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Effects of the 340B Drug Pricing Program on Hospitals' Prescribing Behavior, Patient Mix, and Quality of Care

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by

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Abstract

In 1992, Congress created the 340B Drug Pricing Program that requires drug manufacturers to provide outpatient drugs to participating hospitals with substantial discounts. Although the intent of the program is to allow covered entities to increase access to care for more vulnerable patients, hospitals are not required by law to pass on the discounts. Therefore, a concern is that hospitals might over-prescribe. This dissertation includes three chapters to study the effects of the 340B program on hospitals' behavior changes:

Chapter 1 uses state aggregate hospital service spending data from the Centers for Medicare and Medicaid Services (CMS) to study the nation-wide impact of state 340B hospital participation on state hospital service spending. Controlling for state fixed effects, time fixed effects and state specific time trends, I find, on average, a 1 percentage point increase in state 340B hospital share leads to a 12.8% increase in state hospital service spending per capita. With only hospital spending data, analysis in this chapter cannot distinguish between a scenario where hospitals increase their spending to improve quality of care, consistent with the intent of the 340B program, and a scenario where hospitals are simply increasing spending without improving quality to maximize profit.

Chapter 2 complements the analysis in Chapter 1 by exploring the causal impact of the 340B program on hospitals' medication cost, patient mix and quality of care. Working with 15 million ambulatory visits to Florida hospitals from 2005 to 2015, I use a series of difference-in-difference (DID) and synthetic control methods (SCM) based on the 2010 340B eligibility expansion, I find an average increase of $111.35 in medication cost per visit due to the 2010 expansion. Quantile regressions reveal that hospitals with the highest proportion of charity care and uninsured patients keep medication cost low and on the most expensive visits, they significantly reduce medication cost for patients. The remaining newly eligible hospitals significantly raise medication cost after the expansion. The increase becomes larger the more expensive the treatment is. Finally, I find some indications that newly eligible hospitals increased Medicaid patient mix and improved quality of care, but the evidence is not strong enough to be conclusive.

Chapter 3 further extends the analysis by examining the impact of market power on 340B hospitals' behavior changes. Using the CMS nation-wide state aggregate data, I find the positive relationship between the state's 340B hospital share and state aggregate hospital service spending is stronger when hospitals' market share is higher. Working with the Florida data, using a series difference-in-difference-indifference (DDD) regressions, complemented by DID and SCM estimations, I find the 340B hospitals with low market shares seem to fulfill the mission of the program by keeping medication cost low, treating more low-income patients covered by Medicaid and Medicaid managed care and provide more charity to the communities. Compared to them, hospitals with high market shares significantly raise additional medication cost, treat fewer low-income patients but substantially more commercially insured patients. There are some signs of

post-expansion quality improvement among all the newly eligible hospitals, measured by the post-operative adverse reaction rates, but heterogeneity exists in hospitals' length of stay and nonroutine discharge rates. Hospitals with high market shares seem to treat more patients in their own outpatient facilities with a shorter length of stay. While the ones with low market shares experience increased length of stay, possibly due to worse health conditions among the additional Medicaid and Medicaid managed care patients they treat.

As a summary, this dissertation finds the average 340B hospital raise their medication cost upon participation in the program, but heterogeneity exists that some of them seem to fulfill the mission of the program. There are signs of quality improvement in the data, but future research could adopt more quality measures to study the cost-effectiveness on the price increase, as well as the welfare influence on the cost reduction.

Introduction

The 340B Drug Pricing Program was created in 1992 that requires drug manufacturers to provide outpatient drugs to participating entities with substantial discounts. Although the intent of the program is to provide financial relief and allow covered entities to increase access to care for more vulnerable patients, hospitals are not required by law to pass on the discounts. Therefore, a concern is that hospitals might over-prescribe.

To evaluate such concern, I first use the state aggregate hospital service spending from Centers for Medicare and Medicaid Services (CMS) in Chapter 1 to acquire a nationwide overview on whether state 340B hospital shares are associated with the state aggregate hospital service spending that includes the majority of the 340B drug dispensing.

However, the state aggregate data does not have patient details and the fixed effects models used in Chapter 1 have the concern of potential selection endogeneity. In Chapter 2, using hospitals' patient visit data from the Florida Agency from Health Care Administration (AHCA), I use difference-in-difference (DID) models based on the exogenous 2010 340B hospital eligibility expansion to tackle potential selection endogeneity and identify causal estimates of the impact of the 340B program on 340B hospitals' prescribing patterns, patient mix, and quality of care.

Inspired by the IO literature that finds market power leads to hospitals' price increase, in Chapter 3, I use two measures of market power to construct a series of DDD models that examine the heterogeneity in the impact of the 340B program on the newly eligible hospitals by market power.

This research provides the first evidence on the impact of the 2010 expansion of the 340B program. Findings from this work provide important evidence on how hospitals react to the program in terms of hospitals' prescribing behavior patterns, quality of care, and their patient mix, and whether the program has uniform effects across hospitals and markets. These findings are crucial to understand the effectiveness of the 340B program in achieving its goals, and they inform future reforms to the program.

Background on 340B Drug Pricing Program

The 340B Drug Pricing Program was established in 1992 to correct an unintended consequence of the 1990 Medicaid prescription drug rebate program which left the Department of Veterans Affairs and safety-net providers paying higher drug prices (Coukell and Dickson, 2018). Some lawmakers involved in the design of the 340B program hoped that lower drug prices would help safety-net providers or covered entities (CEs) to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" (RAND, 2014).[1][2] It derives its name from Section 340B of the Public Health Service Act (PHSA).

Participation is voluntary for both covered entities and drug manufacturers, but there are strong incentives to participate. For example, drug manufacturers must offer 340B discounts to covered entities as a condition to participate in Medicaid, while covered entities can realize substantial savings through discounted price, estimated to be 30% - 50% off the Average Manufacturer Price (AMP), known as the 340B ceiling price.[3][4] In

[1] Covered entities include certain types of hospitals, health centers, and specialized clinics. (https://www.hrsa.gov/opa/eligibility-and-registration/index.html)
[2] https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE121/RAND_PE121.pdf
[3] AMP is defined as the average price paid to the manufacturer for the drug in the US by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer. (§ 1927(k)(1) of the Act)
[4] The 340B ceiling price refers to the maximum amount that a manufacturer can charge a covered entity for the purchase of a 340B covered outpatient drug. The 340B ceiling price is statutorily defined as the Average Manufacturer Price (AMP) reduced by the rebate percentage, which is commonly referred to as the Unit Rebate Amount (URA). HRSA obtains the AMP and URA data from the Centers for Medicare & Medicaid Services (CMS) as part of quarterly reporting for the Medicaid Drug Rebate Program. This figure

addition, the government also established a Prime Vendor Program (PVP) to negotiate additional discounts from drug manufacturers for 340B participants, known as the sub-ceiling price.[5] Therefore, a typical 340B hospital can earn both a drug unit rebate discount (known as the Unit Rebate Amount, URA, which is the difference between 340B the ceiling-price and the Average Market Price) and a PVP negotiated discount (namely, the difference between the ceiling-price and the sub-ceiling price) at the same time.

However, there is an exception if the payer is Medicaid because of the Medicaid Rebate Program.[6] Both the Medicaid Rebate Program and the 340B Drug Pricing Program require drug manufacturers to provide significant discounts on their products. In the former program, the discount is paid to state Medicaid as a rebate, while in the latter case, the discount goes to covered entities directly in the forms of URA. Since drug manufacturers are not required by law to offer a drug rebate to Medicaid and to covered entities (URA) for the same drug, known as the Duplicate Discount Prohibition, if a 340B hospital prescribes 340B drugs on Medicaid patients, Medicaid only reimburses them at the 340B ceiling-prices (instead of the Average Manufacturer Prices), so the URA is eliminated (refer to Appendix E for more details).[7] As a result, for Medicaid patients, 340B

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is then multiplied by the package size and case package size to produce a price that is used in the marketplace for purchasing covered outpatient drugs (https://www.hrsa.gov/opa/updates/2015/may.html).

[5] The Prime Vendor Program contracts with nearly 100 manufacturers and 40,000 covered entities to negotiate sub-ceiling prices on pharmaceuticals. It is a voluntary program for covered entities with no additional fees to enroll and participate.

[6] The Medicaid Drug Rebate Program (MDRP) requires participating drug manufacturers to pay drug rebates on a quarterly basis to states to help offset the Federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. (https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html)

[7] HRSA Duplicate Discount Prohibition (https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion/index.html)

hospitals may only obtain the remaining PVP negotiated discounts, which are much smaller than the URA.

Two criteria are common to most 340B-eligible hospitals: they must have a disproportionate share of hospital (DSH) adjustment percentage above specific thresholds, and the hospitals must either be owned or operated by state or local government, or they must be private nonprofit hospitals that have some sort of government contract to provide care to indigent patients.[8][9] Hospitals with high DSH percentage rates indicate they serve a large proportion of poor patients as measured by their relative inpatient days.[10]

The eligibility of covered entities has been expanded by Congress over time. While only DSH hospitals were allowed to participate from the inception, the 2010 Affordable Care Act (ACA) expanded 340B eligibility to four additional types of hospitals: non-profit outpatient cancer hospitals, rural referral centers, sole community hospitals and critical access hospitals.[11]

Administered by Health Resources and Services Administration (HRSA), the number of covered hospital sites almost quadrupled from 2005 to 2011 (GAO 2011). Over 46%

[8] DSH adjustment percentage > 11.75% for DSH hospitals, children's hospitals and cancer hospitals; > 8% for sole community hospitals and rural referral centers

[9] HRSA (https://www.hrsa.gov/opa/eligibility-and-registration/index.html)

[10] The DSH patient percentage is equal to the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not entitled to Medicare Part A. In particular, the formula is defined as following:
DSH Patient Percent = (Medicare SSI Days / Total Medicare Days) + (Medicaid, Non-Medicare Days / Total Patient Days)
*Supplemental Security Income (SSI) is a Federal income supplement program funded by general tax revenues to help aged, blind, and disabled people, who have little or no income

[11] Hospitals that are eligible to receive Medicare DSH adjustment payments. (https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Disproportionate_Share_Hospital.pdf)

of all U.S. hospitals participated in the 340B program as of 2018, with $29.9 billion spent on purchasing 340B drugs at 340B discounted prices in 2019 with a compound average growth rate (CAGR) of 27.1% from 2014 to 2019 (Figure 1.1).[12][13]

To fulfill the mission of this program, participating hospitals are expected to provide reduced-price drugs and expand health services to more low-income and uninsured patients. However, by law, covered entities are not required to pass the drug discounts on to patients or insurers. For instance, they can prescribe low-cost medications to well-insured, high-income outpatients, get fully reimbursed, and retain the profits without specifying how they use them. As a result, a principal-agent model would suggest moral hazard in this context: Congress, being the principal, expects all the participating hospitals to use 340B drug discounts to serve more vulnerable patients. However, hospitals possess some private information regarding the most cost-effective plans of treatment that the principal does not know. Since the agents' interests are not fully aligned with the principal and it is too costly to fully monitor agents' behaviors, it creates an incentive for participating hospitals to over-prescribe medications for additional drug discount profits, without necessarily increasing the access to care for more vulnerable patients or providing higher quality of care.

There have been a number of arguments on the merits of the program. When the Trump administration planned to slash this pharmaceutical subsidy at the end of 2017 by saying hospitals "reaped substantial profits", two major lobbying groups, Safety Net

[12] In 2018, the HRSA 340B CE database records 2876 hospitals participating in the program, compared to 6146 all U.S. hospitals estimated by the American Hospital Association (AHA).
[13] Drug Channels, New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales (https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html)

Hospitals for Pharmaceutical Access (SNHPA) and American Hospital Association (AHA) lobbied Congress to halt the new rule.[14] They further sued U.S. Department of Health and Human Services (HHS), alleging it exceeded its authority with cuts to the 340B program as Congress intended Medicare to pay more than what hospitals paid for the drugs, allowing hospitals to use the savings to benefit local communities, so the administration's new rule is contrary to congressional intent. They also argued the cuts threatened programs paid for by the subsidies, such as community outreach and transportation for patients.[15] On Dec. 29th, 2017, federal judge Rudolph Contreras in Washington dismissed the suit and since January 1, 2018, 340B hospitals received a 27% cut in Medicare Part B reimbursement for drugs purchased at the 340B price.[16]

It is clear that this program was initiated with good intention, but without additional specific legal bindings on the usage of drug discounts, it is unclear whether participating hospitals will fulfill the mission to increase access to care for the vulnerable populations.

