The Impact of the 340B Drug Pricing Program on Critical Access Hospitals: Evidence from Medicare Part B

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Abstract

The 340B Drug Pricing Program allows qualifying public and not-for-profit hospitals to acquire most outpatient drugs from manufacturers with sizable discounts. Since the Affordable Care Act (ACA) extended hospital eligibility for 340B, over 1,000 Critical Access Hospitals (CAHs) have joined the program. Because CAHs are reimbursed by Medicare at 101% of costs, they receive less payment per outpatient drug covered by Medicare Part B under 340B. This creates a unique circumstance in which both the behavioral response of CAHs and its implications for their patients are not well understood. Exploiting the ACA's 340B expansion and leveraging the geographic variation in the outpatient market share of CAHs via a difference-in-difference (DD) framework, I find that allowing CAHs to participate in 340B led to a significant reduction in total payment and beneficiary cost sharing for Part B drugs per patient without noticeable effect on Part B drug utilization. Since Part B coinsurance at CAHs is based on charges (list prices set by hospitals) instead of total payment, I show that the observed reduction in beneficiary cost sharing under 340B was driven by CAHs reducing outpatient drug charges upon becoming eligible for 340B (DD) and participating in 340B (event study). I argue that the pass-through of 340B discounts to patients was not financially motivated.

JEL classification: I1, L2

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1 Introduction

In 1992, Congress established the 340B Drug Pricing Program to allow qualifying providers to purchase most prescription drugs for outpatient use with discounts estimated between 20% and 50% of the cost of the drugs (Government Accountability Office, 2011). Roughly 45% of the nation's hospitals currently participate in the program. Once enrolled, hospitals can provide the discounted drugs to almost any patients regardless of their health insurance coverage. In many cases, insurers have continued to reimburse 340B-covered drugs and non-340B drugs at the same rates, rendering 340B-covered drugs more profitable. Mounting evidence suggests that hospitals may be financially incentivized by 340B to increase the use of outpatient drugs particularly for well-insured patients, creating a tension between the two initial motivations of the program – financial relief for providers and better care for disadvantaged patients (Conti and Bach, 2014; Desai and McWilliams, 2018).

Yet, for the majority of rural hospitals participating in 340B, known as the Critical Access Hospitals (CAHs), the impact of 340B is ambiguous. Unlike non-CAH hospitals, CAHs are reimbursed by Medicare at 101% of costs for most services.[1] As 340B discounts bring down the costs of outpatient drugs for participating CAHs, Medicare reimbursement and profit for these hospitals also adjust downwards proportionally, obscuring the financial incentive and leading to a potential trade-off for CAHs given that these hospitals tend to have a relatively high Medicare payer mix. Considering the essential role that CAHs play in the rural health care safety net and the vulnerable financial situation facing rural hospitals in general (iVantage Health Analytics, 2016), the impact of 340B on CAHs has important policy implications. Furthermore, the behavioral responses of CAHs to 340B can shed light on the motive of not-for-profit (and public) hospitals, which has long been a topic of academic interest. It is also highly relevant as the public increasingly questions the justification for not-for-profit hospital tax exempt status (Rosenthal, 2013).

In this work, I study the effects of 340B on the utilization of and spending on Medicare-covered physician-administered outpatient drugs (hereinafter "Part B drugs") at CAHs, taking advantage of a policy change under the Affordable Care Act (ACA) that extended the eligibility for 340B to most CAHs. Drawing from the literature on the economic behaviors of hospitals, I discuss a simple conceptual framework to illustrate how CAHs may change their behaviors in response to

[1] Typically, general acute care hospitals that are not CAHs are reimbursed by Medicare at pre-determined national payment rates set forth in the Prospective Payment System rules. Payment rates for outpatient drugs covered by Medicare Part B are primarily based on the average sales price for a drug. The average sales price excludes any sales to 340B providers and therefore remains largely unaffected by 340B discounts.

340B across several dimensions. Using data from Medicare claims over the period 2008-2013, I estimate the effects of 340B expansion through difference-in-different methods (DD). I begin with a hospital-level identification, comparing outcomes between 340B-eligible CAHs and a group of hospitals that did not experience a change in 340B eligibility. My main identification strategy relies on the pre-ACA outpatient market share of 340B-eligible CAHs in a geographic area to approximate the treatment intensity of 340B expansion in that area. By comparing changes in outcomes across areas with varying degrees of exposure to 340B expansion, I generate dose-response type estimates that encapsulate general equilibrium effects.

In contrast to existing knowledge of the cost impact of 340B, I show that, in areas with higher CAH market share – thus potentially affected by ACA's 340B expansion to a greater extent – 340B led to a significant reduction in Part B drug spending in the hospital outpatient setting. Per every 10-percentage point increase in predicted treatment intensity of the 340B expansion, 340B decreased total payment, Medicare program payment and beneficiary copayment for Part B drugs by an average of $77, $69 and $24 per patient (or 3.7%, 4.3% and 5.7% of sample means), respectively. I estimate larger spending reductions after removing areas unaffected by the expansion due to an absence of CAHs in those areas and zooming in on the more policy-relevant population. Meanwhile, I do not find evidence that 340B increased or decreased Part B drug utilization, which is measured as the probability of receiving Part B drugs and the number of Part B drug events per patient. I show that these findings are generally robust to different patient samples and alternative functional form, and are unlikely to be driven by differential substitution towards Part D drugs and low-cost Part B drugs or contemporary changes in Part B drug payment rates. As a placebo test, I show that for non-elderly Medicare beneficiaries, the majority of whom had Medicaid coverage and therefore should not be affected by 340B due to a special Medicaid billing rule, the 340B expansion had little impact on the outcomes.

When focusing on Part B drugs administered by non-institutional providers (i.e., physicians practicing in an office setting), I do not observe any disproportionate changes in the outcomes in areas more affected by 340B expansion relative to those less affected by it. Nor do I find evidence for 340B-associated shift towards billing for Part B drugs with a place of service code indicating hospital outpatient department – the presence of which would imply increased hospital-physician integration.

Given that Medicare beneficiaries pay 20% of the list price set by hospitals for Part B drugs

received in CAHs, I show that the observed reduction in beneficiary copayment was driven by a reduction in charges for outpatient drugs among CAHs upon becoming eligible for 340B (DD) as well as participating in 340B (event study). This provides suggestive evidence that CAHs passed a fraction of the 340B discounts along to Medicare beneficiaries, potentially alleviating the financial burden facing those with no or only partial supplemental insurance coverage. The pass-through of 340B discounts likely benefits uninsured and other self-paying patients as well, since these patients are typically billed at full charges upon receiving hospital care (Tompkins, Altman, and Eilat, 2006; T. Xu et al., 2017). Moreover, this result implies non-financial motive of public and not-for-profit CAHs concerning patient welfare. I discuss in the conceptual framework why financial incentives for these hospitals to adjust charges based on 340B pricing are weak.

My research contributes to the understanding of 340B by studying an overlooked but important group of hospitals that account for almost half of all 340B-covered hospitals. It is also related to the literature on hospital response to payment policies. My analysis uncovers meaningful cost reductions under the 340B expansion for both the Medicare program and rural patients. Using the estimates from my analysis, a back-of-envelope calculation suggests that, by allowing CAHs to join 340B, the expansion reduced Medicare program payment by roughly $160 million and beneficiary cost sharing by $49 million in the aggregate over the five quarters after the 340B expansion took effect. Since CAHs are prohibited from purchasing orphan drugs through 340B, the results highlight a missed opportunity for helping rural hospitals to provide the least affordable yet life-saving medications. Finally, the null effects of 340B expansion in non-institutional settings are in line with prior research showing a lack of evidence for hospital-physician integration associated with the 340B expansion (Alpert, Hsi, and Jacobson, 2017). In complementary work, I explore the financial impact of 340B on hospitals by describing the nature of the 340B financial shocks for CAH and non-CAH hospitals separately and examining how hospitals respond to these shocks in terms of pharmacy staffing and service offering (Han, 2019).

2 Institutional Background

2.1 The 340B Drug Pricing Program

In 1992, Congress created the 340B program under the Veterans Health Care Act as an extension of the Medicaid Drug Rebate Program to certain clinics and public or private not-for-profit hospitals.

Upon participating in 340B, providers can acquire outpatient drugs from manufacturers at prices substantially lower than what they otherwise would have paid.[2] The initial intent of 340B was to reduce the financial stress facing safety-net providers, with the expectation that these providers will use the extra resources to improve patient care and access.[3] Most prescription drugs, including over-the-counter drugs written on a prescription, and certain biological products other than vaccines are subject to 340B pricing.[4]

Drug manufacturers may charge a 340B-covered provider up to a maximum price, referred to as the 340B ceiling price, for the purchase of a 340B-covered drug. Theoretically, the 340B ceiling price is similar to the price paid by Medicaid under the drug rebate program. In practice, providers can obtain further discounts by joining the 340B Prime Vendor Program, which negotiates prices below the ceiling prices on behalf of its participants. It is estimated that the discounts realized through 340B range from 20% to 50% off non-340B prices (Government Accountability Office, 2011). In 2015, the program saved an estimated $6 billion for participating providers on outpatient drugs that would have cost $18 billion (Health Resources and Services Administration, 2017).

340B-acquired drugs may be administered or dispensed to almost any patients regardless of their health insurance coverage.[5] Most insurers, including Medicare prior to 2018, reimburse providers for outpatient drugs at rates irrespective of 340B pricing, making 340B-acquired drugs more profitable.[6] For example, in 2013, Medicare payments for Part B-covered outpatient drugs exceeded 340B ceiling prices by an average of 58%; for several high-expenditure cancer drugs, the difference between Part B payment and acquisition cost for 340B covered providers was at least 10 times higher than it was for non-340B providers (Office of Inspector General, 2015). On the other hand, State Medicaid programs generally require 340B providers to use drugs purchased through non-340B channels for Medicaid patients, or to bill Medicaid at acquisition costs if they choose to

[2]Drug manufacturers must agree to offer discounts to 340B-covered providers in order for their drugs to be included in Medicaid's drug formulary.

[3]Many claimed that the Medicaid Drug Rebate Program led to drug price hike for non-Medicaid purchasers, as drug manufacturers rolled back discounts for these purchasers to increase the "best price" involved in the Medicaid rebate calculation. 340B was the result of lawmakers' attempt to counter the unintended consequence of the drug rebate program.

[4]In the past, rural hospitals and cancer hospitals were allowed to purchase orphan drugs for off-label use through 340B (78 FR 44016); beginning in 2015, these hospitals could no longer use 340B to acquire orphan drugs.

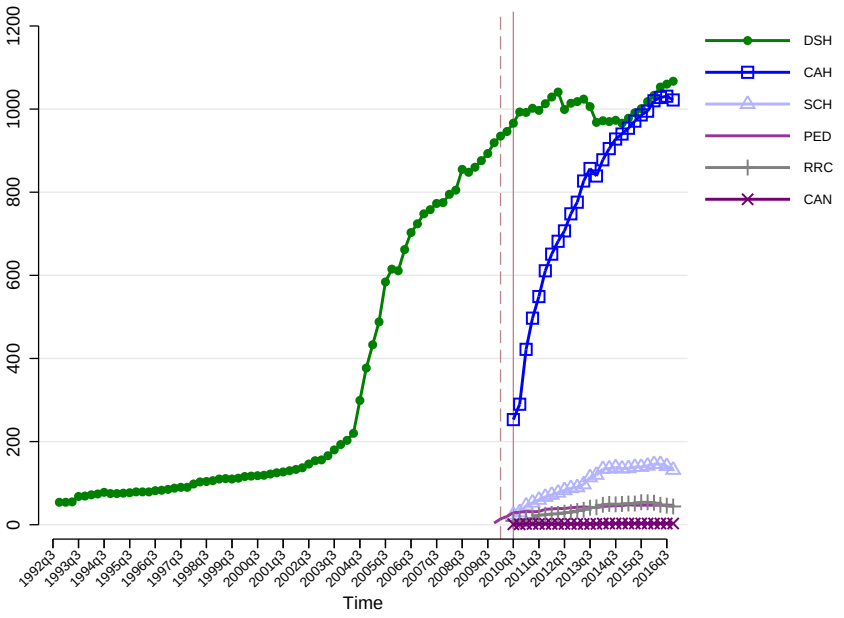
[5]Specifically, to qualify for 340B-acquired drugs, a patient must receive a health care service other than dispensing of drugs for subsequent self-administration or administration in the home setting from a 340B covered provider and the 340B provider is medically responsible for the care rendered to the patient.

[6]In 2018, Medicare cut Part B payment to most 340B hospitals paid under the Outpatient Prospective Payment System (OPPS) for 340B discounted drugs by almost 30 percent.

use 340B-acquired drugs for Medicaid patients, effectively eliminating any financial gain from the discounts (Office of Inspector General, 2011b).[7]

As of 2016, roughly 45% of the nation's hospitals participated in 340B. Table A1 presents a brief timeline of 340B and the policies that led to each expansion of the program. Initially, only public and not-for-profit general acute care hospitals with a Medicare disproportionate share payment adjustment ("DSH" adjustment) above 11.75% were eligible for 340B. A major expansion of the program took place in 2010, when the ACA extended 340B eligibility to public and not-for-profit Critical Access Hospitals (CAH), and lowered the DSH adjustment threshold to 8% for a small number of other rural hospitals. Because CAHs do not receive Medicare DSH adjustment, they are not subject to the DSH adjustment percentage eligibility threshold, allowing them to participate in 340B more easily. By the end of 2016, slightly over 80% of eligible CAHs have joined the program, nearly doubling the number of 340B covered hospitals (Figure 1).

Figure 1: Hospitals Participation in 340B, 1992-2016



Notes: Cumulative participation based on author's analysis of the 340B administration records. DSH = Disproportionate Share Hospital, CAH = Critical Access Hospital, SCH = Sole Community Hospital, PED = Children's Hospital, RRC = Rural Referral Center, CAN = Free-Standing Cancer Hospital. Children's hospitals became eligible for 340B in 2006 under the Deficit Reduction Act; free-standing cancer hospitals become eligible under the ACA. See Table A1 for more details.

[7]The goal of Medicaid's billing requirement for 340B-acquired drugs is to prevent drug manufacturers from paying duplicate Medicaid rebates.

2.2 Critical Access Hospitals

CAHs are small rural hospitals that represent over 60% of rural hospitals in the US (Medicare Payment Advisory Commission, 2016). The CAH designation was created as part of the Medicare Rural Hospital Flexibility Program (the Flex Program) under the Balanced Budget Act of 1997. Under this designation, hospitals opt out of Medicare's Prospective Payment System and instead receive Medicare cost-based reimbursement. In return, they must be located in rural areas at more than a certain distance from other hospitals or CAHs, maintain 25 or fewer inpatient beds, and operate 24/7 emergency services, among other requirements.[8]

There are about 1,300 CAHs across 45 states. Five state do not participate in the Flex Program and therefore cannot certify the CAH designation.[9] The number of CAHs grew considerably before 2006 but has remained relatively stable since then.[10] Given the uneven distribution of rural areas across the US, around 40% of CAHs are in the Midwest.

Due to their rural location, CAHs have a predominant public payer mix, and are especially dependent on Medicare (Moss, Holmes, and Pink, 2015). On average, over 70% of CAHs' inpatient revenue and about 40% of their outpatient revenue come from Medicare.[11] In addition, Medicare Part B drugs account for about 45% of total outpatient drug costs at CAHs, as compared to approximately 30% among non-CAH hospitals.[12] Moreover, over 90% of CAHs are either not-for-profit or publicly owned. Despite their unique institutional setup, CAHs provide a range of services similar to those commonly provided by general acute care hospitals (Office of Inspector General, 2013).

CAHs serve as the major hospital care providers in rural areas, accounting for over 50% of inpatient days and close to 60% of non-emergency hospital outpatient visits in rural counties; they

[8] A review of the legislative history for CAHs can be found at http://www.aha.org/advocacy-issues/cah/history.shtml. More details about CAHs requirements can be found https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CritAccessHospfctsht.pdf

[9] These states are New Jersey, Delaware, Rhode Island, Connecticut and Maryland.

[10] Before 2006, hospitals that failed to meet the distance requirement could still be certified as CAHs per state-specific designation of "necessary provider" to serve areas in short supply of health care resources. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 prohibited certifying new "necessary provider" CAHs, but existing "necessary provider" CAHs have been allowed to retain their status as long as they continue to meet all the other CAH requirements. The majority of CAHs today remain "necessary provider" CAHs (Office of Inspector General, 2013).

