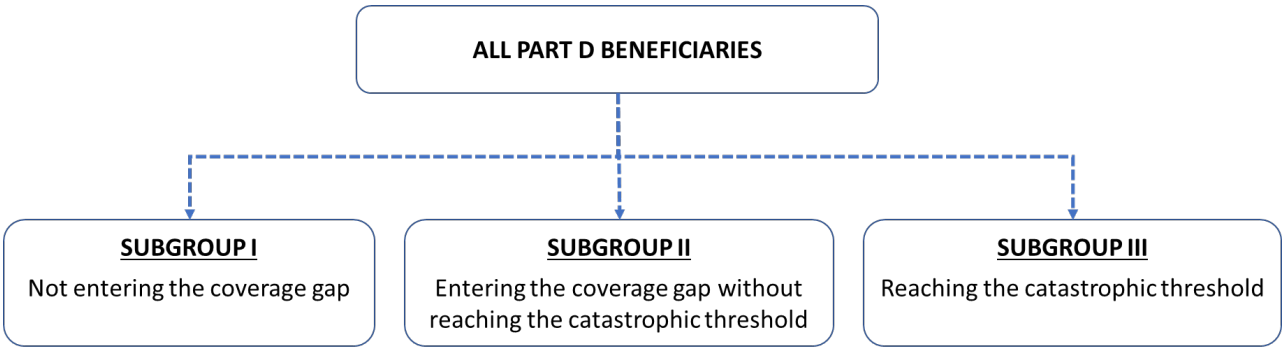
Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Appendix B-4 Full regression results of the parallel trend assumption test by subgroup

	Subgroup I			Subgroup II			Subgroup III		
	Total spending	OOP spending	30-day fills	Total spending	OOP spending	30-day fills	Total spending	OOP spending	30-day fills
Time (2009)	-2.14	3.93	1.37	266.26***	10.35	3.20**	549.34	-42.31	3.42
	(21.82)	(6.61)	(0.73)	(46.96)	(27.61)	(0.98)	(410.40)	(77.33)	(2.59)
Time (2010)	-16.00	15.18*	4.14***	434.63***	2.26	5.27**	1044.88*	-3.35	-0.26
	(33.91)	(7.59)	(1.21)	(86.13)	(22.30)	(1.79)	(508.69)	(54.81)	(3.62)
Treat	-85.75*	291.66***	-0.12	-395.50***	1321.35***	-6.68***	-1924.14*	3055.46***	-11.19*
	(37.71)	(9.88)	(1.03)	(66.62)	(52.84)	(1.93)	(895.52)	(203.48)	(4.42)
Time × Treat	7.73	0.79	-0.48	-40.56	33.92	-1.05	1303.62	-17.80	1.94
	(19.98)	(6.45)	(0.68)	(48.93)	(28.53)	(1.07)	(998.08)	(127.93)	(2.49)
Male	24.25	-17.35*	-0.54	24.97	-16.10	0.27	-1398.77	-166.40	0.88
	(24.58)	(7.64)	(0.65)	(45.42)	(36.56)	(1.16)	(903.25)	(115.23)	(3.04)
Age 75-84	48.76	23.74**	2.93***	77.84*	113.83**	2.52*	-1623.16	-113.57	1.61
	(25.63)	(8.97)	(0.71)	(37.11)	(34.09)	(1.08)	(837.67)	(110.45)	(3.07)
Age 85+	85.12**	44.49***	4.49***	177.64***	103.92*	3.11*	-1790.89	-265.73*	-2.32
	(28.87)	(9.90)	(0.84)	(49.66)	(41.26)	(1.46)	(1133.08)	(124.36)	(3.58)
Black, non-Hispanic	-44.90	-24.19*	-1.15	-33.09	-33.39	-0.33	-344.00	-116.08	-0.66
	(39.96)	(11.99)	(1.17)	(62.55)	(40.79)	(2.11)	(1793.50)	(143.67)	(4.90)
Hispanic	-3.68	-57.35***	-1.99	29.63	-26.42	-4.55	-1032.31	77.93	-12.40**
	(87.47)	(13.02)	(2.81)	(104.78)	(109.19)	(2.60)	(719.78)	(137.16)	(4.57)
Other, non-Hispanic	-9.97	-13.80	-2.67	-54.28	-97.24	-3.52	-1689.23	168.72	-2.12
	(72.28)	(17.40)	(2.13)	(152.84)	(57.71)	(2.72)	(886.62)	(122.98)	(6.69)
High school graduate	44.79	24.12***	1.32	-38.79	85.57	0.95	-1155.87	-23.88	-0.43
	(33.72)	(6.89)	(0.92)	(54.59)	(52.67)	(1.57)	(663.37)	(121.49)	(3.39)
Some college or more	2.16	17.93	-1.50	-31.06	91.93	-2.34	1477.00	413.95***	4.67
	(31.80)	(9.28)	(0.91)	(53.78)	(47.89)	(1.52)	(985.15)	(118.27)	(3.30)
Family income (125-200%)	53.50	33.43**	0.61	-11.64	86.99*	0.14	558.26	95.74	-5.61
	(27.36)	(10.60)	(0.77)	(56.96)	(40.32)	(1.31)	(907.88)	(88.21)	(3.30)
Family income (200-400%)	70.80**	49.89***	1.24	35.37	131.65*	0.20	1777.52	340.41	-6.01
	(24.49)	(9.79)	(0.74)	(58.58)	(50.51)	(1.44)	(1180.58)	(180.85)	(4.30)
Family income (>400%)	204.48***	96.25***	0.68	80.57	184.36*	0.30	261.66	-28.86	-6.93
	(29.21)	(15.11)	(1.00)	(70.08)	(73.40)	(1.93)	(1617.23)	(323.11)	(4.92)
Urban	53.61*	5.57	0.37	82.78	-44.88	-2.84	1765.50**	-126.63	-1.18
	(25.79)	(11.68)	(0.75)	(55.83)	(48.74)	(1.61)	(627.46)	(81.67)	(3.72)
Number of chronic conditions, 3-4	339.68***	93.60***	12.60***	135.97**	211.11***	9.16***	674.20	108.97	12.69***
	(25.43)	(9.40)	(0.77)	(50.90)	(44.33)	(1.35)	(909.78)	(137.22)	(3.33)
Number of chronic conditions, 5+	570.01***	132.14***	22.01***	323.18***	257.96***	16.40***	-646.42	-61.69	30.03***
	(38.08)	(12.75)	(1.10)	(53.04)	(45.47)	(1.49)	(844.77)	(148.08)	(3.87)
Having MA-PDs	-151.85***	-80.26***	0.02	-176.36***	-392.22***	1.67	-617.53	-618.51***	-3.76
	(26.92)	(10.53)	(0.74)	(42.48)	(35.76)	(1.31)	(1378.39)	(167.43)	(3.61)
constant	957.66***	2.55	24.13***	4061.44***	-15.96	62.55***	10986.27***	403.28**	94.32***
	(44.22)	(14.99)	(1.24)	(95.05)	(72.60)	(2.22)	(1023.48)	(143.90)	(5.08)
n	43589	43589	43589	45655	45655	45655	45673	45673	45673

Subgroup I: Those not reaching the coverage gap, Subgroup II: Those entering the gap without reaching the catastrophic threshold, Subgroup III: Those reaching the catastrophic threshold
Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Appendix B-5 Subgroups of study sample



Appendix B-6 Total drug spending criteria for subgroups, 2008-2015

	Subgroup I (Not entering the coverage gap)	**Subgroup II** (Entering the coverage gap without reaching the catastrophic threshold)	**Subgroup III** (Reaching the catastrophic threshold)
2008	< $2,510	$2,510 - $5,726	≥ $5,726
2009	< $2,700	$2,700 - $6,154	≥ $6,154
2010	< $ 2,830	$2,830 - $6,440	≥ $6,440
2011	< $ 2,840	$2,840 - $6,484	≥ $6,484
2012	< $ 2,930	$2,930 - $6,730	≥ $6,730
2013	< $2,970	$2,970 - $6,955	≥ $6,955
2015	< $2,960	$2,960 - $7,062	≥ $7,062

Appendix B-7 Pre- vs. Post-ACA difference-in-differences regression results for all beneficiaries

	Total spending	OOP spending	30-day fills
Post	511.81*	-111.67**	2.76*
	(207.40)	(14.81)	(1.24)
Treat	-1552.93**	662.89**	-12.14**
	(130.69)	(18.47)	(0.97)
Post × Treat	-333.53	-88.05**	-1.27
	(180.26)	(18.58)	(1.11)
Male	244.90*	12.55	2.14**
	(97.29)	(13.35)	(0.53)
2009.year	64.39	-6.83	1.10*
	(59.47)	(13.09)	(0.46)
2010.year	55.52	-29.18	2.05**
	(73.66)	(16.80)	(0.61)
2011.year	-228.50	133.78**	0.74
	(122.70)	(18.30)	(0.69)
2012.year	-243.73	97.38**	2.23**
	(137.53)	(19.15)	(0.70)
2013.year	-132.22	58.18**	3.50**
	(128.89)	(16.62)	(0.65)
2015.year	0.00	0.00	0.00
	(.)	(.)	(.)
Age 75-84	-119.08	33.78*	2.99**
	(98.19)	(15.15)	(0.53)
Age 85+	-348.93**	26.95	2.07**
	(96.59)	(18.47)	(0.71)
Black, non-Hispanic	-170.51	-39.09	-3.43**
	(187.08)	(20.55)	(0.95)
Hispanic	102.66	-44.94	-4.79**
	(253.90)	(23.97)	(1.53)
Other, non-Hispanic	-378.69	-12.75	-4.07**
	(217.91)	(30.75)	(1.47)
High school graduate	-123.80	-8.47	-0.15
	(97.86)	(19.50)	(0.71)
Some college or more	109.63	37.53*	-2.65**
	(125.32)	(18.06)	(0.75)
Family income (125-200%)	132.75	45.59**	-0.37
	(110.48)	(14.64)	(0.63)
Family income (200-400%)	317.82**	118.88**	0.48
	(101.17)	(20.52)	(0.65)
Family income (>400%)	363.70**	141.13**	0.97
	(120.77)	(20.56)	(0.76)
Urban	267.51*	11.74	-0.20
	(124.23)	(17.01)	(0.68)
Number of chronic conditions, 3-4	1080.41**	262.90**	19.57**
	(67.18)	(12.45)	(0.52)
Number of chronic conditions, 5+	2925.88**	540.96**	39.37**
	(121.82)	(19.03)	(0.66)
Having MA-PDs	-786.95**	-220.83**	-3.04**
	(85.34)	(13.20)	(0.51)
constant	2660.74**	-126.41**	40.93**
	(169.75)	(25.69)	(1.02)
n	34677	34677	34677

Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$

Appendix B-8. Pre- vs. Post-ACA difference-in-differences regression results for those who did not enter the coverage gap (Subgroup I)