[14] Melanie Evans, Hospitals to Defend Drug Subsidies, The Wall Street Journal, Nov. 2nd, 2017
[15] Melanie Evans, Hospitals Sue to Block HHS From Slashing Lucrative Drug Subsidies, WSJ, Nov. 13th, 2017
[16] Melanie Evans, Judge Dismisses Hospital-Industry Suit That Attempted to Stop Medicare-Subsidy Cuts, WSJ, Dec. 29th, 2017

Literature Review

Below I discuss existing literature on the 340B program. Conti and Bach (2013) summarize the cost consequences of the 340B Drug Pricing Program. They point out that, since the program does not require hospitals to only provide the discounted drugs to patients who are poor and in need, nor does it require the savings on drugs be passed on to patients or insurers, dispensing 340B drugs may become a profit generator to hospitals, physicians and pharmacies as described below.

Covered entities may prescribe higher dose or use more expensive drugs for treatment. The potential profits from administering expensive cancer drugs is known to alter physician's prescribing behavior. Mireille Jacobson et al. (2010) use Medicare claims data for lung cancer patients to study the impact of Medicare's payment cuts for outpatient cancer chemotherapy drugs on the change of treatment pattern. They conduct a simple likelihood time-series regression and find that, after implementing the new payment system from 2005, the likelihood that lung cancer patients received chemotherapy was increased, and physicians switched from dispensing the drugs that experienced the largest cuts in profitability to other high-margin drugs. Bach and Ohn (2018) summarizes the findings of another five papers which show that oncology drug prescription patterns shift towards treatments with larger absolute mark-ups.

The Government Accountability Office (GAO, 2015) released a 340B review to Congress, in response to the concerns contending that participating hospitals might not use the program to help vulnerable patients (low income uninsured patients), but to maximize the revenue they earn through it. Some 340B hospitals are also acquiring independent oncology practices to expand their outpatient base to generate higher revenue.[17] Using 2008 and 2012 data from both HRSA and CMS, the report found that, after risk adjustment for each hospital, the average per beneficiary Medicare Part B drug spending in 340B DSH hospitals was more than double that of non-340B DSH hospitals in both years. This finding implies a pattern that on average, beneficiaries at 340B hospitals either prescribed more drugs or more expensive drugs than non-340B hospitals.

Bach and Sachs (2018) argue that the growth of the 340B program has distorted prescribing patterns of physicians based on the GAO's finding (2018) that when hospitals enter the 340B program, their profits from expensive drugs increase more than their profits from less expensive drugs; hospital's prescription also shifts to more expensive drugs. Patients do not directly benefit because many 340B hospitals do not discount the drugs they dispense to poorer individuals.

Covered entities offer more outpatient services. Claudia Schur et al. (2007) designed a survey to interview pharmacy directors of 150 340B-participating rural hospitals, to compare the result from another survey of eligible but non-participating hospitals. By comparing basic summary statistics, they find participating hospitals' mean saving from 340B drug discount is approximately $236,400 per year. Participation rates of the 340B

[17] Policy Statement on the 340B Drug Pricing Program by the American Society of Clinical Oncology, Sept. 21st, 2016

program increase directly with hospitals' annual revenue and participating hospitals provide a much higher volume of outpatient services, such as ambulatory surgery, emergency departments and primary care clinics, where the ability to offer reduced price drugs might be advantageous. They also find participating hospitals administer much higher doses of high-cost drugs such as Aranesp or Epogen.[18] But without any further analysis, they did not draw any causal conclusion as to what leads to the volume and spending increase.

Nikpay, Buntin and Conti (2018) use multivariable OLS to compare 340B hospital participants with those that never participated and find participating institutions overall were less financially stable and had a slightly higher burden of uncompensated care; however, they were not more likely than nonparticipants to provide low-profit services, except for early entrants who joined the program before 2004.

340B program leads to more vertical consolidation and other responses. Pollack (2013) mentions that the 340B program is one reason that more than 400 oncology practices have become part of hospitals in the past few years. He suggests that a single practicing oncologist can generate about one million in profits for a hospital by obtaining drugs at 340B-discounted prices and using them to treat well insured patients.

Conti and Bach (2014), using nationally representative data on 340B participants matched to data from the US Census Bureau on communities' socioeconomic characteristics, find that 340B-qualified hospitals are expanding their base into more

[18] Drugs used in treatment of anemia in patients with chronic renal failure on dialysis.

affluent and well-insured communities to generate more profits, which counters the original intention of this program.

Desai and McWilliams (2018) use CMS Medicare claims and a regression-discontinuity design to study hospital-physician consolidation and changes in outpatient parenteral drug spending around the 340B hospital eligibility threshold (DSH percentage > 11.75%) in three specialty areas: hematology-oncology, ophthalmology and rheumatology. They find that the 340B program is associated with hospital-physician consolidation in hematology-oncology and a higher number of parenteral drug claims billed in hematology-oncology and ophthalmology due to consolidation, but no evidence of expanded care or lower mortality among low-income patients.

Nikpay, Buntin and Conti (working), explore hospitals' manipulation of patient mix in order to gain entry to the program, which requires hospitals' Medicare DSH adjustment percentage to be greater than 11.75%. Specifically, they test for manipulation and estimate changes in patient and service line mix in anticipation of gaining eligibility to the program. They find strong evidence of manipulation by hospitals after 2003.

HRSA lacks oversight. The GAO (2011) generated a report to Congress, addressing the factors and the extent to which covered entity (CE) generates revenue through their participation in the 340B program. They interviewed 29 DSH hospitals in the process. Even though about half of covered entities reported generating profits from the 340B discount, and some of them could use it to serve more patients that they might not have otherwise, the report concluded that HRSA's oversight of the program is inadequate because it primarily relies on participant self-policing to ensure program compliance, but participants have little incentive to comply with program requirements. In addition, the

hospital environment provides greater opportunity for 340B drug diversion compared to small community clinics: first, inpatients might get 340B drugs that they are not supposed to through in-hospital care; second, 340B drugs can be dispensed in multiple locations in a hospital setting, which make diversion harder to detect; third, hospitals dispense a much larger volume of drugs than other entity types. For example, DSH hospitals, representing 27% of all covered entities, purchased 75% of all 340B drug purchases by July 2011.

A review of the 340B Drug Pricing Program by the Energy and Commerce Subcommittees (2018), finds that the lack of reporting requirements has led to unreliable self-reported data in terms of savings, charity care and other program values. It suggests that HRSA place more regulatory authority to promote compliance and provide further guidance for covered entities to best utilize the program to improve patient care.

Conti and Bach (2015) also propose three reforms to the 340B Drug Pricing Program, which include redefining 340B hospital qualifications based on the vulnerability of their outpatient population, passing 340B discount through to payers and patients, and limiting distribution of discounted drugs by patients' economic circumstances, irrespective of the provider's qualification for safety net status.

My Contribution

While most papers in the literature have examined the association between participation in the 340B program and hospital spending, no paper has evaluated the impact of the 2010 ACA 340B hospital eligibility expansion on 340B hospitals' prescribing behavior and quality outcomes.

The three chapters of my paper provide a comprehensive look at the impact of program participation from nation-wide state aggregate level, Florida all hospital visit level as well as market power interaction with the changes of hospitals behaviors.

Further, my paper simultaneously explores the change in hospital prescribing behavior and the change of outpatient quality of care to better understand the overall impact of the program. It also empirically investigates heterogeneous effects of the 340B program across different payers (Chapter 2) and across different CE types (Chapter 1 & 3) that as far as I am aware, no other work has examined to date.

The paper also complements GAO's report to the Congress (2015) where the report only used statistical summary to show that the average per beneficiary Medicare Part B drug spending in 340B DSH hospitals was more than doubled than non-340B DSH hospitals. It does not lead its analysis in a ceteris paribus fashion to empirically address the issue. By controlling a number of important characteristics at the same time, my empirical analysis will reveal more causal relationship between the participation of the

program on the change of hospitals' behavior patterns. Meantime, GAO's report focuses on only one type of 340B eligible hospitals, leaving other types of hospitals unexamined, which I will add on as well. The analysis on each type of covered hospitals unveils heterogeneity among them, and thus can provide guidance of tailored policy towards specific type of hospitals, instead of slashing the entire program, regardless of its positive influences.

Finally, I explore the unknown effects of market power on the impact of the 340B program to explore more heterogenous responses and evaluate the extent to which the covered entities fulfill the intent of the 340B program to keep the price low and make medical care more accessible to the vulnerable population. This study may help regulators to better understand their agents' heterogeneous behavior patterns so the policy makers may adjust the design of the program to make it function more effectively and efficiently.

Chapter 1 Impact of 340B Hospital Participation on Nationwide State Hospital Service Spending

1.1. Introduction

Chapter 1 provides a nationwide overview of the impact of 340B Drug Pricing Program on hospitals' spending behaviors. It examines at state aggregate level, whether a higher hospital participation ratio of the 340B program leads to an increase in aggregate state hospital spending.

1.2. Data

To study this question at state level, I have assembled a panel data from various sources to cover 51 states from 2003 to 2014 period.[19] State hospital service expenditures and retail prescription drugs expenditures are extracted from Centers for Medicare and Medicaid Services (CMS) National Health Expenditure (NHE) Account. 340B covered entities (CE) data are constructed from Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs' (OPA) online database. Other covariates like household income, insurance coverage, education, population and its

[19] On top of the 50 states, the data also lists the District of Columbia, a federal district, as a state.

demographics are from the U.S. Bureau of Labor Statistics (BLS) current population survey (CPS). State community hospital counts are from Kaiser Family Foundation.

1.2.1. Measures of the Participating Hospitals' Prescribing Behavior

I use two variables to measure hospitals' prescribing behavior. The first one is hospital service spending per capita, derived from the CMS NHE account, by using state hospital service spending divided by state resident population.

The advantage of using hospital service expenditure as the dependent variable is because majority of 340B discounted drugs are sold to hospitals and direct dispense of 340B drugs is included in hospital service account, but excluded from prescription drug expenditure.[20][21] Therefore, hospital service expenditure captures the potential swing of potential hospital behavior changes, such as choosing more expensive drugs for treatment, or favoring certain procedures that prescribe higher dose per patient to raise the drug discounts hospitals gain from participating the program.

The major limitation of this variable is that the hospital service expenditure does not separate outpatient service from inpatient service, while 340B is an outpatient only program. Thus, using total hospital spending to study the impact of the outpatient-only program, the result might be confounded by potential fluctuations of inpatient service changes.

The alternative variable that I use to capture behavior changes of participating hospitals is the retail prescription drugs expenditure from CMS, which captures all drug

[20] Government Accountability Office (GAO 2015), MEDICARE PART B DRUGS Action needed to reduce financial incentives to prescribe 340B drugs at hospitals
[21] National Health Expenditure Accounts Methodology (2014)

expenditure dispensed indirectly by the hospitals, such as retail pharmacies, drug stores, grocery store pharmacies, etc. (direct dispense in hospitals will be included in the hospital service expenditure account), as well as by other physicians and clinics. The advantage of using this variable is that since 340B is a Drug Pricing Program, any potential exploitation of this program will eventually be reflected in prescription drug spending.

However, there are several major concerns for the alternative: first, direct dispenses of drugs by hospitals are not included in this account, while majority of 340B drugs are sold to hospitals; second, the retail prescription drugs expenditure is confounded by the portion of drugs that are prescribed by other 340B covered entities that are not hospitals, as well as all those non-340B hospitals and providers; third, one reason explaining the fact that most 340B drugs are sold to hospitals is that 340B hospitals need to share profits with contracted pharmacies if hospitals include outside pharmacies in their distribution channel. As a result, it reduces the incentives of hospitals to dispense 340B drugs outside the hospitals if they can dispense them inside. Table 1.1 lists the summary statistics for these dependent variables.