[11] Author's analysis of Medicare cost reports.

[12] *Ibid.*

also account for nearly 60% of Medicaid-covered inpatient days in rural counties.[13] Considering their small bed size, CAHs care for a disproportionate share of low-income patients, playing an essential role in the rural health care safety net.

2.3 Medicare Part B Drug Reimbursement and 340B

Medicare covers outpatient drugs administered by physicians in a hospital outpatient setting or office setting through its medical insurance component known as Part B. There are two payment schemes under Part B, the prevailing Outpatient Prospective Payment System (OPPS), and the cost-based reimbursement system that applies only to CAHs (Table A2).

For non-CAH hospitals, OPPS calculates the payment rate for a Part B drug based on the average sales prices (ASP) of the drug. ASP excludes any sales to 340B purchasers and is therefore largely unaffected by 340B pricing. Because OPPS pays all hospitals at the same rate for the same drug, hospitals participating in 340B could obtain bigger profit margin on Part B drugs given the discounts they get from 340B. Beneficiary Part B cost sharing, which is 20% of the OPPS payment rate, and Medicare portion of the payment, do not differ by hospital's 340B participation status.

By contrast, Medicare reimburses CAHs at 101% of the cost of a Part B drug, guaranteeing full-cost reimbursement and allowing for a 1% profit margin. As a result, CAHs that participate in 340B incur less expense on outpatient drugs but are also paid less by Medicare on a per-drug basis. In addition, beneficiaries receiving Part B drugs in CAHs are responsible for 20% of charges for those drugs in cost sharing. Since CAHs (and hospitals in general) can set charges arbitrarily, price reductions like the ones introduced by 340B do not necessarily lead to reductions in charges for the benefit of the patient. Without charge adjustment, beneficiaries could still face the same cost sharing even when the total payment rates for CAHs decrease, whereas the Medicare program would absorb most of the cost savings from the 340B discounts.

2.4 Hospital Response to 340B

The extent to which 340B benefits hospitals versus patients has been a politically charged issue in recent years. Drug companies argued that many hospitals capitalize on 340B without helping low-income patients, compromising the original intent of the program (Pollack, 2013). Such concern has

[13] Author's calculation based on the 2013 American Hospital Association's Annual Survey of Hospitals. County urban-rural stats is based on the National Center for Health Statistics classification, more details please see https://www.cdc.gov/nchs/data_access/urban_rural.htm.

received increasing attention from policy makers (Pollack, 2013; Government Accountability Office, 2015; Office of Inspector General, 2015). In an effort to curtail the excessive financial incentive created by 340B, in 2018 the Centers for Medicare and Medicaid Services (CMS) implemented a near-30% payment cut to most OPPS hospitals participating in 340B for Part B drugs acquired through the 340B program (81 FR 79562).

There is a small literature on the topic of hospitals' response to 340B, and the research has almost exclusively focused on non-CAHs hospitals. Using a regression discontinuity design that exploits the DSH adjustment threshold, Desai and McWilliams (2018) find that 340B increases hospital-physician integration in drug-intensive specialties and per-patient Part B drug utilization but has no effect on the care for low-income patients or patient mortality. Descriptive work by Conti and Bach (2014) suggests that increasingly, non-CAH hospitals participating in 340B have allowed affiliated clinics located in less disadvantaged communities to claim 340B discounts. Recent work by Nikpay, M. Buntin, and Conti (2018) shows that hospitals joining 340B between 2004 and 2015 do not differ from non-participating hospitals in terms of operating margin, uncompensated care burden and the offering of low-profit services.[14]

Alpert, Hsi, and Jacobson (2017) is directly related to the institutional setting of my study. Using data from SK&A and the American Hospital Association annual survey over 2003-2015, the authors show that hospital ownership of oncology practices in counties with and without hospitals newly eligible for 340B evolved on similar trends before and after the ACA's 340B expansion. They conclude that 340B expansion is unlikely to be driving the upward trend in consolidation observed after the ACA.[15]

To date, CAHs have stayed insulated from the debate over 340B, despite accounting for almost half of all 340B-covered hospitals. Given the important role they play in the rural health care system, it is imperative to understand how 340B affects these hospitals and the communities they serve. Moreover, past studies examining the effect of 340B on charity care often rely on hospital-level administrative data that are potentially prone to measurement errors (Government Accountability Office, 2015; Nikpay, M. Buntin, and Conti, 2018), whereas in the CAH context it is possible to

[14]Their sample is limited to urban hospitals with 100 and more beds.

[15]A related study by Jung, W. Y. Xu, and Kalidindi (2018) suggests a disproportionate shift in the site of cancer drug administration from office setting to hospital outpatient settings in markets that had a new 340B covered hospital compared to markets that did not between 2010 and 2013. However, the authors do not identify the source for the observed shift, and so it is unclear whether it was driven by CAHs or by non-CAH hospitals.

directly measure pass-through of 340B discounts by observing the movement of outpatient drug charges. Finally, while a number of studies have looked at the effect of the Flex Program and CAH conversion on hospital closure and patient welfare (Gowrisankaran et al., 2018; Carroll, 2019), few address the interaction of health care policies and CAH cost-based reimbursement and its implications in terms of hospital behaviors. This study contributes to the literature by describing hospital response to an exogenous cost reduction in a context where hospitals' ability to respond to incentive may be limited by reimbursement policies and their rural location.

3 Conceptual Framework

3.1 Utilization of Part B Drugs

The impact of 340B on Part B drug utilization largely depends on whether there is a response of CAHs and physicians to lower drug prices. 340B could drive CAH supply of Part B drugs through two main channels – cash constraints and profit incentive.[16] First, under cost-based reimbursement, CAHs always have the incentive to provide more drugs but may be unable to do so due to liquidity constraints. 340B reduces the acquisition cost of outpatient drugs, which allows CAHs to increase provision of Part B drugs assuming fixed budgets. Second, lower Medicare payment rates for Part B drugs due to cost reduction could negatively impact CAHs' profits and their ability to cover fixed cost or finance unprofitable services, which creates an incentive for CAHs to provide more drugs to recoup the foregone profits. While the decision to prescribe medications is made by the physician rather than hospital administrator, given that the supposed interest of patients and that of hospitals in pursuing more treatment are generally aligned in a cost-based reimbursement environment, presumably physicians would be willing to increase treatment as long as the benefits to patients remain positive (Ellis and McGuire, 1986).[17]

[16] Throughout the study, I assume (but cannot verify precisely given lack of transaction/invoice data) that 340B lowers outpatient drug acquisition costs for CAHs. Although the level of actual cost reduction may vary from hospital to hospital, the large number of CAHs joining 340B suggests that there is some real and important benefit of being part of the program to CAHs.

[17] While this appears to paint a picture of provider-induced demand, it could also be a response to unmet patient needs for Part B drugs due to hospital budget constraints.

3.2 Spending on Part B Drugs

The effect on total Part B drug spending is ambiguous, as it depends on the extent to which reductions in spending as a result of 340B discounts would be offset by any increase in spending as a result of greater use of Part B drugs. If there is no change in utilization, per-patient spending on Part B drugs should go down. If utilization goes up, per-patient spending on Part B drugs could remain unchanged or even increase.

A central question is whether CAHs would pass along 340B discounts to patients in the form of lower cost sharing by reducing charges for outpatient drugs. Note that while in this study I focus on Medicare beneficiaries – among whom only a small fraction are directly exposed to charges for a lack of supplemental insurance – charges mostly affect uninsured and other self-paying patients, therefore pass-through of 340B discounts have implications beyond the Medicare population. Here I consider both non-financial and financial mechanisms by which CAHs may adjust charge according to 340B pricing. My main hypothesis is that the altruistic motive of publicly owned and not-for-profit CAHs drives reductions in charges. Owing to non-distribution constraints, public and not-for-profit hospitals are assumed to maximize a combination of profit and the welfare of patients (e.g., Dranove, 1988; Gruber, 1994). Empirically, these hospitals have been shown to differ from pure profit-maximizer, providing more socially beneficial yet unprofitable services and responding less aggressively to financial incentives (e.g., Dafny, 2005; Horwitz, 2005; Chang and Jacobson, 2017). Following this model, as long as the utility of providing benefits to patients outweighs any financial loss for doing so, CAHs would adjust charges downwards voluntarily so that more patients can afford treatment.[18]

Financial incentives are an unlikely mechanism for the following reasons. First, the majority of Medicare beneficiaries are protected fully or partially by supplemental insurance against Part B cost sharing, meaning that lowering charges do not necessarily bring in more Medicare business for CAHs. Second, although charges do not reflect costs, there is evidence that a positive correlation exits between charges and commercial payer payment rates and overall revenue (Bai and Anderson,

[18] Aside from altruistic motive, CAHs may reduce charges to avoid Medicare overpayment. Medicare determines interim payment rates for CAH services based on submitted charges and cost-to-charge ratio reported in last year's cost report. A retroactive payment adjustment based on actual costs is made at the end of the current year. CAHs may reduce charges as costs go down to avoid returning large overpayment upon final settlement, yet they could also directly request adjustment to the interim rates by informing Medicare Administrative Contractors of any changes in expenses (42 CFR § 413.64). Besides, payment settlement is at the hospital level, so overpayment in one department could offset underpayment in another department. Therefore, it is unclear whether intention to avoid overpayment plays a role, but my analysis would not be able to completely rule out this mechanism.

2016; Cooper et al., 2018). In fact, some commercial payers reimburse CAHs at rates based on charges, suggesting that financially there could be an disincentive to lower charges.[19] Finally, while high charges may cause some patients to fail to pay their copayments, CAHs can report these unpaid copayments as bad debt and receive full reimbursement from Medicare before 2013 – the last year of my data.[20]

3.3 Site of Drug Administration

340B can potentially affect the site of drug administration, even in the absence of any changes in utilization. Since off-site clinics affiliated with 340B hospitals are entitled to 340B discounts, there is an incentive for physician practices and 340B hospitals to integrate, shifting the site of drug administration from independent office to hospital outpatient department. Although this incentive proves to be salient under OPPS (Desai and McWilliams, 2018; Jung, W. Y. Xu, and Kalidindi, 2018), it is unclear whether it exists in the cost-based reimbursement system. In particular, while integrating with physician practices can bring in more patients, it requires sufficient liquidity and access to capital, which may not be readily available for many CAHs (Stensland et al., 2002; Gregg, 2005).

4 Empirical Strategy

To estimate the effect of the ACA's expansion of 340B on Part B drug utilization and spending among patients served by CAHs, I use a difference-in-difference (DD) framework featuring two complementary strategies – a hospital-level treatment variation and an area-level variation. The area-level identification is my main strategy, and I will discuss the merits of both approaches below. Since 340B participation is voluntary and the decision to join 340B may be influenced by factors associated with the outcomes, I focus on estimating the effect of 340B eligibility instead of 340B participation. The data primarily come from Medicare outpatient claims between 2008 and 2013.

[19] According to slides prepared by a consulting firm advising CAHs on business strategies and author's discussion with a CAH pharmacist.

[20] Medicare reimbursement for allowable bad debt at CAHs has been reduced to 88% in 2013, 76% in 2014, and 65% in 2015 and on as a result of the Middle Class Tax Relief and Job Creation Act of 2012.

4.1 Hospital-Level Identification

The hospital-level identification compares changes in the outcome for patients treated in CAHs becoming eligible for 340B under the expansion and those treated in hospitals that did not experience a change in 340B eligibility. The treatment group excludes a small number of hospitals that were certified as CAHs during the study period to ensure that the results are not confounded by 1) hospitals converting to CAHs in order to join 340B, and 2) hospitals with prior exposure to 340B before converting to CAHs.

A key concern with this approach is whether the comparison group provides a proper counterfactual. Given that only a small number of CAHs are ineligible for 340B due to for-profit ownership, the comparison group is broadly defined to include patients treated in any short-term acute care hospitals whose eligibility for 340B was not substantively affected by the ACA expansion.[21] While the ACA also lowered the DSH threshold for certain non-CAH rural hospitals, in Table A3 I show that most of these hospitals would have qualified for 340B before the expansion.

The estimating equation is straightforward:

$$Y_{ift} = \delta_t + \alpha_f + \sum_{t=2008Q1}^{2013Q4} \beta_t \times \mathbb{I}(\text{EligibleCAH})_f \times \mathbb{I}(\text{Time})_t + \boldsymbol{X}_{ift}\boldsymbol{\phi} + \epsilon_{ift} \tag{1}$$

Where Y_{ift} is the outcome of interest for patient i at hospital f at time t; $\mathbb{I}(\text{EligibleCAH})_f$ is an indicator for 340B-eligible CAHs; $\boldsymbol{X}_{ift}$ is a vector of patient demographics characteristics and severity. I use hospital fixed effects α_f to control for time-invariant hospital characteristics that may inherently affect hospital behaviors, and time fixed effects δ_t to account for any secular trends. Standard errors are clustered at the hospital level. Unless indicated otherwise, models are estimated using ordinary least squares (OLS).

I estimate the coefficient of interest β for each point in time (i.e., year-quarter) during the study period by interacting $\mathbb{I}(\text{EligibleCAH})_f$ with a series of time indicators. By estimating these coefficients flexibly, this specification allows for detecting any pre-existing differences in the level or trend of dependent variables. Examining the time-series pattern of β is also helpful in addressing whether any effects of 340B were only temporarily or persisted over time.

[21] Under this definition, the comparison group includes all the non-CAH short-term acute care hospitals, as well as the rest of CAHs that do not meet the treatment group criteria. Other hospitals such as children's, cancer, or long term hospitals are excluded.

4.2 Area-Level Identification

The area-level identification exploits the geographic variation in the impact of the ACA's 340B expansion determined by pre-ACA characteristics. Areas where CAHs captured a higher share of the market for Medicare-covered hospital outpatient services prior to the 340B expansion should experience a bigger shock from the expansion. Hence, I approximate the expected impact of the expansion using public and not-for-profit CAHs' share of Medicare outpatient visits in an area in 2009, one year before the policy change (hereinafter CAHshare_h, with subscript h denoting an area). To construct CAHshare_h, I identify hospital outpatient visits in CAHs and other short-term acute care hospitals using Medicare outpatient claims for 2009 and hospital ownership status using the 2009 Medicare cost reports. Each visit is uniquely identified by beneficiary identifier, claim identifier, visit date, and Medicare provider number. These visits are then aggregated to the Hospital Referral Region (HRR) level mapped to each patient's residence zip code.[22] Since CAHshare_h is unlikely to be randomly assigned, I expect to see difference in the level of the outcomes of interest across areas with different CAHshare_h. The identifying assumption is that, absent the expansion of 340B under the ACA, any pre-existing differences between areas with a higher CAHshare_h and those with a lower CAHshare_hwould have persisted on similar trends in the post-ACA era.

This area-level identification has several advantages. First, CAHshare_h is a continuous treatment intensity variable that allows for estimating a dose-response type treatment effect that alleviates concerns over the stark contrast between CAHs and non-CAH hospitals. Second, due to competition and other interactions between CAHs and other hospitals or other types of providers, the estimated impact of 340B at the hospital level may over- or understate the impact in the aggregate. Area-level analysis of 340B encapsulates market-level effects and informs whether the policy change altered hospital practice style on a wider scale. Finally, it is difficult to study Part B drug administered by non-institutional providers with the hospital-level identification unless I explicitly link individual prescribers to hospitals, but creating such linkage could introduce additional errors.

Figures 2 and 3 illustrate the heterogeneity of CAHshare_h across HRRs. Consistent with the geographic distribution of CAHs, Figure 2 indicates that HRRs with a higher CAHshare_h are concentrated in the Midwest. The average CAHshare_h is 12.1%, with a standard deviation of 14.3%

[22]This variable could be based on either patient residence location or the location where service was provided. I am able to construct the variable in both ways since I observe both patient zip code and provider zip code. Going from patient zip code to provider zip code does not affect the general findings.

(Figure 3). In Figure A1, I also plot CAHshare_h against a measure of treatment intensity based on actual 340B participation and Medicare outpatient visits using 2013 data to show that CAHshare_h strongly predicts the level of actual exposure to 340B post-ACA.