	Total spending	OOP spending	30-day fills
Post	-332.15**	-48.92**	4.37**
	(39.25)	(7.66)	(1.03)
Treated	-47.03	307.56**	0.77
	(28.93)	(5.61)	(0.89)
Post × Treat	-106.17**	-74.61**	-1.91
	(36.78)	(6.92)	(1.06)
Male	12.47	-10.69*	1.30**
	(15.03)	(5.03)	(0.46)
2009.year	3.40	4.20	1.01*
	(16.97)	(6.37)	(0.47)
2010.year	-3.64	16.23*	3.31**
	(22.83)	(7.53)	(0.60)
2011.year	289.44**	82.61**	0.34
	(22.03)	(6.96)	(0.67)
2012.year	237.50**	60.58**	2.12**
	(22.17)	(6.70)	(0.65)
2013.year	157.81**	35.98**	2.83**
	(22.67)	(6.92)	(0.56)
2015.year	0.00	0.00	0.00
	(.)	(.)	(.)
Age 75-84	46.65**	19.60**	3.37**
	(16.34)	(5.84)	(0.50)
Age 85+	44.12*	25.39**	3.40**
	(18.62)	(6.66)	(0.62)
Black, non-Hispanic	-0.98	-12.09	-0.73
	(24.13)	(7.92)	(0.87)
Hispanic	-37.59	-51.77**	-2.58
	(45.34)	(7.45)	(1.36)
Other, non-Hispanic	-2.56	-4.07	-1.50
	(38.82)	(12.71)	(1.17)
High school graduate	10.70	14.57*	0.30
	(21.72)	(5.84)	(0.63)
Some college or more	-10.85	6.52	-2.69**
	(21.54)	(6.54)	(0.72)
Family income (125-200%)	20.34	24.11**	-0.40
	(17.53)	(5.76)	(0.60)
Family income (200-400%)	48.39**	33.81**	-0.48
	(17.73)	(5.78)	(0.60)
Family income (>400%)	120.79**	56.91**	-0.80
	(25.14)	(8.48)	(0.74)
Urban	38.39	4.72	-0.58
	(21.39)	(6.84)	(0.50)
Number of chronic conditions, 3-4	331.88**	92.16**	15.01**
	(14.51)	(4.94)	(0.50)
Number of chronic conditions, 5+	592.26**	143.77**	25.73**
	(21.21)	(6.94)	(0.70)
Having MA-PDs	-123.28**	-63.17**	0.57
	(15.09)	(5.84)	(0.42)
constant	979.29**	3.72	23.56**
	(37.30)	(9.86)	(0.88)
n	39462	39462	39462

Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$

Appendix B-9. Pre- vs. Post-ACA difference-in-differences regression results for those who entered the coverage gap without reaching the catastrophic coverage threshold (Subgroup II)

	Total costs	**OOP costs**	**30-day fills**
Post	396.82**	-90.39*	6.65**
	(70.58)	(37.04)	(1.70)
Treated	-461.77**	1353.64**	-6.52**
	(45.82)	(36.01)	(1.31)
Post × Treat	67.90	-123.04**	-0.05
	(62.62)	(39.38)	(1.55)
Male	-16.50	-10.45	1.69
	(30.47)	(26.29)	(0.89)
2009.year	236.10**	26.69	2.59**
	(34.25)	(28.39)	(0.81)
2010.year	375.82**	37.43	3.86**
	(47.24)	(35.36)	(1.00)
2011.year	-130.62**	207.02**	-3.23*
	(48.56)	(39.30)	(1.43)
2012.year	-67.89	134.45**	1.32
	(55.77)	(50.02)	(1.51)
2013.year	14.73	63.24	4.32**
	(48.71)	(37.76)	(1.47)
2015.year	0.00	0.00	0.00
	(.)	(.)	(.)
Age 75-84	50.52	60.31*	1.52
	(33.61)	(24.99)	(0.98)
Age 85+	101.08**	77.78*	2.87*
	(34.09)	(31.50)	(1.11)
Black, non-Hispanic	-66.17	-45.44	-0.91
	(49.52)	(32.00)	(1.31)
Hispanic	-39.83	-23.45	-2.81
	(83.44)	(60.13)	(2.49)
Other, non-Hispanic	-10.93	27.46	-1.58
	(89.02)	(72.50)	(2.22)
High school graduate	-10.85	3.56	-1.33
	(32.77)	(34.28)	(1.19)
Some college or more	15.45	79.94**	-4.43**
	(37.40)	(28.45)	(1.13)
Family income (125-200%)	-25.79	63.78*	0.24
	(43.63)	(31.04)	(1.14)
Family income (200-400%)	20.25	116.43**	0.06
	(45.34)	(37.25)	(1.29)
Family income (>400%)	87.70	138.57**	0.05
	(48.67)	(48.02)	(1.52)
Urban	40.25	-102.17**	-2.82*
	(36.73)	(27.99)	(1.34)
Number of chronic conditions, 3-4	144.68**	153.66**	11.51**
	(36.22)	(33.15)	(1.06)
Number of chronic conditions, 5+	324.55**	217.41**	21.49**
	(41.94)	(34.78)	(0.99)
Having MA-PDs	-123.55**	-248.16**	1.20
	(34.90)	(23.34)	(1.00)
constant	4147.35**	78.09	61.13**
	(57.07)	(50.60)	(1.89)
n	44369	44369	44369

Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$

Appendix B-10. Pre- vs. Post-ACA difference-in-differences regression results for those who reached the catastrophic coverage threshold (Subgroup III)

	Total costs	**OOP costs**	**30-day fills**
Post	5996.70**	-221.94**	2.79
	(1194.71)	(81.03)	(3.15)
Treated	173.42	3057.83**	-11.69**
	(1258.32)	(152.33)	(3.50)
Post × Treat	920.76	-179.82	-5.48
	(1496.46)	(164.67)	(4.24)
Male	915.75	107.34	1.64
	(964.37)	(90.71)	(2.11)
2009.year	1076.73	-50.60	4.10
	(586.89)	(95.60)	(2.23)
2010.year	1924.49**	-42.42	1.05
	(725.20)	(104.82)	(2.79)
2011.year	-4617.33**	265.97*	2.46
	(1013.02)	(105.77)	(2.79)
2012.year	-3867.48**	310.50**	3.46
	(1243.81)	(84.82)	(2.74)
2013.year	-1808.90	224.00*	5.98
	(1280.97)	(89.19)	(3.35)
2015.year	0.00	0.00	0.00
	(.)	(.)	(.)
Age 75-84	-2002.70*	-42.79	1.76
	(891.07)	(79.05)	(1.86)
Age 85+	-2810.10**	-165.17	-4.05
	(917.64)	(91.98)	(2.40)
Black, non-Hispanic	2746.30	27.99	-3.13
	(1588.68)	(108.76)	(3.58)
Hispanic	2342.83	-122.20	-8.89*
	(1406.18)	(85.11)	(3.61)
Other, non-Hispanic	733.76	241.93	-6.35
	(2343.16)	(123.51)	(5.32)
High school graduate	-805.57	-43.43	1.74
	(796.86)	(78.62)	(2.33)
Some college or more	1788.44	222.76*	0.77
	(1053.51)	(86.46)	(2.91)
Family income (125-200%)	1573.81	112.40	-0.32
	(1075.26)	(77.00)	(2.50)
Family income (200-400%)	940.79	338.47*	-1.49
	(1018.15)	(144.67)	(2.80)
Family income (>400%)	96.20	-8.42	-1.62
	(1636.25)	(181.77)	(3.27)
Urban	420.06	-41.33	0.46
	(1093.52)	(73.78)	(2.88)
Number of chronic conditions, 3-4	-125.72	43.45	16.94**
	(962.57)	(108.78)	(2.25)
Number of chronic conditions, 5+	481.02	111.43	33.90**
	(997.27)	(117.83)	(2.52)
Having MA-PDs	-920.50	-382.34**	-2.95
	(1041.69)	(81.14)	(2.49)
constant	10003.25**	164.89	88.57**
	(1417.30)	(133.96)	(3.10)
n	44286	44286	44286

Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$

Appendix B-11. Year-by-year changes difference-in-differences regression results for all beneficiaries

	Total spending	OOP spending	30-day fills
2011.year	81.00	0.25	2.18
	(159.44)	(9.56)	(1.30)
2012.year	-63.65	-31.35**	3.77**
	(156.07)	(9.88)	(1.27)
2013.year	171.46	-28.18*	5.06**
	(260.92)	(11.99)	(1.56)
2015.year	938.59**	-63.04**	2.10
	(310.93)	(12.90)	(1.58)
Treat	-1549.23**	662.47**	-12.10**
	(130.91)	(18.42)	(0.98)
2011.year × Treat	-113.90	-41.39*	-0.94
	(190.23)	(20.46)	(1.43)
2012.year × Treat	54.65	-48.67*	-1.08
	(188.13)	(22.98)	(1.43)
2013.year × Treat	-117.61	-104.82**	-1.11
	(277.28)	(26.22)	(1.60)
2015.year × Treat	-942.98**	-135.17**	-1.82
	(333.04)	(26.03)	(1.72)
Male	242.76*	12.39	2.13**
	(97.01)	(13.36)	(0.53)
Age 75-84	-120.52	33.87*	2.98**
	(97.73)	(15.14)	(0.53)
Age 85+	-346.30**	27.12	2.06**
	(96.44)	(18.54)	(0.71)
Black, non-Hispanic	-164.47	-38.36	-3.44**
	(187.84)	(20.61)	(0.95)
Hispanic	94.59	-45.56	-4.79**
	(254.04)	(23.93)	(1.53)
Other, non-Hispanic	-375.51	-12.47	-4.06**
	(216.56)	(30.64)	(1.47)
High school graduate	-129.27	-9.18	-0.14
	(97.12)	(19.53)	(0.71)
Some college or more	112.30	37.33*	-2.62**
	(124.84)	(18.04)	(0.74)
Family income (125-200%)	127.89	46.10**	-0.41
	(110.96)	(14.54)	(0.63)
Family income (200-400%)	311.63**	119.65**	0.41
	(101.18)	(20.36)	(0.65)
Family income (>400%)	373.10**	142.60**	0.95
	(120.47)	(20.53)	(0.76)
Urban	267.43*	11.78	-0.20
	(124.66)	(16.98)	(0.68)
Number of chronic conditions, 3-4	1086.21**	263.19**	19.58**
	(67.41)	(12.44)	(0.52)
Number of chronic conditions, 5+	2925.50**	540.65**	39.38**
	(121.80)	(19.00)	(0.66)
Having MA-PDs	-792.92**	-221.88**	-3.03**
	(85.25)	(13.24)	(0.51)
constant	2701.61**	-138.48**	41.99**
	(167.34)	(23.84)	(1.00)
n	34677	34677	34677

Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$

Appendix B-12. Year-by-year changes difference-in-differences regression results for those who did not enter the coverage gap (Subgroup I)

