

# The Effect of Public Insurance Design on Pharmaceutical Prices: Evidence from Medicare Part D\*

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## Abstract

Public programs that provide benefits through private markets contend with strategic firm behavior. We study this dynamic in Medicare Part D. The Affordable Care Act closed a coverage gap, which required beneficiaries to pay 100% of drug spending on the margin. The closure was partially funded by mandating drug manufacturers cover 50% of branded drug costs in the gap. Beneficiaries became 45% less likely to forgo prescriptions upon reaching the gap. However, manufacturers' response led to 21% higher drug prices, partially offsetting the insurance expansion. While the average beneficiary received a \$55 transfer, the median beneficiary incurred a \$7 cost.

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# 1 Introduction

Public programs often use private markets to provide in-kind benefits. Such markets are typically actively regulated, but prices are determined by private, profit-maximizing firms without direct involvement from the government.<sup>1</sup> Therefore, program design must contend with strategic firm behavior. In particular, policies may have unintended consequences due to equilibrium impacts on the prices of private goods. We study the interaction between public program design and private market outcomes, in particular pharmaceutical prices, in the setting of Medicare Part D.

Since its inception in 2006, Medicare Part D—the federal prescription drug insurance for the elderly and disabled—has become a major payer of drug spending, covering one in every three dollars spent on prescription drugs in the U.S. in 2018 (CMS 2023). In this program, prices of prescription drugs are set by negotiations between private firms without direct involvement from the government.<sup>2</sup> These prices directly impact beneficiaries due to cost-sharing, with beneficiaries frequently reporting struggling to afford their medication (KFF 2019). As the government seeks to ensure prescription drug access through Part D, a first-order question is how its design impacts firm behavior and market outcomes.

We study firms' strategic response to regulation in the context of a major redesign of Medicare Part D: the closing of the coverage gap. The initial design contained an intentional gap in insurance benefits for beneficiaries with high drug spending, also referred to as the “donut hole.” To finance its closure, manufacturers of brand-name drugs were required to highly subsidize drug spending in the gap.<sup>3</sup> We study how beneficiaries responded to the insurance expansion, how manufacturers' response affected the prices of branded drugs, and how this endogenous effect on prices undermined the distributional goal of the policy.

Unlike traditional Medicare, Part D employs a market-based mechanism where private insurers contract with the government to deliver the insurance benefits. The government establishes a standard plan design, which acts as a lower bound on privately provided benefits. Before 2011, the standard design contained a coverage gap. Past the deductible, a

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<sup>1</sup>In the U.S., examples for health care include the Affordable Care Act Health Insurance Marketplace and Medicare Part D. Examples for education include the G.I. Bill and Pell Grants. Examples for food include the Supplemental Nutrition Assistance Program and the Women, Infants, and Children Program. Examples for housing include the Housing Choice Voucher Program and the Low Income Housing Tax Credit.

<sup>2</sup>The Inflation Reduction Act of 2022 amended this non-interference clause. Starting 2026, the government is required to negotiate prices for a small number of single-source brand-name drugs (KFF 2023).

<sup>3</sup>Despite accounting for a declining share of prescriptions, brand-name drugs have faced repeated scrutiny for their soaring prices, increasing the fiscal burden on the government. The CBO estimates that the average price of brand-name prescription drugs, accounting for manufacturer discounts, increased between 2009-2018 from \$149 to \$353 in Medicare Part D. The key drivers were higher launch prices of new drugs and rising prices of drugs already on the market (CBO 2022).

beneficiary paid 25 cents per dollar of drug spending until their annual spending reached the initial coverage limit (\$2,830 in 2010). After that, they entered the coverage gap and paid the full cost of each additional prescription out-of-pocket. Only until their annual out-of-pocket spending reached the out-of-pocket threshold (\$4,550 in 2010) would they qualify for catastrophic coverage and the government would begin to pay for the majority of drug spending. Notably, not all beneficiaries are exposed to these coverage phases: about 1/3 of beneficiaries receive the federal low-income subsidy (LIS), which covers the bulk of out-of-pocket costs.

The coverage gap was a highly controversial design feature. While it was implemented as a political compromise to keep drug expenditure under control, critics argued that it created a financial burden on the elderly with negative ramifications on prescription adherence and health (Oliver et al. 2004).<sup>4</sup> Research indicates that the sudden increase in cost-sharing upon entering the gap caused a pronounced drop in drug consumption and an increase in mortality (Einav et al. 2015; Chandra et al. 2021). After contentious debate, the Affordable Care Act (ACA) stipulated the closure of the gap. For beneficiaries ineligible for the low-income subsidy, cost-sharing during the gap shrank from 100% in 2010 to 25% in 2020. To finance this expansion, manufacturers became responsible for providing a 50% discount on prescription claims for brand-name drugs filled by non-LIS beneficiaries in the coverage gap.<sup>5</sup>

Several institutional features warrant the need to study the effect of the insurance expansion on pharmaceutical prices. First, manufacturers have substantial pricing power. While the federal government is a major payer of drug spending, the Centers for Medicare & Medicaid Services (CMS) are legally limited in their ability to negotiate and act as a price-taker. Second, manufacturers face consumers who become less price-sensitive as the gap closure reduced beneficiaries' exposure to drug prices. Finally, the discount requirement operates as an implicit tax, and manufacturers may attempt to pass through the tax to insurers and beneficiaries.

To study the closing of the coverage gap, we leverage detailed micro-level data on prescription drug purchases from a 20% random sample of Medicare beneficiaries from 2006 to

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<sup>4</sup>The design of Part D is often cited as a driving force behind the increase in prescription drug prices (U.S. Senate Committee on Finance 2018). Insurance plans bear little liability for spending past the initial coverage limit (i.e., spending in the coverage gap or the catastrophic phase). Therefore, for expensive drugs that induce spending past plan liability, insurers have limited incentive to negotiate prices with drug manufacturers. The Inflation Reduction Act of 2022 increased plan liability for spending in the catastrophic coverage phase in 2025.

<sup>5</sup>Insurers were required to finance 75% of spending on generic drugs and 5% of spending on brand-name drugs in the gap. The pharmaceutical industry accepted the discount requirement in return for the broader provisions of the ACA (Conti et al. 2020). However, when the Bipartisan Budget Act of 2018 accelerated the closing of the gap for brand-name drugs by increasing the manufacturer discount to 70%, the pharmaceutical industry launched one of its biggest, yet unsuccessful, lobbying campaigns to overturn the change (Florko 2019).

2018 ([PHS 2023](#)). For each purchase, we observe the retail price of the drug, as well as how the cost is split between payers, depending on the coverage phase. We supplement these data with information on drug characteristics from the Merative™ MarketScan® Redbook ([PHS 2024](#)) and publicly available resources from the Food and Drug Administration (FDA).<sup>6</sup>

We begin by analyzing how beneficiaries responded to the gap closure. In particular, we extend the descriptive analysis by Einav et al. ([2015](#)), who leverage the pre-ACA benefit design to study beneficiary behavior around the coverage gap threshold. Standard economic theory predicts that beneficiaries should bunch at the threshold as the marginal cost of filling a prescription jumps from 25 cents to 100 cents per dollar of spending. Replicating their results, we find substantial excess mass, or “bunching,” in the distribution of annual spending of non-LIS beneficiaries in years before the policy change. In line with the kink in cost-sharing flattening in the first year of the policy change, we find that bunching around the gap threshold decreased by 40% in 2011. In addition, beneficiaries were 45% less likely to forgo prescriptions as they approached the gap. We take this as direct evidence that the coverage gap previously constrained drug consumption and that its closure led to an increase in demand.

In our main analysis, we study the pricing response of manufacturers—in particular, the effect of the gap closure on retail prices of brand-name drugs. We exploit variation in the exposure to the policy change based on the insight that both the demand increase and the discount requirement pushed manufacturers to raise prices more for drugs with a larger share of revenue from non-LIS spending in the gap. Thus, for each drug sold in a Part D market in 2010, we measure exposure by the share of revenue from claims made by non-LIS beneficiaries in the gap relative to the market-wide Part D revenue, excluding spending financed by government subsidies. Variation in exposure arises primarily from cross-drug differences, with high-exposure drugs more likely to treat chronic conditions. Leveraging an event study framework, we find a statistically significant effect in post-closure years: by 2018, retail prices of high-exposure drugs were 21% higher, on average, compared to prices of low-exposure drugs. Because retail prices are negotiated by private firms rather than set by manufacturers, the exposure effect builds gradually over time, with a monotonic increase that suggests sustained upward pricing pressure following the gap closure. Notably, the effect is driven by drugs that face no generic competition or remain patent-protected beyond our sample period.

As beneficiaries are exposed to retail prices via cost-sharing, the strategic firm response

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<sup>6</sup>Certain data were supplied by Merative as part of one or more Merative MarketScan® Research Databases. Any analysis, interpretation, or conclusion based on these data is solely that of the authors and not Merative.

dilutes the intended, distributional goal of the insurance expansion. To provide context for the magnitude of the exposure effect, we analyze the distributional implications of the gap closure and single out the role of the endogenous price response. We provide model-free evidence in the style of a Laspeyres or Paasche price index: holding prescription drug consumption fixed, we let beneficiaries progress through the standard plan design before and after the gap closure, as well as with and without endogenously adjusted prices. With fixed drug prices, the gap closure delivers an average transfer of \$100 across beneficiaries, primarily financed by drug manufacturers. However, accounting for the effect on retail prices, the average transfer falls to \$55, and the median beneficiary incurs a \$7 cost. Thus, by raising out-of-pocket costs, the endogenous price response limited the value of the insurance expansion, with a net negative effect for non-LIS beneficiaries who do not enter the gap.

The main caveat of our analysis is that our results are limited to retail prices, or “list prices,” of brand-name drugs, and cannot speak to the effect of the gap closure on net-of-rebate prices. A widely recognized feature of the pharmaceutical market is that manufacturers provide post-sale rebates to insurers in exchange for preferential coverage. While the government accounts for these price concessions when reimbursing insurers, detailed information on rebates is proprietary and not available for research purposes. As a result, comprehensively analyzing the fiscal incidence of the gap closure for insurers and the government is complicated by increases in retail prices potentially being offset by changes in rebate rates.<sup>7</sup> However, retail prices remain relevant for policy, as they determine beneficiaries’ out-of-pocket costs. While we do not observe post-sale rebates, we can still quantify the effects of the gap closure on costs incurred by beneficiaries.

Our paper contributes to a large literature on Medicare Part D and the coverage gap. Numerous papers have leveraged the pre-ACA variation in cost-sharing to study the demand response to the nonlinear price schedule (Einav et al. 2015; Kaplan and Zhang 2014; Kaplan and Zhang 2017; Abaluck et al. 2018; Dalton et al. 2020), its effect on insurance design (Einav et al. 2018), and the impact of cost-sharing on health outcomes (Li et al. 2012; Zhang et al. 2013; Chandra et al. 2021). These studies are the foundation of our analysis of the beneficiary response, which we extend to years after the gap closure. While some of the papers have simulated the hypothetical effects of closing the coverage gap, we empirically verify the effects of the policy change on beneficiary behavior.

Several papers in the medical literature have directly examined the closing of the coverage gap, in particular the effect on prices and consumption of distinct, high-cost drugs (Dusetzina and Keating 2016; Olszewski et al. 2017; Erath and Dusetzina 2020; Gokhale et al. 2020).

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<sup>7</sup>We present a detailed discussion of post-sale rebates in Medicare Part D and their implications for our results in Online Appendix B.

In line with our results, these papers conclude that affordability remains a concern due to rising retail prices. Complementary to our paper, Park and Look (2022) find that, based on survey data, annual out-of-pocket spending significantly decreased for non-LIS beneficiaries relative to LIS recipients following the gap closure. We present a comprehensive analysis of gap closure and study manufacturers' pricing response explicitly using a novel quasi-experimental design.

Beyond the coverage gap, our paper relates to a small literature that studies market distortions arising from the LIS subsidy (Decarolis 2015; Starc and Swanson 2021) and its optimal design to mitigate those (Decarolis et al. 2020). In our setting, the existence of LIS beneficiaries is central to the dramatic shift of the spending incidence from manufacturers to the government. Lastly, our paper also relates to the literature on the equilibrium effects of insurance design (Morton 1997; Duggan and Scott Morton 2006; McWilliams et al. 2011; Blume-Kohout and Sood 2013; Yurukoglu et al. 2017). Duggan and Scott Morton (2010, 2011) document that the introduction of Medicare Part D and the use of drug formularies increased competition and reduced prices of brand-name drugs. Lakdawalla et al. (2013) and Alpert et al. (2023) find that the introduction of Medicare Part D led to increased advertising of brand-name drugs. Studying a major redesign of the Part D benefit, our key insight is that the insurance expansion ultimately increased pharmaceutical prices by reducing the demand elasticity of the covered population and by making manufacturers directly responsible for financing a substantial share of drug spending.

The rest of the paper proceeds as follows. Section 2 details the design of Medicare Part D. Section 3 presents the data and Section 4 discusses the gap closure and its implementation. Section 5 studies the beneficiary response to the policy change. Section 6 presents the manufacturer response. Section 7 concludes.

## 2 Setting

### 2.1 Medicare Part D

Medicare Part D, the voluntary federal prescription drug insurance available to Medicare beneficiaries, was established under the Medicare Modernization Act of 2003. Since its inception in 2006, Part D has grown in popularity, and in 2018, the last year of our sample, 72% of Medicare beneficiaries were enrolled nationwide.

Part D benefits are typically provided by private insurance sponsors, either as stand-alone prescription drug plans (PDPs) to supplement traditional Medicare or as Medicare Advantage prescription drug plans (MA-PDs) which include drug coverage and other Medicare-

covered benefits. While MA-PD enrollment has dominated in recent years, 58% of Part D beneficiaries enrolled in a stand-alone plan in 2018. Importantly, PDPs and the prescription drug component of MA-PDs are subject to the same regulatory framework upheld by the Centers for Medicare and Medicaid Services (CMS).

In our analysis, we abstract away from the added complexity of providing both medical and prescription drug coverage and focus on beneficiaries enrolled in PDPs.<sup>8</sup> The average beneficiary in 2018 could choose from 23 PDPs offered in their geographic market, and enroll at an average monthly premium of \$43. Across the 34 PDP markets, plan sponsors offered a total of 782 stand-alone plans.<sup>9</sup> However, enrollment is highly concentrated, with three private insurers covering 67% of all PDP enrollees in 2018 (KFF 2017, 2018).<sup>10</sup>

A salient feature of the Part D market is that one in three enrollees qualify for the low-income subsidy (LIS) and receive premium and cost-sharing assistance from the federal government. LIS beneficiaries include recipients of Supplemental Security Income and individuals dually eligible for Medicare and Medicaid, who qualify automatically and receive the full subsidy level. LIS recipients can select any plan offered in their area but may be required to pay a portion of their plan's premium if benefits exceed the standard benefit design.

Medicare Part D is financed by general revenues (71% in 2018), beneficiary premiums (17%), and state contributions (12%) (Board of Trustees 2019). Premiums are determined by a competitive bidding process, where plan sponsors submit a standardized bid that reflects total plan costs and all direct and indirect remuneration, such as manufacturer rebates.<sup>11</sup> The government finances 74.5% of the national average bid, whereas the remainder is paid for by the beneficiary. Thus, each plan receives monthly risk-adjusted direct subsidies from the government, prospective payments for catastrophic drug spending, as well as premium payments from beneficiaries and premium subsidies on behalf of low-income beneficiaries.<sup>12</sup>

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<sup>8</sup>Starc and Town (2020) find that drug-specific retail prices do not differ systematically between PDP and MA-PD plans.

<sup>9</sup>A PDP typically operates in one of 34 service areas and is open for enrollment to all Medicare-eligible beneficiaries who reside in that market. A plan service area spans a single state or a group of small adjacent states.

<sup>10</sup>Chatterji et al. (2024) study consolidation of stand-alone plans and document that increased concentration led to higher out-of-pocket expenditures.

<sup>11</sup>Manufacturer discounts received as part of the *Coverage Gap Discount Program* are not considered direct or indirect remuneration because they do not decrease drug costs incurred by the sponsor. Therefore, they do not enter the bid calculation (CMS 2017).

<sup>12</sup>In 2018, Part D plans received \$301 in direct subsidies and \$923 in reinsurance payments per beneficiary, as well as an additional \$2,219 in subsidies per LIS beneficiary.

## 2.2 Standard benefit design

With the introduction of Part D, CMS established a standard benefit design that serves as a minimum requirement for the coverage provided by private plans. The standard design has four coverage phases: (i) deductible, (ii) initial coverage, (iii) coverage gap, and (iv) catastrophic coverage. Beneficiaries progress through these phases as they accumulate drug spending over the course of a year. Figure 1, Panel (A) illustrates the standard design in 2010 as a function of annual drug spending and annual out-of-pocket spending. After paying the deductible amount, beneficiaries enter initial coverage and pay 25% of each dollar spent, with the remainder covered by the insurance plan. As annual spending crosses the initial coverage limit, beneficiaries enter the coverage gap and become responsible (again) for 100% of drug costs. This insurance gap lasts until beneficiaries reach an out-of-pocket threshold, after which they enter catastrophic coverage. In this last phase, 80% of spending is covered by the federal government and around 15% is paid by the plan.<sup>13</sup> private plans must provide benefits that are either actuarially equivalent to the standard design or more generous, featuring a lower deductible or lower cost-sharing in the initial coverage or gap phase.

Notably, LIS recipients are not exposed to the different coverage phases. Instead, they pay little to no cost-sharing across the entire benefit schedule as out-of-pocket costs are covered by the federal government.<sup>14</sup> Thus, the low-income subsidy creates two consumer segments in the Part D market: non-LIS beneficiaries, who experience a sharp increase in cost-sharing as they enter the coverage gap, and LIS beneficiaries, whose spending in the gap is almost entirely covered by the government.

## 2.3 Pharmaceutical pricing in Part D

Pharmaceutical prices in Part D are determined by private firms, despite the government financing the majority of drug spending. By statute, the government does not interfere with price setting and acts as a price-taker.<sup>15</sup> Thus, at the core of pharmaceutical pricing is the vertical relationship between drug manufacturers, retail pharmacies, insurers, and beneficiaries. Next to direct exposure to the gap closure, we expect a manufacturer's pricing response to depend on factors that impact market power, in particular, whether their brand-

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<sup>13</sup>Key benefit parameters, including the deductible amount, initial coverage limit, and out-of-pocket threshold, are updated annually based on the percentage increase in average spending for Part D drugs.

<sup>14</sup>In 2010, beneficiaries receiving the full LIS subsidy paid no deductible, at most \$2.50 for generic drugs and \$6.30 for brand-name drugs. Partial subsidy recipients had a \$63 deductible and a 15% coinsurance rate up to the out-of-pocket threshold.

<sup>15</sup>Following the passage of the Inflation Reduction Act in 2022, the federal government selected the first ten drugs covered under Part D for price negotiations, which will be effective 2026.

name drug faces generic competition.

**Drug supply chain.** Figure A1 shows a simplified version of the drug supply chain. At the top, manufacturers set a list price for each drug. Wholesalers, which are price-takers in the branded-drug market, purchase drugs at list price minus a negotiated discount and pass on a similar price to pharmacies downstream. Therefore, manufacturers have great influence over acquisition costs for pharmacies (Sood et al. 2017; Seeley 2022). Final retail prices are negotiated by pharmacies and insurers.

**Patent protection and generic competition.** The extent to which a manufacturer enjoys market power depends on the stage of the drug life cycle. During the period of patent protection or marketing exclusivity, the manufacturer enjoys monopoly power and only faces competition from other drugs in the same therapeutic class (Perloff et al. 2006). As these terms expire, generic alternatives enter the market, leading to significant price drops at the molecule level. However, empirical evidence suggests that the price of the brand-name version changes little, and may even rise if price-sensitive consumers switch to the generic alternative (Caves et al. 1991; Grabowski and Vernon 1992; Frank and Salkever 1992, 1997; Frank et al. 2021). Generic competition is an important feature in our setting as a series of top-selling drugs, such as the cholesterol-lowering Lipitor, went off-patent starting in 2011 (DeRuiter and Holston 2012).

**Insurers, drug formularies, and rebates.** As permitted by statute, most private plans deviate from the government-defined standard plan design. While the standard design uses a uniform coinsurance rate in each coverage phase, private plans employ drug formularies that restrict coverage to a select list of drugs and place them on different cost-sharing tiers.<sup>16</sup> Coverage and tier placement of a drug depend on the negotiated retail price and post-sale rebate that the manufacturer directly pays the insurer (or the third-party administrator acting on behalf of the insurer, so-called pharmacy benefit managers).<sup>17</sup> While this feature can exert price pressure by steering consumers to lower-cost drugs,<sup>18</sup> the rebate system has

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<sup>16</sup>In 2014, the majority of Part D plans used a five-tier formulary (KFF 2013). Plans must cover at least two chemically distinct drugs from each of about 150 drug classes, in addition to all drugs in six protected classes. Tier-specific cost-sharing is capped and may not exceed an average of 25% across tiers in the initial coverage phase. See the Code of Federal Regulations, 42 CFR Part 423.

<sup>17</sup>The Anti-Kickback Statute prohibits the use of manufacturer price concessions directly advertised to beneficiaries, such as copay coupons, in government health insurance programs.