As shown in both Figure 1.2 and Figure 1.3, both types of spending per capita increase over time, which raise the question as what factors are leading to the increase: Whether it is due to inflation, or as the literature concerns, it might be because participating hospitals are increasing dose per patient or choosing more expensive drugs for treatment.

1.2.2. Measure of 340B Participation Status

340B hospital participation status can be clearly identified with the HRSA OPA online database. With a panel data on an annual timeline, in order to specify year of participation,

I use calendar year as a natural cut-off. For example, hospitals have a participating start date between Jan. 1st, 2003 to Dec. 31st, 2003 are considered active participation in year 2003. Since there is no standard way to define this, I test different specifications in the robustness check.

340B hospitals can be further differentiated by their covered entity (CE) types because hospital type is one important feature that may determine their behavior patterns and thus different types of hospitals may respond to the program in completely different manners. Table 1.2 provides summary statistics for state hospital CE share, dividing state 340B hospital counts by state all hospitals counts. Figure 1.4 shows the average CE share for each CE type over time.

As is shown, 340B hospital participation rates keep increasing over time, with over 40% of all US hospitals participated in the program by 2014. DSH hospital takes a great share of all covered hospitals and it increases over time, but with a mild speed and it stabilizes around 18%. Since 2010, additional five types of hospitals become eligible to participate under the Affordable Care Act (ACA) expansion, among which, critical access hospitals pick up their participation very fast and take up over 20% of all US community hospitals within a four-year span. Cancer hospitals hardly participate by the end of 2014. Their extreme small participation rate makes it hard to identify any significant behavior changes within the data span due to lack of variations in the participation variable.

As four types of the newly eligible hospitals have relatively small shares compared to those of the DSH and critical access hospitals, Figure 1.5 focuses on these four types to ensure there are enough variations in the share variable for the subsequent regression

analysis. The graph implies, except for cancer hospitals, the remaining three types vary in shares over time.

1.2.3. Other Controls

To identify the association between state CE share and drug spending per capita, I control below variables in my models, so they will not be left in disturbance to impact spending per capita and CE shares at the same time:

Household income is a proxy for population wealth. In general, a wealthier population would demand and be able to afford more health care. The state median household income would represent the population wealth better than mean as income is usually highly skewed to the right so median income is less impacted by outliers. State insurance coverage also influences health care spending since a better insured population can afford more health care and hospitals might prescribe more knowing the patients are financially guarded by insurance.

The state unemployment rate impacts health care spending in a similar mechanism as above two variables through income effect channel. I expect a population with high unemployment rate to have less health care spending, because in addition to less medication prescribed by hospitals in the first place, even with the same level of drug prescriptions, a relatively poorer population could end up fulfilling only partial of the prescription due to their budget constraints. Meantime, I expect state senior residents (≥65) ratios would also increase the health care spending as seniors, on average, need more medical care when they age.

Education level is also controlled in the models because a higher educated population generally monitors their health conditions more closely and they tend to take more preventive cares to stay healthy. Finally, I also include state demographics such as gender and race information to control potential heterogeneity in those aspects of the sample. The according descriptive statistics are listed in Table 1.3.

1.3. Empirical Method

For participating hospitals to fulfill the mission of the program, we expect them to pass on partial of the drug discounts to patients in terms of reduced medication cost. Therefore, ceteris paribus, aggregate hospitals drug spending would decline if that is the case.

However, if participating hospitals intend to make a fortune from the 340B Drug Pricing Program, as Conti and Bach (2013) suggests, they could exploit from below channels: first, to choose more expensive drugs for treatment; second, to prescribe higher dose per patient, which includes favoring procedures that allow them to prescribe more 340B drugs; third, they can increase their patient basis so they can provide more services and prescribe more drugs to further amplify the profits from first two channels; fourth, to accept more well-insured patients to ensure they get well reimbursed for their service rendered.

The behavior patterns in the first two channels would increase hospital's spending per patient, which raise the concern that those hospitals are possibly on the track of either exploiting profits from the 340B program without improving quality of care, or they may prescribe more to improve quality of care, which requires additional cost-effective analysis to evaluation if the increase in spending is well justified. To distinguish above paths,

appropriate quality data is necessary. Since CMS the state aggregate data does not contain such information, I focus on testing whether there is a nationwide positive correlation between the state aggregate 340B hospital participation ratio and the state hospital medication spending per capita.

The third channel of serving more patients and providing more outpatient services complies with the design of the program. The fourth channel is not in line with the intention of the program to use the drug discounts to serve more vulnerable and uninsured patients, but it will be examined with hospital uninsured visit ratio in Chapter 2 and Chapter 3.

The first model below examines whether changes in the state 340B hospital share have an impact on the state hospital service spending per capita:

$$(1.1) \qquad lny_{it} = \beta_0 + \beta_1 S_{it} + \beta_2 X_{it} + \beta_3 \tau_t + c_i + \varepsilon_{it}$$

y_{it} is the aggregate spending variable in state i, year t, measured by hospital service spending per capita and retail prescription drug spending per capita. S_{it} is a matrix that represents the 340B participating hospital shares. β_1 is the estimator of interest that measures the impact of 340B participation on hospitals' drug spending. As mentioned previously, X_{it} includes a series of covariates that will impact hospital service spending, they are explicitly controlled in the model, which includes median household income, insurance coverage, unemployment rate, senior resident's ratio, education, other population demographics such as gender and race. Since the data is clustered at state level, I factor in state heterogeneity that impacts hospital spending and other covariates

at the same time. Such heterogeneity includes time invariant elements such as climate and geographic features, policy propositions on health care spending, the advancement of health care infrastructures, etc. Therefore, I include a state fixed effect c_i to control state time invariant factors. Additionally, as there exist strong increasing trends in hospital service spending, τ_t is a series of year dummies to control time fixed effect. ε_{it} is the disturbance term for each state over time. Estimated standard errors are clustered at state level.

In Model 1.2 below, considering each state could have its unique trend that affects their spending patterns, I test a random trend model to allow each state to have its own time trend:

$$y_{it} = \beta_0 + \beta_1 S_{it} + \beta_2 X_{it} + g_i t + c_i + \varepsilon_{it} \quad (1.2)$$

Specifically, the difference in Model 1.2 is that it includes the state specific trending effect g_i. The mechanism of this random trend regression is to first OLS regress every variable, clustered by state, an intercept and a linear trend T, get the residuals, which are the remaining effects that are not explained by state-specific time trend, then by Frisch-Waugh theorem, OLS regress the residuals of dependent variable on the residues of explanatory variables, without an intercept. If the estimates from this regression are consistent and significant, it is more compelling that the participation of the program does have an impact on hospitals' spending per capita.

1.4. Results

Table 1.4 presents the estimates for Model 1.1. The aggregate state 340B hospital share seems to have a significant impact on the increase of state hospital service spending per capita. The key estimate is significant at 1% significance level. On average, 1 percentage point increase in 340B hospital share leads to 12.8% increase in hospital service spending per capita. Median household income and black population also have a positive impact on hospitals' service spending. The estimates of insurance coverage and education are negative, but insignificant from zero with large standard errors to be a concern.[22] The signs of unemployment and senior population are as expected, though not statistically significant.

On prescription drug spending side, the aggregate CE share does not have a statistically significant impact on state retail prescription drug spending, though the sign is positive, as expected. The insignificance is likely due to the majority of 340B drugs are sold to hospitals and thus excluded from the retail prescription drugs spending. Therefore, the remaining retail proportion of the 340B prescription drugs is too small to pick up enough significance at the state level, in addition to the confoundment from the drugs prescribed by non-340B hospitals, physicians, clinics and other providers at state level. Therefore, I rely more of my analysis on the hospital service spending.

Table 1.5 shows the results for the state random trend regression. The estimate suggests even controlling state fixed effects, time fixed effects as well as allowing unique state time trends, the change in state 340B hospital share still significantly influences the change of hospital service spending per capita, in a slightly larger magnitude, which gives

[22] The negative estimate for insurance could be due to the adoption of Medicaid expansion in many states that leads to higher state insurance coverage, but lower hospital spending.

us more confidence that participation in the 340B program seems to induce hospitals to spend more per capita, which indicates the average participating hospital either spends more to increase quality of care, or it exploits drug profits from the 340B.

1.5. Robustness Check

As explained in the data section, though I use calendar year as the cut-off rule to construct the participation variable, there might be lagged effects of participation on future hospital spending. Table 1.6 and Figure 1.6 present the participation frequency by different months for all CE hospitals. There is a clear pattern that most hospitals participate in the program from the beginning of each calendar quarter. There is a little more than 56% hospitals joined the program in the latter half of the year, which poses an idea that using the lagged CE share might be a natural choice to extend the robustness check. Therefore, I test above main models with lagged CE share by one year.

The results for Model 1.1, using lagged CE share, are presented in Table 1.7 column (1) and column (2). Compared to its no-lag counterpart in column (3) and (4), estimate on lagged share are still significant, with its magnitude reduced by around 3%. Estimates on retail prescription drug spending become marginally significant, with an 3% increase in magnitude. Overall, the results are consistent. Likewise, Table 1.8 presents the result of using lagged share in the random trend model. Though lagged share loses the marginal significance, and shrinks in magnitude, the estimates are similar and consistent.

As a conclusion, the estimated results are robust to the alternative specification of year of participation variable.

1.6. Summary and Conclusions

In Chapter 1, I examine the impact of participation in the 340B Drug Pricing Program on state hospital service spending per capita and state retail prescription drugs expenditure per capita. Consistent with the existing literature, by controlling state fixed effect, time fixed effect and even allowing state unique time trend, I find strong evidence that participating hospitals tend to increase their spending per capita, which implies they either are heading to increase quality of care, or they are taking advantage of the program as their profit generator. Without quality outcomes at state aggregate level, this chapter cannot further determine which track they are on, but it will be further examined in the next chapter.

Chapter 2 Effects of the 340B Drug Pricing Program on Florida Hospitals' Prescribing Behavior, Patient Mix and Quality of Care

2.1. Introduction

In 1992, the U.S. Congress created the 340B Drug Pricing Program that requires drug manufacturers to provide outpatient drugs to eligible hospitals at significantly reduced prices. The intent of the program is to allow covered entities (CEs) to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[23] However, hospitals are not required by law to pass on the discounts, which raises a concern that hospitals may over-prescribe for more drug profits. Given there are more than 46% of U.S. hospitals participating in this program as of 2018, with over $29.9 billion spent on purchasing 340B drugs at 340B discounted prices in 2019, understanding the impact of the 340B program on hospitals' prescribing behaviors, patient mix and quality of care is important in evaluating the effectiveness of this public program.[24]

[23] Health Resources and Services Administration (HRSA) (https://www.hrsa.gov/opa/index.html)
[24] Drug Channels, New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales (https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html)

From the beginning of the program, only Disproportionate Share Hospitals (DSH), which serve a disproportionately larger number of low-income patients, were eligible to participate. On March 23rd, 2010, Congress passed the Affordable Care Act (ACA), which further broadened the 340B hospital eligibility to free-standing cancer hospitals, rural referral centers, sole community hospitals, critical access hospitals, and children's hospitals.[25][26] Using data on 15 million ambulatory visits to Florida hospitals from 2005 to 2015, this paper uses the ACA expansion as an exogenous policy to set up a series of difference-in-difference regressions, complemented by synthetic control methods, quantile regressions to examine the impact of the 340B eligibility expansion on newly eligible hospitals' prescribing behaviors, patient mix for the most vulnerable subpopulations, measured by uninsured, charity and Medicaid visits ratios, as well as on several quality measures, such as length of stay, nonroutine discharge and ambulatory surgery post-operative adverse reaction rates. [27]

As a result, I find an average increase of $111.35 in medication cost per visit among newly eligible hospitals after the expansion. Event study results indicate the parallel trends assumption is satisfied. As the typical way of calculating the cluster-robust standard errors (at hospital level) for my difference-in-difference setting is inappropriate due to few treated clusters in the sample that leads to a poor approximation from the T

[25] HRSA (https://www.hrsa.gov/sites/default/files/opa/stakeholderpres.pdf)
[26] Although children's hospitals were legally allowed to participate in 2006, since HRSA did not formalize its guidelines to complete registration till 2009Q3, children's hospitals were practically not able to participate till 2010 (https://www.340bhealth.org/newsroom/theyre-in-childrens-hospitals-qualify-for-340b/). The first children's hospital ever participated in the 340B program in Florida was till Oct. 1st, 2010.
[27] Ambulatory care refers to medical services performed on an outpatient basis, without admission to a hospital or other facility. Ambulatory care is provided in settings such as dialysis clinics, ambulatory surgical centers, hospital outpatient departments, and the offices of physicians and other health professionals. - The Medicare Payment Advisory Commission

distribution (Cameron and Miller 2015), I use synthetic control methods to provide inference under random permutations of assignment to the treated and untreated groups.[28] The one-sided p-value equals 2.14%, implying the increase in medication cost found in the main difference-in-difference analysis is statistically significant. Quantile regressions further reveal distinct heterogeneity in hospitals' prescribing patterns: newly eligible hospitals that provide the most charity and treat the highest proportion of uninsured patients keep their medication costs low post-policy. [29] These hospitals even significantly reduce medication costs for their patients on the most expensive visits. In contrast, the remaining newly eligible hospitals significantly increase their medication cost after the expansion, and the increase becomes greater the more expensive the treatment is.