	Total spending	OOP spending	30-day fills
2011.year	-62.20	1.04	2.80*
	(44.34)	(5.46)	(1.21)
2012.year	-93.65*	-18.47**	4.96**
	(43.16)	(4.62)	(1.16)
2013.year	-174.73**	-11.69*	6.78**
	(39.11)	(5.49)	(1.45)
2015.year	-319.32**	-27.98**	2.35
	(48.91)	(5.81)	(1.35)
Treat	-47.07	308.01**	0.83
	(28.94)	(5.59)	(0.90)
2011.year×Treat	-81.73	-42.96**	-1.42
	(49.32)	(8.58)	(1.31)
2012.year×Treat	-107.21*	-46.04**	-1.90
	(48.96)	(8.48)	(1.28)
2013.year×Treat	-105.50*	-84.92**	-3.26*
	(45.24)	(9.16)	(1.55)
2015.year×Treat	-121.63*	-109.02**	-1.31
	(54.53)	(9.93)	(1.53)
Male	12.42	-10.73*	1.30**
	(15.06)	(5.02)	(0.46)
Age 75-84	46.68**	19.46**	3.34**
	(16.34)	(5.83)	(0.49)
Age 85+	44.13*	25.45**	3.39**
	(18.67)	(6.69)	(0.62)
Black, non-Hispanic	-0.87	-11.83	-0.77
	(24.10)	(7.90)	(0.87)
Hispanic	-37.42	-52.09**	-2.59
	(45.51)	(7.37)	(1.37)
Other, non-Hispanic	-2.31	-3.66	-1.47
	(38.82)	(12.67)	(1.17)
High school graduate	10.44	14.18*	0.31
	(21.61)	(5.75)	(0.63)
Some college or more	-10.92	6.70	-2.66**
	(21.54)	(6.52)	(0.72)
Family income (125-200%)	20.47	23.85**	-0.45
	(17.56)	(5.74)	(0.60)
Family income (200-400%)	48.50**	33.26**	-0.55
	(17.77)	(5.76)	(0.59)
Family income (>400%)	121.13**	57.23**	-0.84
	(25.09)	(8.43)	(0.74)
Urban	38.44	4.75	-0.59
	(21.35)	(6.78)	(0.50)
Number of chronic conditions, 3-4	331.90**	92.32**	15.02**
	(14.54)	(4.93)	(0.50)
Number of chronic conditions, 5+	591.99**	143.37**	25.74**
	(21.23)	(6.92)	(0.71)
Having MA-PDs	-123.44**	-63.47**	0.58
	(15.10)	(5.81)	(0.42)
constant	979.21**	10.88	25.05**
	(35.12)	(8.81)	(0.83)
N	39462	39462	39462

Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$

Appendix B-13. Year-by-year changes difference-in-differences regression results for those who entered the coverage gap without reaching the catastrophic coverage threshold (Subgroup II)

	Total costs	OOP costs	30-day fills
2011.year	-127.37	8.85	-2.35
	(79.40)	(15.68)	(1.72)
2012.year	-59.13	-22.63	3.32
	(90.04)	(17.31)	(2.04)
2013.year	-8.23	-11.40	4.68*
	(83.02)	(19.17)	(2.18)
2015.year	30.81	-18.37	3.11
	(103.60)	(25.88)	(2.15)
Treat	-480.29**	1385.81**	-7.50**
	(74.02)	(45.44)	(1.65)
2011.year×Treat	97.20	-11.76	2.99
	(93.48)	(47.98)	(1.95)
2012.year×Treat	84.56	-82.81	1.23
	(107.94)	(59.56)	(2.36)
2013.year×Treat	128.89	-206.14**	3.52
	(99.06)	(61.42)	(2.15)
2015.year×Treat	49.45	-283.37**	-0.55
	(124.75)	(66.03)	(2.77)
Male	-30.48	-10.25	2.11
	(37.12)	(30.76)	(1.15)
Age 75-84	27.72	30.43	0.88
	(41.56)	(30.22)	(1.23)
Age 85+	78.17	54.51	2.19
	(41.02)	(36.23)	(1.34)
Black, non-Hispanic	-52.65	-53.12	-0.24
	(60.31)	(36.67)	(1.42)
Hispanic	-71.28	-26.54	-2.46
	(100.97)	(59.57)	(2.87)
Other, non-Hispanic	0.08	70.11	-0.39
	(99.44)	(91.19)	(2.73)
High school graduate	9.32	-35.99	-2.76*
	(41.32)	(37.45)	(1.36)
Some college or more	48.45	60.80	-5.34**
	(45.93)	(35.26)	(1.37)
Family income (125-200%)	-46.00	46.64	-0.13
	(54.92)	(38.34)	(1.43)
Family income (200-400%)	-5.82	123.25*	-0.15
	(54.37)	(48.68)	(1.72)
Family income (>400%)	83.62	152.64*	-0.12
	(58.22)	(59.29)	(1.83)
Urban	14.98	-125.08**	-3.24
	(53.19)	(31.95)	(1.65)
Number of chronic conditions, 3-4	138.58**	149.62**	12.68**
	(44.41)	(39.37)	(1.24)
Number of chronic conditions, 5+	340.52**	230.90**	23.74**
	(55.47)	(40.19)	(1.26)
Having MA-PDs	-104.92*	-206.25**	0.90
	(42.13)	(26.82)	(1.14)
constant	4557.31**	131.70**	65.77**
	(77.79)	(46.30)	(2.45)
n	42006	42006	42006

Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$

Appendix B-14. Year-by-year changes difference-in-differences regression results for those who reached the catastrophic coverage threshold (Subgroup III)

	Total costs	OOP costs	30-day fills
2011.year	322.22	14.98	1.15
	(628.81)	(34.84)	(3.00)
2012.year	475.06	-50.55	5.13
	(600.21)	(31.51)	(3.24)
2013.year	2747.07*	1.23	6.50
	(1185.98)	(50.08)	(4.81)
2015.year	5815.25**	-23.65	2.89
	(1271.90)	(39.23)	(3.90)
Treat	204.04	3059.44**	-11.60**
	(1268.37)	(152.93)	(3.49)
2011.year×Treat	1135.75	-32.15	0.65
	(1324.94)	(198.62)	(4.80)
2012.year×Treat	2421.88	189.06	-6.68
	(1872.48)	(203.02)	(5.18)
2013.year×Treat	1861.29	-119.45	-4.28
	(2318.27)	(228.02)	(5.83)
2015.year×Treat	-602.58	-503.13*	-8.86
	(2096.39)	(196.03)	(5.80)
Male	938.15	109.21	1.55
	(963.17)	(89.85)	(2.11)
Age 75-84	-1998.08*	-43.22	1.78
	(896.82)	(78.93)	(1.87)
Age 85+	-2750.72**	-160.38	-4.00
	(939.42)	(93.34)	(2.38)
Black, non-Hispanic	2804.18	33.63	-3.09
	(1588.89)	(109.01)	(3.61)
Hispanic	2361.90	-122.40	-8.89*
	(1405.47)	(82.92)	(3.62)
Other, non-Hispanic	688.56	237.99	-6.30
	(2370.60)	(124.78)	(5.33)
High school graduate	-815.48	-53.68	1.71
	(797.46)	(76.94)	(2.31)
Some college or more	1755.38	218.49*	0.79
	(1043.38)	(85.97)	(2.91)
Family income (125-200%)	1485.86	107.89	-0.35
	(1068.92)	(75.59)	(2.50)
Family income (200-400%)	848.29	335.80*	-1.44
	(1015.45)	(143.33)	(2.81)
Family income (>400%)	150.26	5.77	-1.44
	(1657.17)	(184.93)	(3.26)
Urban	397.93	-52.57	0.38
	(1112.13)	(72.04)	(2.89)
Number of chronic conditions, 3-4	-13.82	50.69	16.93**
	(962.43)	(106.79)	(2.25)
Number of chronic conditions, 5+	587.50	117.80	33.94**
	(999.42)	(115.50)	(2.54)
Having MA-PDs	-900.96	-386.86**	-3.03
	(1036.15)	(80.85)	(2.50)
constant	10897.82**	141.39	90.24**
	(1403.82)	(129.42)	(2.99)
n	44286	44286	44286

Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$

Appendix B-15. Sensitivity analysis for year-by-year changes difference-in-differences regression using 2008, 2009, and 2010, instead of the pooled pre-ACA period, for all beneficiaries

	2008 vs. Years			2009 vs. Years			2010 vs Years		
	Total spending	OOP spending	30-day fills	Total spending	OOP spending	30-day fills	Total spending	OOP spending	30-day fills
2011.year	106.26	-3.99	3.09	126.14	7.79	2.71	6.42	-4.10	0.75
	(197.57)	(13.47)	(1.60)	(181.95)	(11.08)	(1.59)	(142.68)	(10.35)	(1.27)
2012.year	-40.12	-36.11*	4.69**	-19.94	-24.47*	4.30**	-140.01	-36.57**	2.32
	(175.57)	(14.68)	(1.51)	(179.63)	(10.73)	(1.59)	(160.75)	(10.32)	(1.30)
2013.year	190.65	-33.17*	5.97**	211.32	-21.83	5.56**	89.63	-34.21*	3.59*
	(274.50)	(15.30)	(1.62)	(265.37)	(12.73)	(1.78)	(272.43)	(13.56)	(1.76)
2015.year	939.89**	-69.05**	2.92	961.33**	-57.74**	2.50	833.67*	-70.86**	0.53
	(318.36)	(16.26)	(1.72)	(319.62)	(14.38)	(1.72)	(321.52)	(13.77)	(1.75)
Treat	-1569.09**	673.78**	-12.21**	-1433.61**	683.44**	-11.10**	-1626.76**	636.21**	-12.26**
	(159.97)	(26.37)	(1.28)	(154.19)	(21.81)	(1.35)	(178.63)	(23.19)	(1.18)
2011.year × Treat	-87.60	-52.42	-0.66	-206.85	-59.30*	-1.70	-33.57	-12.90	-0.33
	(229.06)	(28.64)	(1.78)	(216.23)	(24.35)	(1.74)	(177.03)	(17.76)	(1.36)
2012.year × Treat	79.42	-59.28*	-0.82	-40.28	-66.30*	-1.86	133.65	-19.71	-0.47
	(209.36)	(29.58)	(1.70)	(216.65)	(26.72)	(1.81)	(192.63)	(21.37)	(1.36)
2013.year × Treat	-88.88	-114.44**	-0.82	-210.08	-121.70**	-1.85	-33.95	-73.88**	-0.46
	(289.46)	(30.60)	(1.66)	(292.80)	(29.22)	(1.86)	(286.65)	(26.98)	(1.80)
2015.year × Treat	-905.16**	-142.51**	-1.46	-1029.77**	-150.34**	-2.55	-849.81*	-102.27**	-1.15
	(343.00)	(30.22)	(1.83)	(349.09)	(28.13)	(1.88)	(341.40)	(28.25)	(1.94)
Male	298.08*	17.59	2.45**	291.56*	19.38	2.50**	289.37*	18.64	2.72**
	(114.79)	(14.45)	(0.61)	(118.40)	(14.63)	(0.63)	(117.37)	(14.77)	(0.65)
Age 75-84	-128.28	34.00*	3.16**	-108.32	38.49*	3.20**	-110.48	39.76*	3.10**
	(118.76)	(16.96)	(0.60)	(120.03)	(16.97)	(0.61)	(121.05)	(17.05)	(0.67)
Age 85+	-475.62**	15.84	1.26	-459.79**	13.72	1.60	-442.91**	13.07	1.38
	(121.01)	(20.51)	(0.77)	(118.05)	(20.45)	(0.82)	(120.06)	(20.98)	(0.84)
Black, non-Hispanic	-111.97	-31.63	-3.50**	-77.11	-34.16	-3.40**	-39.31	-34.39	-2.92**
	(224.14)	(21.98)	(0.95)	(226.64)	(23.38)	(1.01)	(230.12)	(23.39)	(1.04)
Hispanic	191.83	-58.93**	-4.65**	220.20	-42.19	-4.39**	257.45	-44.36	-4.58**
	(306.43)	(22.24)	(1.68)	(307.05)	(24.04)	(1.63)	(313.72)	(24.59)	(1.64)
Other, non-Hispanic	-365.87	4.66	-3.91*	-356.79	-0.36	-4.03*	-326.07	0.00	-3.66*
	(283.60)	(35.81)	(1.62)	(277.20)	(35.80)	(1.58)	(287.04)	(36.62)	(1.62)
High school graduate	-123.32	-25.52	-0.62	-163.80	-19.56	-0.41	-124.46	-24.76	-0.52
	(121.95)	(19.24)	(0.78)	(124.49)	(20.11)	(0.79)	(124.09)	(20.93)	(0.81)
Some college or more	100.80	23.03	-3.37**	90.91	35.68	-3.13**	100.74	22.68	-3.31**
	(143.21)	(19.54)	(0.81)	(150.73)	(20.00)	(0.82)	(150.00)	(20.95)	(0.82)
Family income (125-200%)	192.03	60.42**	0.09	186.01	44.46**	-0.13	237.81	52.65**	-0.19
	(131.43)	(17.78)	(0.75)	(129.51)	(16.73)	(0.73)	(140.75)	(18.51)	(0.81)
Family income (200-400%)	362.11**	127.11**	0.76	375.01**	122.80**	0.58	413.01**	119.51**	0.26
	(119.65)	(24.89)	(0.75)	(126.41)	(25.08)	(0.80)	(124.83)	(26.37)	(0.86)
Family income (>400%)	400.32**	138.27**	1.01	409.80**	130.84**	1.14	440.60**	141.67**	0.94
	(145.50)	(24.73)	(0.82)	(146.43)	(24.01)	(0.87)	(146.69)	(24.72)	(0.90)
Urban	215.49	5.39	-0.29	239.36	8.07	-0.29	249.03	9.91	-0.65
	(145.13)	(18.89)	(0.80)	(155.46)	(18.07)	(0.89)	(152.00)	(17.19)	(0.78)
Number of chronic conditions, 3-4	1117.48**	259.31**	20.22**	1133.61**	258.95**	20.54**	1155.09**	263.87**	20.55**
	(73.95)	(14.15)	(0.53)	(75.47)	(13.41)	(0.55)	(74.96)	(14.49)	(0.56)
Number of chronic conditions, 5+	3124.58**	551.70**	40.54**	3149.68**	556.45**	40.93**	3192.10**	562.01**	40.91**
	(151.55)	(22.94)	(0.77)	(150.59)	(22.06)	(0.78)	(155.47)	(23.64)	(0.79)
Having MA-PDs	-797.20**	-202.81**	-2.90**	-818.03**	-212.72**	-2.99**	-784.58**	-192.28**	-2.73**
	(101.28)	(14.16)	(0.58)	(102.84)	(14.10)	(0.58)	(102.39)	(14.84)	(0.58)
constant	2627.36**	-132.30**	40.65**	2571.46**	-148.49**	40.61**	2615.84**	-144.51**	42.79**
	(205.35)	(26.83)	(1.38)	(215.49)	(25.20)	(1.51)	(208.10)	(25.73)	(1.23)
n	25833	25833	25833	25543	25543	25543	25515	25515	25515

Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$

Appendix B-16. Characteristics of the study sample by year in the pre-ACA period, 2008-2010

	Non-LIS Beneficiaries			LIS Beneficiaries		
	2008	**2009**	**2010**	**2008**	**2009**	**2010**
Sample size (n)	3,260	3,076	3,084	1,466	1,360	1,324
Population size (N)	12,400,843	13,123,739	13,599,760	4,897,219	4,928,701	5,018,561
Female (%)	59	60	60	71	73	71
Age (%)						
65-74	46	48	48	40	41	42
75-84	39	37	36	40	39	38
85+	15	15	15	21	20	20
Race/ethnicity (%)						
White, non-Hispanic	92	91	92	67	65	66
Black, non-Hispanic	5	5	5	19	20	18
Hispanic	1	1	1	6	7	7
Other, non-Hispanic	2	2	2	8	8	9
Education (%)						
Less than high school	20	19	19	58	56	55
High school graduate	33	33	32	24	25	22
Some college/college graduate	47	48	48	18	19	21
Family income (percent of poverty, %)						
< 125%	15	17	18	70	72	80
125%-200%	25	24	25	21	18	15
200%-400%	43	43	38	8	9	4
> 400%	16	16	19	1	1	1
Rural (%)	15	14	14	17	16	16
Chronic conditions (%)						
0-2	40	39	39	27	27	26
3-4	41	42	43	43	43	43
> 5	19	18	18	30	30	31
Having MA-PDs (%)	41	43	44	19	21	23

C. Appendices for Manuscript #3

Appendix C-1. Technical specification of regression analyses

1) Logistic Regression Equation – Parallel Trend Assumption Test

$$\log\left(\frac{P_{it}}{1-P_{it}}\right) = \beta_0 + \beta_1 Time_t + \beta_2 Treat_i + \beta_3 Time_t \times Treat_i + \beta_4 X_i + \epsilon_{it}$$

where *i* indexed individuals and *t* indexed year in the pre-ACA period. P_{it} represents the probability that individual *i* experiences cost-related medication adherence or engages in drug cost-reduction strategies in year *t*. *Time* is a time trend variable indicating the years 2008 to 2010. *Treat* is a treatment indicator equal to one for treatment group (non-LIS beneficiaries), and zero for control group (LIS beneficiaries). *Xi* is a vector of sociodemographic control variables for age, sex, race/ethnicity, education level, family income as percentage of poverty level, number of chronic conditions, and an indicator variable for having Medicare Advantage Prescription Drug plans, for individual *i* in time period *t*, respectively. In **Appendix C-2.** Sensitivity Analysis, we see the parallel trend assumption is valid because the coefficients of the interaction term, β_3, is statistically insignificant.

2) Simple Adjusted Logistic Regression Equation – Among Treatment Group

$$\log\left(\frac{P_{it}}{1-P_{it}}\right) = \beta_0 + + \beta_1 Post_t + \beta_2 X_i + e_{it}$$

where *i* indexed individuals and *t* indexed year. P_{it} represents the probability that individual *i* experiences cost-related medication adherence or engages in drug cost-reduction strategies in year *t*. *Post* is a dummy variable equal to zero for years 2008-2010 and one for years

2011-2015. *Xi* is a vector of sociodemographic control variables for age, sex, race/ethnicity, education level, family income as percentage of poverty level, number of chronic conditions, and enrollment in Medicare Advantage Prescription Drug plans, for individual *i* in time period *t*, respectively. Therefore, β_1 reflects the simple adjusted odds of having CRN or adopting cost-reduction strategies in the post-ACA period relative to the pre-ACA period for the non-LIS beneficiaries. Full regression results are described in **Appendix *C-4*** and **Appendix *C-5***.

3) Regression Equation – Pooled Difference-in-Differences Model (Pre- vs. Post-ACA)

$$\log\left(\frac{P_{it}}{1-P_{it}}\right) = \beta_0 + + \beta_1 Post_t + \beta_2 Treat_i + \beta_3 Post_t \times Treat_i + \beta_4 X_i + e_{it}$$

where *i* indexed individuals and *t* indexed year. P_{it} represents the probability that individual *i* experiences cost-related medication adherence or engages in drug cost-reduction strategies in year *t*. *Post* is a dummy variable equal to zero for years 2008-2010 and one for years 2011-2015. *Treat* is a treatment indicator equal to one for treatment group (non-LIS beneficiaries), and zero for control group (LIS beneficiaries). β_3 measures the difference-in-differences estimate for the change in outcome in the treatment group in the post-ACA period, compared to the control group. *Xi* is a vector of sociodemographic control variables for age, sex, race/ethnicity, education level, family income as percentage of poverty level, number of chronic conditions, and enrollment in Medicare Advantage Prescription Drug plans, for individual *i* in time period *t*, respectively.

4) Regression Equation – Year-by-Year changes Difference-in-Differences Model (Pre-ACA vs. 2011, 2012, 2013, and 2015)

$$\log\left(\frac{P_{it}}{1-P_{it}}\right) = \beta_0 + \beta_1 2011_t + \beta_2 2012_t + \beta_3 2013_t + \beta_4 2015_t + \beta_5 Treat_i + \beta_6 2011_t \times Treat_i + \beta_7 2012_t \times Treat_i + \beta_8 2013_t \times Treat_i + \beta_9 2015_t \times Treat_i + \beta_{10} X_i + e_{it}$$

where *i* indexed individuals and *t* indexed year. P_{it} represents the probability that individual *i* experiences cost-related medication adherence or drug cost-reduction strategies in year *t*. β_1 captures the direct effect of treatment group (non-LIS beneficiaries) at baseline compared to the control group (LIS beneficiaries), and β_2-β_5 adjust for the year. β_6 measures the difference-in-differences estimate for the change in outcome in the treatment group in 2011, compared to the control group, while β_7, β_8, and β_9 provide the comparable estimates for 2012, 2013, and 2015, respectively. *Xi* is a vector of sociodemographic control variables for age, sex, race/ethnicity, education level, family income as percentage of poverty level, number of chronic conditions, and an indicator variable for having Medicare Advantage Prescription Drug plans, for individual *i* in time period *t*, respectively.

Appendix C-2. Sensitivity Analysis

We conducted several sensitivity analyses using different methods for constructing the outcome measures. Instead of a binary indicator of CRN and CRS, we used two different approaches to construct them. First, we used each of the 4 measures of CRN and CRS as separate dependent variables, resulting in a total of 8 outcome measures (4 measures of CRN and 4 CRS). Second, ordinal 5-point scales (0 to 4) were constructed for the measures of CRN and CRS. The use of an ordinal scale was based on the assumption that each of the variables equally contributed to the CRN and CRS. For example, 0 indicates that the respondent has never experienced any CRN or CRS during the year, while 4 indicates the respondent experienced all 4 CRN or CRS. As the dependent variable was a 5-point ordinal scale, we employed difference-in-differences approaches using two different models: ordinal least squares (OLS) and ordinal logistic regression.