Figure 2: Geographic variation in CAHshare_h (%)

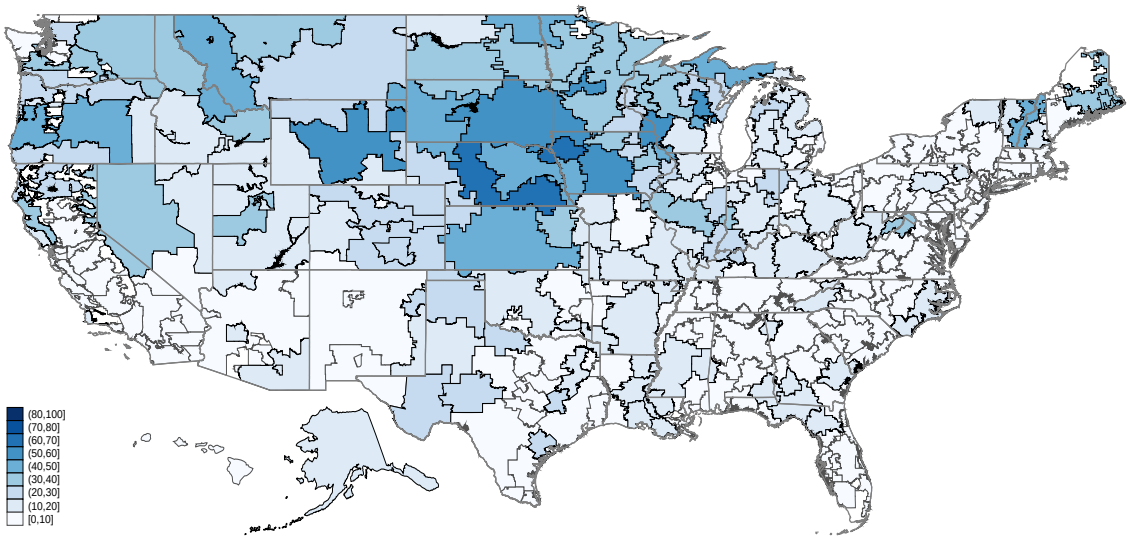
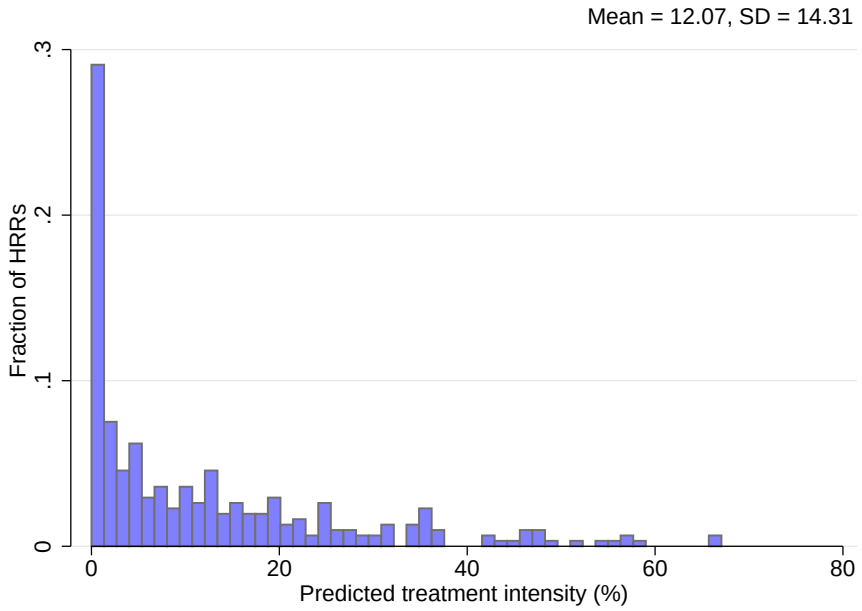


Figure 3: Distribution of CAHshare_h(%)



Reconstructing the data to the patient-HRR-time level, the estimating equation is:

$$Y_{iht} = \delta_t + \alpha_h + \sum_{t=2008Q1}^{2013Q4} \beta_t \times \text{CAHshare}_{h|2009} \times \mathbb{I}(\text{Time})_t + \boldsymbol{X}_{ift}\boldsymbol{\phi} + \epsilon_{iht} \quad (2)$$

Where Y_{iht} is outcome of interest for patient i at HRR h at time t; $\boldsymbol{X}_{ift}$ is a vector of patient characteristics and disease indicators as described in equation 1. The model includes HRR fixed effects α_h to control for time-invariant HRR characteristics and time fixed effects δ_t to account for secular trends. Again, the estimates of interests are $\beta_t's$, which trace over time the pattern of the outcomes for HRRs with higher predicted treatment intensity relative to HRRs with lower predicted treatment intensity. For this specification, I cluster standard errors at the HRR level.

Figure 3 shows that the mass point of 27% of HRRs have a level of CAHshare_h less than 1%. These HRRs include those that are part of the five states that do not certify CAHs, as well as a number of HRRs located in predominantly urban regions (see HRR urban classification in Table A4). As the ensuing summary statistics will indicate, these HRRs differ considerably from the other HRRs in terms of average Part B drug spending and variation in Part B drug spending. To ensure that the treatment effect estimates are not influenced by these HRRs, in alternative specification, I interact a full set of time dummies with an indicator for CAHshare_h being less than 1%. By doing so, I utilize only the variation within HRRs with non-negligible treatment intensity to estimate the effect of 340B expansion.

4.3 Data and Measures

The analytic data set is constructed using primarily Medicare outpatient hospital claims and non-institutional provider claims for a random 5% sample of fee-for-service (FFS) beneficiaries over the period 2008-2013. Medicare beneficiaries may receive certain Part B drugs such as nebulizer medications from Durable Medical Equipment suppliers (DME). DME claims are not included in my data, but the absence of these claims is expected to be a minor issue, as they account for only about 8.6% of total spending and around 3% of 340B-covered spending on Part B drugs (Office of Inspector General, 2015).

The overall patient sample includes Medicare FFS beneficiaries with full-year coverage of Part A and Part B in a given year. I drop beneficiaries under age 65, who generally differ from aged

beneficiaries in utilization patterns and are considerably more likely to have Medicaid coverage.[23] I also remove beneficiaries who were enrolled in Medicare Advantage Plans at some point during a year, as their billing or treatment information would be incomplete.

In addition to claims, I use Medicare hospital cost reports to identify short-term acute care hospitals and 340B-eligible CAHs. I collect information about hospitals ever participating in 340B from the 340B administrative database.

4.3.1 *Outcome measures*

The outcomes of interest consist of five measures at the patient level. For utilization, I include an indicator for any Part B drug use to explore changes at the extensive margin, and the number of Part B drug events to measure the effects at the intensive margin. For spending, I include total payment for Part B drugs, Medicare payment for Part B drugs, and beneficiary copayment responsibility. The number of Part B drug events is measured among patients who received non-zero Part B drugs, while the three payment variables are limited to patients with non-zero total payment for Part B drugs. These sample restrictions allow me to zoom in on the relevant patient populations, as most Medicare beneficiaries do not receive Part B drugs.

I use a combination of HCPCS codes, revenue center indicator status codes and the Berenson-Eggers type of service codes to identify Part B drugs in the hospital outpatient and non-institutional provider claims. I follow the literature to measure the number of Part B drug events by counting the number of line items for Part B drugs in the claims (e.g., Government Accountability Office, 2016).[24] Payment measures are derived from line payment variables associated with each drug, which include payment made by Medicare, beneficiary deductible (if applicable) and coinsurance[25], and payment made by any other payer(s). Total payment for Part B drugs is the sum of these line payments. Denied claims and denied line items are excluded to avoid double counting. Throughout the study, payment data are adjusted using CPI-U to 2013 dollars.[26]

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[23] In my data, 65% of beneficiaries under 65 had Medicaid coverage at some point in a year, compared to 15% of those aged 65 and above.

[24] A caveat with this approach is that line-level utilization may obscure difference in volume between lines for the same drug due to data limitation of Medicare claims. However, because different drugs use different units for dosage, it is difficult to interpret the results based on the total units of drugs used.

[25] Part B deductible makes up a small fraction of beneficiary out-of-pocket costs. In 2010, the deductible was $155.

[26] An alternative adjustment index is the producer price index for prescription pharmaceuticals (PPI). Using PPI or CPI do not change the main findings.

4.3.2 *Covariates*

The regressions adjust for patient age, race, sex, Medicaid dual-eligible status, and patient severity. To properly measure patient severity, I use the CMS Hierarchical Condition Category (HCC) risk adjustment score and the Charlson Index. I also create indicators for cancers, rheumatology, hematology and ophthalmology diagnoses, which are coded following the Chronic Conditions Data Warehouse guidelines.[27] These indicators aim to account for the higher Part B drug utilization and/or spending among patients with conditions treated in more drug-intensive specialties. Both patient risk score measures and diagnosis indicators are constructed using diagnosis codes and/or procedure codes reported in the Medicare claims.

4.3.3 *Part B drugs sample restriction*

Given that 340B covers most outpatient drugs and that the sample size of my data is relatively small, I do not target any particular class of treatment.[28] A sample restriction however is imposed on hospital outpatient claims to address issues arising from change in the OPPS billing rule. Under OPPS, a number of drugs – typically low cost – are packaged into the procedure during which the drug is administered.[29] Payments for these "packaged drugs" are not made separately and are therefore not observed in the claims. The packaging status of a drug could change over time, which may affect spending in a mechanical way absent any policy changes. For example, several antiemetic drugs were paid separately before 2010 despite costing less than $10 per day, but have been packaged into other services since 2010 (Office of Inspector General, 2010; Office of Inspector General, 2011a). Because of this change in billing rule, I observe a substantial increase in 2010 in per-patient total payment for Part B drugs conditioning on positive payment, which is likely because some patients only received the antiemetic drugs plus some other packaged drugs. To address this

[27] For cancer diagnoses, I use the list of reportable neoplasms available on the National Cancer Institute's SEER program website (https://seer.cancer.gov/tools/casefinding). For diagnoses in hematologic and rheumatolgy, I hand collect relevant ICD-9 codes from the website of the American Association of Hematology and the American College of Rheumatolgy; these include hematologic conditions such as sickle cell disorders, aplastic anemia and other bone marrow failures, and rheumatic conditions such as gout, rheumatoid arthritis and osteoarthritis. For diagnoses in ophthalmology, I include ICD-9 codes for conditions that are common among the Medicare population and may be treated with Part B drugs, which include age-related macular degeneration, diabetic retinopathy, diabetic macular edema and central retinal vein occlusion.

[28] The definition of 340B covered outpatient drugs excludes those that are bundled with other services for payment purpose under Medicaid; however, this restriction does not apply to drugs bundled with hospital outpatient services billed to Medicare or other third-party payer (80 FR 52300).

[29] Drugs may be packaged due to considerations other than costs.

issue, I remove all claims for drugs that experienced a change in the OPPS packaging status during the study period, including those administered in CAHs even though packaging does not apply in cost-based reimbursement.

Orphan drugs are exempt from 340B pricing for CAHs and other rural hospitals, but I do not remove orphan drug claims for the following reasons. First, before 2015, the orphan drug exclusion was enforced only when the drug was used to treat the designated orphan indication, i.e., the rare disease or condition for which the drug is designated as orphan drug. Second, it is technically difficult to identify orphan drugs in the claims, and not possible to differentiate those used to treat orphan indications because claims do not identify the indications. Moreover, orphan drugs represent a very small share of the total units of drugs acquired by CAHs (Wallack and Sorensen, 2012), and so the results are unlikely to be influenced by orphan drug claims.

For analyses of Part B drugs administered by non-institutional providers, I include all relevant claims submitted as either office-based service or professional service performed in a hospital outpatient setting. I use place of service (POS) code to identify office-based claims (POS = 11) and hospital-based claims (POS = 22). POS 22 is used when a physician furnishes a service in a practice affiliated with a hospital.

4.4 Descriptive Statistics

Table 1 summarizes Part B drug utilization and spending in hospital outpatient departments (see Table A5 for patient characteristics and Table A6 for data on Part B drugs provided by non-institutional providers). Several patterns are worth noting. First, the data reveal stark differences in Part B drug spending between comparison hospitals and 340B-eligible CAHs, reflecting the difference in Medicare reimbursement policies. Second, the discrepancies across HRR groups are much smaller than the differences between treatment and comparison hospitals, illustrating the advantages of using a continuous treatment variable over a dichotomous one. Third, patients in HRRs with $\text{CAHshare}_h < 1\%$ (i.e., below 27th percentile) had considerably higher Part B drug spending per patient as well as higher variability in spending than patients in HRRs with $\text{CAHshare}_h > 1\%$. This is also evident in Figure A2, which plots the time series of outcomes across the HRR groups. These data further demonstrate that HRRs with a negligible level of expected treatment intensity could affect the estimation in ways that may be undesirable. For example, including these HRRs in the regression may introduce additional uncertainty. Regression to the mean is another

concern when treatment and comparison groups differ markedly in baseline outcomes.

The sample size for the three payment outcome measures is much smaller than those for the utilization outcome measures. This is because the payment outcomes are conditioning on having non-zero total payment for Part B drugs in the claims. Therefore, patients who received only packaged drugs in OPPS hospitals at a given time are excluded from my sample. This could lead to bias if the selection into my analytic sample is not random and affects HRRs with lower $\text{CAHshare}_{\text{h}}$and those with higher $\text{CAHshare}_{\text{h}}$differently. But it is unclear why such selection, largely determined by external billing rule, may be systematically different across areas. Moreover, while the fraction of observations lost due to this issue has been decreasing over time, the decrease experienced by HRRs with various levels of $\text{CAHshare}_{\text{h}}$ was fairly similar (Table A7).

Table 1: Summary of dependent variables in hospital outpatient departments: 2008-2013

		By hospital treatment status		By HRR-level treatment intensity ($CAHshare_h$)		
		Comparison hospitals	340b-eligible CAHs	< 27th pctile	[27th pctile, 75th pctile]	> 75th pctile
Any Part B drug use	Mean	0.21	0.14	0.21	0.23	0.23
	SD	0.41	0.35	0.41	0.42	0.42
	N	11,100,000	991,823	3,249,175	5,407,340	1,734,993
Number of Part B drug events	Mean	2.82	2.51	2.91	2.94	2.99
	SD	3.78	3.56	3.92	3.90	4.16
	N	2,301,346	139,774	676,244	1,253,857	395,585
Total Part B drug payment	Mean	2604.4	534.9	2963.2	2021.7	1414.0
	SD	6359.0	2661.4	7039.4	5685.5	4421.8
	N	363,652	136,785	114,456	240,187	137,245
Part B drug Medicare payment	Mean	2085.3	294.5	2383.2	1588.8	1042.6
	SD	5217.9	1520.5	5838.3	4587.9	3392.2
	N	363,652	136,785	114,456	240,187	137,245
Part B drug beneficiary copayment	Mean	485.7	236.4	555.6	399.0	358.8
	SD	1073.3	1184.3	1226.1	1034.1	1183.6
	N	363,652	136,785	114,456	240,187	137,245

Notes: Data are at the beneficiary-year-quarter level. N represents the number of beneficiary-year-quarter observations over the study period. The number of Part B drug events is conditioning on having positive Part B drug use; the payment outcomes are conditioning on having positive total payment. HRRs with treatment intensity < 1% fall below the 27th percentile, i.e., $\Pr(CAHshare_h < 1\%) = 0.27$, thus the choice of 27th percentile in dividing HRRs into three groups.

5 Results

The results section is organized as follows. To connect the descriptive statistics and the main DD analysis, I first present event studies of 340B participation and compare the trajectories before and after joining 340B between CAHs and non-CAH hospitals. I then turn to the results from the main DD analysis, discuss the difference in results between the hospital-level and the HRR-level eligibility identifications, and present several sensitivity and placebo tests to verify the main results.

5.1 Hospital-Level Trajectories

The event studies examine changes in outcomes for CAHs that joined 340B between 2010 and 2013, and separately for non-CAH hospitals that joined 340B between 2009 and 2013.[30] By focusing on participation in 340B, the effects are identified both from changes in eligibility and hospitals' decision to take up 340B. Some of this variation is potentially problematic, which motivates the DD design. Nonetheless, these event studies serve two purposes. First, because over 90% of CAHs become eligible for 340B through the ACA, the event studies test if the effect detected in the main DD analysis, which is identified off 340B eligibility, may be driven by factors inherent to CAHs or concurrent policy that affects CAHs as a group instead of 340B. Second, the event studies provide a direct test as to whether non-CAH hospitals that joined 340B during the study period confound the main analysis. In particular, if these hospitals responded to 340B by expanding their use of Part B drugs disproportionately, the main analysis could yield results that appear to suggest a downward effect of 340B on Part B drug utilization or spending among CAHs even if the true effect may be zero.