<sup>18</sup>Duggan and Scott Morton (2010, 2011) show that the inception of Part D significantly slowed down the growth in prescription drug spending, mainly due to the price pressure created by formulary competition and tiered cost-sharing. Hwang et al. (2019) show that drugs in protected classes that face no formulary competition saw substantial price growth over the past decade. Olszen and Demirer (n.d.) estimate post-sale rebates for two branded statins, Lipitor and Crestor, in Part D in 2010 and illustrate their effect on tier

been criticized for undermining insurers' incentives to constrain retail prices and pre-rebate spending on brand-name drugs. Post-sale rebates are rarely passed on to consumers of high-rebate drugs and, instead, are re-channeled to reduce plan premiums and increase profits ([CMS 2017b](#)).

Granular data on post-sale rebates are highly confidential and unavailable to researchers, a well-recognized limitation in the literature ([Kakani et al. 2020](#)). As data on post-sale rebates are confidential, we cannot empirically assess how the gap closure affected net-of-rebate prices. Theoretically, the effect on post-sale rebates is ambiguous: On the one hand, manufacturers have to provide an additional discount in the coverage gap and may prefer to reduce other price concessions. On the other hand, insurers may demand higher rebates as they have to cover at least a small portion of gap spending. Despite this limitation, retail prices are still important in our setting as Part D beneficiaries, in particular those not eligible for LIS, face the retail price, or percentage thereof, as they progress through the different coverage phases. Therefore, retail prices are enough to quantify the effects of the gap closure on out-of-pocket costs for beneficiaries. Higher retail prices also progress beneficiaries more quickly to the catastrophic coverage phase, where the federal government pays for the majority of drug spending at retail price. Online Appendix B summarizes the existing empirical evidence on manufacturer rebates and discusses the implications of rebates in our setting.

### 3 Data

Our primary data source is a 20 percent random sample of the population enrolled in Medicare from 2006 through 2018. For each beneficiary with Part D insurance, we observe basic demographic information, as well as detailed, claim-level data on prescription drugs purchases.

Our sample comprises all beneficiaries enrolled in a Part D standalone prescription drug plan (PDP). We measure a beneficiary's plan enrollment and LIS status in December of a given year and make no restrictions based on age or basis of eligibility.<sup>19</sup> For each beneficiary, we observe all prescription drug purchases covered by the insurance plan. For each claim, we observe the 11-digit National Drug Code (NDC), the retail price of the drug, as well as the amount paid out-of-pocket, the amount covered by the plan, and the amount reimbursed through LIS. Starting in 2012, we also observe the amount of the manufacturer discount

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placement and consumer spending.

<sup>19</sup>We exclude beneficiaries enrolled in Medicare Advantage prescription drug plans. In addition, we drop small geographic markets of the U.S. territories due to small sample size.

for claims filled by non-LIS beneficiaries in the coverage gap. We combine these claims data with NDC-level information from the Merative MarketScan® Redbook about brand status, generic competition, and therapeutic group.<sup>20</sup> We further augment these data with information from the FDA Orange Book about drug approval and patent expiration.

The final sample comprises about 8.2 million beneficiaries and 48 million beneficiary-years, with close to 1.9 billion prescription drug claims for more than 74k unique NDCs. Our analysis of the beneficiary response in Section 5 directly draws on this sample. For the analysis of the manufacturer response, we further construct a derivative sample of brand-name prescription drugs as described in Section 6.

Table 2 presents basic demographics for our sample. In 2010, beneficiaries were 69 years old on average, 61% were female, and 73% were Medicare-eligible based on the old-age threshold of 65. Half of beneficiaries received cost-sharing assistance through LIS and 41% were dual-eligible for Medicare and Medicaid. Among non-LIS, 23% of beneficiaries entered the coverage gap at some point in 2010. Between 2006-2018, the total number of beneficiaries in our sample increases by almost 30%, while the share receiving LIS decreases from 50 to 36%. In line with the patent cliff in 2011 and 2012, the share of non-LIS beneficiaries entering the coverage gap decreases slightly over time. However, in 2018, still 16% of non-LIS beneficiaries entered the coverage gap at some point in the year.

Table 3 shows trends in average plan enrollment, separately for three beneficiary groups: (a) non-LIS who consume before the coverage gap, (b) non-LIS who enter the gap at some point in the year, and (c) LIS who are not exposed to the different coverage phases. We report the average monthly premium paid by beneficiaries, the average deductible and initial coverage amounts, and the percentage of beneficiaries with additional gap coverage for brand-name or generic drugs.<sup>21</sup> Overall, non-LIS beneficiaries who enter the gap tend to enroll in plans with more generous cost-sharing compared to the other beneficiary groups. They pay a higher monthly premium, face a lower deductible, and are more likely to receive additional gap coverage. Consistently across groups, average premium payments remained constant over time, while deductible amounts increase. This trend could reflect a change in plan characteristics, beneficiary preferences, or a compositional change in the beneficiary population. Notably, there is essentially no variation in the initial coverage limit that beneficiaries face, indicating that private plans largely follow the standard benefit plan in setting the spending limit that marks the start of the coverage gap.

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<sup>20</sup>Merative MarketScan® is a health analytics company that provides life science research databases. Online Appendix A provides additional information on data sources and sample construction.

<sup>21</sup>All dollar amounts are inflation-adjusted using the September Consumer Price Index for All Urban Consumers (CPI-U; for all items; not seasonally adjusted), in line with the approach used by CMS to update the threshold amounts of the standard benefit plan. We use September 2010 as reference period.

## 4 Policy change

### 4.1 Gap closing and manufacturer discount program

Signed into law in March 2010, the Affordable Care Act (ACA) stipulated the gradual closing of the coverage gap in the standard benefit design.<sup>22</sup> Figure 1, Panel (B) illustrates the standard design for 2011. Within one year, the effective coinsurance rate for non-LIS beneficiaries in the gap dropped from 100% to almost 50%. To finance this expansion, manufacturers of brand-name drugs became responsible for covering 50% of branded drug spending in the gap. In contrast, the ACA retained the original benefit design for LIS recipients, with no liability for plans or manufacturers in the coverage gap. Thus, costs arising in the gap from LIS beneficiaries remained to be borne almost entirely by the federal government.

Table 1 details how cost-sharing in the gap evolved for non-LIS beneficiaries from 2010 to 2020. For generic drugs, the coinsurance rate decreased by 7 percentage points each year. This decline was offset by a one-to-one increase in the share paid by insurance plans.<sup>23</sup> For brand-name drugs, the reform demanded an immediate drop in patient cost-sharing from 100% to 50% in 2011 and an additional, slower decline in subsequent years.<sup>24</sup> The remaining share was primarily levied on drug manufacturers: starting 2011, manufacturers had to cover 50% of branded drug spending by non-LIS beneficiaries in the coverage gap. Following the Bipartisan Budget Act of 2018, this share further increased to 70% in 2019, reducing plans' liability to 5%. To facilitate beneficiary progression from the coverage gap to the catastrophic phase, manufacturer discounts are treated as though they were out-of-pocket spending.

As part of the reform, CMS created the *Coverage Gap Discount Program*, which commits manufacturers to providing the price discount in the coverage gap. The discount requirement applies to all drugs approved under a New Drug Application (NDA) or a Biologics License Application (BLA)—broadly, all drugs with (former) patent protection or marketing exclusivity that are sold under a proprietary trademark-protected name.

To enforce participation, a manufacturer's drugs may only be covered by Part D if they sign the agreement annually. By participating, manufacturers agree to pay 50% of the retail price of claims filled by non-LIS beneficiaries in the gap.<sup>25</sup> In practice, insurance plans pay

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<sup>22</sup>Online Appendix C summarizes further provisions of the ACA related to the pharmaceutical market.

<sup>23</sup>The category of generic drugs includes authorized generic drugs, biosimilars, and compounded drugs.

<sup>24</sup>Already in 2010, non-LIS beneficiaries received \$200 discount when reaching the coverage gap.

<sup>25</sup>The retail price is negotiated by the pharmacy and insurer, and comprises the ingredient cost and dispensing fee. Only the ingredient cost is subject to the manufacturer discount requirement. For claims that "straddle" the coverage gap, the discount applies to the portion of the price that falls above the initial coverage limit and below the out-of-pocket threshold. If a plan offers coverage in the gap, the discount applies to the remaining cost after supplemental coverage has been applied. If the coverage eliminates the

the manufacturer discount upfront at the point of sale and report these payments to CMS together with their claims records. CMS coordinates the collection of discount payments and sends out invoices to manufacturers which directly reimburse the plans. Importantly, the discount program runs in parallel to other agreements between insurers and manufacturers, such as price concessions via post-sale rebates (CMS 2010).

The total amount of gap discounts has steadily grown over time, from \$2.3 billion in 2011 to \$5.8 billion in 2015. Consistently, blood sugar-lowering drugs, cholesterol-lowering drugs, asthma-related drugs, and drugs used to prevent blood clots have generated the highest manufacturer discount payments (CMS, n.d.).

## 4.2 Implementation of gap closure

As most Part D plans deviate from the standard benefit design along some dimension, we assess empirically the extent to which PDPs followed the policy change and how cost-sharing for non-LIS beneficiaries in the gap evolved.

Separately for brand-name and generic drugs, Figure 2 illustrates how spending in the coverage gap is divided up between beneficiaries, plans, and manufacturers, and how these shares evolve. We construct these empirical cost-sharing rates for each non-LIS beneficiary who entered the gap in a given year and plot the average across beneficiaries.<sup>26</sup> Overall, PDPs closely tracked the policy proposal and generated cost-sharing rates similar to the standard plan, especially for brand-name drugs: In 2010, the average non-LIS beneficiary paid 92% of brand-name spending out-of-pocket. This percentage dropped to 48% in 2011. In subsequent years, any additional gap cost-sharing that PDPs may provide seems ineffective.<sup>27</sup> Overall, plans tend to provide more generous coverage for generic drugs—beneficiaries paid 84% out of pocket in 2010—but the additional coverage fades out and converges to the standard design.

This exercise provides an intuitive summary of the implementation of the policy change but abstracts away from other plan features that may have changed following the closing of the coverage gap. For example, we do not account for potential changes in the design of

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gap, no discount needs to be made.

<sup>26</sup>For this exercise, we restrict our sample to non-LIS beneficiaries who remain in the same plan and hold the same LIS status throughout the year. We exclusively use claims that start and end in the coverage phase (i.e., we drop “straddle” claims) and exclude beneficiaries with spending in the bottom and top percentile of the gap spending distribution of a given year.

<sup>27</sup>For example, in 2015, more than 18% of non-LIS beneficiaries who entered the gap were enrolled in a PDP with some additional gap coverage for brand-name drugs (see Table 3). However, we find that these beneficiaries paid 43% of drug spending out-of-pocket, on average, which is close to the 45% cost-sharing rate in the standard plan design.

drug formularies or changes in the types of drugs consumed by beneficiaries in the gap.<sup>28</sup> We leave the analysis of an insurer response to future work.

## 5 Beneficiary response

We now examine how the closure of the coverage gap affected beneficiaries' spending behavior. This analysis extends the descriptive evidence in Einav et al. (2015), who document that the discontinuous increase in cost-sharing causes consumers to bunch at the start of the coverage gap, indicating postponed or forgone drug consumption. We investigate whether the policy change was successful in mitigating this problem.

### 5.1 Trends in average drug spending

We begin by summarizing average trends in drug spending. As before, we distinguish between (a) non-LIS who consume before the coverage gap, (b) non-LIS who enter the gap at some point in a given year, and (c) LIS who are not exposed to the different coverage phases. For each group, Table 4 reports the average annual drug spending, out-of-pocket spending, and total days' supply, as well as the average percent that is accounted for by brand-name drugs.<sup>29</sup>

Consistently across groups, beneficiaries' consumption of prescription drugs increases over time, while a decreasing share stems from brand-name drugs. However, we find diverging trends in annual drug spending across groups: While annual spending significantly decreased for non-LIS who consume before the gap, it increased by more than 200%, from \$4,233 in 2006 to \$10,288 in 2018, for non-LIS who enter the gap. Over the years, brand-name drugs consistently account for about 80% of drug spending in this beneficiary group, implying that the increase in spending is driven by rising prices. Notably, beneficiaries' out-of-pocket spending remained fairly stable over time: The average non-LIS who enters the gap paid \$2,177 on prescription drugs in 2010, \$1,661 in 2011, and \$1,800 in 2018.

In line with the dramatic rise in annual spending, non-LIS beneficiaries who enter the gap do so earlier in a given year and are more likely to move on to the catastrophic phase. In 2006, 11% of non-LIS beneficiaries in the gap eventually entered the catastrophic phase; this share increased to 25% in 2018.

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<sup>28</sup>For instance, Bignon et al. (2023) show that the number of cost-sharing tiers for generic drugs in Part D plans substantially increased between 2013-2017. However, the authors do not link this phenomenon to the closing of the coverage gap.

<sup>29</sup>As before, dollar amounts are inflation-adjusted to September 2010 dollars.

## 5.2 Bunching at the kink

Next, we zoom in on beneficiaries' consumption behavior around the start of the coverage gap. To build intuition for this exercise, we return to the standard benefit design. Before the ACA, when beneficiaries entered the gap, they became responsible for 100% of drug spending on the margin. As illustrated in Figure 1, the ACA gradually removed the wedge in the marginal cost of filling a prescription between the initial coverage phase and the gap. Moving into the gap, the out-of-pocket price increased, on average, by 75 cents for every \$1 spent before the ACA, by 29 cents in 2011, and by 11 cents in 2018.

Standard economic theory suggests that, as long as preferences for prescription drugs are well-behaved and smoothly distributed in the population, we should observe beneficiaries bunching at this convex kink point of their budget set.<sup>30</sup> Beneficiaries consume until the marginal cost of filling a prescription equals the marginal benefit of filling a prescription. The jump in the marginal cost then induces bunching of beneficiaries whose marginal benefit of filling a prescription lies in between the old and new marginal cost. Beneficiaries whose marginal benefit no longer exceeds the marginal cost in the gap will stop or slow down consumption, leading to bunching at the start of the gap. The magnitude of the bunching should reduce with the policy change as the kink in cost-sharing becomes less drastic.

For beneficiaries in our sample, Figure 3 presents histograms of total annual prescription drug spending between 2010-2018. The response to the pre-ACA cost-sharing kink is apparent: There is a noticeable spike in the distribution of annual spending of non-LIS beneficiaries around the coverage gap threshold. As a placebo test, we confirm that we do not see a similar response to the kink for LIS recipients, who do not experience the coverage gap and, therefore, should not bunch around the threshold. Over time, the response to the kink diminishes and is greatly moderated by 2018.

To quantify the amount of excess mass around the coverage gap threshold, we follow Chetty et al. (2011) and approximate the counterfactual distribution of annual spending in the absence of the kink. Specifically, we fit a cubic polynomial to the empirical spending distribution in Figure 3, using beneficiaries with spending between \$1,000 and \$10,000 and omitting those with spending within \$200 around the coverage gap threshold.<sup>31</sup>

Figure A3 presents estimates of the excess mass around the threshold for each year from 2006 until 2018. In line with the policy change, we find a sharp drop in the amount of excess mass for non-LIS beneficiaries in 2011 that continues to decline gradually. Excess

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<sup>30</sup>In practice, beneficiaries are expected to cluster in a narrow area around the coverage gap threshold due to real-world frictions such as the lumpiness of drug purchases and uncertainty about future health shocks (Saez 2010).

<sup>31</sup>We estimate the excess mass for spending within \$200 of the coverage gap threshold.

mass around the coverage gap threshold was 2.7 percentage points in 2010, 1.6 percentage points in 2011, and only 0.6 percentage points in 2018. Again, for LIS beneficiaries, we find no evidence of excess mass around the threshold of the coverage gap.

### 5.3 Timing of purchases

The bunching around the kink presumably reflects beneficiaries forgoing or postponing prescriptions that they would otherwise have filled. To study this aspect more closely, we look at beneficiaries' propensity to fill a prescription as they approach the coverage gap.

Absent a price response, standard economic theory suggests that the share of beneficiaries with a drug purchase in a given month should monotonically increase with the level of annual spending (Einav et al. 2015). Figure 4 depicts the share of non-LIS and LIS beneficiaries with a prescription drug purchase in December as a function of their annual drug spending. In line with the theoretical prediction, the share of LIS beneficiaries with a prescription drug purchase is monotonically increasing in the level of spending. In contrast, we find a slowdown in the probability of end-of-year purchases for non-LIS beneficiaries both as they approach the coverage gap and while they are in the gap.<sup>32</sup>

In an exercise similar to Section 5.2, we estimate the missing mass for purchases around the coverage gap threshold by fitting the following cubic polynomial to the conditional probability distribution function,

$$\text{share}_{gb} = \alpha + \beta_1 \times \text{spending}_{gb} + \beta_2 \times \text{spending}_{gb}^2 + \beta_3 \times \text{spending}_{gb}^3 + \kappa_g + \varepsilon_{gb} \quad (1)$$

where each observation is a spending bin  $b$  for beneficiary group  $g \in \{\text{LIS}, \text{non-LIS}\}$ . The outcome variable measures the share of beneficiaries of group  $g$  in bin  $b$  with at least one prescription drug purchase in December,  $\text{spending}$  is the average amount of annual drug spending in the respective group and bin, and  $\kappa_g$  is a fixed effect for whether the bin is for LIS beneficiaries. In the estimation, we omit spending bins of non-LIS beneficiaries close to the gap threshold (within \$200). Thus, we use the purchasing behavior of LIS beneficiaries, who do not experience the coverage gap, to impute counterfactual purchasing behavior for non-LIS beneficiaries.

We find that, in 2010, non-LIS beneficiaries with annual spending near the kink were 9.8 percentage points less likely to fill any prescription in December.<sup>33</sup> The slowdown in drug

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<sup>32</sup>We repeat this exercise for beginning-of-year purchases and find no evidence of such a slowdown (see Figure A2). This is expected, as non-LIS beneficiaries are unlikely to have reached the coverage gap early in the year.

<sup>33</sup>Figure A4 presents the full estimation results.

purchases becomes less prevalent in post-ACA years and, in 2018, non-LIS beneficiaries close to the kink were only 4.3 percentage points less likely to fill any prescription in December.

Overall, we find that the coverage gap has a more modest impact on slowing down the drug consumption of non-LIS beneficiaries after the gap closure. In return, this suggests an increase in the demand for prescription drugs. While this effect is unsurprising, and indeed the intended goal of the policy change, it warrants the need to study manufacturers' response: As the coverage gap no longer restrains drug purchases and beneficiaries become less price-sensitive, manufacturers should increase drug prices.

In Appendix C, we conduct a back-of-the-envelope exercise to quantify the implications of less price-sensitive beneficiaries for manufacturer price-setting. We calibrate a simple model of beneficiary demand using the propensities to fill a prescription estimated in this section. This allows us to benchmark how much manufacturers should optimally increase drug prices in response to the closure of the coverage gap due to the increase in beneficiary demand alone. We find that manufacturers should optimally increase drug prices by 6%, motivating the importance of analyzing strategic responses by manufacturers.

## 6 Manufacturer response

In this section, we investigate the effect of the gap closure on retail prices by exploiting variation in policy exposure across brand-name drugs and markets. Intuitively, manufacturers that generate a higher share of revenue from claims in the gap are more exposed to the policy change as they face a higher demand increase and higher discount payments in future years. We link this variation to trends in retail prices of brand-name drugs sold in Part D in 2010.<sup>34</sup> We begin by describing the construction of our analysis sample.

### 6.1 Variable construction

**Defining drugs.** To be able to track brand-name drugs over time, we need a consistent definition of a prescription drug. Specifically, we cannot measure prices at the NDC level as these codes change frequently and multiple codes may describe the same drug product.<sup>35</sup> Instead, we rely on information from the Merative MarketScan® Redbook and combine NDCs that describe pharmaceutically equivalent products with the same brand status and

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<sup>34</sup>By focusing on drugs already on the market in 2010, our analysis does not speak to the effect on launch prices of new drugs.

<sup>35</sup>Manufacturers are required to update the NDC when one of the following changes: proprietary product name, active ingredient, strength, dosage form, status of the product (e.g., whether it is a prescription or over-the-counter drug), intended use, distinguishing characteristics (e.g., size, shape, color), package size, or package type. See Code of Federal Regulations 21 CFR 207.35.

trade name.<sup>36</sup> We augment these data with information from the FDA on drug approval and patent expiration.<sup>37</sup>

**Constructing average retail prices.** In our analysis, we focus on a drug's average retail price per days' supply, measured at the market-year level. The retail price is the total cost of a prescription drug event and comprises the ingredient cost and dispensing fee. Specifically, it is the price paid by the insurer and beneficiary to the pharmacy at the point of sale. By measuring prices at the market-year level, we capture the market-wide response of manufacturers, pharmacies, and insurers, but abstract away from intra-market price variation across plans.

To limit measurement error from non-standard claims, we exclude prescriptions filled at out-of-network pharmacies and drop drugs with less than ten claims for the most common package size in a market and year.<sup>38</sup> Although the latter restriction drops many infrequently purchased drugs, we retain more than 98% of all claims and revenue for brand-name drugs. For the remaining drugs, we take the five most common package sizes to compute the average price per days' supply across all claims in the same market and year.