For Medicaid patients, due to Duplicate Discount Prohibition, the 340B drug discount is eliminated. Hospitals may still obtain an additional discount under what is called the Prime Vendor Program (PVP program), which is available to hospitals participating in the 340B program.[30] But the discount under the PVP program is much smaller than the 340B drug discount that hospitals would otherwise obtain under the 340B program. Consistent with the reduced discount, I find newly eligible hospitals only raise their medication cost by less than a third of the average increase under all types of payers.

[28] 12 hospitals are treated among total 184 hospitals in the study.
[29] Hospital's charity ratios that are greater than the 90th percentile, uninsured ratios greater than 70th percentile along their respective distribution among newly eligible hospitals prior to the expansion of charity distribution among newly eligible hospitals prior to the 2010 ACA expansion.
[30] I discuss more details about the PVP program and the Duplicate Discount Prohibition in the following background section.

I find no evidence of increased access to care for the most vulnerable populations in terms of hospital uninsured and charity care ratios. Newly eligible hospitals seem to treat higher proportions of Medicaid patients after the 2010 expansion and there are some indications that they have improved quality of care in terms of length of stay, nonroutine discharge and post-operative adverse reaction rates, but the estimates for the last two variables are not statistically significant.

These findings suggest the 340B Drug Pricing Program enables some newly eligible hospitals, that provide the most charity and treat highest proportion of uninsured patients, to reduce their medication cost to increase patients' access to the most expensive treatments, but it is not so effective on the remaining hospitals. I find some weak evidence that newly eligible hospitals treat higher proportion of Medicaid patients after the expansion and they are in the direction of improving quality of care, but the evidence is not strong enough to be conclusive.

This paper contributes to the existing literature in several aspects. First, while most previous studies have examined the association between participation in the 340B program and DSH hospitals' medication spending, little has been done to investigate the role of the 2010 ACA expansion in determining the effects of the 340B program on the additional four types of newly eligible hospitals: free-standing cancer hospitals, rural referral centers, critical access hospitals and children's hospitals. It thus broadens our understanding of the effects of the program to most types of 340B eligible hospitals.[31] Second, previous studies are generally based on dataset with sole payer claims (i.e.

[31] The only type of eligible hospitals that is not covered in my study is sole community hospital due to missing data.

Medicare claims), leaving hospitals' responses with other payer arrangements largely unknown. This paper includes patient visits with all types of payers to fill the gap of understanding 340B hospitals' prescribing behavior changes on the most vulnerable subpopulations, such as uninsured, charity, and Medicaid patients. Third, it is the first study to investigate the heterogeneity in changes of 340B hospitals' prescribing behaviors according to their uncompensated care and uninsured patient ratios, as hospitals differing in these aspects may respond to policies with large economic incentives in distinctive manners. Fourth, my paper adds the ambulatory surgery post-operative adverse reaction rates to the outpatient quality measures in evaluating the effects of the pure outpatient 340B program. Finally, 15 million hospital visits over 11-year span provide a large sample size that leads to better estimations of the real impact of the program on Florida hospitals.

2.2. Data

I have extracted 15 million hospital ambulatory visits data from the Florida Agency from Health Care Administration (AHCA) and organized them in a panel structure. Observations are identified by visit record IDs, and clustered by hospitals' Medicare Provider Numbers (MPNs) on a quarterly basis from 2005 to 2015. These visits are outpatient by nature and thus fit outpatient only requirement of the 340B Drug Pricing Program. Table 2.1 provides their summary statistics. I have two types of files for this study. The patient visits files include patient characteristics, basic facility characteristics, diagnosis, surgery performed, and hospital charges for each visit over time on a quarterly basis. Hospital financial files include hospital revenues and expenses at different cost center levels, but they are only available annually. All cost center revenues are separated

between inpatient and outpatient sectors, but there is no such separation on the expense side.

2.2.1. Dependent Variables

1. *Medication Charge, CRR, and Estimated Medication Cost.* To study changes in hospitals' prescribing behavior, I use drug charge per visit.[32] The concern with charges is that they may have extreme markups and therefore, may not reflect the true cost that hospitals or patients incur (Bai and Anderson, 2015).[33] Typically, studies use cost-to-charge ratios (CCR) to convert charges to estimated costs (Gerald F. Riley, 2009; Robert M. Williams, 1996; Philip J. Schneider, 1995). A drug-sold center CCR ratio would be calculated as below:

$$Drug\ Cost\text{-}to\text{-}Charge\ Ratio\ (CCR) = \frac{drug\text{-}sold\ cost}{drug\ charge}$$

However, in the AHCA data that I work with, outpatient drug-sold costs are not available to construct the outpatient drug-sold CCR.[34] Similarly, hospital drug-sold costs are available, but hospital drug charges are not available to

[32] Charges are the initial list prices a hospital must set for items and services it provides, known as a "chargemaster", which appear on medical bills. Although Medicare requires hospitals, for regulatory reporting purposes, to submit full charges (i.e., prices from the chargemaster) when submitting claims, the charges have no direct relation to the pre-determined Medicare payment that a hospital receives, nor to the out-of-pocket amount that a patient is expected to pay. It is sometimes used as a benchmark or reference list price to negotiate payment rates with insurers. Neither the government nor private insurers actually pay a hospital's full charges. Even patients not covered by Medicare, Medicaid or private insurance are almost never expected to pay full charges. (https://www.fah.org/blog/words-matter-defining-hospital-charges-costs-and-payments-and-the-numbers-t)

[33] Costs are the expenses incurred by a hospital in providing patient care.

[34] They are mixed with inpatient drug-sold cost.

construct a hospital level CCR.[35] Therefore, I use the hospital cost-to-revenue ratio (CRR) to approximate the hospital CCR ratio:

$$Drug\ Cost\text{-}to\text{-}Revenue\ Ratio\ (CRR) = \frac{drug\ sold\ cost}{drug\text{-}sold\ revenue}$$

The only difference between these two ratios is in the denominator: since drug-sold revenue ≤ drug charge, CRR ≥ CCR. Therefore, the estimated medication cost, using drug charge times CRR, sets an upper bound for the true medication cost.[36]

2. *Uninsured, Charity, Medicaid, and Medicaid Managed Care Visits Ratios.* These are four types of payers that I use to evaluate whether 340B hospitals may change their patient mix to increase access to care for the most vulnerable patients.

3. *Length of Stay (in days).* Length of stay (LOS) is used in the literature to proxy for hospitals' performance (Thomas JW et al., 1997; John Moran et al., 2008; Martine C. de Bruijne et al., 2013). It is related to quality of care in the sense that if poor quality of care causes more complications, it would prolong length of stay. In addition, a longer length of stay may imply less efficient use of

[35] I have only outpatient charges, no inpatient charges data.
[36] After calculating hospital specific drug center CRRs from AHCA hospital financial files, all the CRRs were screened for potential outliers (CRR > 1). None were found in my sample.

resources. Under these assumptions, longer than expected LOSs can be viewed as indications for poorer quality of care.

Outpatient LOSs are generally no more than two days due to the inpatient '2-Midnight Rule', defined by the CMS.[37] In my sample, over 97% of the ambulatory visits have less than two days of LOS, so the remaining outliers are removed when I use LOS as the dependent variable.

4. *Nonroutine Discharge*. Any patient disposition at the end of the visit other than "Discharged to home or self-care (routine discharge)" are considered nonroutine discharge for outpatient visits. I use this dummy as another proxy for quality of care during ambulatory visits because nonroutine discharges are highly correlated with general in-hospital complications, any surgery-related complications, post-discharge complications, and returns to the operating room (Matthew J. Best et al., 2015; Lakomkin et al., 2017; Raj M. Amin et al., 2018).

5. *ICD-9-CM Diagnosis and Post-Operative Adverse Reactions*. The AHCA data contains ten diagnosis variables that use International Classification of Diseases, Ninth Revision, Clinical Modification, ICD-9-CM codes, to document diagnoses chiefly responsible for the services performed during each visit.[38] Based on the ICD-9 codes, I construct a post-operative adverse reaction

[37] CMS, Inpatient Admission and Medical Review Criteria (https://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2014-01-14-Midnight-Presentation.pdf)

[38] ICD-9-CM is the international standard diagnostic tool for epidemiology, health management and clinical purposes, used worldwide for morbidity and mortality statistics, reimbursement systems, and automated decision support in health care. Since Oct. 2015, AHCA system switched to ICD-10-CM.

dummy that indicates the occurrence of any one of following nine post operation complications during an ambulatory outpatient visit: infection, mechanical wounds, urinary, pulmonary, cardiovascular, gastrointestinal, central nervous system, systematic complications and surgery accidents during operations (Thomas L. Sutton, Etienne E. Pracht et al., 2015). The ICD-9 codes used for this categorization are listed in Appendix C.

2.2.2. Independent Variables

1. *Types of Hospitals.* HRSA documents covered entity types for 340B participating entities. I construct following five dummies to identify whether a hospital is a disproportionate share hospital (DSH), children's hospital (PED), cancer hospital (CAN), rural referral center (RRC), or critical access hospital (CAH).[39] Among 184 Florida hospitals in my data, 43 are DSH hospitals, 6 are critical access hospitals, 2 are rural referral centers, 3 are children's hospitals, 1 is a cancer hospital, and the remaining are 340B-non-eligible hospitals.

2. *Participation in the 340B Program.* HRSA's 340B CE database documents hospitals' participation history over time. Entities are generally approved to participate on the first day of each quarter and required to re-certify every year. Based on the database, I construct a participation dummy to indicate hospitals'

[39] Although six types of hospitals are allowed to participate in the program, ambulatory data for the only two sole community hospitals (SCH) ever participated in the 340B program in Florida are missing, leaving only five types of hospitals in the study.

participation status. Refer to Table 2.1, about 28.8% of all the patient visits took place in 340B hospitals among all 184 hospitals in my sample.[40]

3. *Ownership.* Hospital ownership is extracted from the CMS hospital general information file. There are three types of hospitals: for-profit, nonprofit, and government owned hospitals. Various ownership may lead to difference in cost of care, patient mix, as well as quality of care.

   For-profit hospitals pay property and income tax while nonprofit and government hospitals do not. However, since for-profit hospitals answer to shareholders, they have more avenues to raise capitals to upgrade equipment and systems, which may improve quality of care. Nonetheless, for-profits may not share the same interests with local communities; therefore, they may provide different levels of uncompensated care, but they tend to respond more quickly and more dramatically to economic incentives (Jill R. Horwitz, 2005).