Outcome measures and analytical models for primary and sensitivity analyses

	Outcome Measures		**Difference-in-differences regression models**	
			Pooled pre- and post-ACA	**Year-by-year changes**
Primary Analysis	CRN	Binary aggregate measure (Y/N)	Logistic	Logistic
	CRS	Binary aggregate measure (Y/N)	Logistic	Logistic
Sensitivity Analysis I	CRN	Each of the 4 questions	Logistic	Logistic
	CRS	Each of the 4 questions	Logistic	Logistic
Sensitivity Analysis II	CRN	5-point ordinal scale (0-4)	1) OLS 2) Ordinal logistic	1) OLS 2) Ordinal logistic
	CRS	5-point ordinal scale (0-4)	1) OLS 2) Ordinal logistic	1) OLS 2) Ordinal logistic

CRN: Cost-related medication nonadherence, OLS: Ordinary least square

Appendix C-3. Full regression results of the parallel trend assumption test using aggregate binary outcome measure

	Cost-related nonadherence	Cost-reduction strategies
Time (2009)	1.029	0.745**
	(0.114)	(0.044)
Time (2010)	1.102	0.820*
	(0.174)	(0.070)
Treat	1.258	1.666**
	(0.196)	(0.150)
Time × Treat	1.021	1.097
	(0.098)	(0.057)
Male	0.903	1.072
	(0.073)	(0.053)
Age 75-84	0.641**	0.921
	(0.047)	(0.047)
Age 85+	0.327**	0.608**
	(0.034)	(0.040)
Black, non-Hispanic	1.256*	0.768*
	(0.140)	(0.082)
Hispanic	0.892	0.837
	(0.250)	(0.126)
Other, non-Hispanic	1.004	0.740**
	(0.202)	(0.083)
High school graduate	0.985	1.235**
	(0.121)	(0.088)
Some college or more	1.173	1.263**
	(0.138)	(0.091)
Family income (125-200%)	1.005	0.947
	(0.087)	(0.079)
Family income (200-400%)	0.684**	0.822*
	(0.070)	(0.061)
Family income (>400%)	0.445**	0.778**
	(0.072)	(0.071)
Number of chronic conditions, 3-4	1.895**	1.617**
	(0.187)	(0.075)
Number of chronic conditions, 5+	2.905**	2.173**
	(0.332)	(0.131)
Having MA-PDs	0.854	0.737**
	(0.080)	(0.037)
n	40033	40000

Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Appendix C-4. Full regression results of simple adjusted logistic model (pooled pre- and post-ACA) among non-LIS beneficiaries, using aggregate binary outcome measure

	Cost-related nonadherence	**Cost-saving behaviors**
Post	1.366**	0.444**
	(0.124)	(0.031)
2009.year	1.033	0.845**
	(0.105)	(0.045)
2010.year	1.139	0.990
	(0.123)	(0.071)
2011.year	0.824	1.987**
	(0.084)	(0.155)
2012.year	1.124	1.676**
	(0.098)	(0.111)
2013.year	0.888	1.333**
	(0.075)	(0.083)
Male	0.775**	1.105*
	(0.045)	(0.044)
Age 75-84	0.569**	0.825**
	(0.034)	(0.034)
Age 85+	0.274**	0.542**
	(0.021)	(0.026)
Black, non-Hispanic	1.144	0.725**
	(0.120)	(0.056)
Hispanic	0.723	1.132
	(0.165)	(0.150)
Other, non-Hispanic	0.853	0.900
	(0.159)	(0.125)
High school graduate	0.857*	1.099
	(0.062)	(0.062)
Some college or more	0.970	1.242**
	(0.076)	(0.069)
Family income (125-200%)	0.861*	1.004
	(0.061)	(0.057)
Family income (200-400%)	0.627**	0.893*
	(0.043)	(0.050)
Family income (>400%)	0.407**	0.781**
	(0.038)	(0.051)
Number of chronic conditions, 3-4	1.825**	1.537**
	(0.118)	(0.060)
Number of chronic conditions, 5+	2.713**	2.269**
	(0.237)	(0.128)
Having MA-PDs	0.817**	0.749**
	(0.045)	(0.025)
n	33417	33303

Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$

Appendix C-5. Full regression results of simple adjusted logistic model (year-by-year) among non-LIS beneficiaries, using aggregate binary outcome measure – Primary analysis

	Cost-related nonadherence	**Cost-saving behaviors**
2011.year	1.062	0.938
	(0.091)	(0.060)
2012.year	1.450**	0.791**
	(0.094)	(0.035)
2013.year	1.145	0.629**
	(0.080)	(0.030)
2015.year	1.289**	0.472**
	(0.099)	(0.028)
Male	0.775**	1.105*
	(0.045)	(0.044)
Age 75-84	0.568**	0.825**
	(0.034)	(0.033)
Age 85+	0.274**	0.542**
	(0.021)	(0.026)
Black, non-Hispanic	1.144	0.725**
	(0.120)	(0.056)
Hispanic	0.722	1.131
	(0.165)	(0.150)
Other, non-Hispanic	0.854	0.900
	(0.159)	(0.126)
High school graduate	0.857*	1.099
	(0.062)	(0.062)
Some college or more	0.970	1.241**
	(0.076)	(0.069)
Family income (125-200%)	0.860*	1.004
	(0.061)	(0.057)
Family income (200-400%)	0.625**	0.892*
	(0.042)	(0.050)
Family income (>400%)	0.407**	0.782**
	(0.038)	(0.051)
Number of chronic conditions, 3-4	1.827**	1.537**
	(0.118)	(0.059)
Number of chronic conditions, 5+	2.714**	2.270**
	(0.237)	(0.128)
Having MA-PDs	0.818**	0.748**
	(0.045)	(0.025)
n	33417	33303

Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$

Appendix C-6. Full regression results of pooled pre- and post-ACA difference-in-differences model using aggregate binary outcome measure - Primary analysis

	Cost-related nonadherence	**Cost-saving behaviors**
Post	1.110	0.353**
	(0.120)	(0.029)
Treat	1.307**	1.704**
	(0.127)	(0.122)
Post × Treat	1.191	1.187*
	(0.130)	(0.092)
2009.year	1.042	0.796**
	(0.091)	(0.036)
2010.year	1.131	0.941
	(0.100)	(0.057)
2011.year	0.898	2.132**
	(0.077)	(0.144)
2012.year	1.152	1.687**
	(0.087)	(0.095)
2013.year	0.914	1.380**
	(0.068)	(0.074)
Male	0.795**	1.081*
	(0.039)	(0.035)
Age 75-84	0.561**	0.838**
	(0.028)	(0.029)
Age 85+	0.271**	0.572**
	(0.019)	(0.023)
Black, non-Hispanic	1.102	0.716**
	(0.089)	(0.054)
Hispanic	0.786	0.692**
	(0.129)	(0.070)
Other, non-Hispanic	0.792	0.778**
	(0.115)	(0.069)
High school graduate	0.931	1.117*
	(0.069)	(0.053)
Some college or more	1.072	1.264**
	(0.079)	(0.058)
Family income (125-200%)	0.942	1.032
	(0.056)	(0.047)
Family income (200-400%)	0.652**	0.906*
	(0.043)	(0.045)
Family income (>400%)	0.423**	0.798**
	(0.036)	(0.049)
Number of chronic conditions, 3-4	1.734**	1.529**
	(0.098)	(0.050)
Number of chronic conditions, 5+	2.586**	2.157**
	(0.191)	(0.095)
Having MA-PDs	0.831**	0.779**
	(0.043)	(0.023)
constant	0.125**	1.408**
	(0.013)	(0.110)
n	30871	30709

Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$

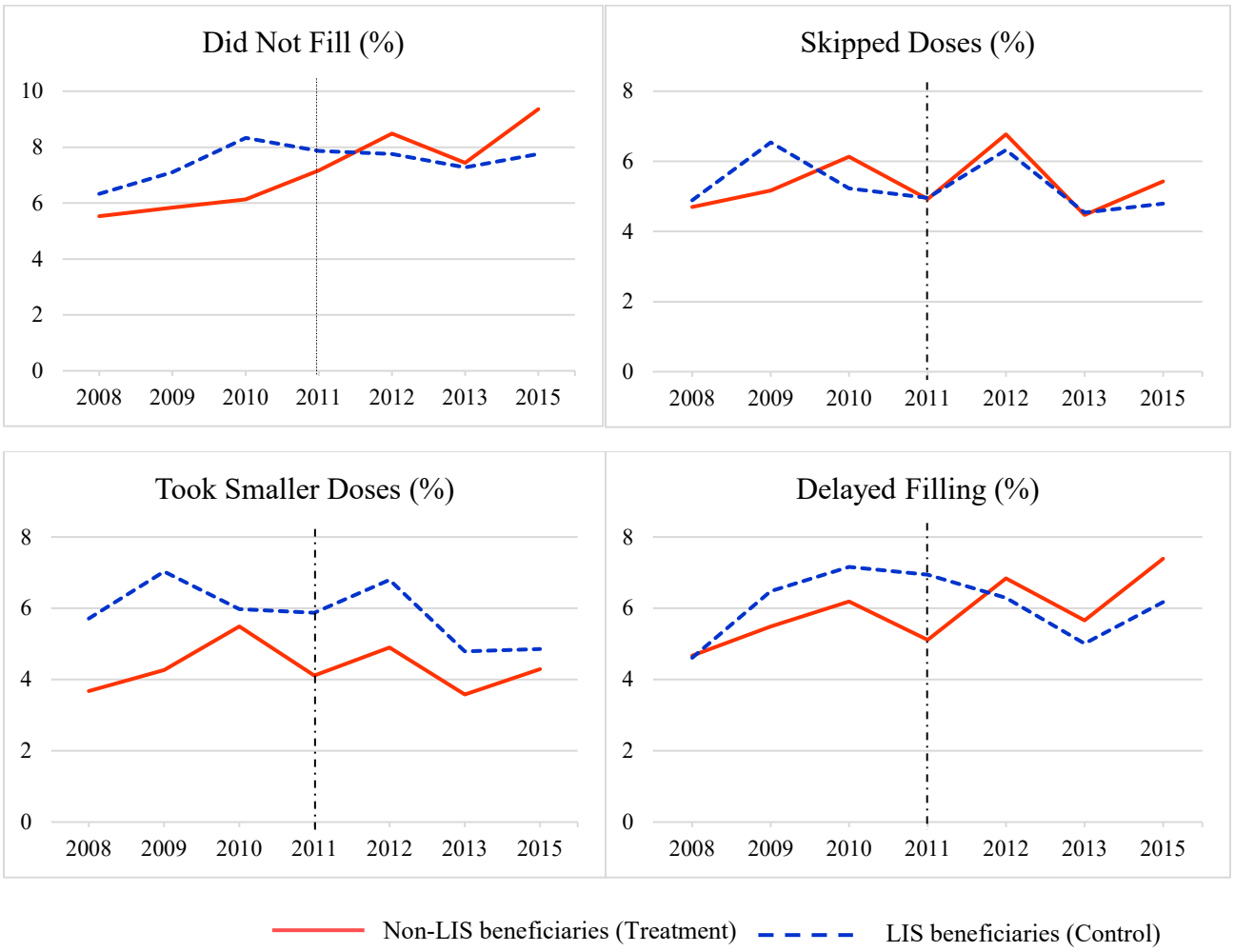
Appendix C-7. Full regression results of year-by-year changes difference-in-differences model using aggregate binary outcome measure - Primary analysis

	Cost-related nonadherence	Cost-saving behaviors
2011.year	1.108	0.958
	(0.144)	(0.080)
2012.year	1.196	0.629**
	(0.137)	(0.057)
2013.year	0.958	0.561**
	(0.123)	(0.051)
2015.year	0.937	0.346**
	(0.125)	(0.038)
Treat	1.310**	1.701**
	(0.127)	(0.122)
2011.year × Treat	0.957	0.978
	(0.148)	(0.090)
2012.year × Treat	1.206	1.258*
	(0.168)	(0.125)
2013.year × Treat	1.190	1.124
	(0.186)	(0.112)
2015.year × Treat	1.370*	1.376*
	(0.208)	(0.171)
Male	0.795**	1.082*
	(0.039)	(0.035)
Age 75-84	0.560**	0.839**
	(0.028)	(0.029)
Age 85+	0.271**	0.572**
	(0.019)	(0.023)
Black, non-Hispanic	1.101	0.715**
	(0.089)	(0.054)
Hispanic	0.787	0.691**
	(0.129)	(0.070)
Other, non-Hispanic	0.791	0.776**
	(0.115)	(0.068)
High school graduate	0.933	1.118*
	(0.069)	(0.053)
Some college or more	1.072	1.262**
	(0.079)	(0.058)
Family income (125-200%)	0.940	1.033
	(0.056)	(0.047)
Family income (200-400%)	0.650**	0.907
	(0.043)	(0.045)
Family income (>400%)	0.420**	0.797**
	(0.036)	(0.048)
Number of chronic conditions, 3-4	1.733**	1.526**
	(0.098)	(0.050)
Number of chronic conditions, 5+	2.586**	2.157**
	(0.191)	(0.096)
Having MA-PDs	0.834**	0.780**
	(0.044)	(0.023)
constant	0.133**	1.277**
	(0.012)	(0.098)
n	30871	30709