**Measuring policy exposure.** Our research design exploits variation in the exposure to the closing of the coverage gap. We measure policy exposure as drug  $j$ 's revenue from non-LIS beneficiaries in the gap relative to the *variable* revenue in market  $m$  in 2010,

$$\text{gap share}_{jm|2010} = \frac{\text{non-LIS gap}_{jm|2010}}{\text{Part D}_{jm|2010} - \text{Part D government}_{jm|2010}} \quad (2)$$

The numerator of the *gap share* is spending from claims by non-LIS beneficiaries in the gap in 2010.<sup>39</sup> The denominator is market-wide Part D spending minus government-financed Part

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<sup>36</sup>Following the [FDA definition](#), drug products are pharmaceutically equivalent if they contain the same active ingredient(s), are of the same dosage form and route of administration, and are identical in strength or concentration. For example, we group together 24 NDCs that describe a 40mg oral tablet of brand-name Lipitor with the active ingredient atorvastatin calcium. In this case, we combine products from 12 different manufacturers, or drug labelers, offered in 7 different package sizes.

<sup>37</sup>We combine the Part D claims data with the National Drug Code Directory, which links NDCs to their drug application number. This number allows us to link NDCs to the DrugsFDA and Orange Book databases, which contains information on drug approval and patent/exclusivity expiration. Drugs may be protected by multiple patents and we use the last year of patent or exclusivity expiration. See Appendix A for more information on data sources and sample construction.

<sup>38</sup>About 98% of all claims for brand-name drugs are filled at in-network pharmacies. The median brand-name drug in our data is prescribed in three different package sizes, or numbers of days' supply, in a market and year. The most common package size is prescribed in more than 80% of filled claims.

<sup>39</sup>Specifically, we add up the total cost of non-LIS claims that end up in the coverage gap. This comprises claims that start in the deductible phase, the initial coverage phase, or the coverage gap. We do *not* count claims that start in the coverage gap and end in the catastrophic phase.

D spending, comprising LIS cost-sharing subsidies and non-LIS reinsurance in the catastrophic phase. We subtract government subsidies as recipients of cost-sharing assistance are shielded from the retail price and their demand is price-inelastic. Thus, we consider government-financed spending as “guaranteed” revenue for the manufacturer and assume that the manufacturer responds to the gap closure by updating its price to maximize revenue from price-sensitive consumers.<sup>40</sup> In total, the exposure measure combines two sources of identifying variation: First, consistently across markets, there are drugs more versus less commonly consumed by non-LIS beneficiaries in the coverage gap. Second, the composition of the beneficiary population differs across markets with high versus low shares of non-LIS beneficiaries.<sup>41</sup>

**Analysis sample.** Our sample comprises 2,452 brand-name drugs (40,652 drug-markets) that were sold in Part D in 2010. These drugs made up 76% of total spending in 2010 and 27% of total days’ supply.<sup>42</sup> Table 5 presents key summary statistics and Figure 5 shows the distribution of the *gap share* across drug-markets. Decomposing the variance of the exposure measure, we find that drug fixed effects explain 68% of the variation in the *gap share*, while market fixed effects explain 8%. Thus, our empirical strategy primarily leverages variation in exposure across drugs rather than across markets.<sup>43</sup> We also find that our exposure measure is very persistent over pre-closure years, implying that it is highly predictive of the relative revenue impact of the policy reform.<sup>44</sup>

We also assess which drug characteristics are related to policy exposure. Table 6 compares drugs with a *gap share* below versus above the 25th percentile, in line with our empirical

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<sup>40</sup>In addition, we want to avoid that government-financed revenue “deflates” our exposure measure. For example, suppose that 80% of drug revenue comes from LIS beneficiaries and 20% from non-LIS beneficiaries. As LIS beneficiaries pay close to zero cost-sharing, they are essentially sheltered from variation in the retail price.

<sup>41</sup>In Appendix D, we consider a variation of our exposure measure that includes spending from claims by commercial beneficiaries. Our results are robust to incorporating commercial spending into our exposure measure. We use the measure defined in Equation (2) as our preferred measure of policy exposure given that commercial and Part D beneficiaries are institutionally segmented. For example, manufacturers can directly provide price concessions to commercial beneficiaries through copay coupons, whereas the Anti-Kickback Statute prohibits Part D beneficiaries from using such coupons.

<sup>42</sup>As illustrated in Table A2, drugs in our analysis sample make up 99% of brand-name spending, days’ supply, and number of claims in Part D in 2010. With the entry of new, high-priced drugs, the share of spending accounted for by our sample declines (46% of brand-name spending in 2018). Yet, these drugs remain central to Part D beneficiaries and capture 60% of total brand-name days’ supply and claims in 2018.

<sup>43</sup>To decompose the variance of the exposure measure, we first regress the gap share on full sets of drug fixed effects and market fixed effects. We compute the variance of estimated drug (market) fixed effects across all 2010 drug-markets and divide it by the variance of the gap share.

<sup>44</sup>To estimate the serial correlation of the exposure measure, we construct the *gap share* for each drug-market for years  $t = 2006, \dots, 2010$  and estimate the following AR(1) model,  $\text{gap share}_{jmt} = \alpha + \rho \text{gap share}_{jmt-1} + \varepsilon_{jmt}$ . We estimate an autocorrelation coefficient of  $\hat{\rho} = 0.6688$  (0.0121).

strategy. We find that high-exposure drugs tend to be cheaper per days' supply and are more likely to treat primarily chronic conditions. While the vast majority of drugs in our sample were patent-protected in 2010, a lower share of high-exposure drugs lost protection before 2018. Despite this difference, both groups have the same approval year and patent expiration year, on average, and roughly 70% of drugs have a generic alternative available.<sup>45</sup>

## 6.2 Event study

To relate the variation in policy exposure to trends in retail prices, we estimate event study models of the following form,

$$p_{jmt} = \alpha + \sum_t \beta_t \times \delta_t \times f(\text{gap share}_{jm|2010}) + \lambda_{jm} + \tau_{mt} + \eta_{e(j)t} + \varepsilon_{jmt} \quad (3)$$

Here,  $p_{jmt}$  is the log-average retail price per days' supply for drug  $j$  in market  $m$  in year  $t$ .<sup>46</sup> We interact the exposure measure, or transformations therefore, with a series of year fixed effects,  $\delta_t$ , normalized to 2010. The parameters of interest,  $\beta_t$ , capture the average exposure effect in our sample. We include drug-market fixed effects,  $\lambda_{jm}$ , to control for time-invariant drug characteristics and absorb differences in relative market size. Market-year fixed effects,  $\tau_{mt}$ , capture changes in insurer or pharmacy competition and their average effect on retail prices. We also allow time trends to vary by year of patent expiration  $e$ ,  $\eta_{e(j)t}$ , to account for varying pricing incentives along the drug life cycle.<sup>47</sup> Thus, identification comes from deviations in market-level trends in retail prices between drugs with the same patent expiration year but different policy exposure. In addition, we rely on the assumption of parallel trends in the absence of the policy change, which we can assess empirically in pre-policy years. In the estimation, we weigh observations by their respective drug-market spending in 2010. As most of the variation in policy exposure stems from cross-drug variation, we cluster standard errors at the drug level.

To permit a flexible functional form of the exposure effect, we run two specifications of the event study model in parallel: First, we dichotomize the exposure measure and compare

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<sup>45</sup>We define a brand-name drug as having a generic alternative if we ever observe a NDC in the Part D claims data that is labeled as generic and pharmaceutically equivalent to the brand-name product in the Merative MarketScan® Redbook.

<sup>46</sup>Retail prices are heavily right-skewed, with a per days' supply mean of \$31 and a median of \$6.8 in 2010. See Table 5.

<sup>47</sup>For roughly 24% of brand-name drugs in our analysis sample, we fail to identify a patent expiration year. These drugs account for less than 5% of brand-name spending in 2010. We assign these drugs to one of two “placeholder” categories, depending on whether we linked them to an NDA or not, so that we do not lose these observations in the estimation.

drug-markets with a *gap share* below versus above the 25-th percentile.<sup>48</sup> In this case, policy exposure is captured by the indicator variable,

$$f(\text{gap share}_{jm|2010}) = \mathbb{1}\{\text{gap share}_{jm|2010} > Q_1\}$$

A natural extension is to augment the model by separate indicator variables for drug-markets in the second, third, or fourth quartile of the *gap share* distribution. We present the event study with exposure quartiles in Online Appendix D. In the second specification, we impose a linear effect of policy exposure on log retail price such that

$$f(\text{gap share}_{jm|2010}) = \text{gap share}_{jm|2010}$$

Figure 6 illustrates the regression results. Column (1) in Tables A3 and A4 show the point estimates. In both specifications, we find a positive and statistically significant effect of policy exposure on retail prices in the years following the gap closure. Notably, the effect size is monotonically increasing over time, consistent with sustained upward pricing pressure from manufacturers that gradually raised retail prices. Starting in 2015—that is, five years after the gap began to close—the effect size stabilizes. Importantly, we detect no significant difference in prices in the years leading up to the policy change.

Focusing on the specification with exposure indicator, we find that, compared to low-exposure drugs, prices of high-exposure drugs were 2% higher in 2011 and 21% higher in 2018, on average. To put these numbers into context: The average *gap share* in the two exposure groups differs by 9 percentage points (10.8% versus 1.9%), implying that high-exposure drugs made roughly four times more of their “variable” revenue from non-LIS beneficiaries in the gap. To the extent that low-exposure drugs were still impacted by the gap closure and responded by raising prices, our estimates understate manufacturers’ pricing response. For the specification with linear exposure effect, we find that a one percentage point increase in the *gap share* yields a 1.5% higher retail price in 2018. This implies a 13% higher price in 2018 for the average drug in our sample, compared to no policy exposure.

We implement several robustness checks, summarized in Columns (2)-(5) of Tables A3 and A4. First, we add therapeutic group  $\times$  year fixed effects to allow aggregate price trends to differ across therapeutic groups.<sup>49</sup> Next, we estimate the baseline specification on a bal-

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<sup>48</sup>Drug-markets at the 25th percentile make 4.32% of their *variable* revenue from non-LIS beneficiaries in the coverage gap. See Table 5.

<sup>49</sup>We use a coarse categorization provided by the Merative MarketScan® Redbook, which assigns drugs in our analysis sample to one of 26 therapeutic groups. The three therapeutic groups with the highest branded drug spending in 2010 are central nervous system agents (e.g., analgesics, anticonvulsants), cardiovascular agents (e.g., antihypertensives, beta-blockers), and hormones & synthetic substitutes (e.g., estrogens, antidi-

anced panel of drug-market-years and on the subset of drugs successfully linked to a New Drug Application number.<sup>50</sup> Lastly, we implement our baseline specification with a simplified exposure measure that does not subtract government-financed spending from total spending in 2010. Our estimation results are robust to these alterations. With the exposure indicator, we estimate that prices of high-exposure drugs are between 19-21% higher in 2018 compared to low-exposure drugs. With a linear exposure effect, we find that a one percent increase in the *gap share* implies a 1.2-2.0% higher price in 2018, on average.

**Role of generic competition and patent protection.** Next, we investigate the role of generic competition and patent protection in manufacturers' pricing response. For that, we estimate Equation (3) separately for drugs with or without a generic alternative, as well as for drugs that lose patent protection between 2011-2018 or remain protected beyond our sample period.<sup>51</sup> Columns (6)-(9) in Tables A3 and A4 report the results.

Consistently, we find that prices of drugs with *less* competition responded faster to the closing of the coverage gap and show a more persistent exposure effect. For example, with a linear exposure effect, a one percent increase in policy exposure implies a 17% higher price for patent-protected drugs and only an 8% higher price for drugs that lose protection. Thus, under patent protection or without generic competition, manufacturers were able to pass through a higher share of the discount requirement. In addition, these manufacturers also faced a higher demand increase as beneficiaries' cost-sharing in the gap decreased. Both mechanisms contribute to higher retail prices in equilibrium.

### 6.3 Distributional incidence

Thus far, we document two effects of the policy change: Non-LIS beneficiaries are less likely to forgo prescription drugs upon reaching the coverage gap, and retail prices increased in response to the discount requirement and demand increase that manufacturers faced. To illustrate the qualitative implications of the endogenous effect on prices, we examine the distributional incidence of the closing of the coverage gap across beneficiaries. We provide two pieces of model-free evidence: We first illustrate how drug spending is reallocated mechanically by the redesign of the coverage gap, and then isolate the effect of the price increase on the relative incidence across beneficiaries.

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abetic agents). We refrain from using a more granular classification as those fixed effects would absorb the exposure effect.

<sup>50</sup>Due to market entry after 2006 and exit before 2018, our drug-market-year panel is unbalanced.

<sup>51</sup>When splitting by patent protection, we exclude drugs without observed patent expiration year. We also exclude drugs that lost patent protection in 2010 or earlier as they account for less than 2% of brand-name spending in 2010.

Overall, we find that the insurance expansion intended a per capita transfer of \$100 to beneficiaries that is primarily financed by manufacturers. However, accounting for the price response dramatically shifts the incidence: beneficiaries only receive a per capita transfer of \$55 that is largely financed by the government. Notably, the majority of beneficiaries actually experience higher out-of-pocket costs, with the median beneficiary incurs a \$7 cost. To highlight the heterogeneous impact of the insurance expansion, Figure A8 shows a histogram of the distributional incidence across beneficiaries when allowing for an endogenous price response. The majority of beneficiaries—i.e., non-LIS beneficiaries who do not spend in the gap and LIS beneficiaries—mechanically cannot benefit from the gap closure. However, higher retail prices increase their out-of-pocket costs due to cost-sharing in all coverage phases. The closure of the coverage gap therefore results in welfare losses for the majority of beneficiaries without compensatory changes in plan premiums.<sup>52</sup>

Our analysis highlights why program design must contend with strategic responses by private firms. Redistributive policies may have unintended consequences due to equilibrium impacts on the prices of private goods. Appendix E walks through our analysis in detail.

## 7 Conclusion

Our analysis provides novel evidence on the equilibrium effect of the closure of the coverage gap and its distributional implications. Prior literature has documented that the increase in cost-sharing at the start of the coverage gap caused consumers to forgo drug consumption. We find that the benefit redesign was successful in mitigating this problem and that beneficiaries increased demand in response to lower cost-sharing in the gap.

However, we also find a sustained increase in retail prices due to manufacturers' response to the discount requirement. The coverage gap was closed with an implicit tax on manufacturers with the creation of the manufacturer discount program. Therefore, we predict that manufacturers should pass through discounts and that the increase in equilibrium retail prices should be greater for drugs with a larger share of revenue coming from spending in the coverage gap. Accordingly, we find that brand-name drugs with greater exposure to the policy change—measured by the share of non-government Part D revenue in 2010 coming from spending in the gap—experienced a 21% higher price increase. Our back-of-the-envelope calculations suggest that the endogenous effect on prices considerably altered the distributional incidence of the policy change. We find that the closure of the gap intended a per

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<sup>52</sup>Inflation-adjusted beneficiary premiums are almost constant from 2010 to 2018 (Table 3). Premiums are determined by a competitive bidding process, where plan sponsors submit a bid that reflects actuarial costs for standard benefits. The government finances 74.5% of the national average bid, whereas the remainder is paid for by beneficiaries.

capita transfer of \$100 to beneficiaries, primarily financed by manufacturers. However, by raising prices, manufacturers substantially shift the incidence of the insurance expansion to the government. As a consequence, beneficiaries only receive a per capita transfer of \$55, with some beneficiaries even facing substantially higher out-of-pocket costs.

Several caveats of our study need to be pointed out. First, our analysis of the manufacturer response is limited to drugs sold in Part D in 2010 and does not directly extend to launch prices of new drugs. Second, while the gap discount operates in parallel to other price concessions that manufacturers directly pay to insurers, in particular post-sale rebates, we cannot speak to the effects of the gap closure on net-of-rebate prices. Lastly, our analysis of the distributional implications provides bounds on the spending incidence as we do not explicitly model and account for beneficiaries' consumption response.

Understanding the effect of public insurance design on pharmaceutical prices continues to be critical to policy as the Part D benefit design is an ongoing topic on the political agenda. Most recently, as part of the Inflation Reduction Act of 2022, the Biden administration abolished manufacturer discounts and completely overhauled the Part D benefit design.

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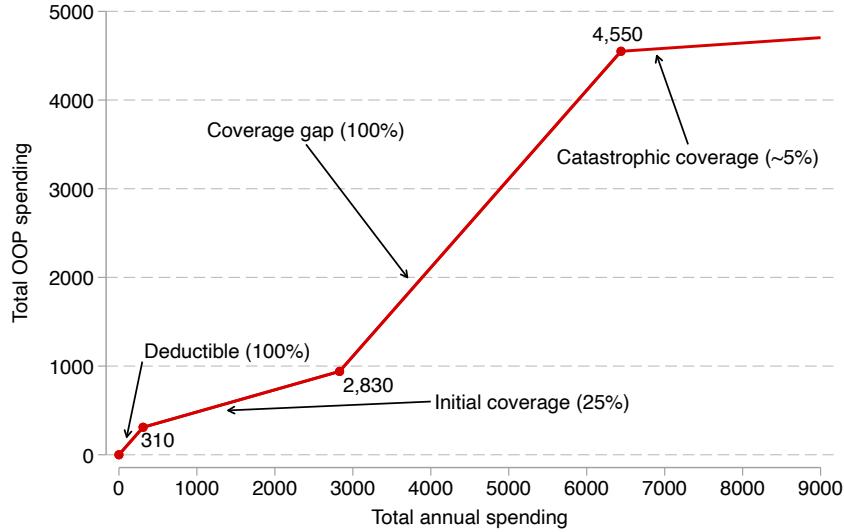
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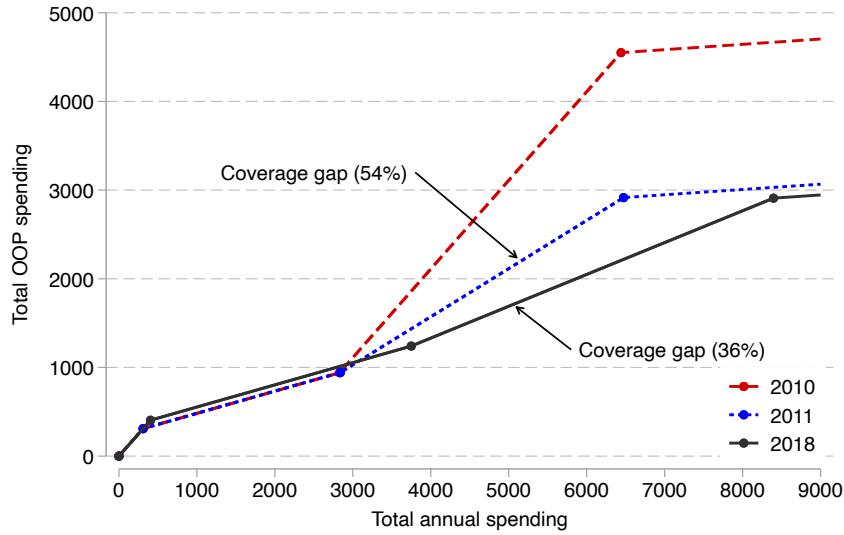
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Figure 1: Standard Medicare Part D benefit design