Data are aggregated to annual averages of quarterly Part B drug utilization or spending per patient in a hospital.[31] The estimating equation 3 includes a set of event time dummies coded relative to the year of 340B participation, calendar year δ_t and hospital α_f fixed effects, as well as time-varying covariates $\boldsymbol{X}_{ft}$ that capture patient characteristics at the hospital-year level (averaging across quarterly data). I include control group hospitals – those that did not participate in 340B during the study period – to help identify secular trends. Standard errors are clustered at the

[30] Non-CAH hospitals that joined 340B in 2008 have no pre-340B data and are therefore removed from the event studies.

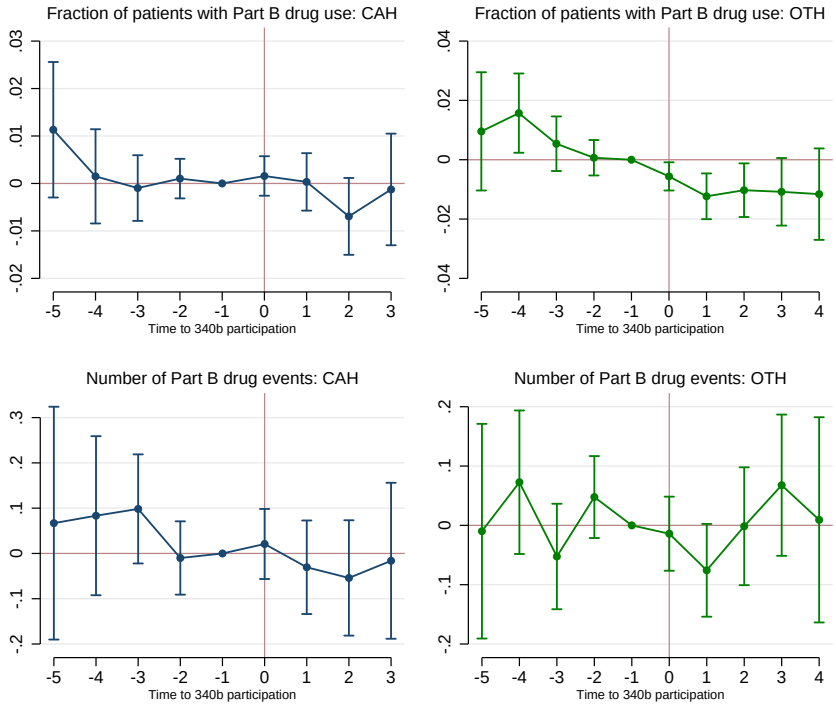
[31] To ensure that changes in sample composition over time do not bias the estimate, I remove hospitals with fewer than 5 years of observations, reducing the sample by less than 5%.

hospital level.

$$Y_{ft} = \delta_t \ + \ \alpha_f \ + \ \sum_{k=-m}^{+n} \beta_k \times \mathbb{I}(\text{Time})_k \ + \ \boldsymbol{X}_{ft}\boldsymbol{\phi} \ + \ \epsilon_{ft} \tag{3}$$

Estimated coefficients $\beta_k' s$ and their 95% confidence intervals are plotted against event time for CAHs and non-CAH hospitals (labeled "OTHs") for side-by-side comparison. As shown in Figure 4, I do not find a sudden trend break in Part B drug utilization at the time when a hospital joined 340B for either hospital type.

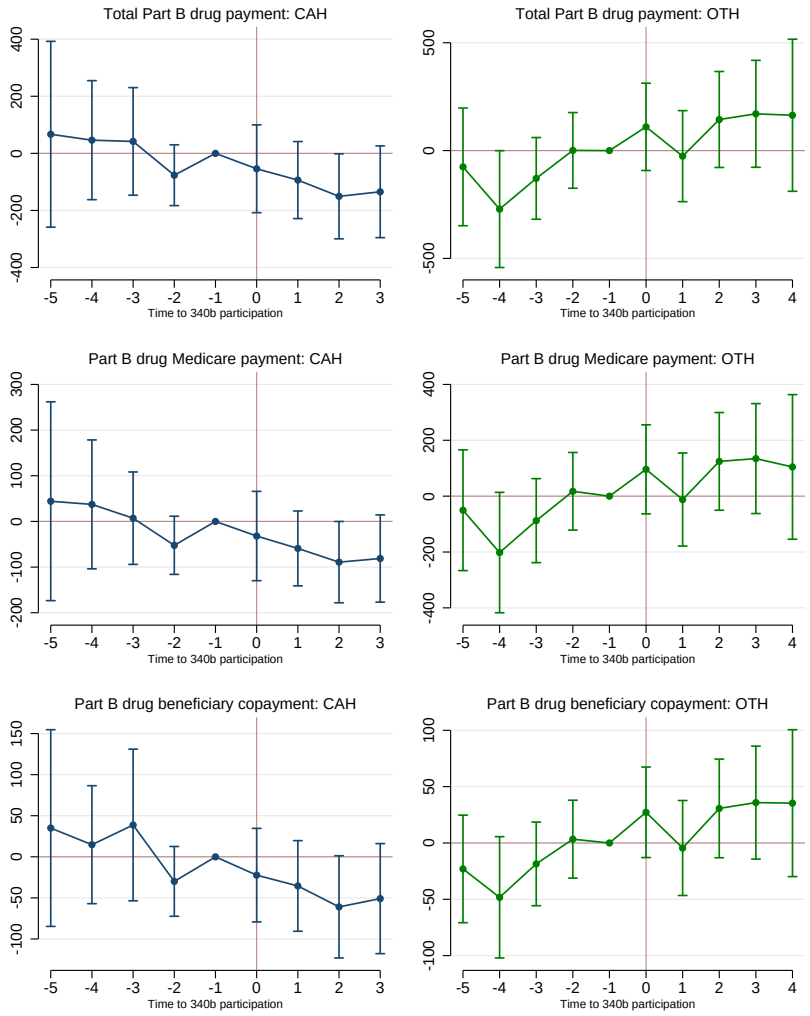
Figure 4: Event study of hospital 340B participation and Part B drug utilization



Notes: Estimated event time coefficients and associated 95% confidence intervals based on model 3 are presented separately for CAHs and other acute care hospitals ("OTH"). These results show the conditional relationship between 340B participation and the outcomes.

On the other hand, Figure 5 reveals a more consistent post-340B downward trend in Part B drug spending at CAHs around and after k = 0 without pre-trend. Given the noise in the spending data, the 95% confidence intervals are wide.

Figure 5: Event study of hospital 340B participation and Part B drug spending



Notes: Estimated event time coefficients and associated 95% confidence intervals based on model 3 are presented separately for CAHs and other acute care hospitals ("OTH"). These results show the conditional relationship between 340B participation and the outcomes.

The null effects among OTHs appear to contradict Desai and McWilliams (2018), but the use of different study methods may contribute to the discrepancy. The event study treats 340B participation as an absorbing state, and so hospitals that joined 340B earlier – also the ones likely to benefit more from 340B – are excluded from the analysis. Another major distinction lies in the type of Part B drugs included in the outcome measures. As discussed earlier, I include a much wider range of Part B drugs to be consistent with the broad scope of 340B.

The event studies offer some previews of the main DD results; however, they are not intended for drawing causal conclusion given the concern over why hospitals choose to enroll in 340B when

they do. Although the lack of pre-trend for CAHs is reassuring, potential endogeneity issues in event studies would be better addressed in the ensuing DD analyses, which leverage the change in eligibility instead of participation as the source of variation.

5.2 Main Difference-In-Difference Results

5.2.1 *Hospital-level eligibility identification*

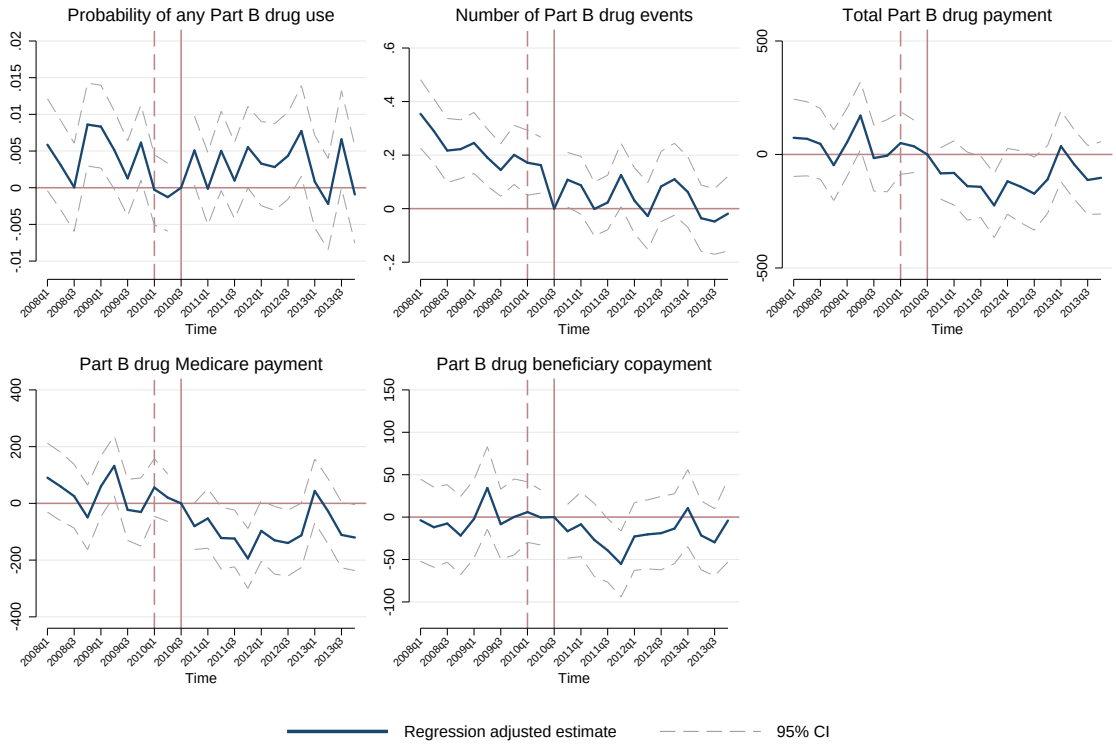
The estimated $\beta's$ and their 95% confidence intervals based on model 1 are plotted against calendar time in Figure 6. The dash vertical line indicates the first quarter of 2010, when the ACA was signed into law; the solid vertical line indicates the third quarter of 2010 (2010Q3), when newly eligible hospitals started joining 340B. All $\beta's$ are estimated relative to 2010Q3.[32] As mentioned earlier, the effect on the number of Part B drug events is estimated among patients with positive Part B drug use, while the effects on the payment outcomes are estimated among patients with positive payment for Part B drugs.

Several patterns emerge in these graphs. First, I do not find that patients became more or less likely to receive Part B drugs at 340B-eligible CAHs than at comparison hospitals after the 340B expansion. Second, there was a downward pre-trend in the number of Part B drug events followed by a trend break around the time when 340B expansion took effect, suggesting that patients treated in CAHs used relatively more drugs after the 340B expansion as CAHs became eligible for the program. Lastly, I observe a post-policy downward trend for the three payment outcomes, indicating a relative decrease in overall Part B drug spending and beneficiary cost sharing at 340B-eligible CAHs. Yet, the spending effects did not sustain in the long term, as the trend reverted back to baseline level at a later point. There is no indication of a strong pre-existing trend for the payment outcomes.

[32]For the binary outcome indicating any use of Part B drug, this means a linear probability model (LPM) with fixed effects. LPM is preferred over conditional logit model because of its flexibility of model specification and ease of interpretation. In addition, as shown in the summary statistics, the overall sample rate of any Part B drug use for treatment hospitals is around 14 percent per year, whereas logistics regression is known to cause downward bias in rare event situations (King and Zeng, 2001). Finally, conditional logit is computationally complex and difficult with large panel size and small event incidence.

Figure 6: OLS estimated β_t – hospital-level identification

(Part B drugs administered in hospital outpatient departments)



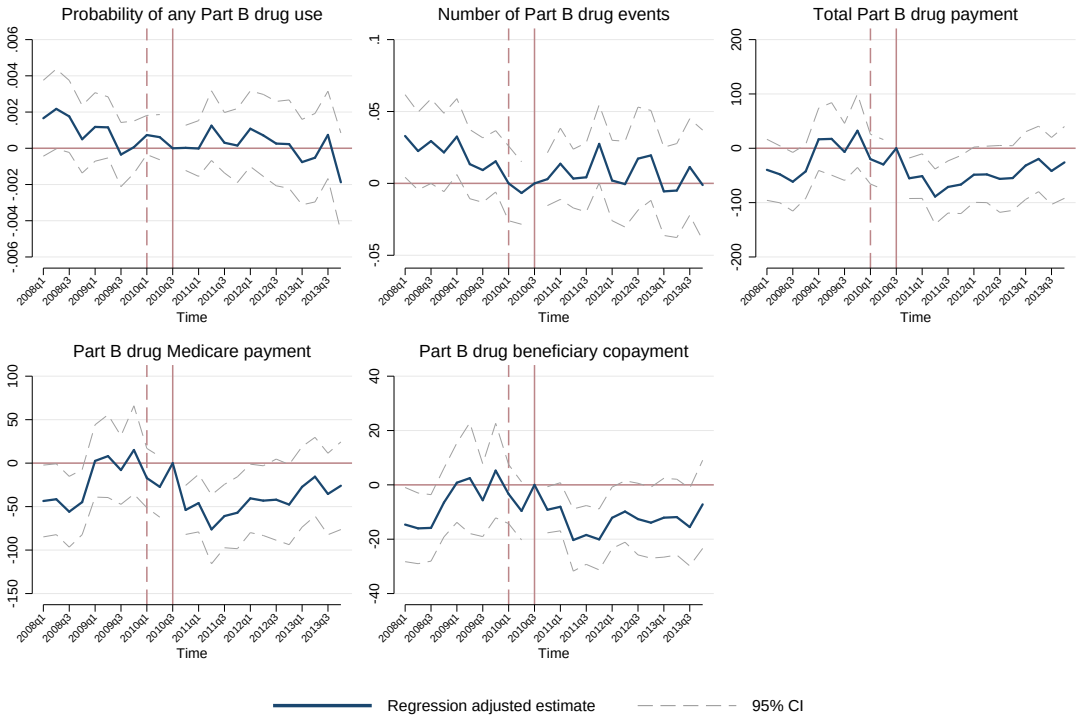
5.2.2 *HRR-level identification: hospital outpatient setting*

Next, I turn to Figure 7 for results based on model 2. The estimates are scaled to represent the change in the outcome per 10 percentage-point increase in CAHshare_h. Results after removing HRRs with $\text{CAHshare}_\text{h} < 1\%$ are presented in the bottom panel.

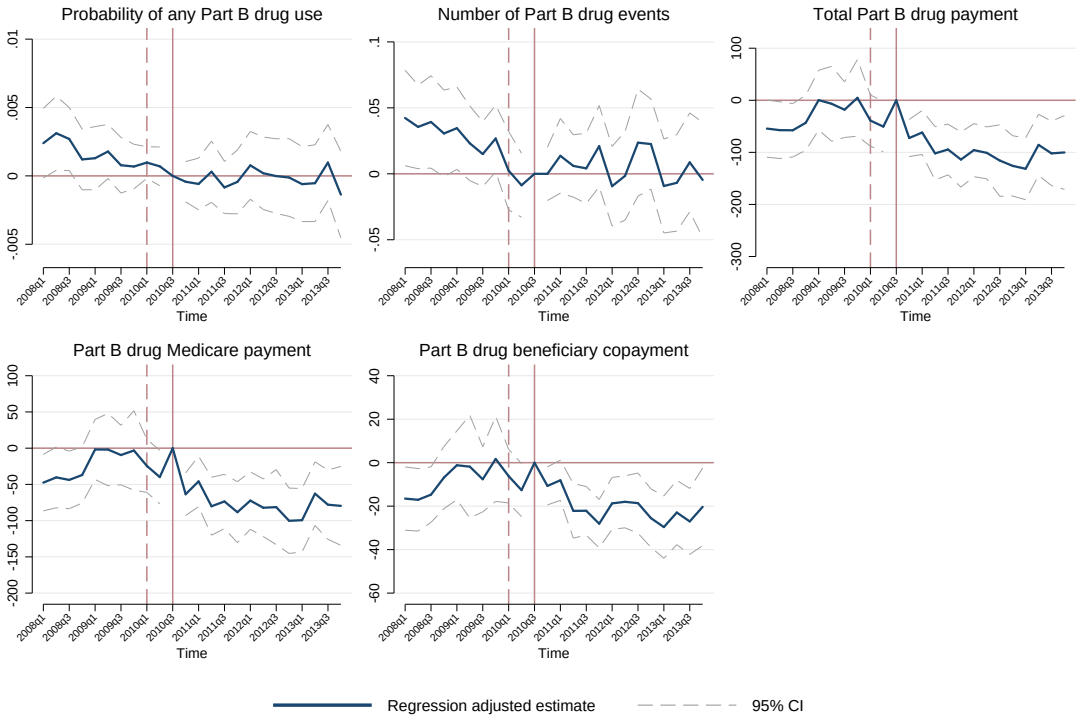
Overall, the results shown in both panels paint a broadly consistent picture, but removing HRRs unaffected by 340B expansion stabilizes the post-policy trends for the payment outcomes. These results suggest a lack of differential trajectories in the probability of receiving Part B drug among patients across HRRs with different levels of CAHshare_h. There was a downward pre-trend in the number of drug events per patient, indicating that utilization among patients in HRRs with higher CAHshare_hhad been decreasing relative to that for patients in HRRs with lower CAHshare_h, but the two converged during the post-policy window. All three payment outcomes decreased disproportionately for patients in HRRs with higher CAHshare_h in the post-policy window; although there was a upward pre-trend, it disappeared in 2009Q1.