4. *Licensed Beds, Teaching Status, County Unemployment and Uninsured Rates.* Licensed bed counts serve as a proxy for hospital size that may lead to potential difference in cost and quality of care like mortality (Fareed N., 2012). Teaching hospitals, partnering with medical schools, generally have the advantage of new treatments, technologies, specialized surgeries that may lead to improved

[40] Some hospitals have multiple sister facility sites that join the program at different time, but since they are all under the same Medicare Provider Number (MPN), I take the earliest participation date among all subsites as the initial participation date for this MPN. Similarly, eligible hospitals could opt in and out of the program, but as long as there is any facility site participating in the program, this MPN is considered to be participating in the program at that time.

quality of care, such as mortality (Burke et al., 2017) but on the other hand, they tend to be more expensive due to teaching intensity (Mechanic et al., 1998), payer mix and high real wages (Sloan 1986). Both variables are extracted from the hospital financial files in the AHCA dataset.

Based on the county where each hospital is located, I also control county unemployment and uninsured rates to reduce other multiplier effects that macroeconomic environments may bring unobserved influences on the outcome variables. Longitudinal county unemployment rates are obtained from Bureau of Labor Statistics, while county uninsured rates are obtained from the Small Area Health Insurance Estimates (SAHIE) by the U.S. Census Bureau.

5. *Demographics.* I control for gender, senior (65+) status and race. The omitted category for race is white.

6. *Charlson Comorbidity Index (CCI)*. Charlson Comorbidity Index is a method of categorizing comorbidities of patients based on the ICD diagnosis codes. Each comorbidity category has an associated weight (from 1 to 6), based on the adjusted risk of mortality or resource use, and the sum of all the weights results in a single comorbidity score for a patient. The score predicts one-year mortality for a patient who may have a range of comorbid conditions. A score of zero indicates that no comorbidities were found. The higher the score, the more likely the predicted outcome will result in mortality or higher resource usage. I adopt Stata Vicki Stagg Charlson module to calculate CCI scores for each visit

to control patients' severity of illness that would affect cost of care as well as quality outcomes in the robustness check section.[41][42]

7. *CPT Procedure Variables*. There are up to thirty CPT codes for procedures or services provided during each visit.[43] I created 14 category dummies for the 42 most frequent CPT procedures that lead to 50% of all the visits in my sample that end up having post-operative adverse reactions. Refer to Appendix D for their distribution and categorization details.

8. *Mortality*. Even though mortality is another possible quality outcome available in the dataset, there are only 1,333 episodes of death among 15 million of outpatient visits during the eleven-year period. Such a low occurrence rate (less than 0.01%) does not provide enough variation for my study. In addition, the fact that death is not sensitive to poor outpatient care also limits its value as a proxy for outpatient care quality.[44]

[41] It is based on a SAS program written by Dr. Hude Quan (Quan H et al. Coding algorithms for defining comorbidities in ICD-9-CM and ICD-10 administrative data. Medical Care 2005 Nov; 43(11):1073-1077.
[42] CCI is not controlled in the main regression model under the concern that the 340B program may potentially influence patient acuity status, when it becomes an outcome variable.
[43] Current Procedural Terminology (CPT) is a medical code set that is used to report medical, surgical, and diagnostic procedures and services to entities such as physicians, health insurance companies and accreditation organizations. CPT codes are used in conjunction with ICD-9-CM or ICD-10-CM numerical diagnostic coding during the electronic medical billing process.
[44] In results not shown in the paper, I have examined the effects of the program on mortality and the results are not significant.

2.3. Empirical Methods

As the 340B Drug Pricing Program is voluntary to participate, I use difference-in-difference and synthetic control methods to minimize hospital selection endogeneity and identify potential causal effects of the program. I also use quantile regressions to study the heterogenous effects of the 340B program. In the following sections, I discuss each approach in detail.

2.3.1. Difference-in-Difference (DID) Analysis

Since participation in the 340B program is voluntary, unobserved factors like high drug acquisition cost, larger proportion of patients with high risk scores could be common among hospitals that opt to join the program, and they also lead to higher medication costs and worse quality outcomes. As these unobserved factors affect the dependent variables, such as medication cost and quality outcomes, and the participation regressor at the same time, selection endogeneity occurs that would confound any causal analysis on the impact of the 340B program. To tackle the potential endogeneities, I take the 2010 ACA expansion as an exogenous policy to set up a difference-in-difference analysis and examine the intent-to-treat effect of the 340B eligibility expansion on newly eligible hospitals' participation and their prescribing behaviors.

The treatment group contains all the hospitals in Florida that became newly eligible to participate in the 340B program after the 2010 ACA expansion, regardless of their actual participation status. The control group includes all other types of hospitals whose eligibility did not change under the ACA. Specifically, it includes hospitals that are not eligible for the 340B program and DSH hospitals that were eligible before 2010. The post-policy

indicator uses 2010 as the cut-off year when the ACA was passed. The identification of the causal effects relies on the parallel trends assumption, which assumes that the outcome variables for hospitals in the treatment group would evolve in the same way as for hospitals in the control group over time if they were not exposed to the 2010 ACA expansion. Below is the model specification:

$$(2.1) \qquad y_{ijt} = \beta_0 + \beta_1 treat_j + \beta_2 post_t + \beta_3 treat_j * post_t + \beta_4 \boldsymbol{X}_{ijt} + \beta_5 \tau_t + \varepsilon_{ijt}$$

y_{ijt} are the outcome variables for outpatient visit i, to hospital j in year t. They include medication charges, estimated hospital medication cost and hospitals' participation status. $treat_j$ identifies hospitals in the treatment group, which includes all cancer hospitals, rural referral centers, critical access hospitals and children's hospitals that became eligible for participation in 2010. $post_t$ is defined as 1 if year equals 2010 through 2015, and 0 otherwise. β_3 is therefore the difference-in-difference estimator that estimates the impact of the 2010 340B hospital eligibility expansion on hospitals' prescribing behaviors and participation. Vector $\boldsymbol{X}_{ijt}$ include hospital licensed bed counts, teaching status, ownership, county unemployment and uninsured rates, patients' gender, seniority, and race. τ_t is a series of year dummies, among which year 2005 and year 2015 are left out for the base as well as for avoiding perfect collinearity with the $post_t$ dummy. ε_{ijt} is the disturbance that includes all other residual effects. Significance level is adjusted to 0.01% to accommodate the large sample size of 15 million observations (Matthew Harding, 2013; Cameron and Trivedi, 2005).

1. *Graphical Evaluation of the Parallel Trends Assumption.* Figure 2.1.1 and Figure 2.1.2 plot the raw data trends for 340B hospital participation rates and estimated medication cost between the treatment group and the control group. Figure 2.1.1 shows the eligibility expansion leads to a significant increase in hospitals' 340B participation rates. Figure 2.1.2 shows that the trends of medication cost for both groups evolved in parallel pre-policy (except for year 2008, when the U.S. experienced the deepest recession since the 1930 Great Depression, which might have led to a spike of medication cost in the treatment group). Despite incurring lower costs than the control group before year 2010, hospitals in the treatment group increased their medication costs dramatically after the expansion, and the rising trend persists through the remaining span of the data, suggesting a strong impact of the 340B program on the affected hospitals' medication cost. Combining the patterns in both graphs, it suggests a strong positive correlation between participation in the 340B program and the increase in hospitals' medication cost.

2. *Event Study.* To formalize the preliminary visual findings, I interact the treatment dummy with year dummies to examine the parallel trends assumption in the model below:

$$y_{ijt} = \beta_0 + \beta_1 treat_j + \beta_2 \tau_t + \beta_{3t} treat_j * \tau_t + \beta_4 \boldsymbol{X}_{ijt} + \varepsilon_{ijt} \quad (2.2)$$

$treat_j$ is the treatment indicator, τ_t are the year dummies, $\boldsymbol{X}_{ijt}$ include the same series of covariates as in Model 2.1. If the parallel trends assumption holds, we expect to see insignificant estimates for the interaction terms, $\beta_{3\mathrm{t}}$, prior to 2010, which implies the treatment group and the control group evolve in parallel over time before the policy. After the policy, if the program is influential, we expect to see significant $\beta_{3\mathrm{t}}$ for the interaction terms.

2.3.2. Synthetic Control Method (SCM)

I use the synthetic control method to supplement the main difference-in-difference analysis under two scenarios:

First, in circumstances where the pre-policy parallel trends assumption does not hold for dependent variables, I construct a weighted combination of hospitals from the control group as the synthetic unit for the treatment group to be compared to after the 2010 ACA expansion. The synthetic unit is constructed in a way that it would evolve in parallel with the treated unit pre-policy and the assumption is that the counterfactual outcomes of the treated unit (newly eligible 340B hospitals) after the expansion policy can be approximated by a fixed combination of hospitals from the donor pool, which include hospitals that are not affected by the 2010 340B eligibility expansion.

The synthetic control matching is conducted at the hospital level by averaging hospital visits data annually. Visits from all 12 newly eligible hospitals are combined and averaged to create a single treatment unit to be matched with. Once unbalanced panels are

removed, 141 hospital units remain for the study.[45] After obtaining the SCM difference-in-difference estimates, I run a permutation test to assign placebo treatments to all 140 untreated hospitals in my sample and generate null distributions and obtain a one-sided p-value for inference. According to Abadie et al. (2015), such p-value can be explained as the probability of obtaining an estimate at least as large as the one obtained for the unit representing the case of interest when the intervention is reassigned at random in the data set.

Second, I also use the synthetic control method for inference when the typical way of calculating cluster-robust standard errors at hospital level for my main difference-in-difference setting is inappropriate. Specifically, among total 184 hospitals in the data, only 12 hospitals are treated. Cameron and Miller (2015) argue if there are few treated groups in a difference-in-difference setting, most of the variation in the regressor is concentrated in just a few clusters (even if the total number of clusters is sufficiently large), which leads to a poor approximation from the T-distribution for inference. In addition, they also argue that serial correlated errors within clusters can lead to great loss of efficiency in OLS estimation. The amount of efficiency loss is larger (1) the more positively associated are the regressors in the same cluster, (2) the more correlated are the errors, and (3) the more observations are in the same cluster. For my main difference-in-difference model, since (1) the interaction regressors $treat_j * post_t$ are highly correlated (i.e. a string of zeroes before 2010, followed by a string of ones thereafter), (2) the error terms, ε_{ijt}, are likely to be correlated across visits within the same hospital over time, and (3) within each

[45] Balanced panels are required by STATA for quantile regression. Out of total 184 hospitals, data of 12 hospitals in the treatment group are well balanced and get collapsed into a single treatment unit. 32 hospitals in the control group (out of 172) are removed for unbalanced panels due to missing data, leaving eventually 140 hospitals in the control group.

hospital cluster, visit counts are huge, leading the typical way of calculating cluster-robust standard errors inefficient as well. Cameron and Miller (2015) thus propose to use the synthetic control method to obtain inference under random permutations of assignment to treated and untreated groups.

2.3.3. Quantile Regression

One limitation of the difference-in-difference OLS regression is that it only examines changes in the conditional mean of hospitals' medication cost. However, hospitals may respond to the 340B program in different manners along the per-visit medication cost distribution. I therefore use quantile regressions to explore the potential heterogeneity in newly eligible hospitals' prescribing patterns.

Due to heavy computational requirements for the quantile regression method, the first practical step I need to take is to reduce the sample size. Only 740,658 out of 15 million observations fall under the treatment group, which is the real target group that I study. The remaining 14 million observations from the control group are used to calculate counterfactual changes over time for the treatment group. Leaving all observations from the treatment group intact, I use simple random sampling to sample 432 observations from each hospital-year stratum to get a stratified sample of total 742,051 observations from the control group. Such sample size of the control group is similar to that of the treatment group and the total 1.48 million observations in the new sample becomes manageable for the statistical software to process quantile regressions.[46]

[46] I use STATA 15.1 for this study.