(A) Pre-ACA design in 2010

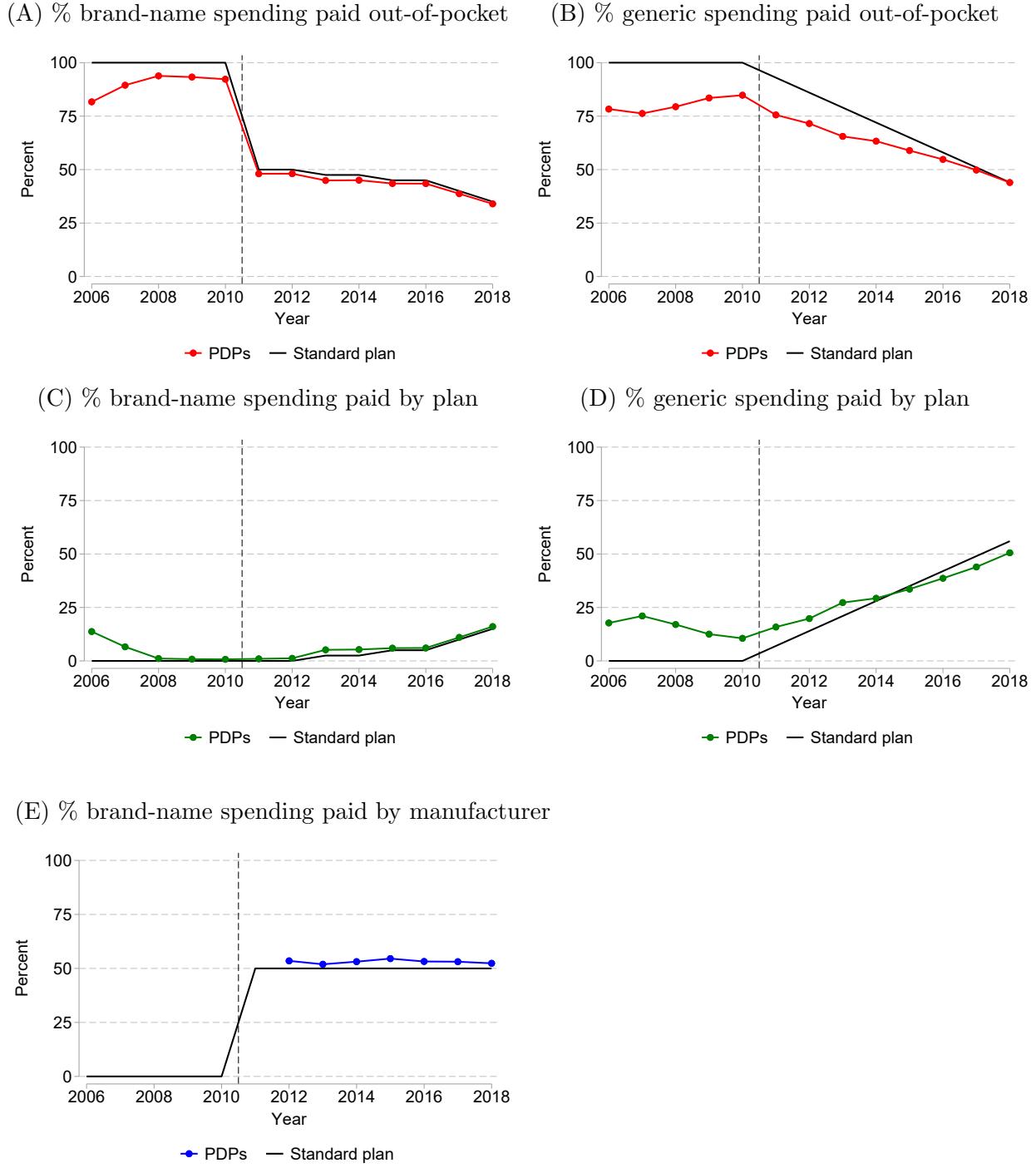


(B) Gap closure: 2010 vs 2011 vs 2018



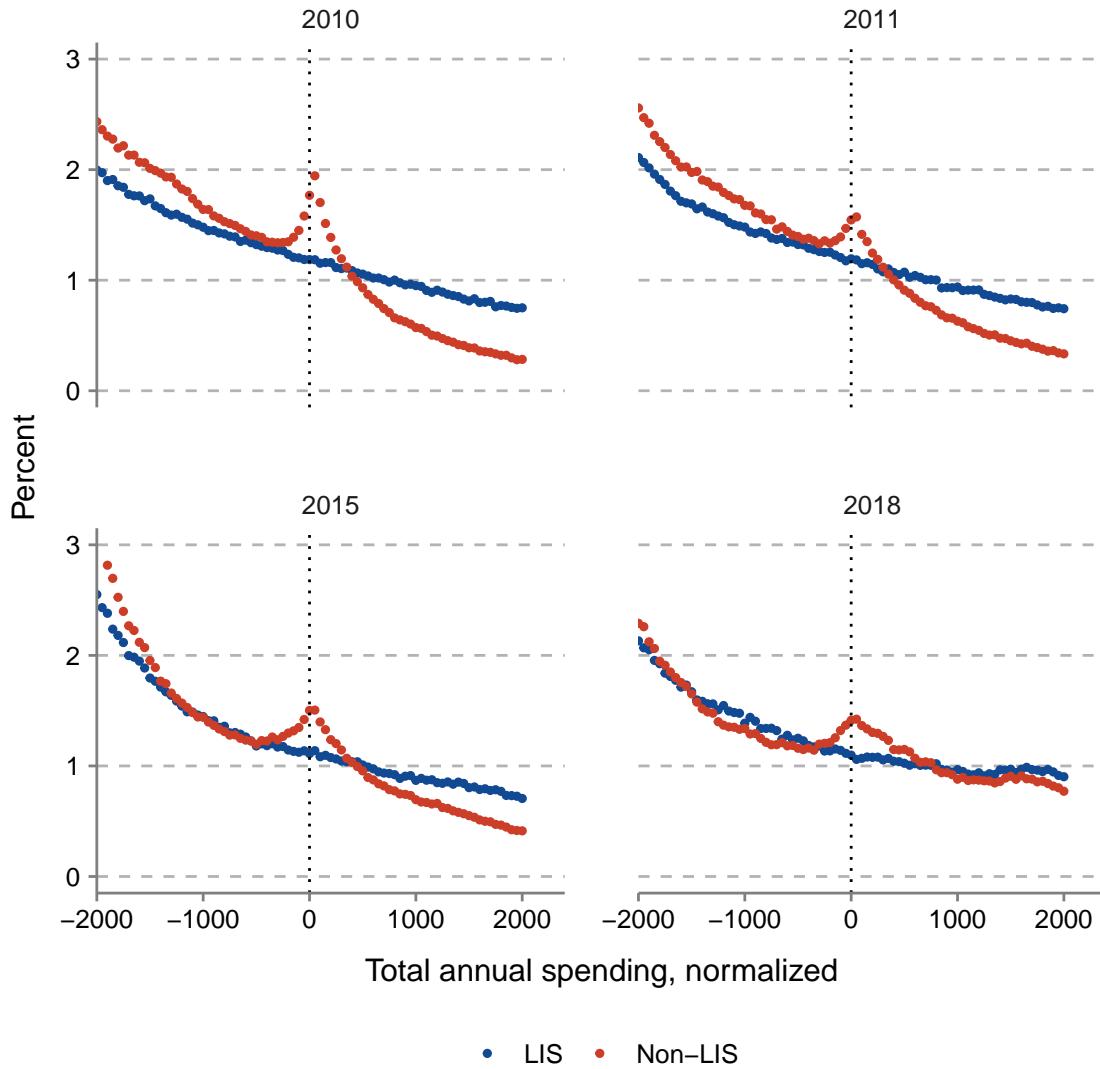
Note: Figure illustrates the government-defined standard benefit design in 2010 (Panel (A)), and the closure of the coverage gap in the standard benefit between 2010, 2011, and 2018 (Panel (B)). The standard benefit design has four coverage phases (deductible, initial coverage, coverage gap, catastrophic coverage), which are a function of annual total drug spending (x-axis) and annual out-of-pocket (OOP) spending (y-axis). In 2010, the deductible phase with a coinsurance rate of 100% lasted until OOP spending reached \$310. The initial coverage phase with a coinsurance rate of 25% lasted until the initial coverage limit of \$2,830 in total spending. The coverage gap with a coinsurance rate of 100% lasted until the OOP threshold of \$4,550. In the catastrophic phase, the coinsurance rate was approximately 5%. Drug benefits reset at the beginning of a calendar year. Only non-LIS beneficiaries are exposed to the different coverage phases. For LIS beneficiaries, the government covers the vast majority of beneficiary contributions, including 100% of spending in the coverage gap. In 2011, i.e., the first year of the gap closure, the coinsurance rate in the gap was 50% for brand-name drugs and 93% for generic drugs. In 2018, i.e., the last year of our data, the coinsurance rate in the gap is 35% for brand-name drugs and 44% for generic drugs. We plot a weighted-average coinsurance rate assuming that the beneficiary consumes 90% branded and 10% generic drugs in the gap. This approach follows the measure used by CMS to estimate total spending at the out-of-pocket threshold (CMS, 2013). Spending and OOP thresholds (nodes), that mark the coverage phase cutoffs, are updated annually based on the Consumer Price Index for All Urban Consumers and the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary.

Figure 2: Non-LIS cost-sharing in the coverage gap



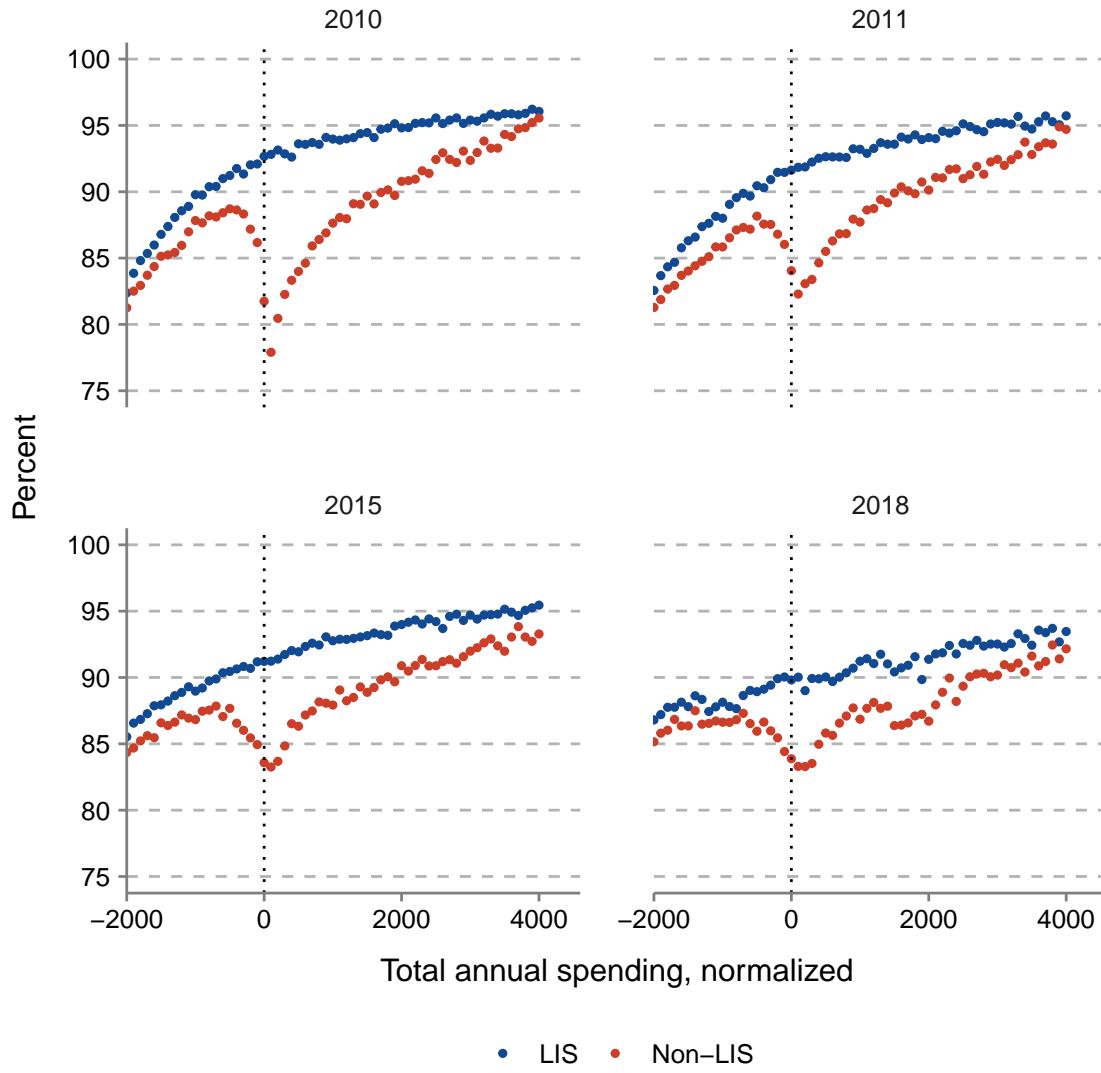
Note: Figure shows how cost-sharing in the coverage gap evolved over time for non-LIS beneficiaries, on average. We compare the empirical gap cost-sharing in Part D standalone plans (“PDPs”) to the standard plan design (“Standard plan”). We measure gap cost-sharing for non-LIS empirically: For a given year, we take all beneficiaries who enter the gap at some point in the year. We take non-LIS beneficiaries who hold this status and remain enrolled in the same plan throughout the year. For each beneficiary, we add up total drug spending, out-of-pocket spending, plan, and manufacturer contributions for claims made entirely in the gap (that is, claims that start and end in the gap). We drop beneficiaries in the bottom and top percentile of the gap spending distribution of a given year. For each beneficiary, we compute the empirical cost-sharing by dividing the total out-of-pocket spending, plan and manufacturer contributions by total drug spending in the gap. The figures plot the average cost-sharing rates across beneficiaries.

Figure 3: Distribution of annual drug spending around start of coverage gap



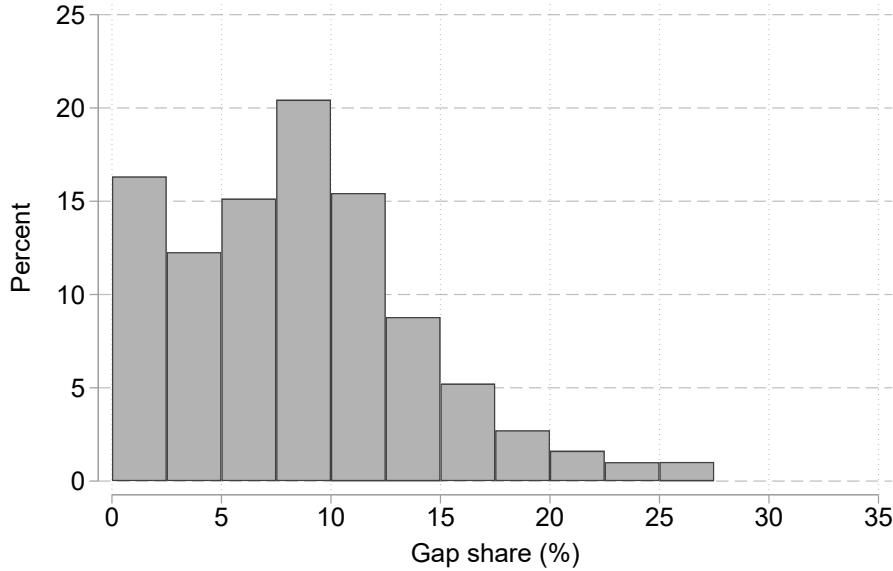
Note: Figure shows the empirical distribution of total annual drug spending in 2010, 2011, 2015, and 2018, separately for non-LIS and LIS beneficiaries. Spending is normalized relative to the initial coverage limit of the respective year which marks the start of the coverage gap. We show the distribution of annual spending within \$2,000 around the initial coverage limit. The initial coverage limit was \$2,830 in 2010, \$2,840 in 2011, \$2,960 in 2015, and \$3,750 in 2018.

Figure 4: Propensity of prescription drug purchase in December by annual drug spending



Note: Figure shows the beneficiary-level propensity of any prescription drug purchase in December as a function of total annual drug spending in 2010, 2011, 2015, and 2018, separately for non-LIS and LIS beneficiaries. Spending is normalized relative to the initial coverage limit of the respective year which marks the start of the coverage gap. The initial coverage limit was \$2,830 in 2010, \$2,840 in 2011, \$2,960 in 2015, and \$3,750 in 2018.

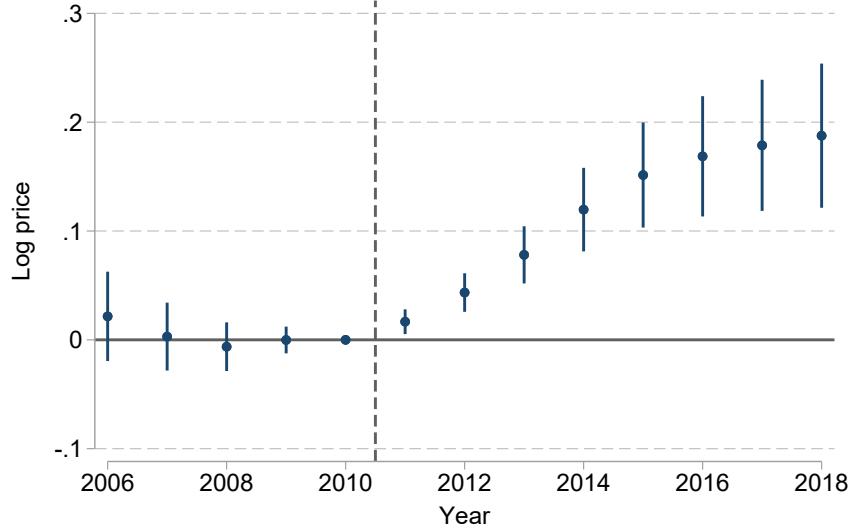
Figure 5: Distribution of drug-market exposure measure



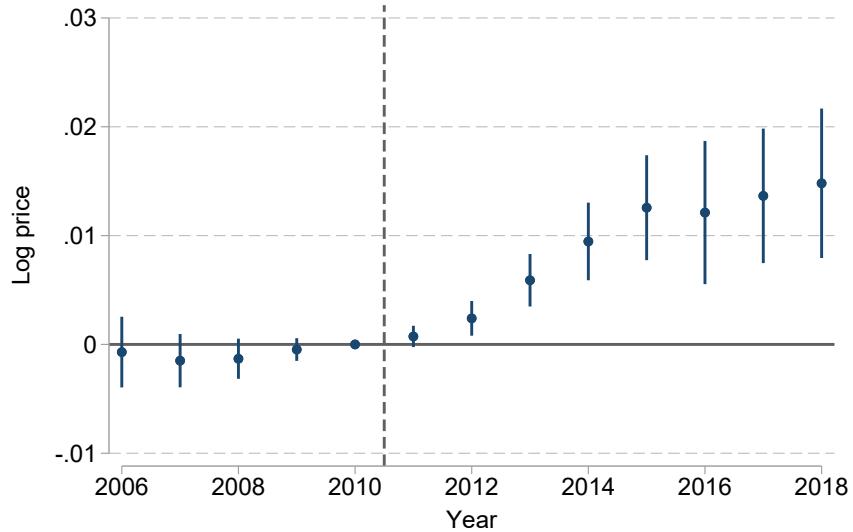
Note: Histogram shows the distribution of the policy exposure measure, *gap share*, across drug-markets in our analysis sample as defined in Equation (2). The exposure measure is the share of variable revenue from non-LIS beneficiaries in the coverage gap of a drug-market in 2010. Variable revenue is the total spending of drug  $j$  in market  $m$ , minus government-financed spending from LIS subsidy and reinsurance in the catastrophic phase. We winsorize the exposure measure at the 99-th percentile.

Figure 6: Effect of policy exposure on log price, baseline specifications

(A) Exposure indicator



(B) Linear exposure effect



Note: This figure illustrates the estimation results for our baseline event study specifications (3), with the exposure indicator (Panel (A)) and the linear exposure effect (Panel (B)). Our analysis sample are brand-name drugs sold in Part D markets in 2010. The exposure measure is defined in Equation (2). In Panel (A), we compare drug-markets above versus below the first quartile of the spending-weighted *gap share* distribution. In Panel (B), we impose a linear effect of policy exposure on log prices. Both event studies include drug×market, market×year, and patent expiration year×year fixed effects. We weight each observation by its drug-market revenue in 2010. Results show the point estimates  $\hat{\beta}_t$  and 95% confidence intervals. Standard errors are clustered at the drug level.

Table 1: Cost-sharing in the coverage gap of the standard benefit design

Year	Brand-name drugs (%)			Generic drugs (%)	
	Beneficiary	Plan	Manufacturer	Beneficiary	Plan
2010	100	0	0	100	0
2011	50	0	50	93	7
2012	50	0	50	86	14
2013	47.5	2.5	50	79	21
2014	47.5	2.5	50	72	28
2015	45	5	50	65	35
2016	45	5	50	58	42
2017	40	10	50	51	49
2018	35	15	50	44	56
2019	25	5	70	37	63
2020+	25	5	70	25	75

Note: Table presents, for years 2010-2018, the cost-sharing rates in the coverage gap for the government-defined standard plan. Specifically, table illustrates how the cost of a prescription drug claim in the coverage gap is split between the patient, insurance plan, and drug manufacturer (in the case of a claim for a brand-name drug filled by a non-LIS beneficiary).

Table 2: Beneficiary characteristics

Year	2010	2011	2015	2018
Age	69.1	68.9	69.4	70.1
Female (%)	60.5	60.1	58.7	57.8
OASI (%)	73.4	73.0	77.7	81.5
Non-LIS, pre gap (%)	38.5	39.3	46.8	53.6
Non-LIS, gap (%)	11.5	11.5	11.6	10.3
LIS recipients (%)	50.0	49.2	41.6	36.1
Dual-eligible (%)	40.8	40.2	34.5	30.0
N (beneficiaries)	3,382,016	3,493,419	3,971,679	4,274,781

Note: Table summarizes key demographics for our sample of beneficiaries enrolled in a Part D standalone prescription drug plan (PDP) for years 2010, 2011, 2015, and 2018. For each year, table shows the total number of beneficiaries, average age at the end of the year, percentage female beneficiaries, percentage of beneficiaries qualifying for Medicare via the “Old age and survivor’s insurance” (OASI), percentage of beneficiaries who are non-LIS and do not enter the coverage gap, percentage of beneficiaries who are non-LIS and enter the coverage gap or catastrophic phase, percentage of beneficiaries who are LIS recipients, percentage of beneficiaries who are dual-eligible for Medicare and Medicaid.