Figure 7: OLS estimated β_t – HRR-level identification

(Part B drugs administered in hospital outpatient departments)



(a) All HRRs



(b) HRRs with CAHshare$_h$ > 1% (within variation)

Informed by Figure 7(b), which shows that the effect of 340B on spending appears to be a downward level shift, I test whether the five-quarter change in β over 2010Q3~2011Q3 is statistically different from that over 2009Q3~2010Q3.[33] This approach resembles methods used in Finkelstein (2007) and in Greenstone and Hanna (2014). The results are reported in Table 2. I also construct the eight-quarter effects, which are reported in Table A8.[34]

Table 2 indicate that, five quarters after the ACA's 340B expansion took effect, the expansion had zero impact on the probability of receiving Part B drugs. It led to an average increase in the number of Part B drug events of 0.17 at 340B-eligible CAHs based on the hospital-level identification, equivalent to 17 more drug events per 100 patients treated in CAHs. But the HRR-level identification fails to detect a similar effect. There are two possible explanations for this discrepancy. First, there could be substitution towards CAHs, that is, some of the utilization was shifted from other hospitals to 340B CAHs potentially due to lower costs to patients. Second, the HRR-level identification estimates a dose-response effect, which by construction is smaller than the effect estimated using a dichotomous treatment variable.

All three columns of Table 2 show a negative effect of 340B expansion on Part B drug spending. In particular, among the subset of HRRs with $\text{CAHshare}_\text{h} > 1\%$, a 10-percentage-point increase in CAHshare_h is associated with an average decrease in total Part B drug payment, Medicare payment, and beneficiary copayment by \$112, \$83, and \$30 per patient, respectively. Although the estimated effects based on the hospital-level identification are not significant or only marginally significant, the 95% confidence intervals reveal that I am able to rule out any increases in Medicare payment and beneficiary copayment above \$28 and \$17 per patient, respectively; in contrast, I cannot reject decrease in Medicare payment and beneficiary copayment by as much as \$322 and \$112. The eight-quarter effects are consistent with these general findings and are more precisely estimated (Table A8).

[33] The formula is $(\beta_{2011Q3} - \beta_{2010Q3}) - (\beta_{2010Q3} - \beta_{2009Q3})$.

[34] Ten-quarter effects are also constructed. They are consistent with the main findings and therefore not shown to save space.

Table 2: Five-quarter effects of 340B (hospital outpatient departments)

	Hospital-level treatment	HRR-level treatment	
		All HRRs	HRRs ($CAHshare_h > 1\%$)
Probability of Part B drug use	0.002	-0.000	-0.000
	(0.004)	(0.001)	(0.001)
	[-0.006, 0.011]	[-0.002, 0.002]	[-0.003, 0.002]
Number of Part B drug events	0.17**	0.01	0.02
	(0.08)	(0.02)	(0.02)
	[0.00, 0.33]	[-0.02, 0.05]	[-0.02, 0.06]
Total Part B drug payment	-158.26	-77.71*	-112.48**
	(121.18)	(45.75)	(44.47)
	[-395.84, 79.31]	[-167.73, 12.31]	[-199.99, -24.96]
Part B drug Medicare payment	-146.82*	-68.79**	-82.99**
	(89.14)	(34.12)	(33.88)
	[-321.58, 27.95]	[-135.93, -1.66]	[-149.66, -16.31]
Part B drug beneficiary copayment	-47.55	-24.08**	-29.75**
	(33.12)	(10.99)	(11.68)
	[-112.47, 17.38]	[-45.69, -2.46]	[-52.74, -6.76]

Notes: Effects of 340B shown for 10 percentage-point increase in HRR-level 340B treatment intensity under the program expansion. Clustered standard errors are in the parentheses, and the 95% confidence interval in brackets. *** $p < 0.01$; ** $p < 0.05$; * $p < 0.1$.

5.2.3 *HRR-level identification: non-institutional setting*

I repeat the HRR-level analysis using non-institutional physician claims for Part B drugs with the place of service (POS) classified as either free-standing office (POS = 11) or hospital outpatient department (POS = 22). When a service is rendered in a hospital-owned practice, the claim for that service would indicate POS 22. Therefore, a shift towards POS 22 on Part B drug claims submitted by non-institution providers may suggest potential CAH-physician pratice integration under the 340B expansion.

Table 3 reports the five-quarter effects on Part B drug administration among these providers (graphical results in Figure A4). The results presented in the right panel of the table exclude patients who did not receive Part B drugs in order to examine shift between POS 11 and POS 22 within the relevant patient population. Overall, the estimates indicate a lack of impact and an absence of meaningful change in billing for Part B drugs among non-institutional providers. It is worth noting that, because claims with POS 22 made up only 12% of claims with either POS 11 or

POS 22 in the data, the effect estimates based on POS 11 claims are numerically similar to those based on claims with either POS code. Since I do not explicitly link non-institutional claims with hospital claims to directly identify integration, the evidence is only suggestive, but it corroborates previous findings based on hospital-level data by Alpert, Hsi, and Jacobson (2017).

Table 3: Five-quarter effects of 340B (non-institutional settings)

	POS: 11 + 22		POS: 11	
	All HRRs	HRRs ($CAHshare_h > 1\%$)	All HRRs	HRRs ($CAHshare_h > 1\%$)
Probability of Part B drug use	0.001 (0.001) [-0.000, 0.002]	0.001 (0.001) [-0.000, 0.002]	-0.001 (0.002) [-0.005, 0.003]	-0.002 (0.002) [-0.006, 0.002]
Number of Part B drug events	0.01 (0.02) [-0.02, 0.05]	0.03 (0.02) [-0.01, 0.07]	0.01 (0.02) [-0.03, 0.05]	0.02 (0.02) [-0.02, 0.06]
Total Part B drug payment	14.26 (11.57) [-8.50, 37.02]	14.49 (13.80) [-12.67, 41.65]	13.88 (11.58) [-8.92, 36.68]	13.99 (13.82) [-13.21, 41.19]

Notes: Effects of 340B shown for 10 percentage-point increase in HRR-level 340B treatment intensity under the program expansion. Clustered standard errors are in parentheses, and the 95% confidence interval in brackets. *** $p < 0.01$; ** $p < 0.05$; * $p < 0.1$. Sample for regressions on Part B drugs with POS 11 is conditioning on receiving at least one Part B drug in the non-institutional provider claim.

5.3 Sensitivity analysis and placebo tests

I perform several sensitivity and placebo analyses to test the robustness of the findings. I first provide results using generalized linear model (GLM). Health care data tend to be right skewed, so OLS may not provide a good fit and the results could be biased due to misspecified functional form. As an alternative, I use GLM with gamma-distributed disturbance and log link function. The choice of the gamma distribution is based on the modified Park test, which determines the relationship between the mean and the variance of the dependent variable at the original scale.

Figure A3 shows the raw GLM coefficients per 10 percentage-point change in $CAHshare_h$ plotted against time. The GLM estimates largely resemble the OLS results. The five-quarter effects reported in Table A9 based on the exponentiated GLM coefficients show that, on average, a 10 percentage-point increase in $CAHshare_h$ led to a 4% to 5% reduction in Part B drug spending per patient. Although most of the GLM results are not statistically significant, the 95% confidence intervals allow me to reject any increase in Part B drug spending by more than 2%, but cannot

reject a reduction in spending by as much as 8% or 9%. This discrepancy between OLS and GLM in terms of statistical significance is not surprising. Intuitively, the proportional change would be small despite sizable change in the absolute term when the baseline level is high. The eight-quarter effects, however, are larger and more precisely estimated, allowing me to reject the null hypothesis (Table A9).

Next, I examine the robustness of the main results to sample selection by restricting the patient sample to those with a confirmed diagnosis for cancer, hematologic diseases, rheumatic or ophthalmic conditions in the current year.[35] Based on the five-quarter effects reported in the second column of Tables 4 and A10, the findings are consistent. Since these conditions are often treated with more drugs and more expensive drugs, the negative spending effects of 340B are larger in size.

I further test robustness to sample selection by removing beneficiaries with Medicaid coverage at any point in a given year. These beneficiaries account for 15% of the main sample. Because I focus on the elderly population, the ACA's Medicaid expansion, which targets adults aged 19-65, is unlikely to be confounding. However, patients with Medicaid could be affected by 340B in a different way due to the special billing and payment rules Medicaid applies to 340B providers. Since 340B discounts are essentially extension of the Medicaid drug rebates, drug manufacturers are required to provide 340B discount or Medicaid drug rebate for the same drug, but not both. To prevent duplicate discounts, a 340B provider may buy a drug at its 340B price and bills Medicaid at the 340B price ("carve-in"); alternatively, she could buy the drug and bill Medicaid at non-340B price, and let Medicaid claim the discount from manufacture as rebate ("carve-out"). If a provider opts for the carve-out method and foregoes the 340B discount, I would not observe an effect of 340B for patients with Medicaid. According to 340B program data, about two thirds of CAHs choose the carve-out method. Certainly, removing all Medicaid-covered patients is a conservative approach to addressing the influence of Medicaid, since some of the patients would be "carved-in".

The results, shown in the third column of Table 4, assure that Medicaid does not have a strong influence on the main DD analysis. Because patients with Medicaid coverage tend to be sicker and some Medicaid patients were "carved-in", removing these patients from the sample reduces the size of the effect on spending.

[35]There is challenge for identifying patients suitable for Part B drug treatment, and so I rely on restricting the sample to patients with conditions treated in specialties/departments that tend to be drug-intensive. For details on how I identify these conditions, please refer to the data and measurement section.

Table 4: Five-quarter effects of 340B robustness to sample selection

HRRs with CAHshare$_h$ > 1% ; hospital outpatient departments

	Main sample (for reference)	Patients with chronic conditions	Remove Medicaid dual-eligibles
Probability of Part B drug use	-0.000 (0.001) [-0.003, 0.002]	-0.001 (0.002) [-0.005, 0.002]	-0.000 (0.001) [-0.003, 0.003]
Number of Part B drug events	0.02 (0.02) [-0.02, 0.06]	0.01 (0.03) [-0.04, 0.07]	0.03 (0.02) [-0.01, 0.07]
Total Part B drug payment	-112.48** (44.47) [-199.99, -24.96]	-151.16** (59.64) [-268.51, -33.81]	-93.00* (48.58) [-188.60, 2.60]
Part B drug Medicare payment	-82.99** (33.88) [-149.66, -16.31]	-108.88** (45.06) [-197.55, -20.21]	-67.07* (36.51) [-138.92, 4.77]
Part B drug beneficiary copayment	-29.75** (11.68) [-52.74, -6.76]	-40.11** (16.26) [-72.10, -8.11]	-26.23* (13.60) [-53.00, 0.53]

Notes: Effects of 340B shown for 10 percentage-point increase in HRR-level 340B treatment intensity under the program expansion for HRRs with CAHshare$_h$> 1%. Drugs used in hospital outpatient departments only. Clustered standard errors are in parentheses, and the 95% confidence interval in brackets. Both the raw and exponentiated coefficients and standard errors derived from GLM are reported. The standard errors for the exponentiated coefficients are derived using the Delta method. *** p < 0.01; ** p < 0.05; * p < 0.1.

Finally, this unique interaction of Medicaid and 340B allows me to conduct placebo test based on beneficiaries under age 65. Because 65% of beneficiaries under 65 had Medicaid coverage at some point in a year, I expect them to be affected by 340B expansion to a much lesser degree. Indeed, as shown in Figure A5, 340B expansion had barely any impact on either utilization of or spending on Part B drugs among these patients.

6 Mechanisms

6.1 Hypothesized mechanism for the spending effect

The main DD results are consistent with the hypothesized mechanism that CAHs pass along 340B discounts to patients in the form of lower cost sharing by reducing outpatient drug charges (list prices). Since I observe charges for all Part B drugs in the Medicare claims regardless of hospital

type or drug packaging status, I can test this hypothesis directly.[36] To do so, I take the logarithm of the average unit charge for a drug across all patients who received that drug in a hospital, where unit charge equals the total charge for the drug divided by the number of units administered to a patient during an outpatient visit. I then estimate the relationship between 340B and this unit drug charge variable using a DD model similar to model 1:

$$Y_{dft} = \delta_t + \alpha_{df} + \sum_{t=2008}^{2013} \beta_t \times \mathbb{I}(\text{EligibleCAH})_f \times \mathbb{I}(\text{Time})_t + \epsilon_{dft} \tag{4}$$

Where Y_{dft} is the logarithm of the average charge per unit of drug d administered in hospital f at time t; δ_t are time fixed effects to capture national trends such as generic entry; α_{df} are drug-hospital fixed effects to adjust for hospital-specific pricing strategy for a given drug.[37] Since utilization of a drug fluctuates over time, to minimize the influence of changing composition of the sample, I aggregate the data to the year level and keep drug-hospital combinations with at least one observation prior to 2010 and two observations after (including the observation for 2010). Results based on 6-month intervals are also presented to allow for a closer inspection of the timing of any trend breaks and/or level shifts.[38]

Figure 8 plots the DD estimates against time. The graph suggests a negative impact of 340B expansion on outpatient drug charge at 340B-eligible CAHs, albeit not immediately after the expansion. The delay in effect is likely because CAHs only started joining 340B in the second half of 2010, and so the coefficient on 2010 represents at most a partial year effect for a subset of the treatment group. The parameterized estimate shows that the 340B expansion led to an average of 3.3% decrease in unit drug charge at CAHs (Table A11).[39] When interacting the treatment variable

[36] It's not entirely clear whether hospitals are required to set and report the same charge for all patients regardless of insurance coverage. However, on many hospitals' website, they claim that their charges are the same for all patients, although some hospitals mention that variation could occur due to patient complications or severity of illness. Also according to these websites, hospitals are required by federal government to use uniform charges as the starting point for all bills. For hospitals paid under OPPS, although they are not directly reimbursed by Medicare for packaged drugs, they are required to report the charge for these drugs.

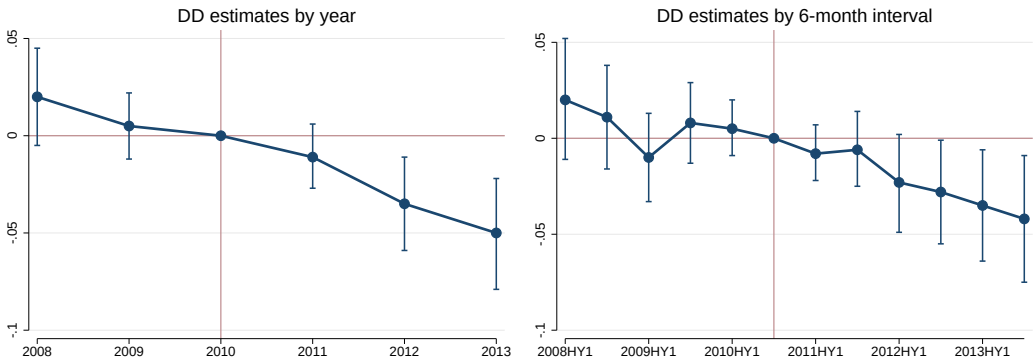
[37] I do not weigh the regression by the number of claims per drug-hospital-time. In many cases the unit charge for a drug is the same across all patients treated at the same hospital within a certain time period but the unit charge for a drug could vary substantially across hospitals. For group-level variance with a large common cluster component and a small individual component, weighing by the size of the group could potentially exacerbate or lead to the issue of heteroskedasticity (Solon, Haider, and Wooldridge, 2015).