2.3.4. Heterogeneous Effects across Different Payers

As different insurer-provider networks and their relative negotiation powers eventually affect hospitals' prescribing behaviors, I expect to find heterogeneous effects across various payers. One of the most interesting ones would be Medicaid due to the interaction between the 340B Drug Pricing Program and the Medicaid Rebate Program.

As is explained in the background section, for Medicaid visits, with the elimination of the 340B Unit Rebate Amount (URA), 340B hospitals can only obtain the PVP negotiated discount, so the economic incentive to over-prescribe Medicaid patients becomes much smaller compared to other payers. Therefore, if I reconstruct a difference-in-difference analysis to keep the same hospitals in the control group as before but limit the treatment group to contain only Medicaid visits among newly eligible hospitals, I expect to see a much smaller effect of the 340B program if hospitals respond rationally to economic incentives.

2.4. Results

2.4.1. DID Effects on Hospitals' 340B Participation and Prescribing Behaviors

Column (1) Table 2.2 presents the result of the difference-in-difference analysis on hospitals' 340B participation. It shows that the 2010 expansion leads to a significant average increase of 59.8% in the 340B participation rates. Event study in Figure 2.2.1 suggests the parallel trends assumption is satisfied and the impact of the 340B eligibility expansion on hospitals' participation rates is significant.

Column (2) Table 2.2 presents the difference-in-difference estimates on estimated hospital medication cost, which is obtained by the product of unadjusted charges and

hospitals' CRR ratios. After controlling hospital, patient characteristics, county unemployment and uninsured rates, as well as year fixed effects, hospitals in the treatment group prescribe $33.47 less per visit on average compared to the control group pre-policy. This is simply because hospitals in the treatment group are safety-net hospitals that serve a larger proportion of indigent patients, so they are more likely to opt for more cost-effective solutions, like prescribing more generic drugs than brand name drugs to keep the medication costs low for patients.[47] Echoing a strong increasing trend of medication spending for all types of hospitals over time (Schumock et al. 2017), even hospitals in the control group, on average, incur $60.50 higher medication cost per visit post-policy period than before. Such an increasing trend is reflected in Figure 2.1.2 as well.

After the 2010 340B hospital eligibility expansion, assuming the pre-post difference in the control group represents the counterfactual difference over time for the treatment group, I find an additional increase of $111.35 in outpatient medication cost per visit among newly eligible hospitals, ceteris paribus. Compared to the post-policy counterfactual medication cost mean of $49.38 for the treated group as if they have not been exposed to the policy, such a change represents a 225.5% increase in outpatient medication cost per visit.[48] Figure 2.2.2 graphs the event study estimates. Except for a minor hump in 2008, there was no significant difference between the slopes of two trends

[47] Participating children's hospitals and cancer hospitals need to have DSH adjustment percentage larger than 11.75%; sole community hospitals and rural referral centers' DSH adjustment percentage larger than 8%; critical access hospitals do not have a minimum DSH percentage requirement, but by nature they are located at a rural area without any other hospitals within 35-mile drive distance.

[48] The $49.38 is calculated by using the post-policy average medication cost among the control group, $82.85, plus the difference between the treatment group and the control group pre-policy, -$33.47, which is estimated from the main difference-in-difference regression (Table 2.2). Alternatively, if compared to the per-visit medication cost mean of post-policy control group, $82.85, the increase of $111.35 represents a 134% increase

pre-policy. The diversion took place since 2010, implying the program exerted a significant influence over the treated group. The pattern suggests that the parallel trends assumption is likely to be satisfied and the 340B Drug Pricing Program causes participating hospitals to raise their outpatient medication cost significantly.

The estimate for the Treat * Post term in the regression is significant at 0.01% significance level when the standard error is robust to heteroskedasticity. As discussed in the methodology section, the typical way of calculating cluster-robust standard errors (at hospital level to allow intra-hospital serial correlations in the errors) is inappropriate for this DID due to small number of treated clusters, I proceed with synthetic control method for inference. Table 2.3 shows the SCM estimate equals $93.35, which is close to the main difference-in-difference estimate, $111.35. Figure 2.3.1 and Figure 2.3.2 imply there is a significant increase in the treated unit after the 2010 expansion. Figure 2.3.3 plots the permutation test results and Figure 2.3.4 summarizes the test estimates in a histogram. As is shown, 3 out of all 140 estimates from the test are larger than the estimate of the real treated unit. The one-sided p-value equals 0.0214, which suggests the 340B eligibility expansion causes the newly eligible hospitals to significantly increase their medication cost, with a type I error equals 2.12%.

Turning to patient characteristics in the difference-in-difference results (Table 2.2), white patients, omitted as base, have higher per-visit medication cost than other races, except Asian. Senior patients generally incur higher medication cost. There is a minor difference in medication cost between male and female patients.

In terms of hospital characteristics, size does not exert much influence on medication cost. Consistent with the literature, teaching hospitals are more expensive to go to.

Compared to nonprofit hospitals, government owned hospitals have lower medication cost. For-profit hospitals prescribe significantly less, which may be because prescribing outpatient medicine is relatively less profitable than moving outpatients to inpatient for more aggressive treatments. This hypothesis is worth further exploring in future studies. Other than that, in areas where unemployment is higher, hospitals relatively prescribe less. However, when the area uninsured rates are higher, hospitals tend to have slightly higher medication cost, which is likely due to delayed treatment among the population that do not have insurance coverage through employment.

Combining the impacts of the expansion policy on both hospitals' participation and their medication cost, the results suggest participation in the 340B program induces hospitals to increase their per-visit medication cost.

2.4.2. Heterogenous Effects on Hospitals' Prescribing Behavior

To explore potential heterogenous responses among newly eligible hospitals across the medication cost distribution, Table 2.4 and Figure 2.4.1 summarize and plot the difference-in-difference estimates along different quantiles, which unveil a more detailed picture of how hospitals' prescribing behaviors change along the medication cost distribution: on visits with low medication cost, hospitals actually do not respond much to the 340B program, while on visits with high medication cost, the newly eligible hospitals increase their medication cost substantially after the eligibility expansion. Take the estimates on the 95^{th} percentile as an example, an increase of $160.62 per visit is

significantly larger than the difference-in-difference OLS mean estimate of $111.35.[49] Figure 2.4.2 shows that the parallel trends assumption for the quantile regression is satisfied.

In addition, there might also be heterogeneity in the changes of hospitals' prescribing behaviors between hospitals that provide high percentage of charity and the ones that provide low (or none) charity. The initial raw data scatter plot in Figure 2.5.1 implies there is some inverse relationship between the two variables that is worth further scrutiny.

Based on the distribution of the newly eligible hospitals' average annual charity ratios prior to 2010, I use the 90th percentile as the threshold to separate newly eligible hospitals into high-charity hospitals and their rest low-charity counterparts.[50] The first two columns in Table 2.5 present the difference-in-difference OLS regression estimates among the low-charity and high-charity hospitals, respectively. As the results show, low charity hospitals, increase their average medication cost by $134.2 per visit post-policy while high-charity hospitals reduce their average medication cost by $7.16 per visit after the expansion policy. Likewise, I also separate newly eligible hospitals into the ones that have a low uninsured visit ratio and the ones with high uninsured visit ratios by the 70th percentile threshold along its distribution.[51] The last two columns in Table 2.5 imply that hospitals with the highest proportion of uninsured patients reduce their average medication cost by $31.89 per visit, while hospitals that treat less uninsured patients, on average, increase medication cost by $112.1 per visit. As a summary, the newly eligible

[49] The counterpart difference-in-difference OLS estimate under the 1.48 million reduced sample size is $110.88, which is very similar to the estimate, $111.35, estimated under 15 million observations.
[50] Newly eligible hospitals are all safety-net hospitals that generally provide high level of charity. If I make my division based on all Florida hospitals, in years like 2006, 2008 and 2009, there is no low-charity providing hospitals in the treatment group, which leads to perfect collinearity in the DID regression.
[51] The 90th percentile threshold for uninsured rates leads to perfect collinearity in some years due to lack of variation in this sample.

hospitals that provide the most charity and the ones that treat the most uninsured patients tend to reduce medication cost, after the 2010 ACA expansion, which is in line with fulfilling the mission of the 340B program to increase access to care for more vulnerable patients. On the contrary, hospitals that provide less charity and treat less uninsured patients, on average, significantly increase medication cost post-policy.

To verify whether high-charity hospitals, high-uninsured hospitals, as well as their counterparts have consistent prescribing patterns as I have unveiled so far, I further run a series of quantile regressions along full spectrums of medication cost per visit in each of the four categories of hospitals separated by their charity and uninsured ratios. Table 2.6 and Table 2.7 summarize the quantile regression estimates, while Figure 2.6.1, Figure 2.6.2, Figure 2.7.1, and Figure 2.7.2 present the corresponding quantile regression graphs. The results suggest that newly eligible hospitals that provide high charity and treat high uninsured patients do not change much of their prescribing behaviors after the 2010 ACA expansion. On visits with most expensive medication treatments, those hospitals even significantly reduce their medication cost to increase access to care for the patients, which is made possible due to the 340B drug discounts. On the contrary, newly eligible hospitals that provide low charity and treat less uninsured patients generally increase their medication cost after the 2010 expansion. Their increase becomes much larger the more expensive the treatment is.

To test hospitals' responsiveness to different economic incentives, I use the interaction between the Medicaid Rebate Program and the 340B Drug Pricing Program (explained in the background section) to set up another difference-in-difference analysis with the same hospitals in the control group as before but restrict the treatment group to include

only Medicaid visits at the newly eligible hospitals. Table 2.8 shows this alternative specification generates a significant but much smaller positive estimate for medication cost. Compared to the average increase of $111.35 in the main difference-in-difference regression, an increase of $35.14 per visit accounts for only 31.6% of the previous scale. Event study in Figure 2.8.1 shows the parallel trends assumption also holds in this alternative specification. This finding suggests when the economic incentives of profiting from drug discounts become much smaller, as with Medicaid visits, the newly eligible hospitals, on average, only increase their medication cost by less than a third of previous scale, which suggests participating hospitals are just rational agents responding to economic incentives.

2.4.3. Effects on Patient Mix and Quality of Care

Up to this point, 340B hospitals have shown distinct heterogenous responses in medication cost by their charity and uninsured patients' ratios. However, apart from using 340B drug discounts to reduce medication cost directly in some hospitals discovered above, it remains unclear how the remaining hospitals use the drug discounts collected from the program. In this section, I examine whether hospitals would use the drug discounts to directly fulfill the intent of the program to increase access to care for the most vulnerable patients through patient mix changes or to improve quality of care. Since the parallel trends assumptions do not hold for the related dependent variables, I use synthetic control method to lead the analysis.

Refer to the SCM trends plotting (Figure 2.9.1) and the placebo test graphs (Figure 2.9.2) for the four patient mix measures, I find no significant changes in hospitals' visit

ratios that are uninsured and charity (Panel A and Panel B in both figures). The newly eligible hospitals seem to treat higher proportions of Medicaid and Medicaid Managed Care patients after the expansion (Panel C and Panel D), but the subsequent permutation test histograms (Figure 2.9.3 and Figure 2.9.4) do not suggest the increases are statistically significant.

To further investigate whether participating hospitals might use the drug discounts to increase quality of care for altruistic motives, or other reasons like competition within a price regulated regime (Gaynor, Ho and Town 2015), I examine the following quality outcome variables: nonroutine discharge, length of stay, and post-operative adverse reaction rates (PO Adverse).[52] SCM trends in Figure 2.10.1 show the signs of the treatment effects are in the directions of suggesting better quality of care, but the subsequent placebo test results in Figure 2.10.2 and the additional histogram for PO Adverse in Figure 2.10.3 suggest the reductions in nonroutine discharge (Panel A) and PO Adverse (Panel B) are not significant. However, the placebo test histogram in Figure 2.10.4 suggests the reduction in length of stay is significant at 0.0212 significance level. The synthetic control estimate is -0.053 (Table 2.9). Compared to what its post-policy mean would be without the treatment of the eligibility expansion (namely, the post-policy mean of the synthetic unit), 0.103, this is a 52% reduction. All above findings suggest improvements in quality of care, but the evidence is weak in terms of statistical significance. These findings also suggest prescribing more, either by prescribing higher doses or choosing more expensive drugs for treatments, will not necessarily lead to improved quality of care, measured by the variables used in my study.