Table 3: Average plan enrollment statistics

Year	2010	2011	2015	2018
a) <i>Non-LIS, pre gap</i>				
Premium (\$)	40.9	39.6	36.2	36.8
Deductible (\$)	74.5	86.0	128.5	188.9
ICL (\$)	2823.9	2734.2	2717.3	3244.9
Gap coverage, brand (%)	0.1	2.5	11.1	22.3
Gap coverage, generic (%)	7.6	22.8	13.2	29.7
N (beneficiaries)	1,303,171	1,372,395	1,859,031	2,291,629
b) <i>Non-LIS, gap</i>				
Premium (\$)	46.7	46.8	45.3	49.9
Deductible (\$)	74.1	66.1	76.3	112.6
ICL (\$)	2824.5	2734.2	2717.3	3244.9
Gap coverage, brand (%)	0.3	5.9	18.2	39.8
Gap coverage, generic (%)	18.9	29.5	21.7	49.2
N (beneficiaries)	387,397	402,261	459,347	441,511
c) <i>LIS</i>				
Premium, charged (\$)	31.4	31.4	27.0	27.4
Premium, paid (\$)	2.4	2.1	2.7	3.0
Deductible (\$)	264.1	223.2	186.5	209.9
ICL (\$)	2829.5	2734.2	2717.3	3244.9
Gap coverage, brand (%)	0.0	0.4	2.2	4.9
Gap coverage, generic (%)	0.9	3.5	2.3	6.0
N (beneficiaries)	1,691,448	1,718,763	1,653,301	1,541,641

Note: Table summarizes key characteristics of Part D standalone prescription drug plans (PDPs) chosen by beneficiaries in our sample for years 2010, 2011, 2015, and 2018. We split the sample into a) non-LIS beneficiaries who do not enter the coverage gap in a given year, b) non-LIS beneficiaries who enter the coverage gap at some point in a year, and c) LIS beneficiaries. Across beneficiaries groups and years, the table shows the average monthly premium amount, the average deductible amount and initial coverage limit (ICL) amount, the percentage of beneficiaries enrolled in a plan with some additional coverage in the gap for brand-name or generic drugs, and the number of beneficiaries. We report the average monthly premium charged by the plan and, for LIS beneficiaries, the average monthly premium paid. All nominal amounts are inflation-adjusted to September 2010. We follow CMS' approach to adjust the threshold amounts in the standard plan design and use the September CPI for All Urban Consumers (CPI-U; all items; not seasonally adjusted).

For comparison, the (not) inflation-adjusted deductible amounts in the standard benefit design for 2006-2018 are: 269.1 (250), 277.6 (265), 274.6 (275), 298.4 (295), 310.0 (310), 298.5 (310), 302.1 (320), 303.2 (325), 284.5 (310), 293.8 (320), 325.7 (360), 354.0 (400), 350.5 (405). The initial coverage limits are: 2,422.3 (2,250), 2,514.5 (2,400), 2,506.1 (2,510), 2,730.9 (2,700), 2,830.0 (2,830), 2,734.2 (2,840), 2,765.8 (2,930), 2,770.7 (2,970), 2,615.4 (2,850), 2,717.3 (2,960), 2,994.8 (3,310), 3,274.6 (3,700), 3,244.9 (3,750).

Table 4: Average annual drug spending and consumption statistics

Year	2010	2011	2015	2018
a) <i>Non-LIS, pre gap</i>				
Annual spending (\$)	1,032	937	704	640
from branded drugs (%)	59.4	56.5	40.7	37.3
Annual OOP spending (\$)	381	345	279	283
from branded drugs (%)	60.6	54.6	31.0	24.0
Annual days' supply	978	990	1,099	1,162
from branded drugs (%)	18.0	14.6	5.1	3.4
b) <i>Non-LIS, gap</i>				
Annual spending (\$)	5,316	5,525	8,234	10,353
from branded drugs (%)	80.6	80.8	85.2	87.8
Annual OOP spending (\$)	2,177	1,661	1,760	1,800
from branded drugs (%)	80.0	74.8	72.2	74.1
Annual days' supply	2,096	2,155	2,255	2,381
from branded drugs (%)	34.9	32.2	20.6	18.5
Days until gap	235	231	212	206
Enters catastrophic phase (%)	14.2	16.2	22.6	24.8
c) <i>LIS</i>				
Annual spending (\$)	4,150	4,193	5,204	5,467
from branded drugs (%)	78.6	78.6	78.3	79.9
Annual OOP spending (\$)	95	86	65	60
from branded drugs (%)	55.9	51.0	36.9	33.5
Annual days' supply	1,572	1,589	1,683	1,716
from branded drugs (%)	29.0	26.4	15.4	12.8
Enters gap (%)	43.9	43.6	40.4	35.3
Days until gap	185	180	168	166
Enters catastrophic phase (%)	19.7	20.7	22.0	21.2

Note: Table summarizes average annual drug consumption and spending patterns for beneficiaries in our sample for years 2010, 2011, 2015, and 2018. We split the sample into a) non-LIS beneficiaries who do not enter the coverage gap in a given year, b) non-LIS beneficiaries who enter the coverage gap at some point in a year, and c) LIS beneficiaries. Across beneficiary groups and years, the table shows the average annual drug spending, annual out-of-pocket spending, and annual days' supply of prescription drugs. For each component, the table also shows the average percentage from brand-name drugs. For sample b) *Non-LIS, gap*, the table also shows the average number of days in a year after which a beneficiary first entered the gap, as well as the percentage of beneficiaries who enter the catastrophic phase at some point of the year. For sample c) *LIS*, the table also shows the percentage of beneficiaries who enter the coverage gap at some point of the year. All nominal amounts are inflation-adjusted to September 2010. We follow CMS' approach to adjust the threshold amounts in the standard plan design and use the September CPI for All Urban Consumers (CPI-U; all items; not seasonally adjusted).

Table 5: Summary statistics of drug-markets in 2010

	Mean	SD	p10	p25	p50	p75	p90
Average price per days' supply (\$)	30.61	145.55	3.49	4.63	6.88	17.80	53.55
Log(average price per days' supply)	2.32	1.16	1.25	1.53	1.93	2.88	3.98
Gap share (%)	8.50	5.46	1.48	4.32	8.26	11.75	15.63
N (drug-markets)	40,652						

Note: Table shows summary statistics for our sample of drug-markets in 2010. Statistics are weighted by drug-market revenue in 2010.

Table 6: Comparison of drug characteristics by policy exposure

	Below Q1		Above Q1	
	Mean	SD	Mean	SD
Average price per days' supply in 2010 (\$)	68.05	211.97	18.14	77.67
Gap share (%)	2.57	1.20	10.51	3.55
Revenue share from non-LIS in gap (%)	1.66	0.78	7.34	2.74
Revenue share from LIS subsidies (%)	28.81	10.79	27.72	6.79
Revenue share from non-LIS reinsurance (%)	5.29	10.58	3.36	6.27
Revenue share from LIS beneficiaries (%)	87.33	15.41	62.99	12.65
Form, tablet (%)	65.85		57.85	
Form, capsule (%)	13.64		18.09	
Form, solution (%)	7.54		12.01	
Route, oral (%)	79.56		73.93	
Route, subcutaneous (%)	3.55		8.65	
Route, ophthalmic (%)	1.25		2.99	
Protected drug class (%)	62.83		13.77	
Therapy, primarily chronic (%)	43.44		65.79	
Generic alternative available (%)	66.80		71.26	
Approval year observed (%)	97.95		99.81	
Approval year*)	1999.80	7.76	1999.32	5.98
Patent expiration year observed (%)	91.41		96.17	
Patent expiration year*)	2020.71	6.10	2020.73	5.76
Loses patent between 2011-2018*)	43.04		29.10	
Stays on patent after 2018*)	54.10		69.25	
N (drugs)	858		1,594	

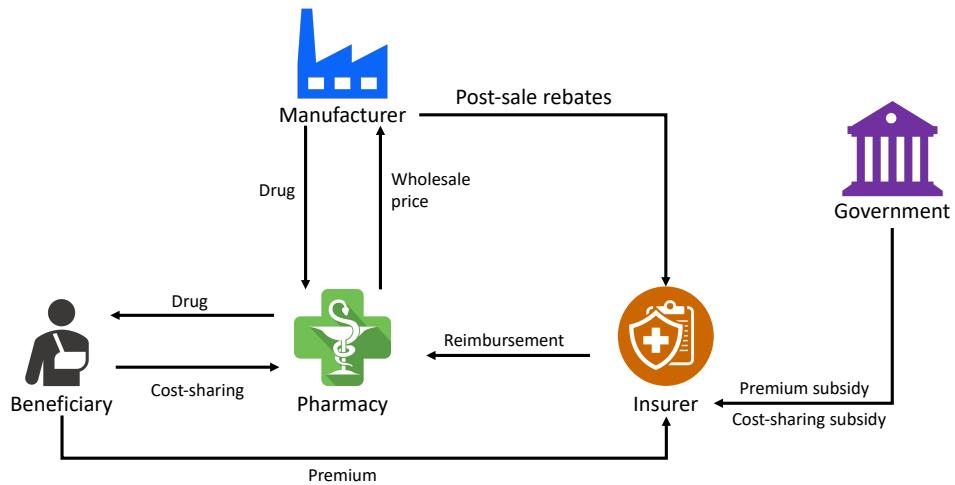
Note: Table compares characteristics of brand-name drugs in our analysis sample by policy exposure. We compare drugs with a revenue-weighted average *gap share* below versus above the 25th percentile of 4.92. Statistics are weighted by Part D spending in 2010.

\*) Only for drugs with observed approval or patent expiration year. Patent expiration is the maximum of patent expiration and marketing exclusivity expiration.

# Appendix

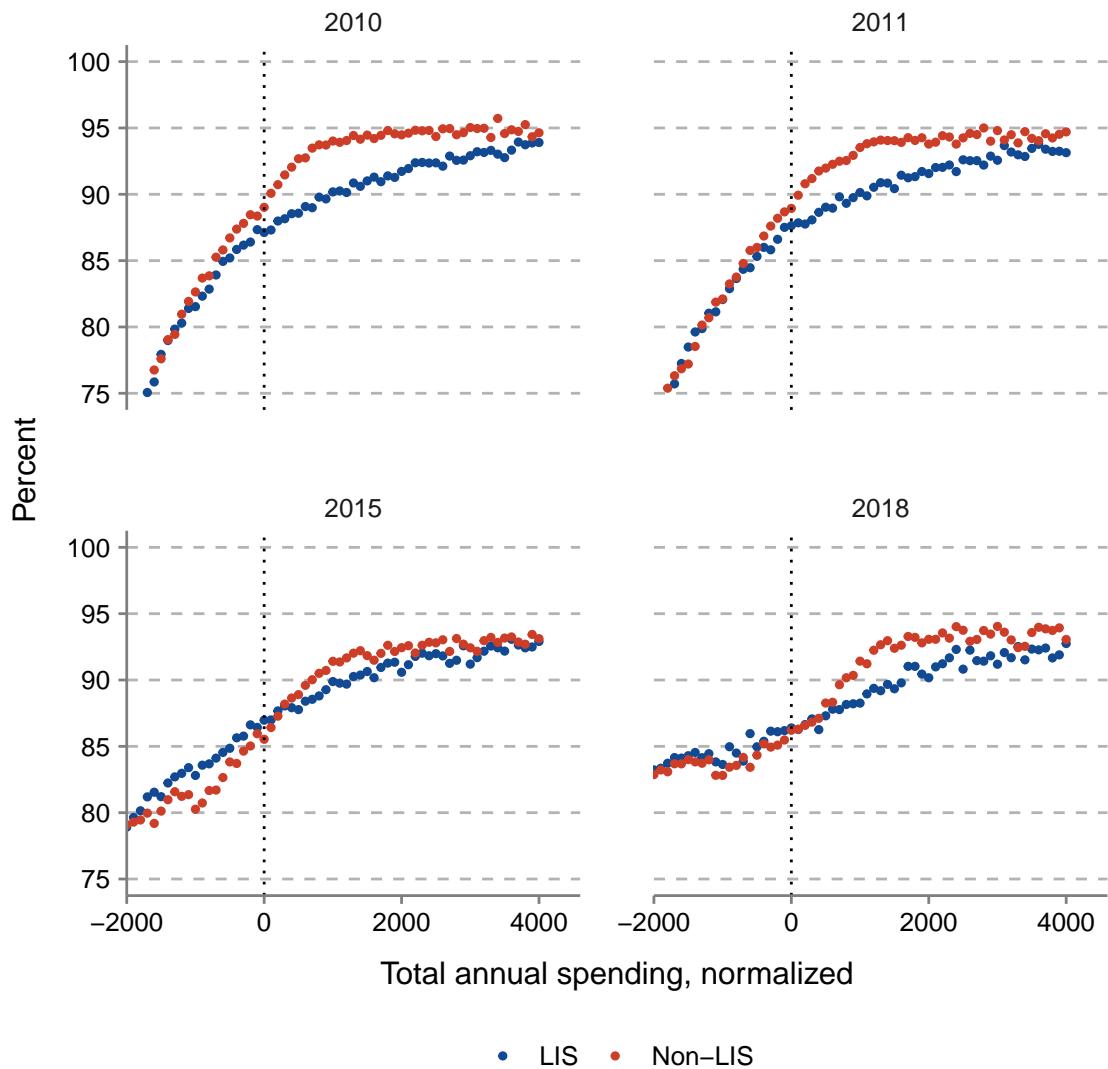
## Appendix A: Additional figures

Appendix Figure A1: Drug supply chain



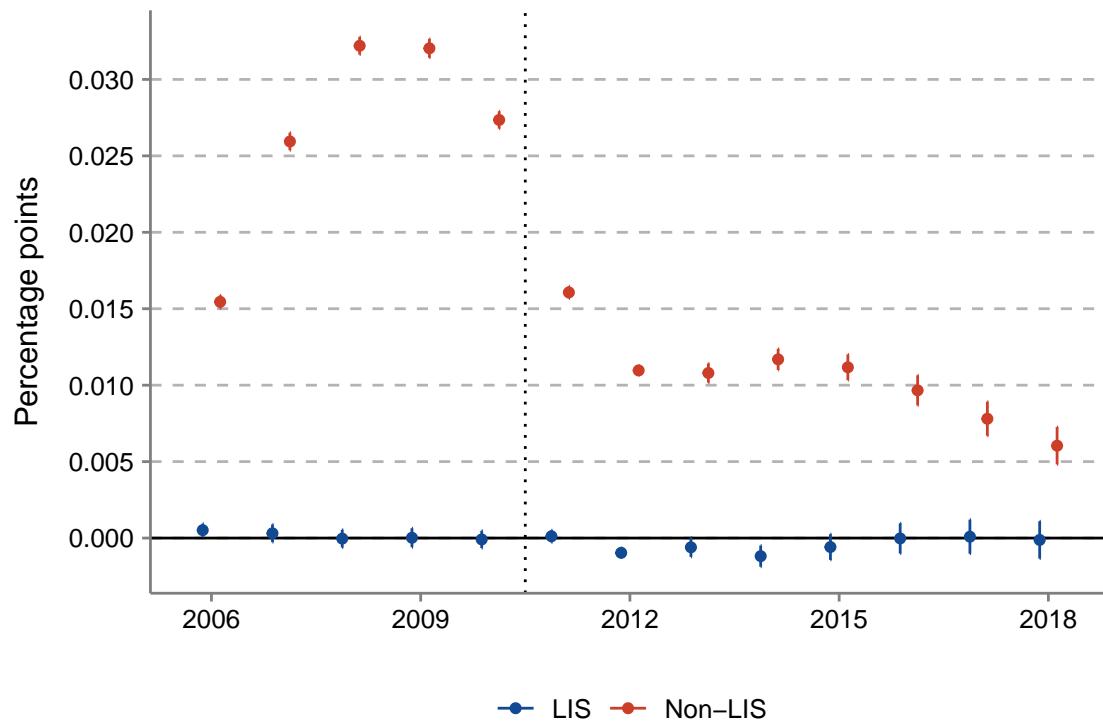
Note: This figure illustrates a simplified version of the supply chain in Medicare Part D. The illustration is based on an industry report by the Drug Channels Institute (2020).

Appendix Figure A2: Propensity of prescription drug purchase in January by annual drug spending



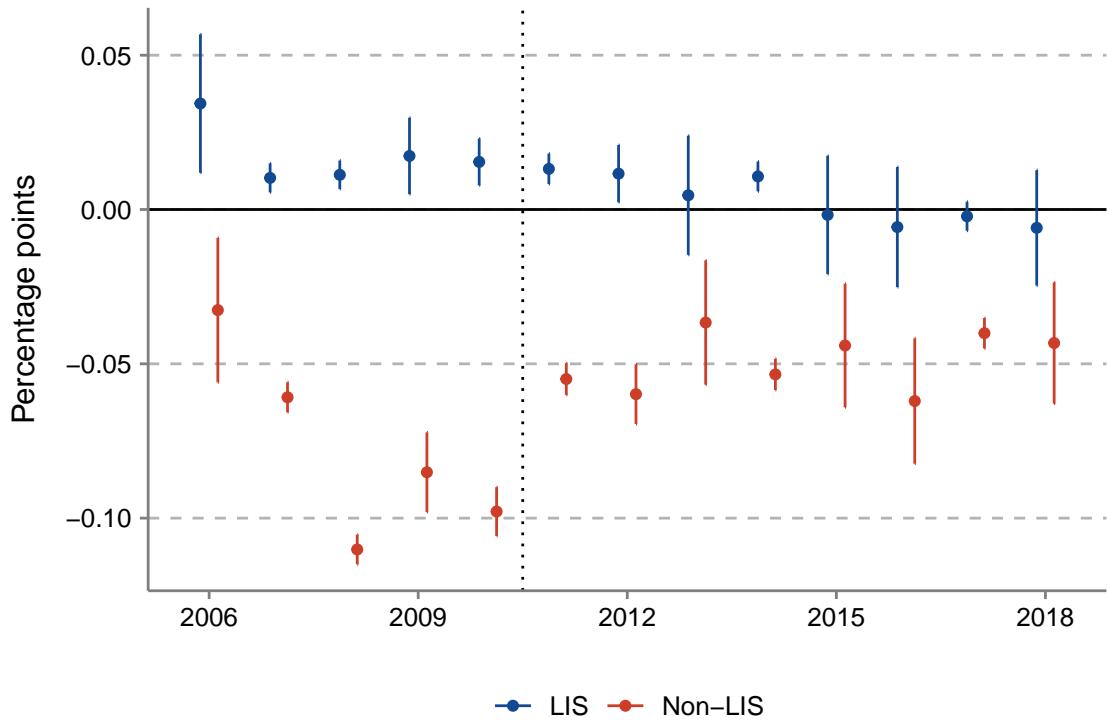
Note: Figure shows the beneficiary-level propensity of any prescription drug purchase in January as a function of total annual drug spending in 2010, 2011, 2015, and 2018, separately for non-LIS and LIS beneficiaries. Spending is normalized relative to the initial coverage limit of the respective year which marks the start of the coverage gap. The initial coverage limit was \$2,830 in 2010, \$2,840 in 2011, \$2,960 in 2015, and \$3,750 in 2018.

Appendix Figure A3: Estimates of excess bunching around start of coverage gap



Note: Figure shows the estimated excess mass near the coverage gap threshold (i.e., within \$200 of the threshold) from 2006 to 2018. To quantify the amount of excess mass, we fit a cubic approximation to the empirical distribution function for non-LIS beneficiaries (shown in Figure 3), using only beneficiaries whose spending is between \$1,000 and \$10,000 and not near the coverage gap threshold (at least \$200 away from the threshold).

Appendix Figure A4: Estimates of missing mass in December purchase propensity around start of coverage gap



Note: Figure shows the estimated dip (in percentage points) in the propensity of a December prescription drug purchase around the coverage gap threshold (i.e., within \$100 of the threshold) from 2006 to 2018. To quantify the dip in the purchase propensity, we impute a cubic approximation to the conditional probability distribution for non-LIS beneficiaries (shown in Figure 4) using Equation 2. We only use beneficiaries whose spending is between \$1,000 and \$10,000, and exclude non-LIS beneficiaries whose spending is near the coverage gap threshold (i.e., within \$200 of the threshold).

## Appendix B: Additional tables

Appendix Table A1: Percent of spending, days' supply, and claims for brand-name drugs

Year	Spending (%)	Days' supply (%)	Claims (%)
2006	79.7	44.7	42.6
2007	79.0	39.4	37.7
2008	76.8	33.3	32.3
2009	76.3	30.3	29.7
2010	76.5	27.0	26.7
2011	76.4	24.1	24.0
2012	73.3	19.4	19.9
2013	72.5	15.9	17.0
2014	74.5	14.3	15.5
2015	76.6	12.7	14.1
2016	77.3	11.5	13.0
2017	77.1	10.3	12.0
2018	78.1	9.8	11.7

Note: Table shows, by year, the percent of total Part D spending, days' supply, and number of filled prescriptions that are accounted for by brand-name prescription drugs.

Appendix Table A2: Percent of spending, days' supply, and claims for brand-name drugs in analysis sample

Year	Spending		Days' supply		Claims	
	Total	Branded	Total	Branded	Total	Branded
2006	73.7	92.5	41.9	93.7	39.5	92.7
2007	74.7	94.6	37.7	95.7	35.9	95.2
2008	74.4	96.9	32.6	98.1	31.6	97.8
2009	75.1	98.5	30.1	99.3	29.4	99.1
2010	75.7	99.0	26.9	99.7	26.6	99.6
2011	74.6	97.6	24.0	99.3	23.8	99.1
2012	69.0	94.2	19.0	98.0	19.4	97.6
2013	64.5	89.1	15.1	95.0	16.0	94.4
2014	57.6	77.3	12.9	90.3	13.8	89.2
2015	50.9	66.5	10.7	84.1	11.7	82.9
2016	46.6	60.3	8.9	77.2	9.8	75.8
2017	41.5	53.8	7.1	69.1	8.1	68.0
2018	35.7	45.6	6.0	61.1	7.0	59.7

Note: Table shows, by year, the percent of total/brand-name Part D spending, days' supply, and number of claims accounted for by the brand-name drugs in our analysis sample.