[38] The sample of drugs consists of all Part B drugs identified in the claims excluding "not otherwise classified" drugs. Drugs that experienced change in packaging status under OPPS are excluded to be consistent with the main analysis. I also remove about 2% of the data that consist of observations with a year-to-year change in unit charge by more than 20 times to reduce the noise in the data.

[39] By replacing $I(\text{EligibleCAH})_f \times I(\text{Time})_t$ with $I(\text{EligibleCAH})_f \times \text{Post}$ in model 4.

with hospital ownership type, I find that the effects are similar for both public and not-for-profit CAHs.

Figure 8: DD estimates of the effect of 340B on log of unit Part B drug charge



A limitation of the DD design in this application is that what motivates a hospital to set charges at which levels could differ between CAHs and non-CAH hospitals, and so it might be more reasonable to compare within hospital type. To do so, I use an event study analysis to examine change in drug charge within CAHs and within non-CAH hospitals using this estimating equation:

$$Y_{dft} = \delta_t \; + \; \alpha_{df} \; + \; \sum_{k=-m}^{+n} \beta_k \times \mathbb{I}(\text{Time})_k \; + \; \epsilon_{dft} \tag{5}$$

Similar to model 3, the event time I(Time)$_k$ in equation 5 is normalized such that it equals zero in the year that a hospital joined 340B. To facilitate identification of secular trends, I include control hospitals and divide these hospitals into two groups based on whether they joined 340B in years after 2013 (future adopters) or never participate in 340B (never adopters) and show separate results using each control group. To be included in the sample, participating hospitals must have at least one observation before joining 340B and two observations after (including the year of participation).[40]

The event study estimates plotted in Figure 9 corroborate the findings based on the DD estimates. For CAHs that joined 340B, there was an upward trend in the log of unit drug charge prior to participation; but the growth slowed down at the time of participation and remained flat afterwards. In contrast, a trend break is not detected for non-CAH hospitals joining 340B at around

[40]The sample definition of outpatient drugs used in the DD analysis applies – excluding "not otherwise classifed" drugs, drugs that experienced change in OPPS packaging status, and those with year-to-year change in unit charge of more than 20 times.

the same time, suggesting that drug charges at these hospitals continue to grow at steady rates after 340B participation.[41]

Figure 9: Event study of the effect of 340B on log of unit Part B drug charge

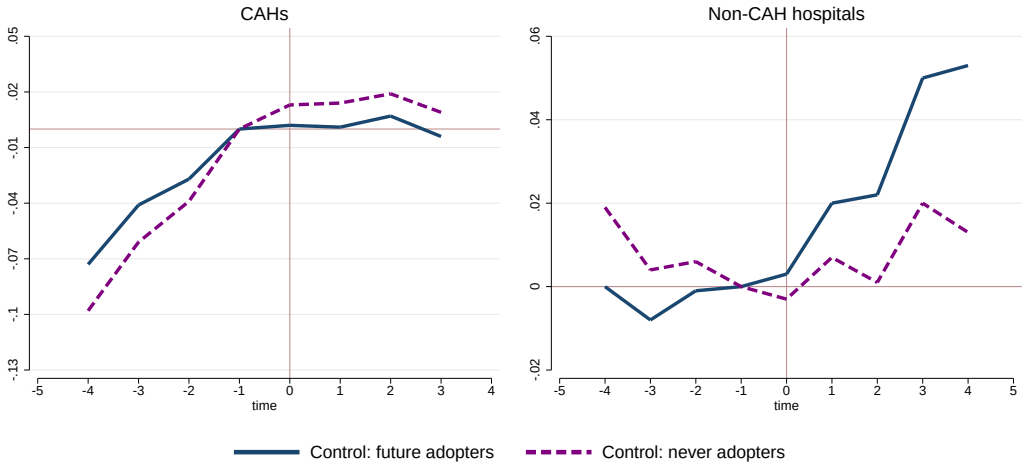


Table A12 in the Appendix shows the event study effects based on a parameterized specification, which includes a level shift post-340B (π), a linear time trend that differs for treatment and control groups (λ), and a post-340B deviation from trend (β).[42] I present the 2-year effect of 340B participation, which equals $\pi + \beta \times 2$. In general, the sign and the size of the point estimates of the 2-year effects are consistent with the DD results and the event study graphs, but the confidence intervals are too wide to reject the null hypothesis of no effect.

6.2 Alternative explanations

I consider the significance of several alternative explanations for the spending effect. Specifically, I discuss whether the observed reduction in Part B drug spending was driven by 1) substitution away from Part B drugs towards Part D drugs; 2) a significant increase in payment rates for Part B drugs under OPPS; and 3) substitution away from expensive Part B drugs towards less costly Part B drugs.

[41] I also estimate an alternative event study specification, where I replace the outcome in model 5 with $Y_{dft} - Y_{df(t-1)}$ and remove the drug-hospital fixed effects from the model. This is essentially a first-difference method. I explore this method to reduce potential endogenous sampling due to the sample restrictions mentioned above. The results based on this first-difference approach are consistent with the event study analysis (results not shown).

[42] Specifically, the estimating equation is:

$$Y_{dft} = \delta_t + \alpha_{df} + \lambda \times \mathbb{I}(340\text{B})_f \times t + \pi \times \mathbb{I}(\text{Post340B})_t + \beta \times \tau_{\text{post340B}} + \epsilon_{dft}$$

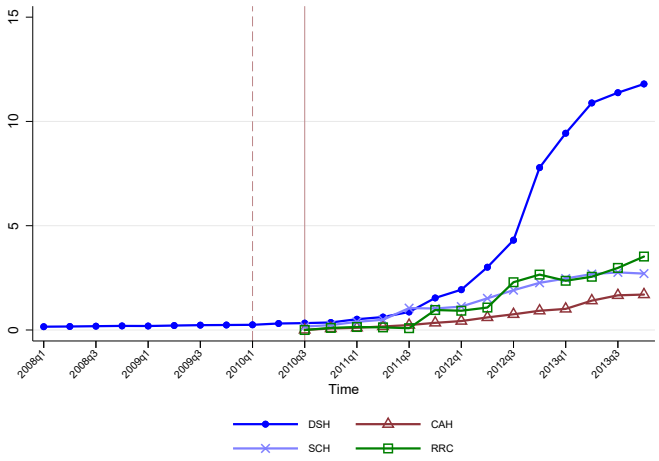
6.2.1 *Substitution towards Part D drugs*

First, the 340B expansion coincided with a number of policy changes that could affect the utilization of self-administered drugs covered by Medicare Part D, giving rise to the possibility of substitution away from Part B drugs toward Part D drugs and the concern that the observed spending effect of 340B may represent differential substitution across HRRs. The ACA introduced a number of cost subsidies for Part D enrollees who reach the Part D coverage gap known as the "donut hole", with the expectation that cost sharing in the coverage gap would be reduced from 100% to 25% by 2020 (Kaiser Family Foundation, 2010). Also in 2010, a restriction on the use of contract pharmacies was lifted to allow 340B-covered hospitals to dispense self-administered drugs acquired from the 340B program via multiple contract pharmacies. Both policy changes could potentially increase the supply and utilization of Part D drugs.[43]

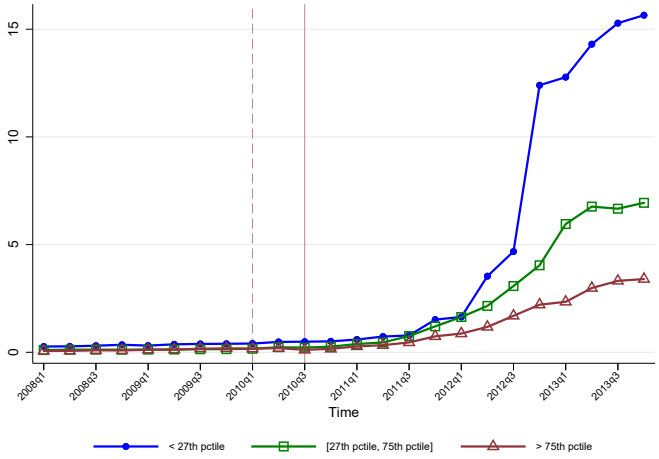
While in theory substitution between Part B and Part D drugs is plausible, in practice the extent and direction of such substitution appear to vary across conditions and/or class of treatments and could depend on Part D formulary design. Due to the small sample size of my data, I am unable to inverstigate substitution directly, but previous research suggests that substitution, if any, is likely to be modest. Taylor (2013) finds that increasing the cost sharing for Part D specialty drugs lead to no effect on utilization of Part B drugs for patients with rheumatoid arthritis or multiple sclerosis, and small and inconsistent effect for cancer patients. Jung, Feldman, and McBean (2017) corroborate this finding by showing that utilization of Part B cancer drugs and chemotherapy is not responsive to increase in copayment for Part D cancer drugs. Some also argue that the ACA's Part D cost sharing cap is unlikely to make a considerable difference in out-of-pocket cost, as many patients on expensive drug treatments would reach the catastrophic coverage regardless (Yazdany, Tonner, and Schmajuk, 2015). Finally, when I plot the number of 340B contract pharmacies that are affiliated with each type of 340B hospitals or available in each group of HRRs (Figure 10), it becomes obvious that, in contrast to what the theory of substitution to Part D drugs would have implied, non-CAH hospitals and hospitals in HRRs with a lower $\text{CAHshare}_{\text{h}}$ potentially have a greater capacity to expand utilization of Part D drugs.

[43] Einav, Finkelstein, and Schrimpf (2015) suggest that closing the donut hole will increase annual total Part D drug spending by $45 per beneficiary after accounting for individual cross-year substitution.

Figure 10: Average number of 340B contract pharmacies 2002-2016



(a) By 340B hospital entity type



(b) By CAHshare$_h$

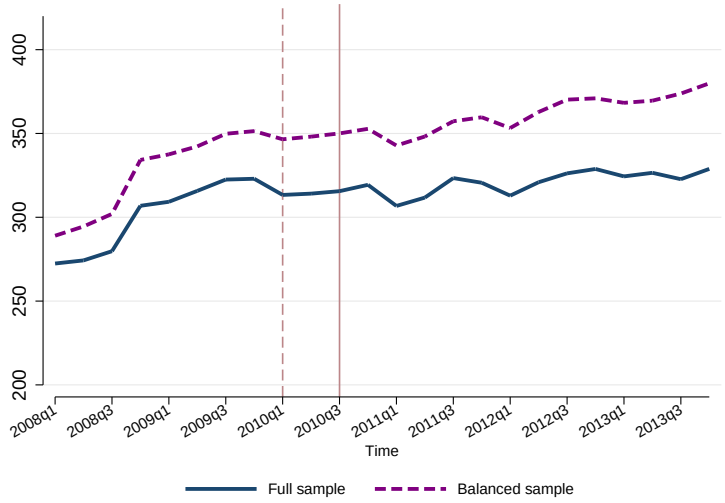
Notes: Number of unique contract pharmacies per hospital based on author's analysis of the 340B administration records. DSH = Disproportionate Share Hospital, CAH = Critical Access Hospital, SCH = Sole Community Hospital, RRC = Rural Referral Center. The dash vertical line indicates when the ACA was signed into law, and the solid vertical line indicates when newly eligible hospitals started to join 340B. The first contract pharmacy was listed with a beginning date of 2002Q3 according to the data.

6.2.2 *OPPS payment rates for Part B drugs*

A second possible explanation is that the observed reduction in Part B drug spending may be driven by an increase in OPPS Part B drug payment rates rather than a 340B-associated decrease in cost-based Part B drug payment rates. This would lead to a disproportionate increase in Part B drug spending in HRRs with a lower CAHshare$_h$ relative to HRRs with a higher CAHshare$_h$,

holding utilization constant. Since the OPPS payment rates for most outpatient Part B drugs are set at ASP plus 4% to 5% over 2008-2013, in Figure 11, I plot the time series of ASP for all drugs that are listed in the ASP data as well as for a fully balanced sample of drugs from that same data. It is clear that the ASP rates did not change abruptly between 2010 and 2011, allowing me to rule out OPPS payment rate increase as a mechanism.[44]

Figure 11: Mean average sales prices (ASP) for Part B drugs by 6-month interval



Note: Graphs show the average of CPI-U adjusted ASP. The data used for this graph include all non-vaccine drugs listed in the ASP pricing files but exclude those whose OPPS packaging status changed. Q2043 (Sipuleucel-T) is excluded due to extremely high initial price, i.e., payment limit > $30,000. Sipuleucel-T treats advanced prostate cancer and was first observed in the second half of 2011. Excluding Q2043 from the main DD analysis does not change the results.

6.2.3 *Substitution towards low-cost Part B drugs*

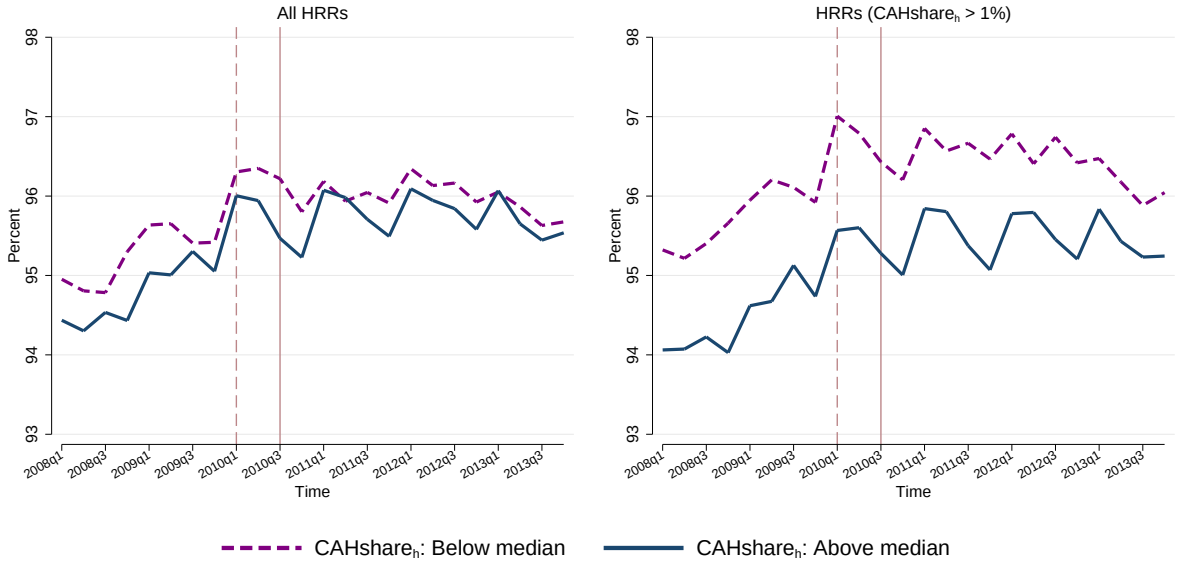
Finally, changes in spending may reflect change in the composition of drugs used, and in this setting I would be worried about CAHs switching towards lower-cost drugs and/or non-CAHs switching towards higher-cost drugs. Again, due to the small sample of my data, I am unable to examine substitution of treatment options for the same condition at the hospital level. I can, however, test whether the overall use of low-cost drugs has been changing disproportionately in HRRs more affected by 340B expansion. To hold constant the definition of "low-cost" drugs over time, a drug is flagged "low-cost" if its per unit ASP rate throughout 2008-2013 averaged below $80 (in 2013

[44]The payment rate was 105% ASP in 2008, 104% ASP in 2009, 104% in 2010, 105% in 2011, 104% in 2012, and 104.3% in 2013. Taking add-on payment into account does not change the results.

dollars), which is roughly the 75th percentile of the overall ASP distribution. Any packaged drugs per OPPS rules would also meet this criterion.[45] I apply this definition of low-cost drug to all drugs in the sample – although CAHs are not paid based on ASP, ASP rates provide reasonable proxies for what may be considered low-cost drugs to CAHs.

Figure 12 shows the average percentage of low-cost Part B drug events by high versus low CAHshare_h. The left panel includes all HRRs, while the right panel removes HRRs with $\text{CAHshare}_h < 1\%$. Not surprisingly, Part B drugs administered in hospital outpatient department settings were predominantly low cost or packaged drugs. Throughout much of the post-policy period, the use of low-cost drugs in HRRs with high and low CAHshare_hevolved on similar trends. In the right panel, the two lines were parallel to each other between 2008 and 2012 and only started to converge slightly in 2013Q1. This mitigates the concern that changes in the composition of drugs might be driving the main results.