[52] In a price regulated regime, hospitals cannot compete directly through pricing, so they opt to compete through quality of care to gain more market share (Gaynor, Ho and Town 2015).

2.5. Robustness Check

To test the robustness of my previous findings on hospitals' prescribing behaviors, I proceed with three modifications based on the main difference-in-difference specification. All the regression results are summarized in Table 2.10.

First, instead of keeping all the hospitals that are not affected by the 2010 expansion in the control group, I only include DSH hospitals there. Unlike other hospitals in the control group that are not affected by the expansion policy, DSH hospitals are also safety-net hospitals that serve a large proportion of low-income patients and therefore, they resemble the hospitals in the treatment group the most. Keeping only DSH hospitals in the control group provides more confidence that their behavior changes over time can be used as the counterfactual difference over time for the treatment group, which is the key assumption for the main difference-in-difference setting. Column (1) Table 2.10 shows the estimate for the interaction term, $112.2, is close to the main regression estimate, $111.35.

In the second alternative specification, I add the Charlson Comorbidity Index as a control for patient acuity. The Charlson index is a comprehensive index that indicates how sick a patient is. It captures many unobserved factors in a patient's status that may lead to higher medication cost for the visit. I do not control it in the main difference-in-difference models because of the concern that the 340B program may bring more vulnerable patients to participating hospitals. If this is the case, the Charlson Comorbidity Index (CCI) becomes an outcome variable that is affected by the program. Column (2) Table 10 shows

while controlling the CCI, the estimate, $107.4, is still close to the estimate of the main DID regression, $111.35.

In the third modification, instead of using the estimated medication cost as the dependent variable, I use unadjusted charges that are not adjusted by any ratios, which itself may bring in additional unobserved noises in the study. The estimate in the last column of Table 2.10 shows the post-policy substantial increase in medication charges is significant and consistent to the finding from the main model.

For post-operative adverse reaction rates, I have three alternative specifications as well. The first modification is to exclude CPT procedures from the SCM regression because the 340B program may also induce hospitals to change their outpatient service lines that are linked to different medication usage and according drug profits, which potentially makes service mix outcome variables of the 340B program. Panel A Figure 2.11.1 suggests that any potential impact of the program on PO Adverse becomes not significant after three years.

Second, unlike the impact on prescribing behaviors that could take effect immediately, any potential quality impact of the program takes time to kick in after proper investment and training have taken place. Therefore, in the alternative specifications, I lead PO Adverse by one and two years, respectively. Panel B and Panel C in Figure 2.11 provide weak evidence that there are lagged impacts on PO Adverse.

Finally, if I only keep DSH hospitals in the control group that resemble the treated unit the most, Panel D Figure 2.11 does not suggest any significant influence from the program either.

2.6. Summary and Conclusions

Employing a series of difference-in-difference regressions and the synthetic control methods based on the 340B hospital eligibility expansion in 2010, I find that newly eligible Florida hospitals, on average, increase their medication cost by $111.35 per visit. Quantile regressions reveal significant heterogeneity among these hospitals. The newly eligible hospitals that provide the most charity (greater than the 90th percentile of charity distribution among newly eligible hospitals prior to 2010) and treat the highest proportion of uninsured patients (above the 70th percentile of uninsured distribution among newly eligible hospitals prior to 2010) continue to keep their medication cost low. On the most expensive visits, they even use the drug discounts to significantly reduce medication costs for the patients. On the contrary, the remaining newly eligible hospitals significantly raise their medication cost after the 2010 expansion, and such over-prescription becomes worse the more expensive the treatment is. Hospitals' over-prescription is sensitive to the amount of economic incentives available as well.

Accompanying a significant increase in average medication cost, newly eligible hospitals have not increased access to care for the most vulnerable patients measured by hospital uninsured, and charity care ratios. There are some indications that newly eligible hospitals have increased their proportions of Medicaid patient visits, and they are in the direction of improving quality of care after the 2010 ACA, but the evidence is not strong enough to be conclusive.

From policy perspective, my findings suggest the 340B Drug Pricing Program is most effective on eligible hospitals that provide the most charity care and treat highest proportion of uninsured patients. The 340B drug discounts allow them to help the

vulnerable patients to gain access to the most expensive treatments. On the other hand, among participating hospitals that do not provide as much charity and treat as much proportion of uninsured patients, over-prescription is prevalent. It becomes especially worrying on the most expensive treatments that are above the 90th percentile of the per-visit medication cost distribution. Further, I find no evidence that over-prescription leads to significantly improved quality of care, with the measures used in my paper.

According to my findings, one proposal to make the 340B Drug Pricing Program more effective at possibly less cost is to factor hospitals' outpatient charity and uninsured patient ratios into the current eligibility criteria of the program, which is only based on hospitals' DSH adjustment percentage, an inpatient income-based criterion. Regulators could set the new criteria high for participation, so it will make less safety-net hospitals eligible, but for those who remain, they are more likely to put the drug discounts for better use to really increase access to care for the most vulnerable patients.

Chapter 3 The Impact of Market Power on 340B Hospitals' Prescribing Behavior, Patient Mix, and Quality of Care

3.1. Introduction

Though the intent of the 340B Drug Pricing Program is to provide financial relief for covered entities (CE) to use the substantial drug discounts to treat more vulnerable patients, in the previous chapters, I find the program has led to a significant average increase in medication cost among the newly eligible 340B hospitals. However, my study also reveals important heterogeneity among the newly eligible hospitals such as those who provide the most charity and treat the highest proportion of uninsured patients would keep their average medication cost low. On the most expensive treatments, they even significantly reduce medication cost to make the treatments more accessible.

This evidence suggests that identifying heterogenous responses to the 340B program is important to evaluate whether the program is able to fulfill its mission. Understanding heterogenous responses among the 340B entities is also critical for policymakers interested in adjusting the design of the program to make it function more effectively and efficiently.

In this chapter, I focus on studying the role of hospitals' market power since a large literature documents a positive association between market power and a hospital's ability to increase prices (Cooper et al. 2019; White et al. 2014; Cutler and Morton 2013; Burgess et al. 2005; Melnick et al. 1999). If 340B hospitals are able to exercise their market power to raise prices without improving quality of care, they operate against the original intent of the program to make medical care more accessible to more vulnerable patients.

I use both the Centers for Medicare and Medicaid Services (CMS) nationwide state aggregate data and Florida hospital visits data, to study the extent to which market power might alter 340B hospitals' prescribing behavior, as well as their patient mix, and quality of care.

Using National Health Expenditure (NHE) account data from CMS, at the aggregate state level, I find that the positive relationship between the state's 340B hospital share and state hospital service spending is stronger when the state's average hospital market share is higher. Using data on visits to Florida hospitals from 2005 to 2015 from the Agency for Health Care Administration (AHCA), I find strong positive correlations between the newly eligible 340B hospitals' market shares, and their medication costs. Higher market share is also positively associated with higher patient ratios that are commercially insured, but negatively associated with the proportion of patients that are covered by Medicaid and Medicaid managed care. Market HHI does not seem to have significant correlations with these outcome variables among these 340B hospitals.

In addition, I find that after the 340B eligibility expansion, hospitals with low market shares seem to fulfill the mission of the 340B program to reduce their medication cost for their patients. They also treat more low-income patients that are covered by Medicaid and

Medicaid managed care and provide more charity to the communities. On the contrary, after the expansion, compared to the 340B hospitals with low market shares, the ones with high market shares significantly raise their medication cost per visit. They have fewer Medicaid managed care insured patients but treat more commercially insured patients.

The study finds signs of post-expansion improvements among both the newly eligible hospitals with high and the ones with low market share measured by post-operative adverse reaction rates. Additionally, there is likely to be a post-expansion treatment pattern change among the newly eligible hospitals with high market shares that they prefer treating patients in their own outpatient facilities with shorter length of stay.

These findings suggest the 340B Drug Pricing program is effective among the hospitals with low market shares, who seem to be able to reach more low-income patients and pass on some of the drug discounts to keep medication cost low for the most vulnerable population, but not so effective among hospitals with significant market power. Such findings indicate the program might be more effective by introducing more market pro-competition elements, adding some market share related requirements, or mandate certain Medicaid, Managed care outpatient ratio floors and commercial insured ratio ceilings to the eligibility of the program.

3.2. Literature Review

Market share is known to be a source of market power that links to firms' high prices and high profits. White et al. (2014) use private insurance claims data to identify high-price hospitals have market shares about three times as large as those of low-price

hospitals. Melnick et al. (1999) construct a series of simulation models to estimate the effects on prices for both for-profit and nonprofit hospitals of hypothetical merger scenarios. They find instead of hospital's ownership, market shares after hospital mergers are highly correlated with hospitals' price increase. Cutler and Morton (2013) use data from American Hospital Association (AHA) to summarize that while consolidation of hospital institutions keeps increasing from 2007 to 2012, and it has both benefits and harms, but consolidation generally increases market share that provides hospitals more market power to charge insurer higher prices, which directly leads to increase in consumer's out-of-pocket insurance premium payments.

Similarly, some papers use Herfindahl Hirschman Index (HHI) as a measure of market concentration to study its impact on hospitals' prices. The HHI is calculated by squaring the market share of each firm competing in the market, then summing the result numbers. A large HHI indicates a high degree of market concentration and raises concerns over firms to abuse their market power to constrain output and raise prices. Compared to market shares, HHI takes into account the relative size distribution of competing firms in a market, which generally increase as the number of firms decrease in the market and the disparity of firms increase in the market. Cooper et al. (2019) use insurance claims data from the Health Care Cost Institute (HCCI) in the U.S. to study the variation in health spending among people with employer-sponsored insurance. They find that hospital market structure, measured by hospital counts and HHI, is strongly associated with price levels and contract structure. Dranove et al. (2008) work with OSHPD data and use OLS and IV regression to find the association between concentration and prices increase during the 1990s and leveled off during the 2000s. Melnick and Keeler (2007) also find

hospital system HHI is positively associated with hospitals' price growth. Burgess et al. (2005) use data from AHA and the Office of Statewide Health Planning and Development (OSHPD) from 1994 to 1998 to estimate generalized estimation equations (GEE) that find hospital system HHI is positively correlated with prices. These positive associations raise the concern that some 340B hospitals with market power may also exercise their market power to raise prices without improving quality of care, which is against the intent of the program to use the drug discount to make medical care more accessible for more vulnerable patients.

Besides hospital pricing, some papers also study the impact of HHI on hospitals' quality of care as well, but the results are mixed. Kessler and McClellan (2000) study how market concentration interacts with the influence of managed care to affect social welfare, which evaluates the impact on expenditures of treatment and patient health outcomes at the same time. By using exogenous hospital and patients' characteristics to predict hospital market shares and construct exogenous HHIs as the measure of competition, they find hospital competition is unambiguously welfare-improving in geographic areas with above-median HMO enrollment rates. Kessler and Geppert (2005) use Medicare claim data and HHI to study nonrural area hospital's readmission and heart attack mortality rates. They find competition leads to lower mortality and readmission rates. Additionally, Gaynor et al. (2010, 2011, 2013), Cooper et al. (2010), and Propper et al. (2010), use various competition measures, such as HHI, number of hospitals, or demand elasticity to study hospital mortality rates in England and they find competition helps lower mortality rates.

On the contrary, other studies find market concentration has no effects on changing quality of care (Mukamel et al. 2001; Ho and Hamilton 2000), while some even find competition leads to decrease in quality of care (Gowrisankaranl and Town 2003; Mukamel et al. 2002; Encinosa and Bernard 2005; Volpp et al. 2003).