Appendix Table A3: Event study, exposure indicator, baseline specification and robustness checks

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
	Baseline	Group-year FE	Balanced panel	Matched NDA	Simple exposure	Without generic	With generic	Stays on patent	Loses patent
$\mathbb{1}\{2006\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.022 (0.021)	0.012 (0.018)	0.011 (0.022)	0.006 (0.021)	0.023 (0.021)	0.035 (0.048)	0.021 (0.018)	0.003 (0.034)	0.010 (0.024)
$\mathbb{1}\{2007\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.003 (0.016)	-0.001 (0.014)	-0.008 (0.017)	-0.006 (0.016)	0.003 (0.016)	0.010 (0.037)	0.014 (0.014)	-0.019 (0.024)	0.008 (0.017)
$\mathbb{1}\{2008\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	-0.006 (0.011)	-0.003 (0.010)	-0.014 (0.013)	-0.014 (0.011)	-0.009 (0.012)	-0.004 (0.025)	0.003 (0.010)	-0.025 (0.017)	0.001 (0.012)
$\mathbb{1}\{2009\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	-0.000 (0.006)	-0.000 (0.006)	-0.007 (0.006)	-0.003 (0.006)	-0.002 (0.006)	0.003 (0.013)	0.003 (0.006)	-0.007 (0.009)	0.002 (0.006)
$\mathbb{1}\{2010\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.000 (.)								
$\mathbb{1}\{2011\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.017*** (0.006)	0.010 (0.006)	0.011* (0.007)	0.021*** (0.006)	0.016*** (0.006)	0.019* (0.011)	0.009 (0.006)	0.032*** (0.007)	0.006 (0.009)
$\mathbb{1}\{2012\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.043*** (0.009)	0.031*** (0.008)	0.031*** (0.010)	0.049*** (0.009)	0.042*** (0.009)	0.046*** (0.016)	0.032*** (0.010)	0.058*** (0.012)	0.035** (0.014)
$\mathbb{1}\{2013\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.078*** (0.013)	0.074*** (0.014)	0.067*** (0.015)	0.084*** (0.014)	0.076*** (0.014)	0.089*** (0.020)	0.053*** (0.014)	0.095*** (0.019)	0.066*** (0.017)
$\mathbb{1}\{2014\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.120*** (0.020)	0.113*** (0.020)	0.107*** (0.021)	0.124*** (0.020)	0.117*** (0.020)	0.120*** (0.027)	0.096*** (0.025)	0.114*** (0.027)	0.143*** (0.029)
$\mathbb{1}\{2015\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.151*** (0.025)	0.131*** (0.023)	0.143*** (0.027)	0.155*** (0.026)	0.149*** (0.025)	0.144*** (0.032)	0.125*** (0.032)	0.143*** (0.033)	0.184*** (0.039)
$\mathbb{1}\{2016\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.169*** (0.028)	0.157*** (0.027)	0.154*** (0.031)	0.172*** (0.030)	0.168*** (0.028)	0.156*** (0.035)	0.141*** (0.036)	0.167*** (0.036)	0.187*** (0.053)
$\mathbb{1}\{2017\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.179*** (0.031)	0.168*** (0.027)	0.169*** (0.034)	0.182*** (0.033)	0.181*** (0.031)	0.162*** (0.035)	0.146*** (0.041)	0.178*** (0.039)	0.192*** (0.058)
$\mathbb{1}\{2018\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.188*** (0.034)	0.186*** (0.030)	0.171*** (0.038)	0.191*** (0.036)	0.188*** (0.034)	0.178*** (0.035)	0.142*** (0.048)	0.202*** (0.039)	0.166** (0.071)
Q <sub>1</sub>	4.32	4.32	4.66	4.34	2.70	4.32	4.32	4.32	4.32
R <sup>2</sup>	0.982	0.985	0.982	0.981	0.982	0.989	0.974	0.984	0.972
N (drug-market-years)	356,446	356,446	178,366	316,712	356,446	118,755	237,691	149,600	153,276

Note: Table summarizes estimation results of our event study with *exposure indicator*. All specifications include drug-market, market-year, and patent expiration year-year fixed effects. Column (1) reports the results of our baseline specification. Column (2) adds therapeutic group  $\times$  year fixed effects to the baseline specification. Column (3) reports our baseline specification estimated on a balanced panel of drug-market-years. Column (4) reports our baseline specification estimated on the subset of drugs successfully linked to a New Drug Application (NDA) number. Column (5) reports our baseline specification using a simplified exposure measure that does not subtract government-financed spending from total drug-market revenue in 2010. Column (6) reports our baseline specification estimated on the subset of drugs that never experience entry of a generic alternative during our sample period. Column (7) reports our baseline specification estimated on the subset of drugs with a generic alternative. Column (8) reports our baseline specification estimated on the subset of drugs that are patent-protected throughout our sample period. Column (9) reports our baseline specification estimated on the subset of drugs that lose patent protection during our sample period. In estimation, we weight each observation by its drug-market revenue in 2010. Standard errors, in parentheses, are clustered at the drug level. N denotes the unweighted number of observations (drug-market-years). \*  $p < 0.05$ ; \*\*  $p < 0.01$ ; \*\*\*  $p < 0.001$

Appendix Table A4: Event study, linear exposure effect, baseline specification and robustness checks

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
	Baseline	Group-year FE	Balanced panel	Matched NDA	Simple exposure	Without generic	With generic	Stays on patent	Loses patent
1{2006} × gap share	-0.001 (0.002)	0.000 (0.001)	-0.001 (0.002)	-0.002 (0.002)	-0.001 (0.002)	0.002 (0.004)	-0.002 (0.002)	-0.002 (0.003)	-0.001 (0.002)
1{2007} × gap share	-0.001 (0.001)	-0.001 (0.001)	-0.002 (0.001)	-0.002 (0.001)	-0.002 (0.002)	-0.001 (0.003)	-0.001 (0.001)	-0.003 (0.002)	-0.001 (0.001)
1{2008} × gap share	-0.001 (0.001)	-0.000 (0.001)	-0.002* (0.001)	-0.002* (0.001)	-0.002 (0.001)	-0.001 (0.002)	-0.002* (0.001)	-0.003** (0.001)	-0.000 (0.001)
1{2009} × gap share	-0.000 (0.001)	-0.000 (0.001)	-0.001 (0.001)	-0.001 (0.001)	-0.001 (0.001)	0.000 (0.001)	-0.001 (0.001)	-0.001 (0.001)	0.000 (0.001)
1{2010} × gap share	0.000 (.)								
1{2011} × gap share	0.001 (0.000)	-0.000 (0.000)	0.001 (0.001)	0.001* (0.001)	0.001* (0.001)	0.002** (0.001)	0.000 (0.001)	0.002** (0.001)	-0.000 (0.001)
1{2012} × gap share	0.002*** (0.001)	0.001 (0.001)	0.002** (0.001)	0.003*** (0.001)	0.003*** (0.001)	0.004*** (0.001)	0.002** (0.001)	0.003*** (0.001)	0.002 (0.001)
1{2013} × gap share	0.006*** (0.001)	0.005*** (0.001)	0.006*** (0.001)	0.006*** (0.001)	0.008*** (0.002)	0.008*** (0.002)	0.006*** (0.001)	0.007*** (0.002)	0.005*** (0.002)
1{2014} × gap share	0.009*** (0.002)	0.008*** (0.001)	0.010*** (0.002)	0.010*** (0.002)	0.013*** (0.002)	0.011*** (0.002)	0.009*** (0.002)	0.009*** (0.003)	0.010*** (0.002)
1{2015} × gap share	0.013*** (0.002)	0.010*** (0.002)	0.013*** (0.003)	0.013*** (0.003)	0.017*** (0.003)	0.013*** (0.002)	0.013*** (0.004)	0.012*** (0.004)	0.013*** (0.004)
1{2016} × gap share	0.012*** (0.003)	0.010*** (0.003)	0.011*** (0.004)	0.013*** (0.004)	0.017*** (0.004)	0.014*** (0.003)	0.011** (0.005)	0.014*** (0.004)	0.010* (0.005)
1{2017} × gap share	0.014*** (0.003)	0.012*** (0.003)	0.013*** (0.004)	0.014*** (0.003)	0.019*** (0.004)	0.014*** (0.003)	0.012** (0.005)	0.015*** (0.004)	0.011** (0.005)
1{2018} × gap share	0.015*** (0.004)	0.014*** (0.003)	0.012*** (0.004)	0.015*** (0.004)	0.020*** (0.005)	0.016*** (0.003)	0.011* (0.006)	0.017*** (0.004)	0.008 (0.007)
R <sup>2</sup>	0.982	0.985	0.981	0.981	0.982	0.989	0.974	0.984	0.971
N (drug-market-years)	356,446	356,446	178,366	316,712	356,446	118,755	237,691	149,600	153,276

Note: Table summarizes estimation results of our event study with *linear exposure effect*. All specifications include drug-market, market-year, and patent expiration year-year fixed effects. Column (1) reports the results of our baseline specification. Column (2) adds therapeutic group × year fixed effects to the baseline specification. Column (3) reports our baseline specification estimated on a balanced panel of drug-market-years. Column (4) reports our baseline specification estimated on the subset of drugs successfully linked to a New Drug Application (NDA) number. Column (5) reports our baseline specification using a simplified exposure measure that does not subtract government-financed spending from total drug-market revenue in 2010. Column (6) reports our baseline specification estimated on the subset of drugs that never experience entry of a generic alternative during our sample period. Column (7) reports our baseline specification estimated on the subset of drugs with a generic alternative. Column (8) reports our baseline specification estimated on the subset of drugs that are patent-protected throughout our sample period. Column (9) reports our baseline specification estimated on the subset of drugs that lose patent protection during our sample period. In estimation, we weight each observation by its drug-market revenue in 2010. Standard errors, in parentheses, are clustered at the drug level. N denotes the unweighted number of observations (drug-market-years). \*  $p < 0.05$ ; \*\*  $p < 0.01$ ; \*\*\*  $p < 0.001$

## Appendix C: Manufacturer response to increased beneficiary demand

In Section 5, we find that beneficiaries became less likely to forgo prescriptions upon reaching the donut hole after the closure of the coverage gap. This implies that beneficiaries increased their demand for prescription drugs, in line with the policy change expanding insurance coverage. Standard economic theory suggests that manufacturers should increase drug prices in response to the gap closure, even had the closure not been partially funded through manufacturer rebates. In this Appendix, we calibrate a simple model of beneficiary demand to benchmark how much manufacturers should optimally increase drug prices due to the increase in beneficiary demand alone.

### Beneficiary demand

Suppose we have a unit measure of non-LIS beneficiaries. In a given month  $t$ , beneficiary  $i$  consumes a single unit of prescription drugs with probability  $\alpha_{it}$ . Denote  $d_{it} = 1$  if beneficiary  $i$  consumes prescription drugs in month  $t$ . Probability of consumption is endogenous and depends on: (i) the price of the prescription drugs  $p$  and (ii) how much the beneficiary has consumed in previous months, which determines their contemporaneous cost-sharing  $c_{it}(\cdot, \sum_{t'=1}^{t-1} pd_{it'})$ .

Expected annual revenue for manufacturers from non-LIS beneficiaries is given by:

$$E[\pi_L] = \sum_{t=1}^{12} E_i[pd_{it}]$$

where for simplicity, we assume that drug manufacturers have no marginal cost of production.<sup>53</sup> Expected revenue in month 1 is given by:

$$E_i[pd_{i1}] = p\alpha_{i1}(c_{i1}(p, 0))$$

and the derivative of expected revenue in month 1 with respect to price is given by:

$$\frac{\partial}{\partial p} E_i[pd_{i1}] = \alpha_{i1}(c_{i1}(p, 0)) + p \frac{\partial \alpha_{i1}(c_{i1}(p, 0))}{\partial c_{i1}(p, 0)} \frac{\partial c_{i1}(p, 0)}{\partial p}$$

We calibrate the probability of consumption  $\alpha_{it}$  to match empirical probabilities in the Medicare Part D data when price is set to  $p = 1$ . We set the cost-sharing function  $c_{it}$  to the standard benefit plan in 2010. We calibrate the out-of-pocket price elasticity of consumption to  $\frac{\partial \alpha_{it}}{\partial c_{it}} = -0.32$ , to match the average price elasticity estimated in Einav et al. (2018) for the 160 most common branded drugs. Expected profit in month 2 is given by:

$$E_i[pd_{i2}] = \alpha_{i1}[p\alpha_{i2}(c_{i2}(p, p))] + (1 - \alpha_{i1})[p\alpha_{i2}(c_{i2}(p, 0))]$$

Therefore, there is an additional indirect effect of price on the probability of consumption in

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<sup>53</sup>The marginal cost of production for a branded drug is typically trivial relative to its sale price.

month 2 due to changes in the beneficiary's contemporaneous cost-sharing via direct effects of price on the probability of consumption in month 1. The dynamic nature of beneficiary consumption means that while an analytical solution to the derivative of expected revenue with respect to price  $\frac{\partial}{\partial p} E[\pi_L]$  exists, in practice, it is unwieldy. Instead, we will numerically solve for the derivative  $\frac{\partial}{\partial p} E[\pi_L]$  via simulation.

## Manufacturer response

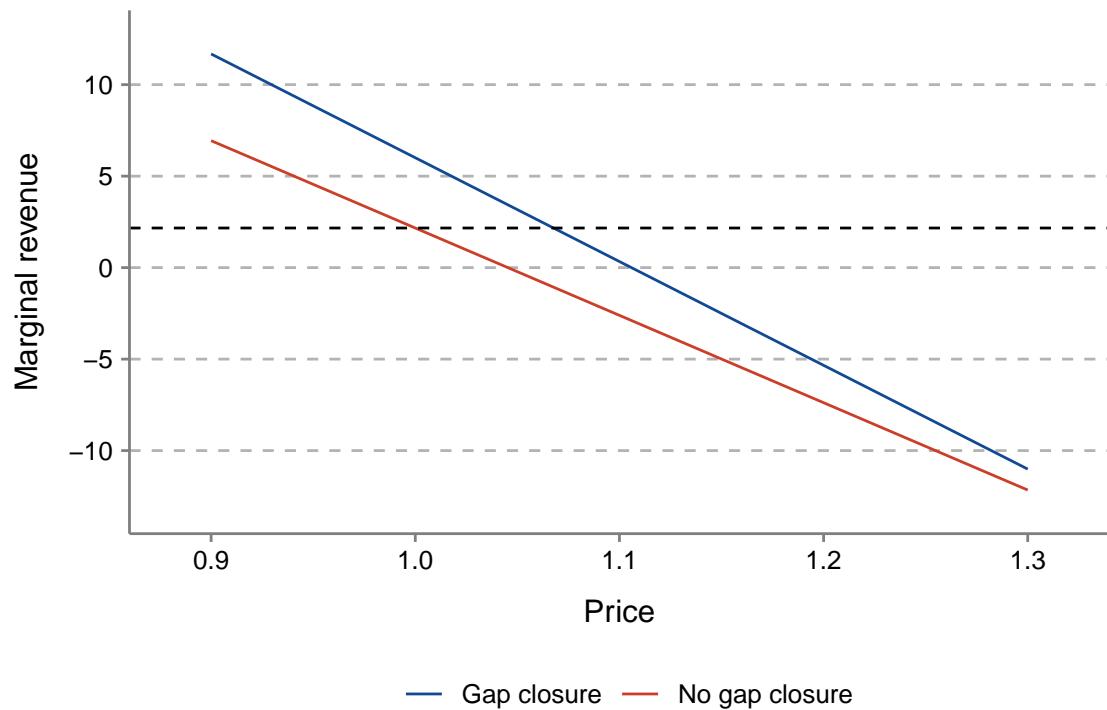
We assume that firms are profit-maximizing, meaning manufacturers set the price of prescription drugs such that marginal revenue equates some constant marginal shadow cost of increasing price:

$$\frac{\partial}{\partial p} E[\pi_L] = \lambda$$

Here, the marginal shadow cost of increasing price captures, for example, an increase in manufacturer rebates to insurers due to an increase in the price of prescription drugs. We can therefore use the firm's first order condition to infer the marginal shadow cost of increasing price. Since we calibrate the probability of consumption  $\alpha_{it}$  to match empirical probabilities in the Medicare Part D data when price is set to  $p = 1$ , this price can be interpreted as the status quo price set by manufacturers. Therefore, the marginal shadow cost of increasing price is equal to the marginal revenue when prices are set to  $p = 1$ .

This allows us to calculate the profit-maximizing price for manufacturers given a change in the cost-sharing function  $c_{it}(\cdot, \cdot)$ . In particular, we calculate the profit-maximizing price from a change in the cost-sharing function due to the closure of the coverage gap. Figure A5 presents marginal revenue for manufacturers with and without the closure of the coverage gap. We find that manufacturers should optimally increase drug prices by 6% due to increase in beneficiary demand alone from the gap closure, warranting the need to analyze strategic responses by manufacturers.

Appendix Figure A5: Marginal revenue for manufacturers with and without gap closure



Note: Figure shows the simulated marginal revenue for manufacturers with and without the closure of the coverage gap. A price of  $p = 1$  can be interpreted as the status quo price set by manufacturers.

## Appendix D: Measuring policy exposure including commercial spending

Our research design exploits variation in the exposure to the closing of the coverage gap. In this Appendix, we replicate our event study analysis using a variation of our exposure measure that additionally includes spending from beneficiaries with commercial insurance. Specifically, we measure policy exposure as drug  $j$ 's revenue from non-LIS beneficiaries in the gap relative to the *variable* revenue in market  $m$  in 2010,

$$\text{gap share}_{jm|2010} = \frac{\text{non-LIS gap}_{jm|2010}}{(\text{Part D}_{jm|2010} - \text{Part D government}_{jm|2010}) + \text{commercial}_{jm|2010}} \quad (4)$$

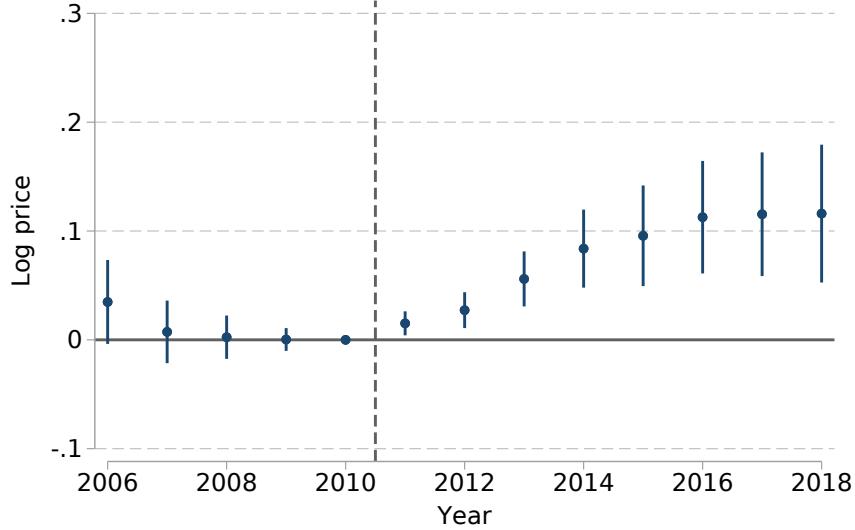
The numerator of the *gap share* is spending from claims by non-LIS beneficiaries in the gap in 2010. The denominator is market-wide total spending in 2010 (i.e., Part D spending and commercial spending) minus Part D government-financed spending, comprising LIS cost-sharing subsidies and non-LIS reinsurance in the catastrophic phase.

To calculate commercial spending, we use 2010 prescription claims from beneficiaries with commercial insurance in the Merative MarketScan® Research Databases. The Merative MarketScan® Research Databases provides deidentified, longitudinal, patient-level claims data from 2007 to 2022 for over 250 million beneficiaries enrolled in commercial plans across the U.S. To ensure comparability across data sources, we use sampling weights derived from the American Community Survey to ensure that commercial spending is nationally representative. Our sample of Part D beneficiaries is derived from a 20% random sample of the Medicare population, and we only include beneficiaries enrolled in a Part D standalone prescription drug plan (PDPs). For comparability, we multiply Part D spending by 5, and for each market, we multiply by the reciprocal of the Part D market share held by PDPs.

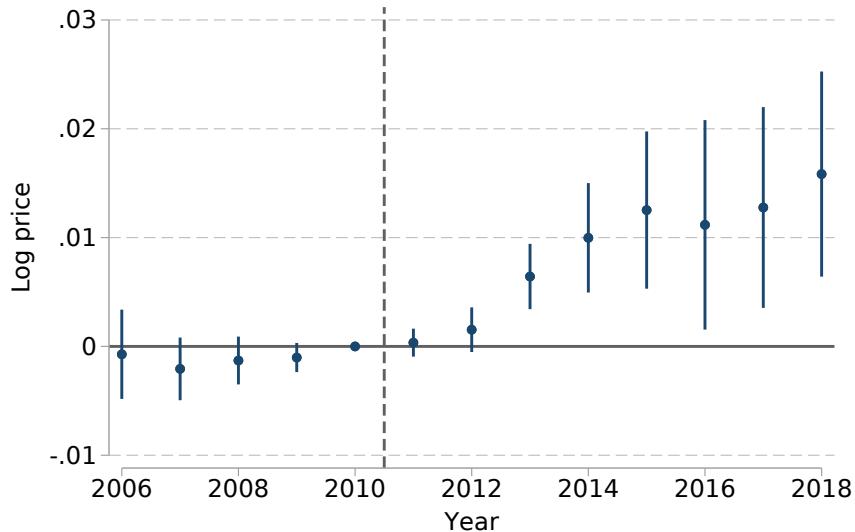
Figure A6 presents the regression results for event study specification (3) using our exposure measure that includes commercial spending. Regression results are less precise, but qualitatively similar. Our results are therefore robust to incorporating commercial spending into our exposure measure. However, we use the measure defined in Equation (2) as our preferred measure of policy exposure given that commercial and Part D beneficiaries are institutionally segmented. For example, manufacturers can directly provide price concessions to commercial beneficiaries through copay coupons, whereas the Anti-Kickback Statute prohibits Part D beneficiaries from using such coupons.