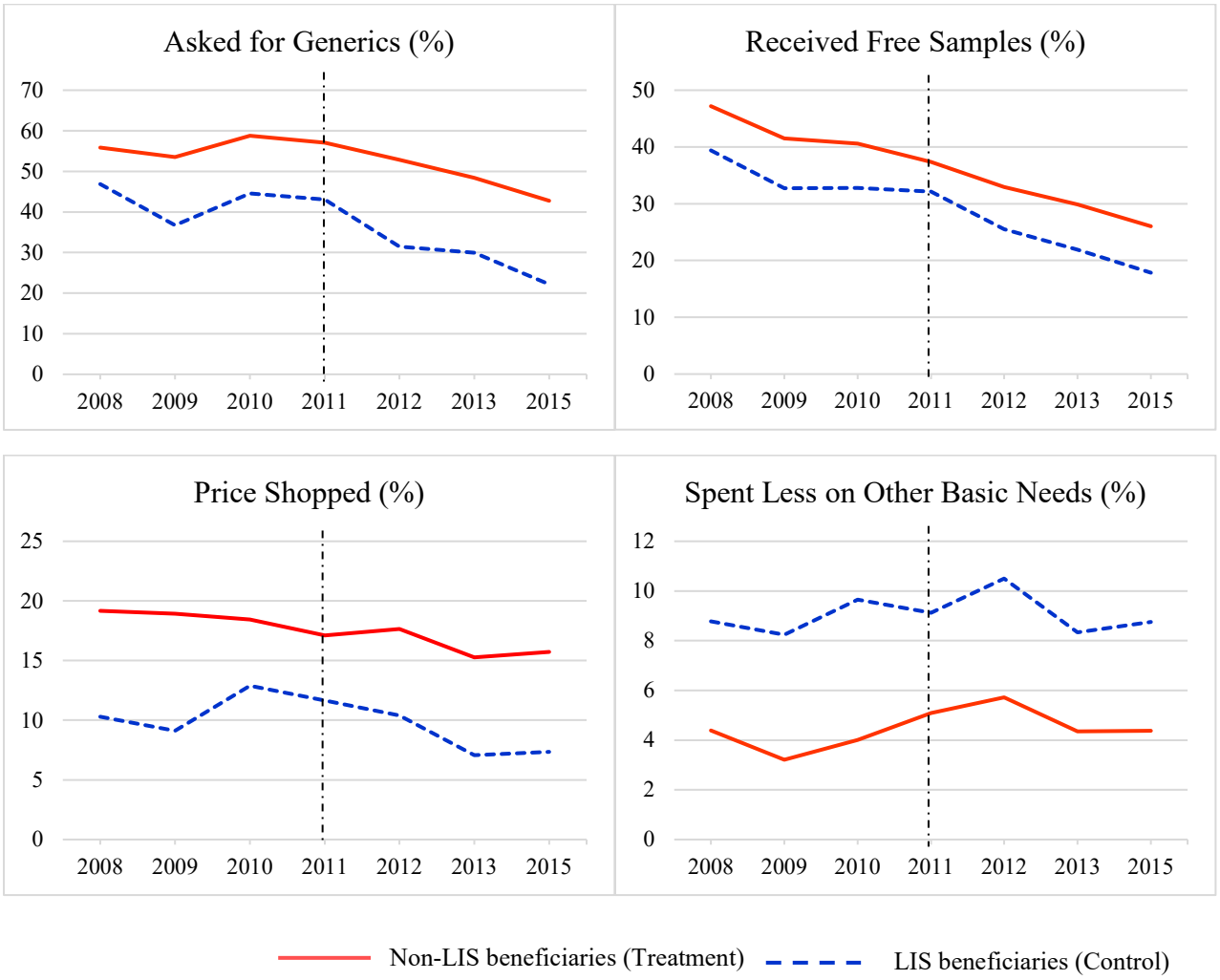
Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$

Sensitivity Analysis I

Appendix C-8. Unadjusted prevalence rates of cost-related medication nonadherence (CRN) among non-LIS and LIS Part D beneficiaries, 2008-2015, using each individual measure of CRN



Appendix C-9. Unadjusted prevalence rates of cost-saving behaviors among non-LIS and LIS Part D beneficiaries, 2008-2015, using each individual measure of the cost-saving behaviors



Appendix C-10. Effect of the ACA's coverage gap reform on cost-related medication nonadherence (CRN) and cost-reduction strategies (CRS) for non-LIS beneficiaries, using each individual measure of CRN and CRS

	Pre vs. Post [a]		Year-by-Year Changes [b]							
	Post-ACA		2011		2012		2013		2015	
	OR	SE	OR	SE	OR	SE	OR	SE	OR	SE
CRN										
1) Did not fill										
Non-LIS	1.67**	0.18	1.25*	0.13	1.51**	0.14	1.28*	0.12	1.60**	0.15
DD estimate	1.44**	0.20	1.18	0.25	1.50*	0.30	1.36	0.25	1.66*	0.33
2) Skipped doses										
Non-LIS	1.08	0.15	0.9	0.11	1.07	0.11	0.77*	0.08	0.89	0.09
DD estimate	1.06	0.16	1.05	0.25	0.98	0.22	1.00	0.24	1.18	0.25
3) Took smaller doses										
Non-LIS	1.05	0.15	0.9	0.10	1.26*	0.12	0.80*	0.08	0.93	0.11
DD estimate	1.17	0.18	0.99	0.20	1.19	0.27	1.11	0.25	1.35	0.30
4) Delayed filling										
Non-LIS	1.51**	0.21	0.91	0.10	1.26**	0.10	1.01	0.10	1.30*	0.14
DD estimate	1.26	0.21	0.84	0.20	1.31	0.27	1.36	0.28	1.50	0.36
CRS										
1) Asked for generics										
Non-LIS	0.55**	0.04	1.04	0.06	0.86**	0.04	0.72**	0.04	0.54**	0.03
DD estimate	1.31**	0.1	1.03	0.10	1.43**	0.14	1.29*	0.13	1.53**	0.21
2) Received free samples										
Non-LIS	0.35**	0.02	0.79**	0.04	0.64**	0.03	0.54**	0.03	0.42**	0.03
DD estimate	1.02	0.08	0.90	0.08	1.02	0.10	1.07	0.12	1.12	0.14
3) Price shopped										
Non-LIS	0.73**	0.07	0.89	0.07	0.91	0.05	0.75**	0.05	0.74**	0.06
DD estimate	1.02	0.09	0.81	0.12	0.95	0.13	1.21	0.18	1.20	0.20
4) Spent less on basic needs										
Non-LIS	0.95	0.14	1.35*	0.17	1.56**	0.20	1.14	0.14	1.13	0.17
DD estimate	1.35	0.19	1.36*	0.21	1.38	0.26	1.34	0.26	1.34	0.31

NOTES ACA = Affordable Care Act; OR = odds ratio; SE = standard error. [a] Pooled estimate for the years 2011-2015 (post-ACA period), compared with the pooled estimates for the years 2008-2010 (pre-ACA). [b] Year-by-year changes estimate compared with the pooled estimates for the years 2008-2010 (pre-ACA period). The Non-LIS OR reflects the simple adjusted odds of having cost-related nonadherence or cost-saving behaviors in the Post-ACA period or 2011, 2012, 2013, and 2015 for the non-LIS beneficiaries. The DD estimate is the ratio of this OR to that for the LIS beneficiaries. Figures in this table are based on the results from Table #. *$p < .0.05$, **$p < 0.01$

Appendix C-11. Full regression results of pooled pre- and post-ACA difference-in-differences model, using each individual measure of CRN and CRS

	CRN				CRS			
	No fill	Skipped	Smaller doses	Delayed filling	Generics	Samples	Price shopped	Spent less
Post	1.164	0.972	0.856	1.204	0.393**	0.342**	0.709**	0.761*
	(0.162)	(0.156)	(0.155)	(0.189)	(0.034)	(0.028)	(0.078)	(0.092)
Treat	1.244*	1.185	1.119	1.518**	1.680**	1.517**	1.891**	0.848
	(0.136)	(0.178)	(0.158)	(0.217)	(0.122)	(0.102)	(0.166)	(0.095)
Post × Treat	1.442**	1.059	1.173	1.258	1.305**	1.016	1.021	1.353*
	(0.195)	(0.158)	(0.177)	(0.212)	(0.100)	(0.076)	(0.091)	(0.187)
2009.year	1.075	1.216	1.140	1.232	0.840**	0.784**	0.968	0.791*
	(0.102)	(0.143)	(0.137)	(0.130)	(0.041)	(0.037)	(0.073)	(0.088)
2010.year	1.148	1.360*	1.223	1.363**	1.069	0.757**	1.006	0.939
	(0.123)	(0.159)	(0.139)	(0.157)	(0.059)	(0.042)	(0.069)	(0.096)
2011.year	0.838	1.041	1.050	0.809	2.067**	1.944**	1.262**	1.175
	(0.085)	(0.136)	(0.138)	(0.095)	(0.141)	(0.121)	(0.100)	(0.134)
2012.year	0.955	1.261	1.390**	0.983	1.590**	1.529**	1.259**	1.337**
	(0.095)	(0.160)	(0.161)	(0.105)	(0.103)	(0.089)	(0.094)	(0.143)
2013.year	0.832	0.895	0.898	0.785*	1.351**	1.296**	1.010	1.003
	(0.080)	(0.104)	(0.109)	(0.085)	(0.071)	(0.070)	(0.073)	(0.113)
Male	0.828**	0.803**	0.852*	0.728**	1.080**	1.059	1.027	0.787**
	(0.052)	(0.061)	(0.061)	(0.048)	(0.029)	(0.032)	(0.045)	(0.050)
Age 75-84	0.515**	0.486**	0.526**	0.470**	0.835**	0.880**	0.682**	0.556**
	(0.029)	(0.041)	(0.039)	(0.032)	(0.030)	(0.031)	(0.029)	(0.039)
Age 85+	0.250**	0.224**	0.259**	0.195**	0.603**	0.714**	0.420**	0.268**
	(0.023)	(0.029)	(0.032)	(0.020)	(0.026)	(0.030)	(0.027)	(0.028)
Black, non-Hispanic	1.137	1.231	1.008	1.389**	0.621**	0.946	0.842	1.531**
	(0.108)	(0.140)	(0.112)	(0.141)	(0.040)	(0.069)	(0.075)	(0.164)
Hispanic	0.678*	0.726	0.528*	0.899	0.767**	0.611**	0.560**	0.757
	(0.113)	(0.209)	(0.148)	(0.233)	(0.068)	(0.064)	(0.086)	(0.161)
Other, non-Hispanic	0.665*	0.889	0.870	0.808	0.800*	0.805*	0.692*	1.027
	(0.133)	(0.168)	(0.157)	(0.185)	(0.074)	(0.078)	(0.100)	(0.195)
High school graduate	0.916	0.901	0.943	0.944	1.172**	1.127*	1.171*	0.813*
	(0.085)	(0.093)	(0.105)	(0.091)	(0.048)	(0.062)	(0.075)	(0.076)
Some college or more	0.985	1.093	1.147	1.145	1.277**	1.247**	1.317**	0.825
	(0.085)	(0.123)	(0.117)	(0.112)	(0.052)	(0.063)	(0.076)	(0.083)
Family income (125-200%)	0.946	1.146	1.101	0.979	1.061	1.052	1.141*	1.063
	(0.074)	(0.107)	(0.101)	(0.085)	(0.039)	(0.051)	(0.070)	(0.067)
Family income (200-400%)	0.634**	0.706**	0.764**	0.596**	0.938	0.960	0.997	0.455**
	(0.057)	(0.079)	(0.076)	(0.057)	(0.045)	(0.043)	(0.066)	(0.046)
Family income (>400%)	0.394**	0.390**	0.547**	0.287**	0.819**	0.880*	0.813**	0.167**
	(0.046)	(0.050)	(0.070)	(0.038)	(0.049)	(0.047)	(0.063)	(0.040)
Number of chronic conditions, 3-4	1.697**	1.902**	1.923**	1.823**	1.384**	1.528**	1.366**	2.242**
	(0.115)	(0.162)	(0.160)	(0.168)	(0.051)	(0.059)	(0.065)	(0.227)
Number of chronic conditions, 5+	2.614**	2.842**	2.897**	3.074**	1.728**	2.253**	1.738**	4.103**
	(0.228)	(0.320)	(0.340)	(0.326)	(0.076)	(0.094)	(0.105)	(0.473)
Having MA-PDs	0.790**	0.864	0.870	0.851*	0.834**	0.768**	0.769**	0.923
	(0.047)	(0.069)	(0.061)	(0.054)	(0.024)	(0.025)	(0.040)	(0.054)
constant	0.072**	0.041**	0.048**	0.046**	0.686**	0.460**	0.116**	0.070**
	(0.009)	(0.006)	(0.008)	(0.007)	(0.057)	(0.034)	(0.011)	(0.010)
n	30889	30897	30900	30894	30775	30868	30886	30881

Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$

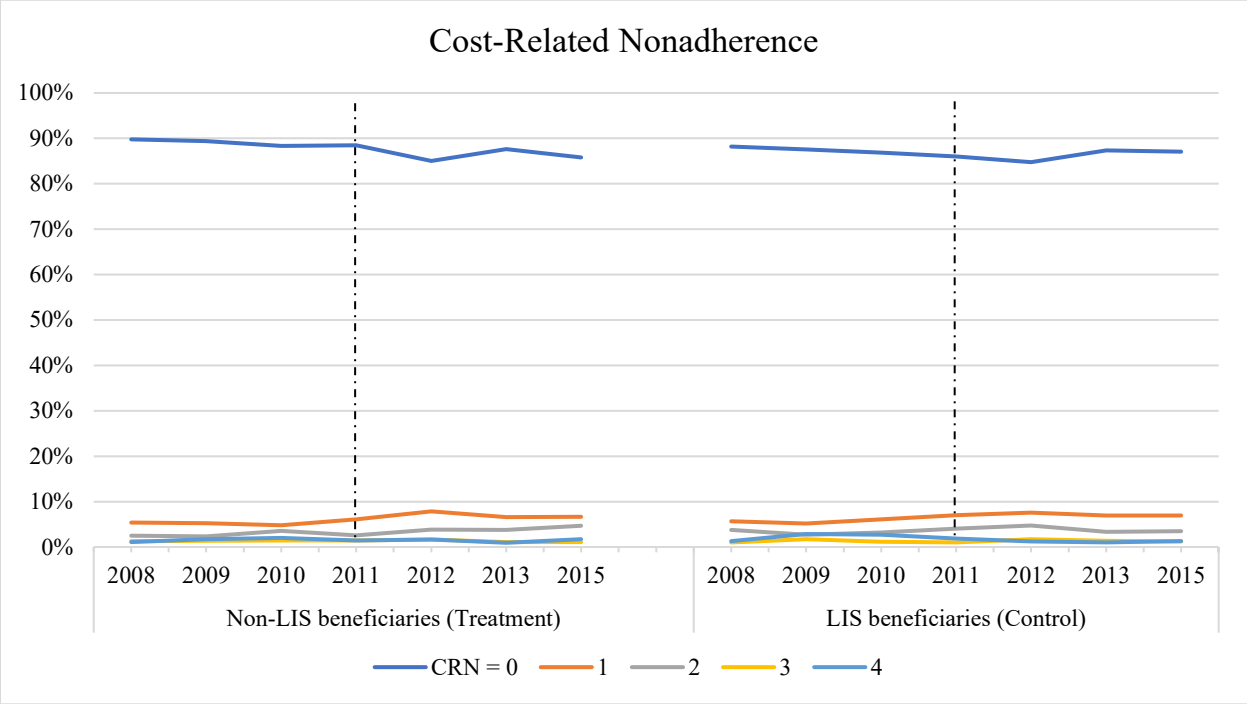
Appendix C-12. Full regression results of year-by-year changes difference-in-differences model, using each individual measure of CRN and CRS

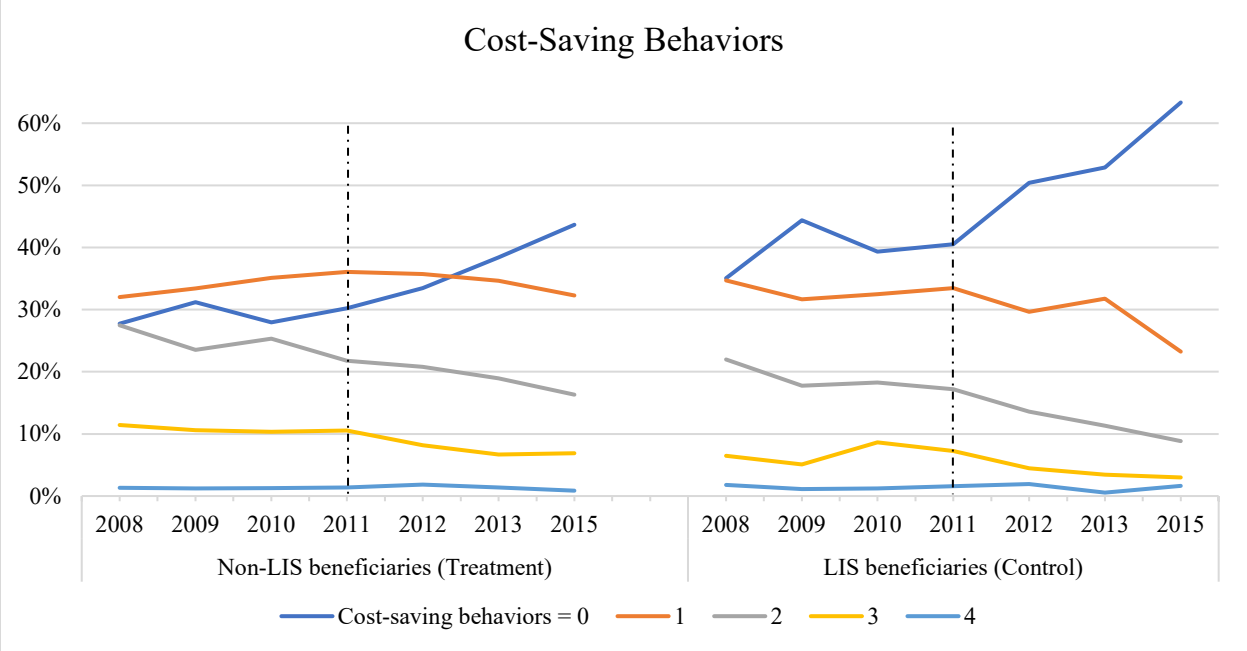
	CRN				CRS			
	No fill	Skipped	Smaller doses	Delayed filling	Generics	Samples	Price shopped	Spent less
2011.year	1.053	0.853	0.907	1.094	1.011	0.875	1.094	0.979
	(0.196)	(0.169)	(0.164)	(0.221)	(0.086)	(0.065)	(0.141)	(0.113)
2012.year	1.002	1.081	1.044	0.951	0.604**	0.625**	0.961	1.106
	(0.168)	(0.207)	(0.189)	(0.173)	(0.060)	(0.057)	(0.116)	(0.158)
2013.year	0.946	0.757	0.712	0.739	0.558**	0.507**	0.623**	0.848
	(0.150)	(0.156)	(0.136)	(0.129)	(0.052)	(0.046)	(0.087)	(0.128)
2015.year	0.962	0.749	0.678	0.868	0.356**	0.377**	0.620**	0.844
	(0.161)	(0.143)	(0.146)	(0.182)	(0.043)	(0.042)	(0.100)	(0.143)
Treat	1.247*	1.193	1.124	1.527**	1.681**	1.506**	1.891**	0.848
	(0.136)	(0.178)	(0.158)	(0.218)	(0.123)	(0.100)	(0.165)	(0.094)
2011.year × Treat	1.183	1.046	0.989	0.835	1.027	0.896	0.809	1.364*
	(0.251)	(0.249)	(0.204)	(0.203)	(0.096)	(0.084)	(0.121)	(0.213)
2012.year × Treat	1.498*	0.983	1.193	1.314	1.425**	1.015	0.946	1.378
	(0.299)	(0.215)	(0.265)	(0.270)	(0.135)	(0.100)	(0.130)	(0.258)
2013.year × Treat	1.355	1.004	1.113	1.357	1.285*	1.071	1.208	1.336
	(0.246)	(0.237)	(0.252)	(0.279)	(0.127)	(0.116)	(0.177)	(0.260)
2015.year × Treat	1.663*	1.175	1.353	1.499	1.531**	1.118	1.200	1.339
	(0.329)	(0.247)	(0.296)	(0.358)	(0.209)	(0.140)	(0.201)	(0.307)
Male	0.828**	0.803**	0.852*	0.727**	1.081**	1.060	1.028	0.787**
	(0.052)	(0.061)	(0.061)	(0.048)	(0.029)	(0.032)	(0.045)	(0.050)
Age 75-84	0.515**	0.485**	0.525**	0.468**	0.835**	0.882**	0.682**	0.557**
	(0.029)	(0.041)	(0.039)	(0.032)	(0.030)	(0.031)	(0.030)	(0.039)
Age 85+	0.250**	0.223**	0.259**	0.194**	0.602**	0.715**	0.420**	0.268**
	(0.023)	(0.029)	(0.032)	(0.020)	(0.026)	(0.030)	(0.027)	(0.028)
Black, non-Hispanic	1.137	1.227	1.007	1.388**	0.621**	0.946	0.841	1.529**
	(0.108)	(0.139)	(0.111)	(0.141)	(0.040)	(0.068)	(0.075)	(0.164)
Hispanic	0.679*	0.728	0.529*	0.900	0.766**	0.611**	0.560**	0.756
	(0.113)	(0.211)	(0.149)	(0.234)	(0.068)	(0.064)	(0.087)	(0.160)
Other, non-Hispanic	0.665*	0.889	0.870	0.806	0.799*	0.803*	0.691*	1.026
	(0.133)	(0.168)	(0.157)	(0.186)	(0.074)	(0.077)	(0.100)	(0.194)
High school graduate	0.918	0.903	0.945	0.947	1.173**	1.126*	1.173*	0.812*
	(0.085)	(0.094)	(0.105)	(0.091)	(0.048)	(0.061)	(0.075)	(0.076)
Some college or more	0.985	1.096	1.148	1.146	1.277**	1.242**	1.317**	0.825
	(0.085)	(0.123)	(0.117)	(0.113)	(0.052)	(0.062)	(0.077)	(0.083)
Family income (125-200%)	0.944	1.139	1.097	0.973	1.058	1.059	1.140*	1.064
	(0.075)	(0.105)	(0.100)	(0.085)	(0.040)	(0.051)	(0.070)	(0.067)
Family income (200-400%)	0.632**	0.700**	0.760**	0.592**	0.934	0.968	0.996	0.454**
	(0.057)	(0.077)	(0.075)	(0.056)	(0.045)	(0.043)	(0.065)	(0.046)
Family income (>400%)	0.392**	0.387**	0.543**	0.284**	0.816**	0.883*	0.811**	0.168**
	(0.046)	(0.049)	(0.070)	(0.038)	(0.048)	(0.047)	(0.063)	(0.040)
Number of chronic conditions, 3-4	1.696**	1.904**	1.922**	1.823**	1.383**	1.523**	1.365**	2.243**
	(0.115)	(0.162)	(0.160)	(0.167)	(0.052)	(0.059)	(0.065)	(0.228)
Number of chronic conditions, 5+	2.615**	2.845**	2.897**	3.077**	1.728**	2.250**	1.738**	4.104**
	(0.228)	(0.320)	(0.340)	(0.327)	(0.076)	(0.095)	(0.105)	(0.471)
Having MA-PDs	0.792**	0.868	0.874	0.857*	0.836**	0.767**	0.770**	0.922
	(0.047)	(0.070)	(0.062)	(0.055)	(0.024)	(0.025)	(0.040)	(0.054)
constant	0.078**	0.049**	0.054**	0.055**	0.664**	0.387**	0.115**	0.064**
	(0.010)	(0.006)	(0.008)	(0.008)	(0.050)	(0.028)	(0.011)	(0.009)
n	30889	30897	30900	30894	30775	30868	30886	30881

Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$

Sensitivity Analysis II

Appendix C-13. Unadjusted prevalence rates of cost-related nonadherence among non-LIS and LIS Part D beneficiaries, 2008-2015, using 5-point ordinal scale





Appendix C-14. Effect of the ACA's coverage gap reform on cost-related medication nonadherence and cost-saving behaviors for non-LIS beneficiaries, using 5-point ordinal scale

	Pre vs. Post [a]		Year-by-Year Changes [b]							
	Post-ACA		2011		2012		2013		2015	
	b / OR	SE	b / OR	SE	b / OR	SE	b / OR	SE	b / OR	SE
Cost-related nonadherence										
1) OLS										
DD estimate	0.05	0.03	0.00	0.04	0.05	0.04	0.04	0.03	0.09*	0.04
2) Ordinal logistic regression										
Non-LIS	1.36**	0.13	1.05	0.09	1.42**	0.09	1.12	0.08	1.28**	0.10
DD estimate	1.20	0.13	0.96	0.15	1.21	0.17	1.19	0.18	1.40	0.21
Cost-saving behaviors										
1) OLS										
DD estimate	0.05	0.04	-0.04	0.05	0.07	0.05	0.06	0.05	0.07	0.05
2) Ordinal logistic regression										
Non-LIS	0.43**	0.03	0.90	0.05	0.77**	0.03	0.62**	0.03	0.47**	0.03
DD estimate	1.16*	0.08	0.94	0.08	1.19	0.11	1.16	0.11	1.37**	0.16

NOTES ACA = Affordable Care Act; OR = odds ratio; SE = standard error. [a] Pooled estimate for the years 2011-2015 (post-ACA period), compared with the pooled estimates for the years 2008-2010 (pre-ACA). [b] Year-by-year changes estimate compared with the pooled estimates for the years 2008-2010 (pre-ACA period). In the ordinal logistic regression model, the Non-LIS OR reflects the simple adjusted odds of having cost-related nonadherence or cost-saving behaviors in the Post-ACA period or 2011, 2012, 2013, and 2015 for the non-LIS beneficiaries. The DD estimate from the ordinal logistic regression is the ratio of this OR to that for the LIS beneficiaries. Figures in this table are based on the results from Table #. $*p < .0.05$, $**p < 0.01$

Appendix C-15. Full regression results of pooled pre- and post-ACA difference-in-differences model, using 5-point ordinal scale

	Cost-Related Nonadherence		Cost-Saving Behaviors	
	OLS	**Ordinal logistic regression**	**OLS**	**Ordinal logistic regression**
Post	0.003	1.099	-0.478**	0.359**
	(0.025)	(0.120)	(0.038)	(0.028)
Treat	0.055*	1.313**	0.290**	1.732**
	(0.026)	(0.130)	(0.036)	(0.118)
Post × Treat	0.049	1.202	0.045	1.161*
	(0.026)	(0.131)	(0.036)	(0.083)
2009.year	0.028	1.054	-0.113**	0.801**
	(0.017)	(0.091)	(0.023)	(0.034)
2010.year	0.048*	1.146	-0.050*	0.906*
	(0.019)	(0.104)	(0.023)	(0.039)
2011.year	-0.016	0.898	0.344**	2.030**
	(0.020)	(0.077)	(0.030)	(0.122)
2012.year	0.028	1.144	0.238**	1.638**
	(0.020)	(0.088)	(0.027)	(0.089)
2013.year	-0.030	0.904	0.123**	1.332**
	(0.017)	(0.067)	(0.024)	(0.066)
Male	-0.044**	0.794**	0.022	1.060*
	(0.011)	(0.039)	(0.013)	(0.029)
Age 75-84	-0.153**	0.547**	-0.150**	0.781**
	(0.012)	(0.027)	(0.016)	(0.023)
Age 85+	-0.264**	0.265**	-0.346**	0.532**
	(0.013)	(0.019)	(0.019)	(0.019)
Black, non-Hispanic	0.043*	1.119	-0.110**	0.774**
	(0.021)	(0.091)	(0.034)	(0.055)
Hispanic	-0.069*	0.776	-0.214**	0.659**
	(0.030)	(0.128)	(0.038)	(0.057)
Other, non-Hispanic	-0.053	0.800	-0.131**	0.764**
	(0.027)	(0.115)	(0.043)	(0.065)
High school graduate	-0.013	0.934	0.065**	1.149**
	(0.018)	(0.071)	(0.023)	(0.051)
Some college or more	0.021	1.079	0.124**	1.287**
	(0.019)	(0.082)	(0.023)	(0.056)
Family income (125-200%)	0.009	0.958	0.045*	1.068
	(0.017)	(0.058)	(0.021)	(0.044)
Family income (200-400%)	-0.093**	0.650**	-0.060*	0.900*
	(0.018)	(0.045)	(0.025)	(0.042)
Family income (>400%)	-0.182**	0.416**	-0.159**	0.763**
	(0.017)	(0.035)	(0.030)	(0.044)
Number of chronic conditions, 3-4	0.108**	1.753**	0.232**	1.554**
	(0.011)	(0.099)	(0.016)	(0.048)
Number of chronic conditions, 5+	0.230**	2.651**	0.445**	2.293**
	(0.021)	(0.201)	(0.021)	(0.090)
Having MA-PDs	-0.035**	0.830**	-0.135**	0.766**
	(0.011)	(0.043)	(0.015)	(0.022)
constant	0.232**		0.929**	
	(0.022)		(0.036)	
n	30884	30884	30709	30709

Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$

Appendix C-16. Full regression results of year-by-year changes difference-in-differences model, using 5-point ordinal scale

	Cost-related nonadherence		Cost-saving behaviors	
	OLS	**Ordinal logistic regression**	**OLS**	**Ordinal logistic regression**
2011.year	-0.003	-0.018	1.089	0.955
	(0.034)	(0.038)	(0.144)	(0.068)
2012.year	0.006	-0.200**	1.172	0.644**
	(0.033)	(0.042)	(0.134)	(0.055)
2013.year	-0.050	-0.315**	0.936	0.533**
	(0.027)	(0.040)	(0.118)	(0.045)
2015.year	-0.053	-0.445**	0.911	0.349**
	(0.033)	(0.045)	(0.122)	(0.036)
Treat	0.056*	0.290**	1.317**	1.728**
	(0.025)	(0.036)	(0.130)	(0.117)
2011.year × Treat	0.002	-0.035	0.964	0.942
	(0.040)	(0.046)	(0.153)	(0.080)
2012.year × Treat	0.048	0.065	1.209	1.188
	(0.038)	(0.048)	(0.169)	(0.112)
2013.year × Treat	0.044	0.064	1.192	1.163
	(0.033)	(0.049)	(0.184)	(0.114)
2015.year × Treat	0.087*	0.073	1.399*	1.372**
	(0.036)	(0.053)	(0.211)	(0.159)
Male	-0.044**	0.023	0.794**	1.062*
	(0.011)	(0.013)	(0.040)	(0.029)
Age 75-84	-0.153**	-0.149**	0.547**	0.781**
	(0.012)	(0.016)	(0.027)	(0.023)
Age 85+	-0.264**	-0.346**	0.265**	0.532**
	(0.013)	(0.019)	(0.019)	(0.019)
Black, non-Hispanic	0.043*	-0.110**	1.119	0.773**
	(0.021)	(0.034)	(0.091)	(0.055)
Hispanic	-0.068*	-0.214**	0.777	0.657**
	(0.030)	(0.038)	(0.128)	(0.057)
Other, non-Hispanic	-0.053	-0.131**	0.799	0.762**
	(0.028)	(0.043)	(0.115)	(0.065)
High school graduate	-0.013	0.065**	0.936	1.150**
	(0.018)	(0.023)	(0.071)	(0.051)
Some college or more	0.021	0.124**	1.078	1.284**
	(0.019)	(0.022)	(0.082)	(0.055)
Family income (125-200%)	0.008	0.045*	0.955	1.070
	(0.017)	(0.021)	(0.058)	(0.044)
Family income (200-400%)	-0.094**	-0.059*	0.648**	0.901*
	(0.018)	(0.025)	(0.044)	(0.042)
Family income (>400%)	-0.184**	-0.159**	0.414**	0.762**
	(0.017)	(0.030)	(0.035)	(0.043)
Number of chronic conditions, 3-4	0.108**	0.231**	1.752**	1.551**
	(0.011)	(0.016)	(0.098)	(0.047)
Number of chronic conditions, 5+	0.230**	0.445**	2.650**	2.293**
	(0.021)	(0.021)	(0.201)	(0.090)
Having MA-PDs	-0.035**	-0.135**	0.833**	0.767**
	(0.011)	(0.015)	(0.044)	(0.022)
constant	0.258**	0.874**		
	(0.021)	(0.037)		
n	30884	30700	30884	30700

Standard errors are in the parenthesis. * $p < 0.05$, ** $p < 0.01$