Figure 12: Average percentage of events of Part B drugs < $80 per unit



Notes: Time series of the average percentage of low cost Part B drugs. A drug is deemed low cost as long as the its CPI-adjusted average ASP payment rate is less than $80 over 2008-2013, including those that are packaged into the procedure for which the drug is used. The dash vertical line indicates 2010Q1, when the ACA was enacted; the solid vertical line indicates 2010Q3, when the CAHs started joining 340B as a result of the program's expansion.

[45]The threshold for packaging per CMS OPPS rules went from $60 in 2008 to $80 in 2013 per day

7 Discussion and Conclusion

Previous research on 340B has come to the conclusion that the program led to higher Part B drug spending in hospital outpatient departments. The concern over not-for-profit hospitals exploiting the program for own financial interest without benefiting patients has put the program under considerable scrutiny (Nikpay, M. J. B. Buntin, and Conti, 2017; Conti, Nikpay, et al., 2018). In this work, however, I uncover substantial cost reductions due to 340B within the CAH setting. The results show that the ACA's extension of 340B eligibility to CAHs has contributed to meaningful cost savings for rural patients and the Medicare program. They also highlight that hospitals' responses to 340B and its resulting implications for patients and payers largely depends on the underlying reimbursement policies. Under cost reimbursement, CAHs share the savings with Medicare whenever costs go down and can redistribute some of the savings to patients by adjusting charges. It is within this setting that 340B appears to provide some financial relief to the targets it originally intended to benefit.

To put the estimated treatment effect on Part B drug spending into perspective, I perform a back-of-envelope calculation of savings in the aggregate. There were roughly 17.9 million aged Medicare fee-for-service beneficiaries with both Part A and Part B coverage that used hospital outpatient services in 2013, an estimated 9.6% of these beneficiaries received Part B drugs in a hospital outpatient department that resulted in a positive payment.[46] Given an average predicted $\text{CAHshare}_{\text{h}}$ of 12% (in other words, an average of 12% of outpatient visits were accounted for by 340B-eligible CAHs), the estimated effects of 340B expansion on Part B drug spending translate into reductions of $160 million and $49 million in Medicare program payment and beneficiary cost sharing respectively over the five quarters after the expansion. Together, they represent approximately 2.9% of total Medicare spending on Part B drugs across all acute care hospitals in 2013, and roughly 6.5% of the amount Medicare and beneficiaries spent on CAH outpatient services in a year.[47]

The negative relationship between 340B and charges for outpatient drugs at CAHs has important implications because high charges disproportionately burden the most financially vulnerable,

[46]The Medicare population by HRR can be found in public use files released by CMS at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/GV_PUF.html

[47]Medicare spending on Part B drugs at 340B-covered acute care hospitals was $3.5 billion in 2013 and represented 48 percent of total Medicare spending on Part B drugs at all acute care hospitals including CAHs (Medicare Payment Advisory Commission, 2015). Medicare and beneficiaries spent a total of $3.24 billion in 2012 (in 2013 dollars) on CAH outpatient services (Office of Inspector General, 2014).

including Medicare beneficiaries with no supplemental insurance and uninsured patients. The latter group often face medical bills at the amount of full charge upon receiving hospital care. It is also relevant as researchers and policymakers seek to understand the motive of public and not-for-profit hospitals, and as the public increasingly questions these hospitals' commitment to community benefits (Rosenthal, 2013).

The lack of response in Part B drug utilization may reflect the challenges CAHs face in increasing patient volume – a persistent problem for rural hospitals. In addition, it is possible that they lack the resources to administer the program on a wider scale, as it has been the case for non-CAH rural hospitals according to a 2007 survey (Schur et al., 2007). Anecdotal evidence also points to caution shared by some CAHs about expanding outpatient drug use under 340B due to its impact on Medicare revenue.[48]

Finally, the orphan drug exclusion rule represents a missed opportunity to achieve greater cost savings. Orphan drugs remains one of the major financial constraint to rural hospitals, but CAHs and other rural hospitals have been prohibited from purchasing orphan drugs through 340B.[49] A recent review of invoice for drug purchases at a number of CAHs in two states reveals that, while orphan drugs only account for a sliver of the total quantity of drugs acquired, they comprise an average 44% of the annual drug budgets (Wallack and Sorensen, 2012). Without sufficient market power and patient volume to negotiate a better price, small, rural hospitals often struggle to keep orphan drugs in stock (Tribble, 2017). Allowing CAHs to acquire orphan drugs at 340B prices can help strengthen the rural health care system and give patients the option to not travel far for life-saving medications.

[48]For example, two pharmacists at CAHs discussed the trade off of using the program such as lower Medicare payment, accountability and costs in a news letter issued by the Illinois Critical Access Hospital Network.

[49]Before 2015, the exclusion only applied to orphan drugs used to treat orphan indications. Starting in 2015, the exclusion applies to both orphan indication and off-label use.

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Appendix

Tables

Table A1: 340B policy timeline

Year	Legislation	340B-related policy change	Added hospital eligibility
1992	Veterans Health Care Act	Created 340B	General acute care hospitals with a Medicare DSH adjustment > 11.75%
2003	Medicare Prescription Drug, Improvement, and Modernization Act	Increased the cap on Medicare DSH adjustment for rural hospitals and urban hospitals with fewer than 100 beds from 5.25% to 12%	Rural and urban hospitals previously unable to participate in 340B due to the cap
2005	Deficit Reduction Act	Expanded 340B	Children's Hospitals with a Medicare DSH adjustment > 11.75%
2010	Affordable Care Act	Expanded 340B	Critical Access Hospitals (rural)
			Free-Standing Cancer Hospitals with a Medicare DSH adjustment > 11.75%
		Lowered DSH adjustment threshold to 8%	Sole Community Hospitals (rural) with a Medicare DSH adjustment between 8%~11.75%
			Rural Referral Centers (rural) with a Medicare DSH adjustment between 8%~11.75%

Notes: General acute care hospitals receiving Medicare DSH payment adjustment are typically referred to as Disproportionate Share Hospitals, or DSH. Sole Community Hospitals and Rural Referral Centers, which are paid under the Prospective Payment System, could also receive Medicare DSH payment. See Mulcahy et al. (2014) for a more detailed discussion of the 340B program history.

Table A2: Medicare payment for Part B drugs

	Cost reimbursement	Outpatient Prospective Payment System (OPPS)
Payment rate	101% of the cost of a drug (specific to the hospital)	104%~105% of the average sales price of a drug (based on sales to non-340B purchasers)*
Beneficiary cost sharing	20% of charge for the drug	20% of OPPS payment rate
Medicare program payment	Difference between total payment rate and beneficiary cost sharing	Difference between total payment rate and beneficiary cost sharing

Notes: During the study period 2008-2013, the OPPS payment rate was between 104% and 105% of the average sales price of a drug.

Table A3: Hospital eligibility based on pre- and post-ACA eligibility criteria

Hospital type	Number of hospitals eligible for 340B	
	Based on pre-ACA criteria	Based on ACA criteria
Critical Access Hospitals	0	1,231
Sole Community Hospitals	161 (70% of 230)	230
Rural Referral Centers	117 (71% of 164)	164

Notes: Author's calculation based on 2009 Medicare cost report data linked to the 340B program database.

Table A4: Predominately urban HRRs

HRR-level treatment intensity ($CAHshare_h$)	Number of HRRs	% HRRs predominately urban
$CAHshare_h < 1\%$	83	
States that do not certify CAH	15	–
Other states	68	62%
$CAHshare_h > 1\%$	223	27%

Notes: Predominately "urban" HRR is defined as HRR where more than half of the zip codes assigned to the HRR are in a metropolitan county.

Table A5: Patient characteristics 2008-2013

		By hospital treatment status		By HRR-level treatment intensity ($CAHshare_h$)		
		Comparison hospitals	340b-eligible CAHs	< 27th pctile	[27th pctile, 75th pctile]	> 75th pctile
Age	Mean	76.0	77.0	76.3	75.8	76.3
	SD	7.3	7.7	7.4	7.2	7.4
Female	Mean	0.58	0.58	0.58	0.58	0.57
	SD	0.49	0.49	0.49	0.49	0.50
White	Mean	0.88	0.96	0.83	0.89	0.96
	SD	0.33	0.20	0.37	0.31	0.20
Black	Mean	0.08	0.02	0.10	0.08	0.02
	SD	0.27	0.14	0.30	0.27	0.14
Medicaid-eligible	Mean	0.16	0.18	0.17	0.16	0.13
	SD	0.36	0.39	0.38	0.36	0.34
CMS-HCC risk score	Mean	1.9	1.8	2.0	1.8	1.7
	SD	1.5	1.4	1.6	1.5	1.4
Charlson Index	Mean	1.4	1.4	1.5	1.4	1.2
	SD	1.7	1.7	1.8	1.7	1.6
Cancer diagnosis	Mean	0.28	0.23	0.30	0.27	0.26
	SD	0.45	0.42	0.46	0.44	0.44
Rheumatology diagnosis	Mean	0.31	0.30	0.33	0.31	0.29
	SD	0.46	0.46	0.47	0.46	0.45
Hematology diagnosis	Mean	0.37	0.33	0.42	0.36	0.31
	SD	0.48	0.47	0.49	0.48	0.46
Ophthalmology diagnosis	Mean	0.04	0.03	0.04	0.03	0.04
	SD	0.19	0.18	0.20	0.18	0.19

Notes: Patients treated in hospital outpatient departments, conditioning on having any Part B drug use. HRRs with treatment intensity less than 1% fall below the 27th percentile, i.e., $\Pr(CAHshare_h < 1\%) = 0.27$, thus the choice of 27th percentile in dividing HRRs into three groups. Data are at the beneficiary-year-quarter level.

Table A6: Summary of dependent variables in non-institutional settings by HRR predicted treatment intensity

		HRR-level treatment intensity ($CAHshare_h$)		
		$<$ 27th pctile	[27th pctile, 75th pctile]	$>$ 75th pctile
Any Part B drug use	Mean	0.17	0.18	0.15
	SD	0.38	0.38	0.36
	N	7,630,311	11,500,000	3,202,639
Number of Part B drug events	Mean	2.77	2.69	2.60
	SD	5.13	5.00	5.05
	N	1,293,974	2,051,117	485,222
Total Part B drug payment	Mean	809.1	713.2	765.2
	SD	2977.8	2901.4	2985.1
	N	1,293,970	2,051,105	485,220
Part B drug Medicare payment	Mean	645.1	568.4	609.7
	SD	2379.9	2318.9	2385.9
	N	1,293,970	2,051,105	485,220
Part B drug beneficiary copayment	Mean	163.9	144.8	155.5
	SD	598.0	582.6	599.4
	N	1,293,970	2,051,105	485,220

Notes: Data are at the beneficiary-year-quarter level. N represents the number of beneficiary-year-quarter observations over the study period. The number of Part B drug events is conditioning on having positive Part B drug use; the payment outcomes are conditioning on having positive total payment. HRRs with treatment intensity $< 1\%$ fall below the 27th percentile, i.e., $\Pr(CAHshare_h < 1\%) = 0.27$, thus the choice of 27th percentile in dividing HRRs into three groups.

Table A7: Fraction of sample loss due to OPPS drug packaging

Year	HRR-level treatment intensity ($CAHshare_h$)		
	$<$ 27th pctile	[27th pctile, 75th pctile]	$>$ 75th pctile
2008	0.87	0.85	0.69
2009	0.85	0.83	0.67
2010	0.84	0.82	0.65
2011	0.83	0.81	0.65
2012	0.81	0.79	0.64
2013	0.80	0.77	0.64

Notes: HRRs with treatment intensity $< 1\%$ fall below the 27th percentile, i.e., $\Pr(CAHshare_h < 1\%) = 0.27$, thus the choice of 27th percentile in dividing HRRs into three groups.

Table A8: Eight-quarter effects of 340B (hospital outpatient departments)

	All HRRs	HRRs ($CAHshare_h > 1\%$)
Probability of Part B drug use	0.001	0.001
	(0.002)	(0.002)
	[-0.002, 0.004]	[-0.002, 0.005]
Number of Part B drug events	0.02	0.03
	(0.02)	(0.03)
	[-0.02, 0.07]	[-0.02, 0.08]
Total Part B drug payment	-90.48**	-144.23***
	(38.87)	(37.59)
	[-166.95, -14.00]	[-218.20, -70.27]
Part B drug Medicare payment	-87.95***	-119.15***
	(29.07)	(28.57)
	[-145.15, -30.75]	[-175.36, -62.94]
Part B drug beneficiary copayment	-16.31*	-24.85**
	(9.37)	(10.08)
	[-34.75, 2.14]	[-44.69, -5.01]

Notes: Effects of 340B shown as the changes in outcomes per 10 percentage-point increase in HRR-level 340B treatment intensity under the program expansion between 2010Q3–2012Q2 relative to 2008Q4–2010Q3 . Clustered standard errors are in the parentheses, and the 95% confidence interval in brackets. *** $p < 0.01$; ** $p < 0.05$; * $p < 0.1$.

Table A9: GLM five- and eight-quarter effects of 340B (hospital outpatient departments)

	Five-quarter effects		Eight-quarter effects	
	All HRRs	HRRs (CAHshare$_h$> 1%)	All HRRs	HRRs (CAHshare$_h$ > 1%)
Number of Part B drug events	1.005	1.007	1.007	1.012
	(0.006)	(0.006)	(0.007)	(0.008)
	[0.994, 1.016]	[0.996, 1.018]	[0.994, 1.021]	[0.995, 1.028]
Total Part B drug payment	0.965	0.957	0.942**	0.922***
	(0.026)	(0.029)	(0.022)	(0.024)
	[0.915, 1.017]	[0.903, 1.015]	[0.899, 0.986]	[0.877, 0.970]
Part B drug Medicare payment	0.958	0.955	0.935***	0.920***
	(0.027)	(0.030)	(0.022)	(0.024)
	[0.906, 1.012]	[0.897, 1.016]	[0.892, 0.979]	[0.875, 0.968]
Part B drug beneficiary copayment	0.963	0.953*	0.953**	0.934***
	(0.023)	(0.025)	(0.022)	(0.023)
	[0.919, 1.008]	[0.906, 1.003]	[0.911, 0.996]	[0.890, 0.980]

Notes: Effects of 340B shown for 10 percentage-point increase in HRR-level 340B treatment intensity under the program expansion. Clustered standard errors are in parentheses, and the 95% confidence interval in brackets. Reported here are the exponentiated coefficients, interpreted as the ratio between the changes in outcomes between 2010Q3–2011Q3 and 2009Q3–2010Q3 for the five-quarter effects, and in outcomes between 2010Q3–2012Q2 and 2008Q4–2010Q3 for the eight-quarter effects . The standard errors are derived using the Delta method. *** $p < 0.01$; ** $p < 0.05$; * $p < 0.1$.

Table A10: Five-quarter effects of 340B robustness to sample selection

All HRRs; hospital outpatient departments

	Main sample (for reference)	Patients with chronic conditions	Remove Medicaid dual-eligibles
Probability of Part B drug use	-0.000	-0.001	-0.000
	(0.001)	(0.002)	(0.001)
	[-0.002, 0.002]	[-0.004, 0.002]	[-0.002, 0.002]
Number of Part B drug events	0.01	0.00	0.03
	(0.02)	(0.03)	(0.02)
	[-0.02, 0.05]	[-0.05, 0.05]	[-0.01, 0.06]
Total Part B drug payment	-77.71*	-106.75*	-48.98
	(45.75)	(60.20)	(49.37)
	[-167.73, 12.31]	[-225.20, 11.70]	[-146.13, 48.18]
Part B drug Medicare payment	-68.79**	-90.13**	-46.51
	(34.12)	(45.11)	(36.27)
	[-135.93, -1.66]	[-178.90, -1.36]	[-117.89, 24.86]
Part B drug beneficiary copayment	-24.08**	-31.87**	-20.22
	(10.99)	(14.93)	(12.52)
	[-45.69, -2.46]	[-61.25, -2.48]	[-44.86, 4.43]

Notes: Effects of 340B shown for 10 percentage-point increase in HRR-level 340B treatment intensity under the program expansion for all HRRs. Drugs used in hospital outpatient departments only. Clustered standard errors are in parentheses, and the 95% confidence interval in brackets. Both the raw and exponentiated coefficients and standard errors derived from GLM are reported. The standard errors for the exponentiated coefficients are derived using the Delta method. *** $p < 0.01$; ** $p < 0.05$; * $p < 0.1$.