Appendix Figure A6: Effect of policy exposure on log price, baseline specifications

(A) Exposure indicator



(B) Linear exposure effect



Note: This figure illustrates the estimation results for our baseline event study specifications (3), with the exposure indicator (Panel (A)) and the linear exposure effect (Panel (B)). Our analysis sample are brand-name drugs sold in Part D markets in 2010. The exposure measure is defined in Equation (4). In Panel (A), we compare drug-markets above versus below the first quartile of the spending-weighted *gap share* distribution. In Panel (B), we impose a linear effect of policy exposure on log prices. Both event studies include drug×market, market×year, and patent expiration year×year fixed effects. We weight each observation by its drug-market revenue in 2010. Results show the point estimates  $\hat{\beta}_t$  and 95% confidence intervals. Standard errors are clustered at the drug level.

## Appendix E: Distributional implications

In Section 5 and Section 6, we document two effects of the policy change: Non-LIS beneficiaries are less likely to forgo prescription drugs upon reaching the coverage gap, and retail prices increased in response to the discount requirement and demand increase that manufacturers faced. To illustrate the qualitative implications of the endogenous price response, we examine the distributional incidence of the closing of the coverage gap across beneficiaries and the other payers in the market. We provide two pieces of model-free evidence: We first illustrate how drug spending is reallocated mechanically by the redesign of the coverage gap, and then isolate the effect of the price increase on the relative incidence across payers.

In our back-of-the-envelope calculations, we let beneficiaries progress through the standard plan design with the pre- and post-ACA cost-sharing in the coverage gap. Using the government-defined cost-sharing function, we can immediately read off how each marginal dollar of drug spending is split between payers—that is, beneficiaries, government, insurer, and manufacturer. We calculate the change in payer-specific spending using both prices and quantities before the policy change in 2010 (in the style of a Laspeyres price index), and prices and quantities after the policy change in 2015 (in the style of a Paasche price index). That is, for each payer  $k$  and beneficiary  $i$ , we compute the following two indices,

$$\Delta L_k^{2010}(i) = C_{k,2015}^{2010} \left( \sum_j p_{jm}^{2010} \times (1 + \beta_{jm}) \times Q_{ij}^{2010} \right) - C_{k,2010}^{2010} \left( \sum_j p_{jm}^{2010} \times Q_{ij}^{2010} \right) \quad (5)$$

and

$$\Delta P_k^{2015}(i) = C_{k,2015}^{2015} \left( \sum_j p_{jm}^{2015} \times Q_{ij}^{2015} \right) - C_{k,2010}^{2015} \left( \sum_j p_{jm}^{2015} \times (1 + \beta_{jm})^{-1} \times Q_{ij}^{2015} \right) \quad (6)$$

Here,  $C_{k,g}^t(\cdot)$  is the cost-sharing function for payer  $k$  implied by the standard plan design in year  $t$  with gap cost-sharing from year  $g$ ,  $p_{jm}^t$  is the retail price of drug  $j$  in market  $m$  in year  $t$ , and  $Q_{ij}^t$  is the quantity of drug  $j$  consumed by beneficiary  $i$  in year  $t$ . The term  $\beta_{jm}$  captures the endogenous price response by manufacturers.

For the Laspeyres-style index,  $\Delta L_k^{2010}$ , we focus on beneficiaries in 2010 and hold their prescription drug consumption fixed throughout. The second term of Equation (5) measures expenditure by payer  $k$  on beneficiary  $i$  at 2010 prices and the 2010 cost-sharing in the coverage gap. This corresponds to observed spending if the beneficiary was indeed enrolled in a plan with the standard benefit design. The first term of Equation (5) measures the counterfactual expenditure at 2010 prices, scaled by the endogenous price response, and the 2015 gap cost-sharing. To get the mechanical effect of the policy change, absent a price response, we set  $\beta_{jm}$  equal to zero. For the full effect, we set  $\beta_{jm}$  equal to the predicted effect based on the event study model with linear exposure effect that splits our sample of brand-name drugs by generic availability.<sup>54</sup> The Paasche-style index,  $\Delta P_k^{2015}$ , is based on

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<sup>54</sup>See Columns (6) and (7) in Table A4 for the estimation results. In the counterfactual, we only change the cost-sharing in the coverage gap and hold the spending limits that mark the coverage phase thresholds fixed.

beneficiaries in 2015. Here, we compare payer-specific spending at 2015 prices and the 2015 gap cost-sharing to counterfactual spending under the 2010 gap design, with and without prices adjusted for the endogenous effect.<sup>55</sup>

We further adjust manufacturer spending to account for reallocation via post-sale rebates, uniformly applying the average rebate rate in each year. For instance, the average rebate rate for brand-name drugs was 15% in 2010 (Boards of Trustees for Medicare 2014). Thus, for the Laspeyres-style index, we apportion 15% of the additional cost per claim for brand-name drugs—arising from the endogenous price response—to post-sale rebates.<sup>56</sup> This amount is then reallocated away from manufacturers. For clarity, we treat changes in post-sale rebates as a separate account, even though rebates are nominally transferred to insurers.<sup>57</sup> See Online Appendix B for a detailed discussion about post-sale rebates in Medicare Part D.

Our distributional analysis is a first-order approximation as we do not account for the beneficiary's spending response to cost-sharing and price changes. Thus, the Laspeyres-style index will overestimate the reduction in beneficiary out-of-pocket spending because it does not capture the demand increase due to the closing of the coverage gap. In return, the Paasche-style index will underestimate the reduction in out-of-pocket spending because it does not capture the decrease in drug consumption as we counterfactually return to the 2010 gap cost-sharing design. Therefore, the indices provide an upper and lower bound on the incidence of the policy change. Due to these caveats, our exercise is intended to demonstrate the qualitative significance of the endogenous price response rather than provide an exact quantification.

Figure A7 illustrates the results of the back-of-the-envelope calculations. Panel (A) shows the mechanical effect of the policy change, that is, the per capita reallocation of spending due to the benefit redesign. Panel (B) shows the combined effect of gap closure and endogenous price response. Overall, we find that the insurance expansion intended a per capita transfer of \$100 to beneficiaries that is largely financed by manufacturers. With prices fixed, insurers bear some cost of the expansion due to additional cost-sharing in the gap, but government financing of drug spending remains unchanged. Accounting for the price response dramatically shifts the incidence: beneficiaries only receive a per capita transfer of \$55. Manufacturers benefit from the policy change by raising prices and the additional spending is primarily financed by the government. Costs borne by insurers from higher prices are compensated by increases in post-sale rebates.

Notably, the majority of beneficiaries actually experience higher out-of-pocket costs. While the average beneficiary receives a \$55 transfer, the median beneficiary incurs a \$7

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<sup>55</sup>We chose the 2015 gap design as our counterfactual because, as in the final gap design in 2020 onward, insurance plans had to cover 5% of branded drug spending in the gap. In addition, the exposure effect stabilized in 2015. We set  $\beta_{jm}$  to zero for generic drugs and brand-name drugs that are not included in our analysis of the manufacturer response.

<sup>56</sup>By applying a uniform rebate rate, we assume that drug-specific changes in rebate rates are uncorrelated with policy exposure or the endogenous price response. The direction of rebate changes is ex-ante ambiguous as manufacturers are required to provide the gap discount in parallel to other direct and indirect remuneration. Based on reports by the Boards of Trustees for Medicare (2014; 2020), we estimate an average rebate rate for brand-name drugs of 15% in 2010 and of 30% in 2015.

<sup>57</sup>CMS accounts for post-sale rebates when determining direct subsidies to insurers. Insurers may also return post-sale rebates to beneficiaries in the form of lower premiums, although we do not observe significant changes in inflation-adjusted plan premiums from 2010 to 2018.

cost. To highlight the heterogeneous impact of the insurance expansion, Figure A8 shows a histogram of the distributional incidence across beneficiaries when allowing for an endogenous price response. The majority of beneficiaries—i.e., non-LIS beneficiaries who do not spend in the gap and LIS beneficiaries—mechanically cannot benefit from the gap closure. However, higher retail prices increase their out-of-pocket costs due to cost-sharing in all coverage phases.

To further illustrate the mechanics behind our aggregate results, Figure A9 decomposes the distributional incidence by beneficiary group. This exercise demonstrates the spillover effects of the low-income subsidy, despite the policy change not directly impacting this consumer segment. We find that, by raising prices, manufacturers can cut their losses from non-LIS beneficiaries who receive the coverage gap discount. Furthermore, manufacturers benefit from LIS beneficiaries, who consume at higher prices at the expense of the government. Via this channel, drug manufacturers can shift the incidence of discount payments onto the government. Insurers are largely unaffected by the policy change and shielded from the price increase due to post-sale rebates.<sup>58</sup>

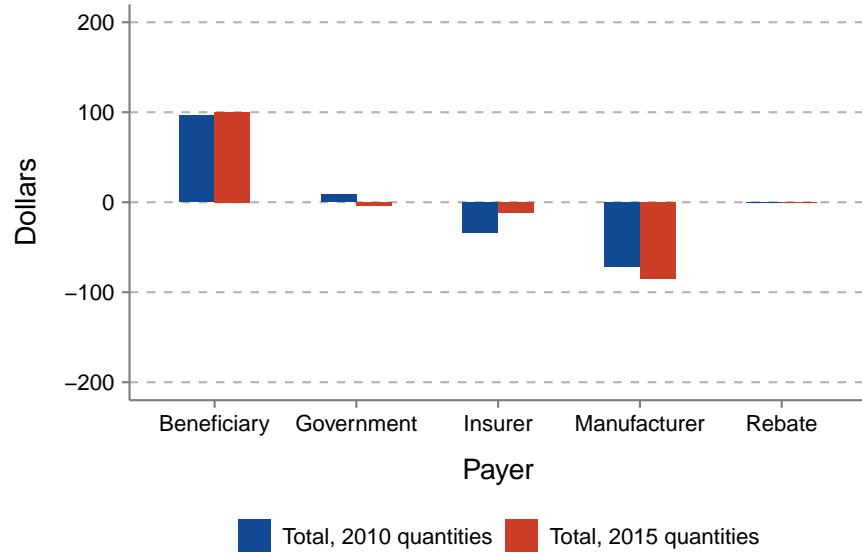
Overall, we find that the endogenous price response by manufacturers is quantitatively important for the incidence of the insurance expansion. We caveat that our results on the manufacturer incidence assume that rebate rates are exogenous, and we hold the average rebate rate in a given year fixed. Although we cannot speak to the effects of the gap closure on net-of-rebate prices, beneficiaries face retail prices when purchasing prescription drugs. Therefore, while we do not observe post-sale rebates, we still quantify the effect of the gap closure on beneficiary out-of-pocket costs.

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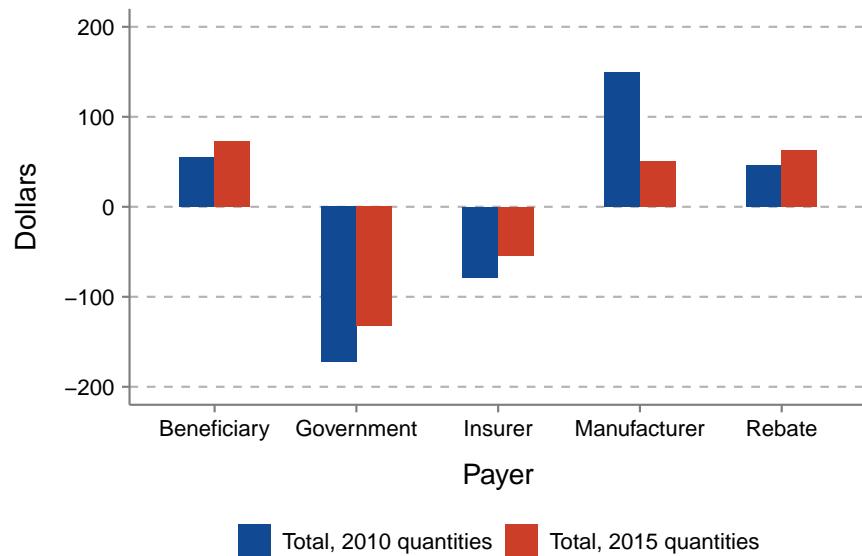
<sup>58</sup>While any losses or gains to insurers could be passed on to beneficiaries via changes in insurance premiums, we do not find significant changes in inflation-adjusted premiums in the years after the gap closure began.

Appendix Figure A7: Distributional incidence of coverage gap closure

(A) Without endogenous price response

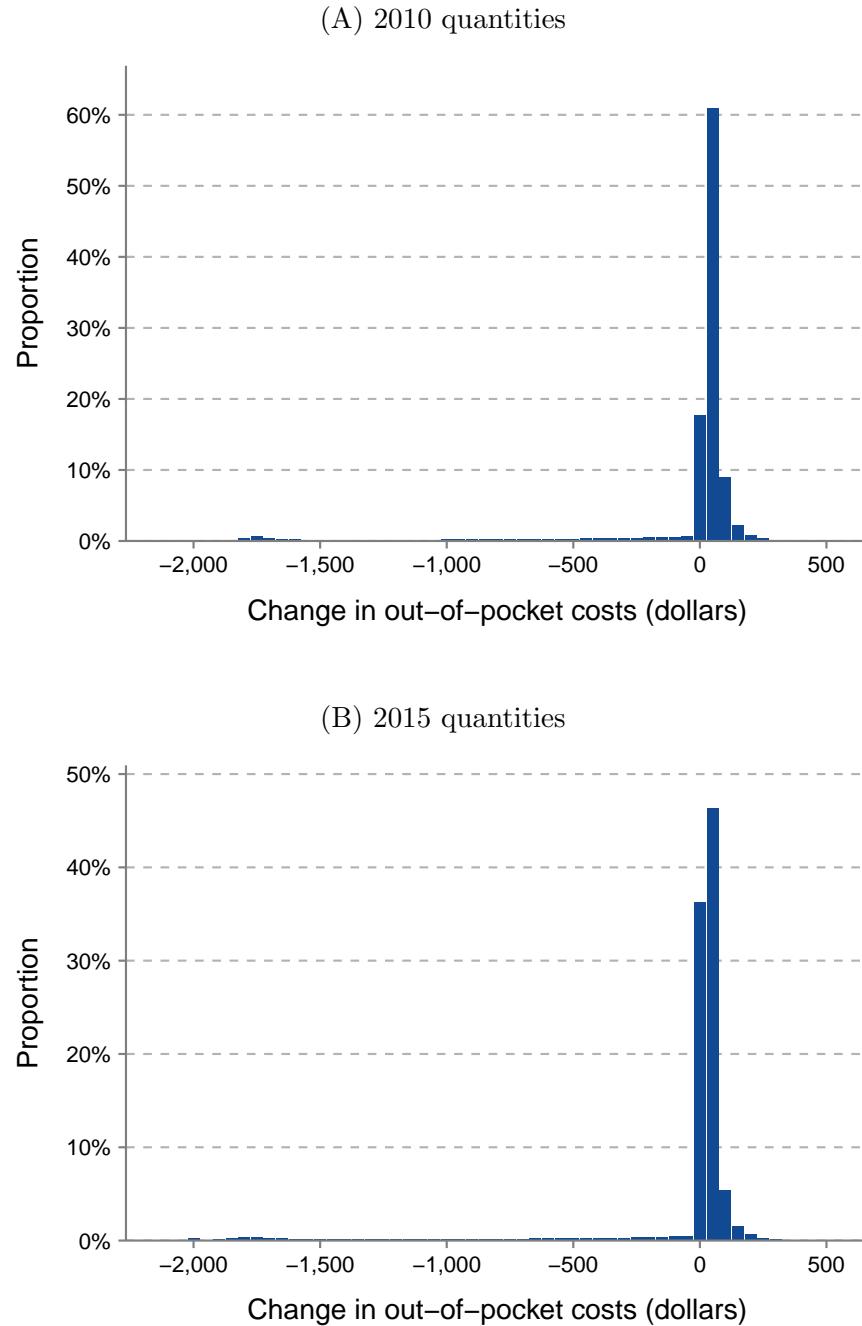


(B) With endogenous price response



Note: Figure shows the distributional incidence of the closure of the coverage gap by payer (beneficiary, government, insurer, and manufacturer) based on 2010 quantities (Laspeyres-style index) and based on 2015 quantities (Paasche-style index). Panel (A) shows the reallocation of spending across payers arising from the benefit redesign, holding prices fixed at their 2010 or 2015 level. Panel (B) shows the reallocation of spending across payers arising from the benefit redesign and the endogenous price response by manufacturers. To calculate the endogenous price response, we use the predicted effect on prices from the event study model with linear exposure effect that splits our sample of brand-name drugs by generic availability. For drugs not in our analysis sample, we hold prices fixed at their respective level. The allocation of spending for ‘manufacturer’ accounts for the average post-sale rebate level for brand-name drugs in 2010 (15%) and in 2015 (30%). Post-sale rebates are separately presented, though nominally would be allocated to insurers.

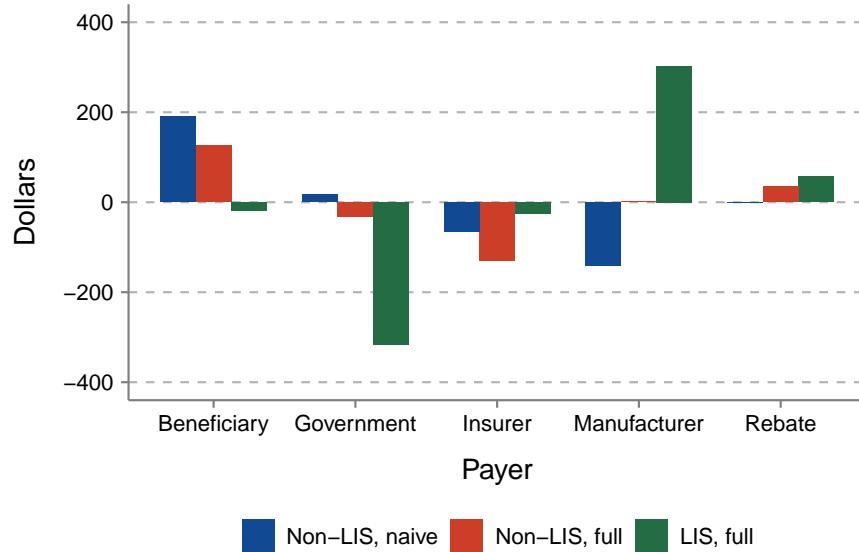
Appendix Figure A8: Distributional incidence of coverage gap closure with endogenous price response, by beneficiary



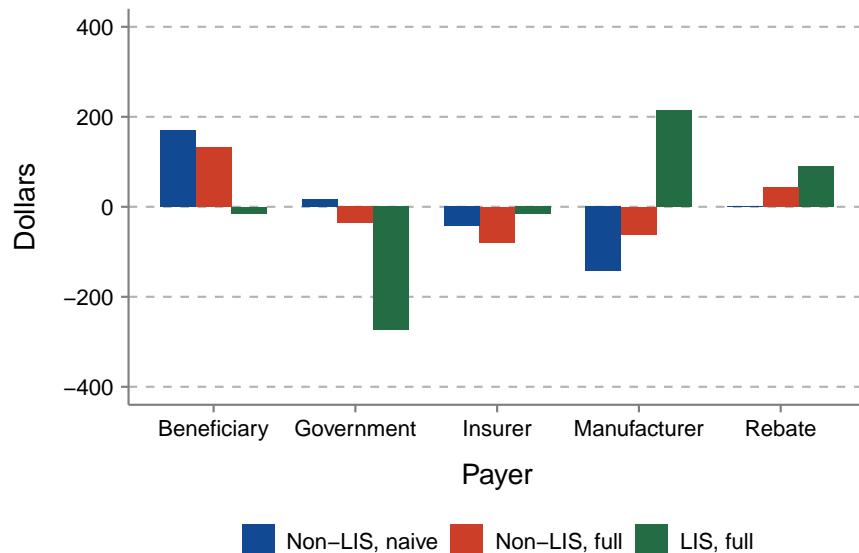
Note: Figure shows the distributional incidence of the closure of the coverage gap on out-of-pocket costs of beneficiary, based on 2010 quantities (Laspeyres-style index) and based on 2015 quantities (Paasche-style index). To calculate the endogenous price response, we use the predicted effect on prices from the event study model with linear exposure effect that splits our sample of brand-name drugs by generic availability. For drugs not in our analysis sample, we hold prices fixed at their respective level.

Appendix Figure A9: Distributional incidence of coverage gap closure, by beneficiary group

(A) 2010 Quantities (Laspeyres-style index)



(B) 2015 Quantities (Paasche-style index)



Note: Figure illustrates the mechanics behind our back-of-the-envelope calculations of the distributional incidence of the closure of the coverage gap based on 2010 quantities (Laspeyres-style index, Panel (A)) and 2015 quantities (Paasche-style index, Panel (B)). Figure shows the reallocation of spending across payers (beneficiary, government, insurer, and manufacturer) for the following cases: “Non-LIS, naive” shows the reallocation of spending by non-LIS beneficiaries that arises mechanically by the benefit redesign, holding prices fixed at their 2010 or 2015 levels. Notably, there is no mechanical reallocation of spending for LIS beneficiaries because they do not experience the coverage gap. “Non-LIS, full” shows the reallocation of spending by non-LIS beneficiaries that arises by the benefit redesign and the endogenous price response. “LIS, full” shows the reallocation of spending by LIS beneficiaries that arises from the endogenous price response. The allocation of spending for ‘manufacturer’ accounts for the average post-sale rebate level for brand-name drugs in 2010 (15%) and in 2015 (30%). Post-sale rebates are separately presented, though nominally would be allocated to insurers.

# Online Appendix

## Online Appendix A: Sample construction

This section details the construction of our analysis samples.

- 1. Administrative Medicare Part D beneficiaries and claims data:** Our sample of Part D beneficiaries is derived from a 20% random sample of the Medicare population from 2006-2018. We select all individuals enrolled in a Part D standalone prescription drug plan. Thus, we exclude Medicare-Advantage, employer-sponsored, and PACE plans—the latter two plan types are not required to report benefit package information. We measure an individual’s plan and cost-sharing group (LIS or non-LIS) in December of a given year. We group together LIS beneficiaries receiving partial or full premium and cost-sharing support. We identify all prescriptions filled by an individual in our sample and exclude claims for drugs not covered by the plan. The final sample comprises 8.2 million beneficiaries, 48 million beneficiary-years, and close to 1.9 billion claims for 74,765 unique NDC codes. This dataset is used to analyze the beneficiary response to the closing of the coverage gap in Section 5.
- 2. Drug characteristics from Merative MarketScan® Redbook:** We combine the Part D claims data with the Merative MarketScan® Redbook, which contains NDC-level information on brand status, form, route of administration, therapeutic group, and the product name given by the manufacturer. Importantly, the Redbook also contains a variable that identifies all NDCs describing pharmaceutically equivalent products, meaning products that contain the same active ingredient(s), are of the same dosage form and route of administration, and are identical in strength or concentration. We successfully merge 94.9% (70,953) of all NDCs from the Part D data, which account for more than 99.9% of Part D revenue.
- 3. National Drug Code Directory, Drugs@FDA, and Orange Book:** We obtained historical versions of NDC Directory, Drugs@FDA, and the Orange Book for the years 2006-2018 from the [Wayback Machine](#). The NDC Directory lists the universe of drug products, at the NDC level, for sale in the U.S. Importantly, it links NDC codes to the FDA-registered drug application number. The Drugs@FDA database includes information in the universe of drugs approved for human use in the U.S., such as application type (e.g., New Drug Application, Biologics License Application, or Abbreviated New Drug Application) and drug approval year. Lastly, the Electronic Orange Book contains patent and marketing exclusivity expiration dates for drugs that were ever granted such a right. We combine these three data source, which allows linkage from NDC codes to patent and marketing expiration dates.

## Online Appendix B: Post-sale rebates for brand-name drugs in Medicare Part D

In this section, we argue that our results are robust to the existence of post-sale rebates for brand-name drugs. These rebates are price concessions that manufacturers pay insurers for preferential formulary placement. Prior studies have documented that such rebates have increased considerably over the past decade. We show that these findings are not directly applicable to our setting and that the evidence on increases in rebates in Medicare Part D is less conclusive. In addition, we demonstrate that our empirical findings hold for brand-name drugs in protected drug classes where manufacturers face limited incentives to provide post-sale rebates.

**Limitations.** In Section 6, we document that the discount requirement and demand increase following the gap close led to an increase in retail prices. One concern is that manufacturers concurrently increased rebate rates, meaning that net-of-rebate prices may have actually remained constant. It is theoretically unclear whether manufacturers would increase or decrease the rebate rate in response to the gap discount. On the one hand, manufacturers have to provide an additional discount in the coverage gap and may prefer to reduce other price concessions. On the other hand, insurers may demand higher rebates as they have to cover at least a small portion of gap spending.

We cannot empirically test whether drug-level changes in rebate rates are correlated with policy exposure due to data limitations.<sup>59</sup> While we cannot account for drug-level changes in rebates, the effect of the gap closure on retail prices is nonetheless important: Beneficiaries who are not eligible for LIS are exposed to this price increase via cost-sharing. Therefore, retail prices are enough to quantify the effects of the gap closure on out-of-pocket costs for beneficiaries. Higher retail prices also push beneficiaries more quickly to the catastrophic coverage phase, where the federal government pays for the majority of drug spending at retail price.

**Evidence from SEC filings.** Several studies have analyzed estimates of net-of-rebate prices derived from SEC filings of publicly traded pharmaceutical companies (Hernandez et al. 2020; Kakani et al. 2020; Sood et al. 2020).<sup>60</sup> These studies consistently find that economy-wide rebate rates increased considerably over the past decade. However, these results are not directly applicable to our setting for two reasons. First, these studies average across all U.S. payers and capture all types of price concessions provided to insurers and consumers. In particular, they include mandatory Medicaid rebates, which are significantly higher than Medicare rebates,<sup>61</sup> copay coupons (or “copay cards”) and 340B discounts, which

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<sup>59</sup>By including market-year fixed effects, our event study flexibly controls for the average change in rebate rates in a market over time. By including patent expiration year  $\times$  year fixed effects, we also control for changes in rebate rates over the drug life cycle (e.g., one could imagine that manufacturers increase rebates as a drug approaches patent expiration).

<sup>60</sup>These studies rely on data from SSR Health, LLC. To estimate net prices, SSR Health aggregates data on net revenue from SEC filings, data on list prices and unit sales from Symphony Health, and dosing information from FDA labels.

<sup>61</sup>Only Sood et al. (2020) single out Medicaid rebates and find that discounts across all other U.S. payers

are both not available to Part D beneficiaries due to the Anti-Kickback Statute.<sup>62</sup> Second, and most notably, net-of-rebate prices derived from SEC filings after 2010 treat manufacturer discounts from the *Coverage Gap Discount Program* as a rebate.<sup>63</sup> Consequently, changes in rebate amounts derived from SEC filings will be mechanically correlated with policy exposure, rendering this data uninformative for our study.

**Evidence from government reports.** Focusing exclusively on Medicare Part D, The Boards of Trustees for Medicare (2014; 2020) report annual rebate payments as a percentage of total drug costs. Figure A10 illustrates the trend in the spending-weighted average rebate rate. Notably, the rate remains fairly stable in the first years after the gap closure, and the subsequent increase coincides with the launch of several high-cost Hepatitis C drugs in 2014-2017, which carry high rebates (The Boards of Trustees for Medicare, 2019). Thus, the trend is likely confounded by compositional changes over time and, therefore, not directly applicable to our analysis as we only consider drugs that were already sold in Part D in 2010.

Closest to our setup, a report by the Office of the Inspector General (2019) studies rebate trends in Part D for 1,510 brand-name drugs that were sold in all years between 2011-2015. The report finds that nominal rebate payments are highly concentrated, with about 10% of drugs accounting for 90% of the total rebate amount. In addition, 58% of reviewed drugs experienced an increase in the per-unit rebate amount over time, while 42% experienced a decrease. While almost all drugs saw an increase in the retail price, the rebated amount increased for only 56% of drugs. Overall, the rebate rate decreased for over half of reviewed drugs: the median rebate rate was 1.6% in 2011 and 0.3% in 2015. These numbers suggest that Part D rebate rates of incumbent drugs were fairly stable over time. In conclusion, there is mixed evidence on the level and trend of rebate rates in Medicare Part D.

**Evidence from drugs in protected drug classes.** As a robustness check, we estimate our baseline event study specification (3) focusing on branded drugs in protected drug classes. Medicare Part D has six protected classes of drugs that all plans must include in their formulary. Manufacturers have little incentive to offer post-sale rebates to insurers if coverage of a drug is required. For example, among the top 15 therapeutic classes of drugs covered under Part D by gross spending, average rebate rates in 2021 were between 0% and 9% for protected classes versus an average of 38% for other classes (MedPAC 2023). Figure A11 illustrates the regression results for branded drugs in protected classes only. In both specifications, we find a positive and statistically significant effect of policy exposure on retail prices in the years following the gap closure. Results are quantitatively similar to our main results in Figure 6, suggesting that our main results reflect an actual increase in drug prices.

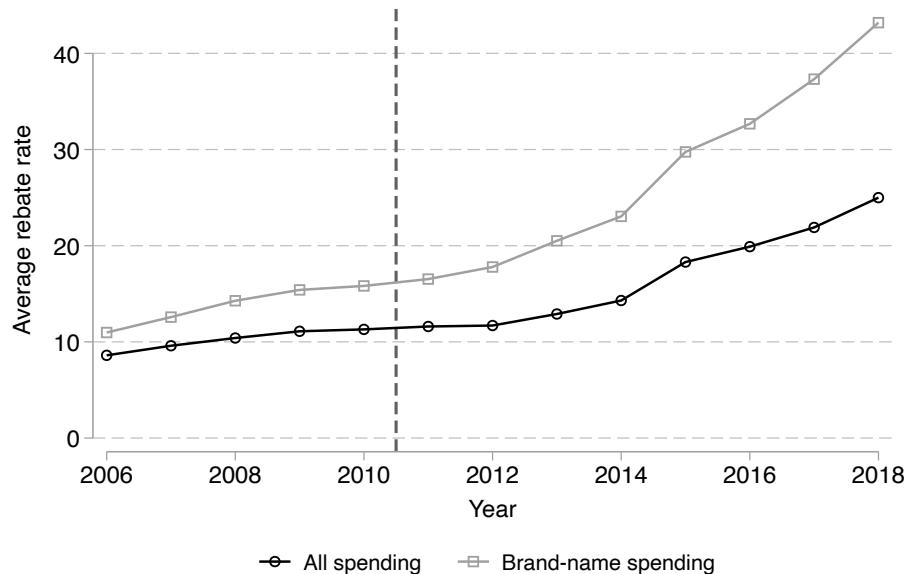
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increased from 23% to 51% between 2007-2018.

<sup>62</sup>Over this period, the availability of copay coupons for brand-name drugs increased considerably and the share of branded drug spending with a coupon in the private insurance market increased from 26% in 2007 to 93% in 2017 (Dafny et al. 2022).

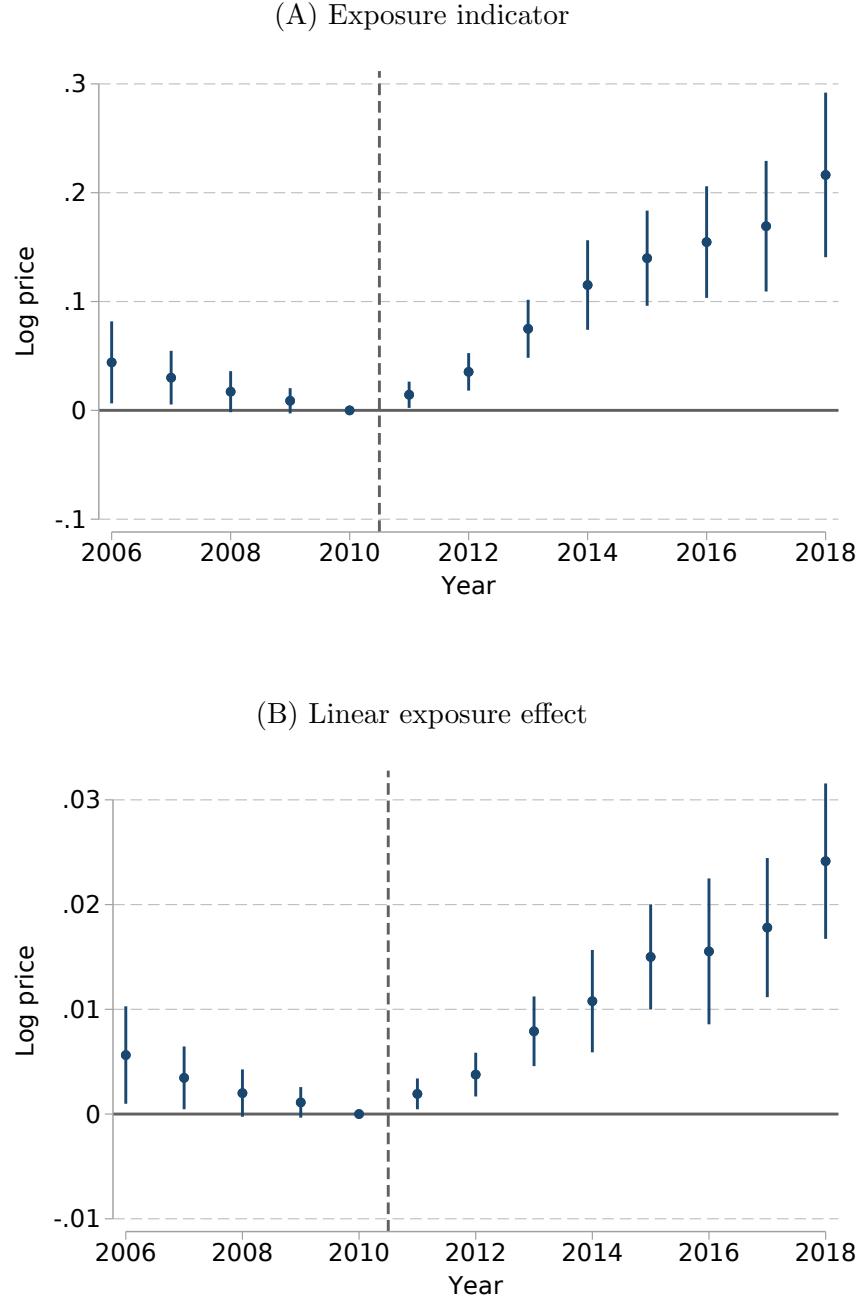
<sup>63</sup>For example, net-of-rebate revenue in the 2015 10-K filing for the Bristol-Myers Squibb Company include adjustments for the “50% point of service discount to the Centers for Medicare & Medicaid Services when the Medicare Part D beneficiaries are in the coverage gap.” Similarly, net-of-rebate revenue in the 2015 10-K filing for Pfizer include adjustments for “discounts on branded prescription drug sales to Medicare Part D participants in the Medicare coverage gap.”

Appendix Figure A10: Average Medicare Part D rebate rate



Note: Figure shows the average rebate rate in Medicare Part D, as reported by The Boards of Trustees for Medicare (2014; 2020). Rebate rate is total direct and indirect remuneration negotiated by Part D plans with drug manufacturers and pharmacies divided by total drug cost. The black line (with circles) illustrates the spending-weighted average rate. The gray line (with squares) is a conservative upper bound for the spending-weighted average rebate rate for brand-name drugs, accounting for the aggregate decrease in spending on brand-name drugs (relative to generic drugs) and assuming that generic drugs have zero remunerations.

Appendix Figure A11: Effect of policy exposure on log price for drugs in protected classes, baseline specifications



Note: This figure illustrates the estimation results for our baseline event study specifications (3), with the exposure indicator (Panel (A)) and the linear exposure effect (Panel (B)). Our analysis sample are brand-name drugs in protected classes sold in Part D markets in 2010. The exposure measure is defined in Equation (4). In Panel (A), we compare drug-markets above versus below the first quartile of the spending-weighted *gap share* distribution. In Panel (B), we impose a linear effect of policy exposure on log prices. Both event studies include drug×market, market×year, and patent expiration year×year fixed effects. We weight each observation by its drug-market revenue in 2010. Results show the point estimates  $\hat{\beta}_t$  and 95% confidence intervals. Standard errors are clustered at the drug level.

## Online Appendix C: Further provisions of the ACA related to the pharmaceutical market

This Appendix summarizes further provisions that were implemented as part of the Affordable Care Act and involved the pharmaceutical market. The timeline is based on the Board on Health Care Services ([2014](#)), Aitken et al. ([2016](#)) and Conti et al. ([2020](#)). We do not believe any of these provisions would differentially impact drugs with high exposure to the *Coverage Gap Discount Program*.

1. Starting January 2010, the mandatory minimum rebate that manufacturers have to provide for brand-name drugs sold under *Medicaid* increased from 15.1% to 23.1%. In addition, manufacturers have to pay an additional rebate if drug prices increase faster than inflation. The latter provision has been the main reason for the rise of Medicaid rebates over time (Office of the Inspector General Inspection General ([2019a](#))). Notably, dual-eligible beneficiaries, who receive both Medicare and Medicaid, receive drug coverage primarily through Medicare and are included in our empirical analysis.
2. Starting January 2011, drug companies with annual sales to government programs exceeding \$5 million have to collectively finance the *Branded Prescription Drug Fee* of \$2.5-4.1 billion annually, which funds the *Medicare Part B* Trust Fund. The fee per drug company is proportional to annual sales.
3. Starting October 2013, the *ACA Marketplaces* opened for enrollment.
4. Starting January 2014, *ACA expansion states* increased Medicaid eligibility criteria for all low-income adults.

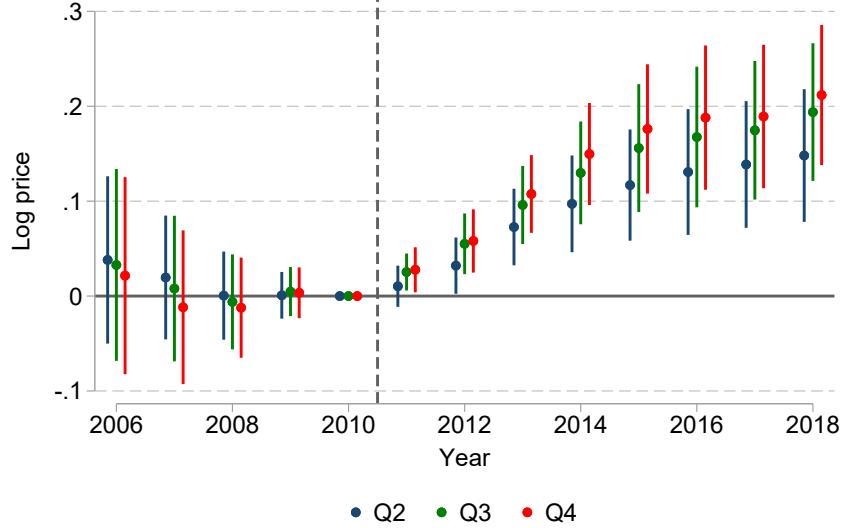
## Online Appendix D: Event study with exposure quartiles

We augment the event study model with exposure indicator by separate indicator variables for drug-markets in the second, third, or fourth quartile of the *gap share* distribution. By splitting the *gap share* into quartiles, we allow the effect on retail prices to be non-linear in exposure. We estimate this specification separately for drugs with and without generic alternative.

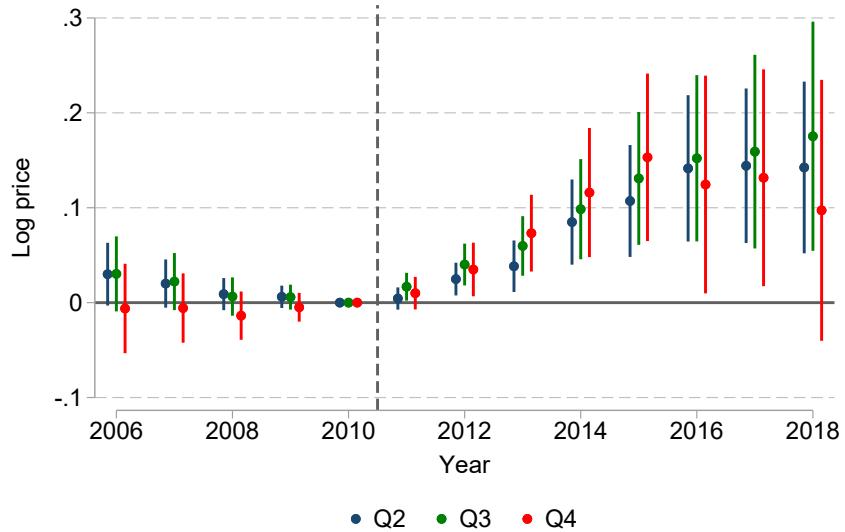
Figure A12 illustrates the results. We find a clear trend for drugs without generic competition: Consistently, the effect on prices is increasing across exposure quartiles, suggesting that manufacturers raised prices more if they were more reliant on revenue from non-LIS beneficiaries in the gap. For 2018, prices are 16% higher for drugs in the second quartile, relative to drugs in the first quartile, 21% higher for drugs in the third quartile, and 24% higher for drugs in the fourth quartile. While this trend holds qualitatively, point estimates are not statistically different across quartiles in most post-policy years. Overall, the results suggest that the effect on retail prices is concave in exposure: On average, drugs in the second quartile made 6.6% of their variable revenue from non-LIS in the gap, compared to 16.2% in the fourth quartile. For drugs with generic alternative, we detect the same trend in early post-policy years. Starting 2016, the differences across quartiles dissipate, presumably reflecting more stringent competition.

Appendix Figure A12: Effect of policy exposure on log price, exposure quartiles

(A) Without generic



(B) With generic



Note: Figure illustrates estimation results for our event study specification with separate indicator variables for the second, third, and fourth quartile of the *gap share* distribution. Our analysis sample are brand-name drugs sold in Part D in 2010. Our drug-market specific exposure measure is defined in Equation (2). In this specification, we compare drug-markets below the first quartile of the spending-weighted *gap share* distribution to drug-markets in the second, third, or fourth quartile. The event study includes drug-market, market-year, and patent expiration year-year specific fixed effects. We implement the event study separately for drugs with and without a generic alternative. We weight each observation by its drug-market revenue in 2010. Results show the point estimates and 95% confidence intervals. Standard errors are clustered at the drug level.