Table A11: DD effect of 340B on log of average unit hospital drug charge

	All	Public	Not-for-profit
$\text{I(EligibleCAH)}_f \times \text{Post}$	-0.033***	-0.032**	-0.041**
	(0.012)	(0.014)	(0.018)
N		488,095	

Notes: Standard errors clustered at the hospital level in parentheses. *** $p < 0.01$; ** $p < 0.05$; * $p < 0.1$.

Table A12: Event study of 340B on log of average unit hospital drug charge (parameterized model)

	All hospitals			Not-for-profit			Publicly owned		
Panel A: CAHs									
2-year effect	-0.060	-0.042	-0.048	-0.054	-0.040	-0.045	-0.065*	-0.045	-0.057
	(0.037)	(0.032)	(0.032)	(0.038)	(0.033)	(0.034)	(0.039)	(0.035)	(0.035)
N	34,396	47,280	45,536	34,329	47,181	45,438	34,329	47,181	45,438
Panel B: non-CAH hospitals									
2-year effect	0.010	0.013	0.012	0.019	0.020	0.018	-0.025	-0.015	-0.017
	(0.027)	(0.025)	(0.024)	(0.028)	(0.026)	(0.025)	(0.032)	(0.030)	(0.030)
N	44,877	104,896	375,476	44,874	104,893	374,807	44,874	104,893	374,807
Control group: None	Y			Y			Y		
Control group: Future adopters		Y			Y			Y	
Control group: Never adopters			Y			Y			Y

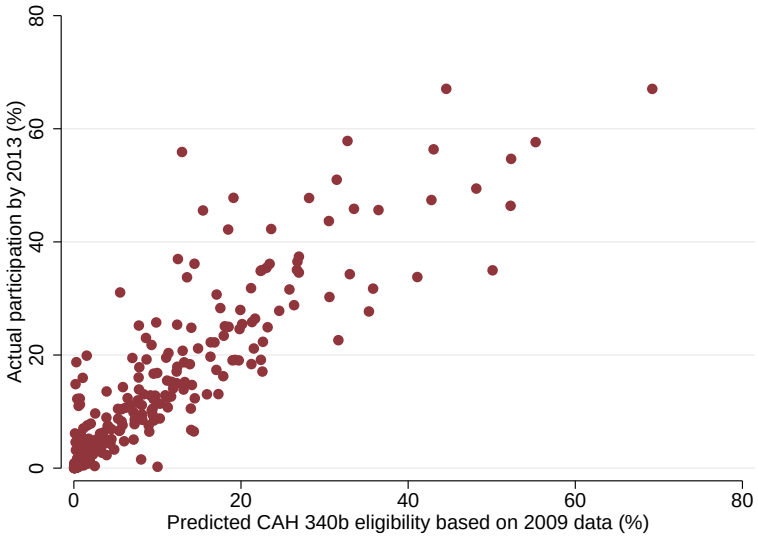
Notes: Effects estimated using parameterized event study specification:

$$Y_{dft} = \delta_t + \alpha_{df} + \lambda \times \mathbb{I}(340\text{B})_f \times t + \pi \times \mathbb{I}(\text{Post340B})_t + \beta \times \tau_{\text{post340B}} + \epsilon_{dft}$$

The 2-year effect equals estimated level shift at k = 0 plus the treat break estimate times 2. Standard errors clustered at the hospital level in parentheses. *** p < 0.01; ** p < 0.05; * p < 0.1.

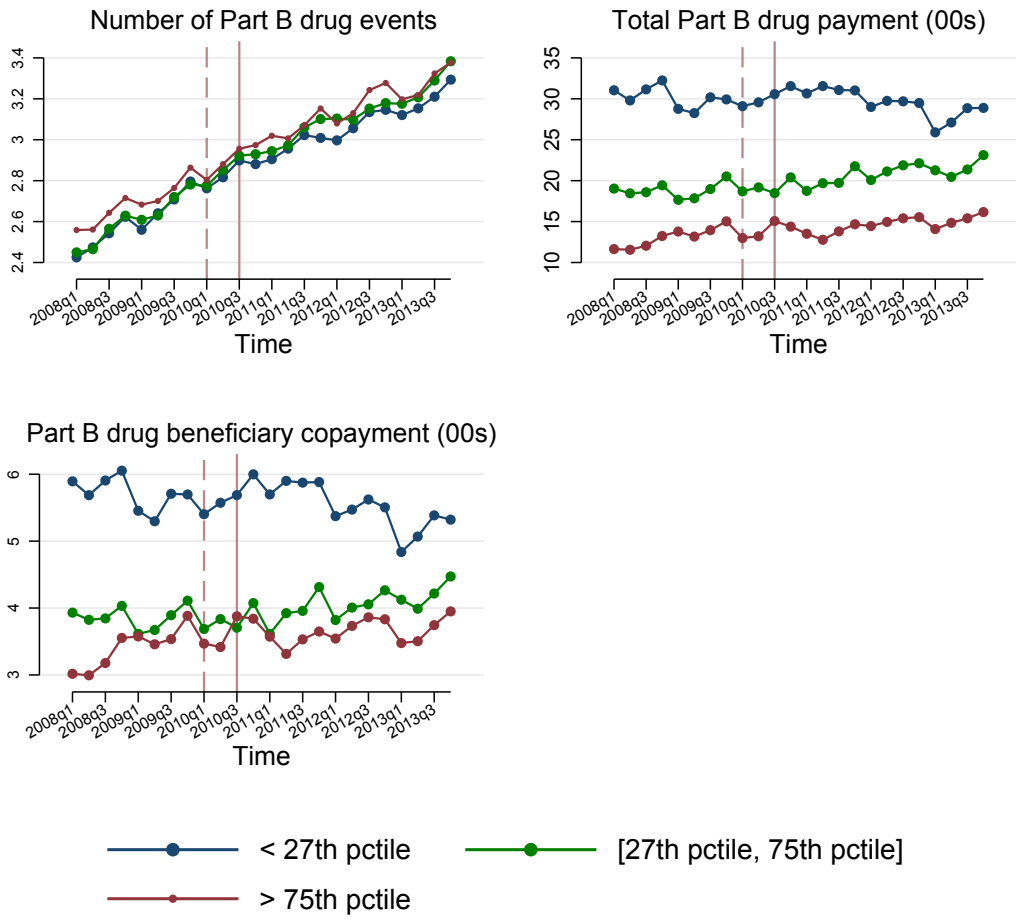
Figures

Figure A1: Relationship between $\text{CAHshare}_{\text{h}}$ and estimated treatment intensity based on actual participation



Notes: Each dot in the graph represents a HRR, the x-axis is the predicted treatment intensity $\text{CAHshare}_{\text{h}}$, the y-axis is the treatment intensity calculated based on actual 340B participation and outpatient visits to CAHs by 2013.

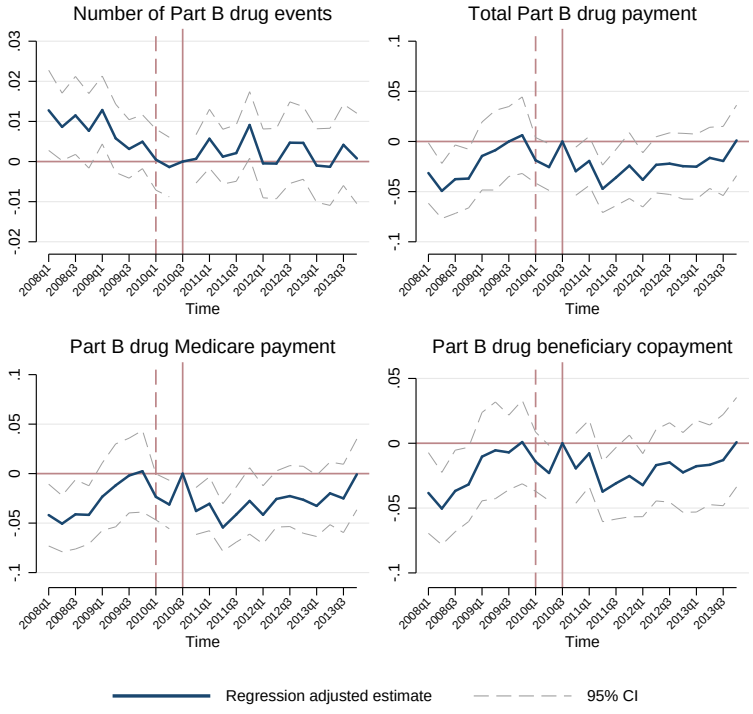
Figure A2: Selected dependent variables in hospital outpatient departments by $\text{CAHshare}_{\text{h}}$



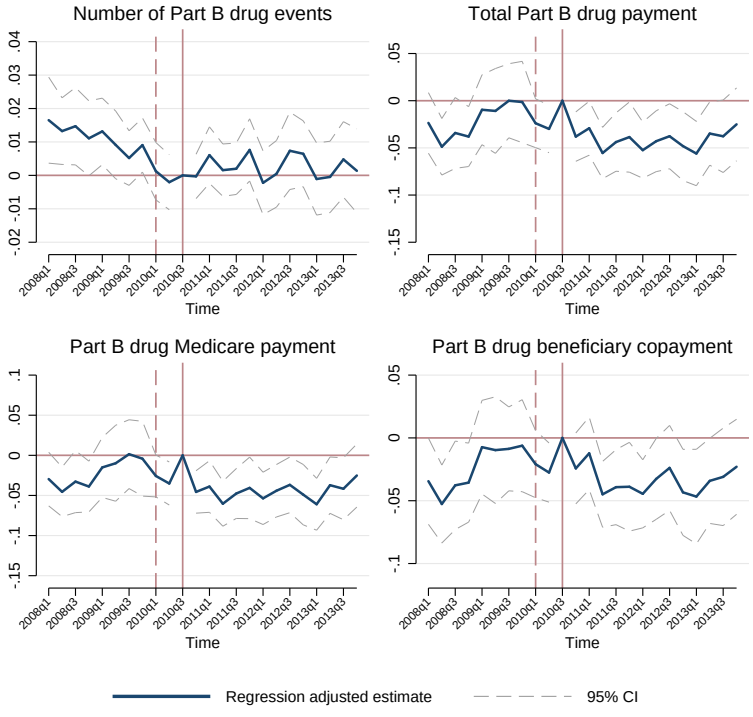
Notes: Time series of dependent variables in hospital outpatient department settings at the beneficiary-year-quarter level by HRR-level 340B treatment intensity ($\text{CAHshare}_{\text{h}}$). The number of Part B drug events is conditioning on having positive Part B drug utilization, while the two payment outcomes are conditioning on having positive total payment. HRRs with treatment intensity of less than 1% fall below the 27th percentile, i.e., $\Pr(\text{CAHshare}_{\text{h}} < 1\%) = 0.27$, thus the choice of 27th percentile in dividing HRRs into three groups.

Figure A3: GLM estimated β_t – HRR-level identification

(Part B drugs administered in hospital outpatient departments)



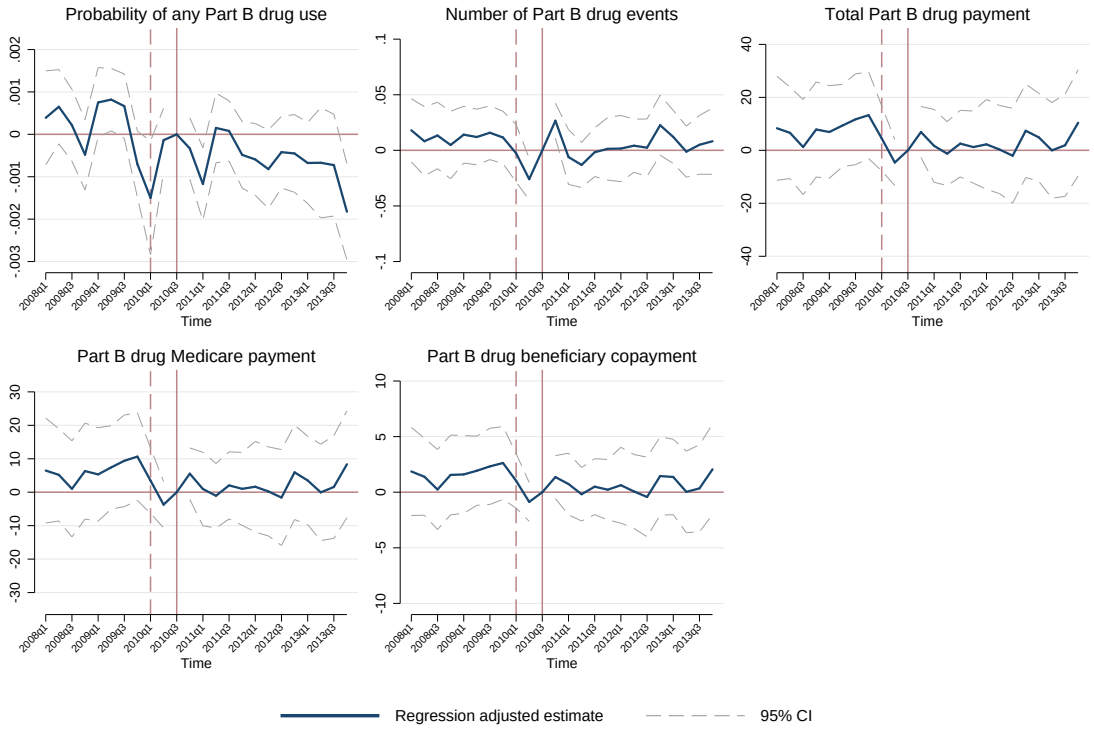
(a) All HRRs



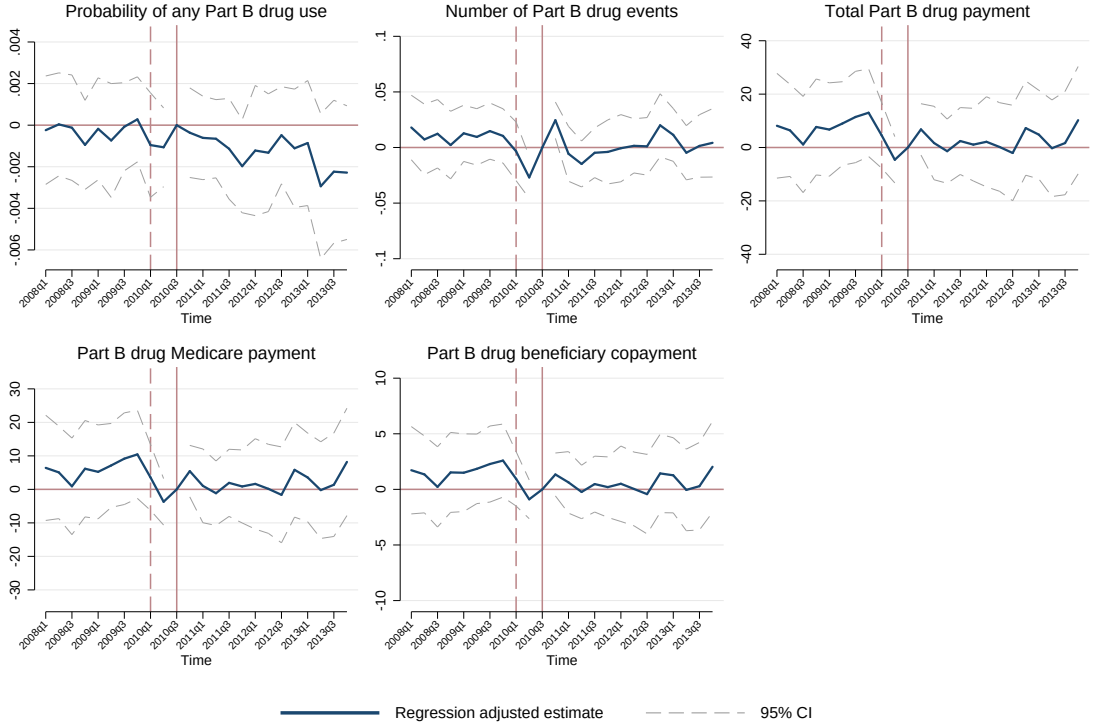
(b) HRRs with CAHshare$_h$> 1% (within variation)

Figure A4: OLS estimated β_t – HRR-level identification

(Part B drugs administered in non-institutional settings)



(a) POS = 11 or 22



(b) POS = 11

Figure A5: OLS estimated β_t – HRR-level identification: beneficiaries under age 65

(Part B drugs administered in hospital outpatient departments)