Given that the literature has found substantial positive associations between market power and hospital pricing, as well as mixed correlations between hospital's performance and market power, I examine this relationship in the context of the 340B program. To my knowledge, no study has examined the relationship between 340B hospitals' behavior and their market power. Given the substantial economic incentives existing in the 340B program and evidence of heterogeneity in the previous chapters, it is important to extend my study to evaluate the unknown impact of market power on 340B hospitals' prescribing behaviors, patient mix and quality of care, which might bring more insights for the regulators to further improve the design of the program to better align its participants to fulfill the original intent of the program.

3.3. Data

I use the same state aggregate National Health Expenditure (NHE) account data from Centers for Medicare and Medicaid Services (CMS) as well as the Florida hospital visits data from Agency for Health Care Administration (AHCA) in this paper. All variables have the same definition as mentioned in previous chapters.

3.3.1. Measure of Market Power using Market Share in the Nationwide State Aggregate CMS Data

Since the publicly available CMS National Health Expenditure (NHE) account data only provides aggregate state hospital service spending for each state without sharing individual hospital's patient flow, I construct the state average hospital market shares by dividing 1 over each state's hospital count over time. Table 3.1 presents its summary statistics. Additionally, I use the median of this variable, 0.012, to create a high share dummy to separate all hospitals into the ones with high market shares (equal to or above the median) and the ones with low market shares (below the median). The intention is to interact this high share dummy with the state 340B hospital shares to test whether market share has any impact on 340B hospitals' prescribing patterns when hospitals have high market shares relative to the ones with low market shares.

3.3.2. Measure of Market Power using Market Share and HHI in the AHCA Data

The market share of each hospital j in year t is calculated by dividing hospital's annual outpatient visits by the sum of all hospitals' annual outpatient visits located in the respective hospital referral regions (HRR) m:

$$S_{jmt} = \frac{Annual\ ambulatory\ patient\ visits\ to\ hospital\ j\ in\ year\ t}{Sum\ of ambulatory\ visits\ to\ all\ hospitals\ located\ in\ the\ same\ HRR\ m}$$

HRRs represent regional health care markets that divide the state of Florida into 19 different markets, whereby the 12 newly eligible hospitals locate in 8 of them. The HRR market Herfindahl Hirschman Index , HHI_{mt}, is then calculated by summing the squares of every hospitals' market shares in each HRR market in year t (Table 3.2). I use both hospital's market share and market HHI in the paper to study the impact of market power on the newly eligible 340B hospitals' behavior changes.

Since the 340B hospital eligibility expansion took place in 2010, after which hospitals' market shares are potentially affected by various changes brought by the policy, such as hospitals' pricing, provider-insurer network reconfiguration, quality of care, and competition, I derive the following categorization dummies by using the pre-policy market shares and HHIs in year 2009 to avoid concerns about reverse causality. Specifically, as among 12 hospitals affected by the expansion, 6 of them have smaller than 3% market shares, while the remaining have at least 9.75% market shares (Table 3.3), I use 3% as the threshold to create the high market share dummy, $Hshare_{j,2009}$, that separates all the 184 hospitals into the high market share group ($Hshare_{j,2009} = 1\ if\ S_{jmt} \geq 3\%$) that contains 50% of all the visits and the low share group ($Hshare_{j,2009} = 0\ if\ S_{jmt} < 3\%$) that contains the remaining 50% of the visits to the 184 hospitals. Likewise, using market HHI as the measure of market power, I use value 1852 as the HHI threshold to create a high HHI dummy, $HHHI_{m,2009}$, that separates 19 Florida HRR regions into the highly concentrated markets ($HHHI_{m,2009} = 1\ if\ HHI_{m,2009} \geq 1852$) and the more competitive markets ($HHHI_{m,2009} = 0\ if\ HHI_{m,2009} < 1852$).

Refer to the distribution of the HHI index in 2009 in Table 3.2, when defining the high HHI dummy, I choose 1852 to be the threshold to ensure I have at least one hospital from

each type of the newly eligible hospitals (PED, RRC, CAH) to represent the behavior pattern changes in both the highly concentrated markets and the more competitive markets. Otherwise, given the small number of the newly eligible hospitals in the sample, and heterogenous responses to the 340B program by hospital type (as shown in Figure 3.1.1), if the distribution by types of the hospitals is unbalanced between the highly concentrated and low concentrated markets, the regression estimates may reflect differences across types of hospitals, rather than the differences across market concentration levels, which is the main focus of this study. For this reason, the only cancer hospital in the sample, located in the most competitive market, is excluded from models using HHI to measure market power.

3.4. Empirical Methods

Since the variables in the CMS National Health Expenditure (NHE) account data are at state aggregate level, while the variables in the Florida AHCA data are at hospital visits level, I adopt different models for each dataset.

3.4.1. State Fixed Effects Using Nationwide State Aggregate Data from CMS

With the CMS state aggregate data, I use state fixed effects to examine the impact of market shares on hospitals' prescribing patterns as given below:

$$\ln(y_{it}) = \beta_0 + \beta_1 S_{it} + \beta_2 Hshare_{it} + \beta_3 S_{it} * Hshare_{it} + \beta_4 X_{it} + \beta_5 \tau_t + c_i + \varepsilon_{it} \quad (3.1)$$

y_{it} is the aggregate hospital service spending per thousand residents in state i in year t. Vector $\boldsymbol{X}_{it}$ includes the same set of covariates as in Chapter 1 that impact hospital service spending. τ_t is a series of year dummies to control for time fixed effects. c_i are the state fixed effects to control state time invariant factors. β_3 is the key parameter of interest that measures the difference in the impact of market share on hospitals' prescribing patterns.

3.4.2. Models Using Florida Hospital Visit Data from AHCA

With hospital visit level information from the AHCA dataset, I use the models below to study the impact of market power on the newly eligible 340B hospitals' prescribing behavior, patient mix and quality of care.

3.4.2.1. The Impact of Market Power on the Newly Eligible 340B Hospitals' Behavior

I begin with using an OLS regression to estimate the association between market power and the newly eligible 340B hospitals' medication cost, patient mix, and quality of care. Model 3.2 below measures market power in the form of market share as well as market HHI by replacing $share_{j,t}$ with $HHI_{m,t}$:

$$(3.2)\quad y_{ijt} = \beta_0 + \beta_1 share_{j,t} + \beta_2 \boldsymbol{X}_{ijt} + \beta_3 \tau_t + \varepsilon_{ijt}$$

y_{ijt} are the outcome variables that include hospitals' outpatient medication costs, uninsured, charity, Medicaid, Medicaid managed care, commercially insured patients ratios, post-operative adverse reaction rates (PO Adverse), length of stay, and nonroutine discharge ratios for visit i to 340B eligible hospital j, located in HRR market m, in year t. β_1 is the estimator of interest that evaluates the association between market power and the outcome variables among the newly eligible 340B hospitals. Vector $\boldsymbol{X}_{ijt}$ include hospitals' licensed bed counts, teaching status, ownership, county unemployment and uninsured rates, patients' gender, seniority, and race. τ_t is a series of year dummies to allow time fixed effects, among which year 2005 is omitted as the base. ε_{ijt} is the disturbance that includes all other residual effects. When using market share to measure market power, estimated standard errors are clustered at hospital level to allow intra-hospital correlations among the error terms. When HHI is used to measure hospital's market power, estimated standard errors are clustered at HRR level to allow intra-market correlations among the error terms.

3.4.2.2. Heterogeneity in the Impact of the 340B Program on Hospitals by High vs. Low Market Power

Though the eligibility of the 340B program ensures most participants are treating significant proportion of low-income patients, the newly eligible hospitals with high market power may respond to the program very differently than the ones with low market power. Building upon the difference-in-difference (DID) models used in Chapter 2 based on the 2010 340B eligibility expansion, I interact the high market power dummy, measured by

either $High\ share_{j,2009}\ or\ High\ HHI_{m,2009}$, with the treatment dummy (to identify the hospitals that become eligible to participate 340B after the expansion policy), and the post policy dummy to construct a series of difference-in-difference-in-difference (DDD) regressions to test the difference in the impact of the 340B program on the newly eligible hospitals with high market power vs. the ones with low market power.[53] The equation below specifies the DDD model:

$$
\begin{aligned}
(3.3)\quad y_{ijt} = {} & \beta_0 + \beta_1 Hshare_{j,2009} + \beta_2 treat_j \\
& + \beta_3 post_t + \beta_4 treat_j * Hshare_{j,2009} + \beta_5 post_t * Hshare_{j,2009} + \beta_6 treat_j \\
& * post_t + \beta_7 treat_j * post_t * Hshare_{j,2009} + \beta_8 \boldsymbol{X}_{ijt} + \beta_9 \tau_t + \varepsilon_{ijt}
\end{aligned}
$$

y_{ijt} includes the same set of outcome variables explained in model (3.2). The $treat_j$ dummy identifies hospitals in the treatment group, which includes all children's hospitals, rural referral centers, critical access hospitals and cancer hospitals that became eligible to participate the 340B program since the 2010 expansion. $post_t$ is defined as 1 if the time is after year 2010, and 0 otherwise. β_7 is the DDD estimator of interest which estimates the difference in the pre vs. post-policy change in the outcome variables between the treatment and control groups among hospitals with high market shares relative to hospitals with low market shares. This captures the relative difference in the effects of the 340B program on the newly eligible hospitals with high market shares

[53] As is explained in detail in Chapter 2, the impact of the 340B program refers to the pre vs. post difference in the difference of outcome variables between the treatment group and the control group (DID).

relative to the ones with low shares. Vector $\boldsymbol{X}_{ijt}$ include hospitals' licensed bed counts, teaching status, ownership, county unemployment and uninsured rates, patients' gender, seniority, and race. τ_t is a series of year dummies, among which I take year 2005 as the base and leave out 2015 as well to avoid perfect collinearity with the $post_t$ dummy that covers the period from 2010 to 2015. ε_{ijt} is the disturbance that includes all other residual effects. Estimated standard errors in the DID results are robust to heteroskedasticity. A concern with the heteroskedasticity-robust standard error is that it does not account for intra-hospital correlations, which is likely to be an important issue in this study because if a hospital tends to over-prescribe on certain procedures, they are likely to over-prescribe from one visit to another within the same hospital over time, leading to serial correlation that makes the estimated variance of the regression coefficients biased. Cluster-robust standard errors at hospitals level is appropriate to tackle this concern, but the typical way of calculating cluster-robust standard errors at hospital level is inappropriate for my DID and DDD settings (due to few treated cluster groups in the sample). Therefore, I use synthetic control method (SCM) to estimate the impact of the policy as well and produce inference under random permutation of assigning placebo treatments to all the treated and untreated groups. The p-value is calculated as the fraction of such placebo effects greater than or equal to the effect estimated for the treated unit. Such p-value has the interpretation as the probability of obtaining an estimate at least as large as the one obtained for the unit representing the case of interest when the intervention is reassigned at random in the data set (Abadie et al. 2015).

The relative magnitude of the estimated difference, $\widehat{\Delta\%}$, is calculated by dividing the estimate, $\widehat{\beta_7}$, by the counterfactual post-policy mean of the outcome variable of the high-

share treated hospitals as if they have not been exposed to the treatment. The denominator is calculated by using the observed post-policy mean outcome variable of the high-share control hospitals plus their pre-policy mean difference between the high-share treated and the high-share control hospitals, $\widehat{\beta_2} + \widehat{\beta_4}$:

$$\widehat{\Delta\%} = \frac{\widehat{\beta_7}}{\text{postpolicy mean outcome variable of the highshare treated hospitals as if they were not treated}}$$

$$= \frac{\widehat{\beta_7}}{\text{post mean of the highshare nontreated} + \text{pre mean difference between highshare treated and highshare nontreated}}$$

$$= \frac{\widehat{\beta_7}}{E(y|treat = 0, Hshare = 1, post = 1) + [E(y|treat = 1, Hshare = 1, post = 0) - E(y|treat = 0, Hshare = 1, post = 0)]}$$

$$= \frac{\widehat{\beta_7}}{E(y|treat = 0, Hshare = 1, post = 1) + [(\widehat{\beta_0} + \widehat{\beta_1} + \widehat{\beta_2} + \widehat{\beta_4}) - (\widehat{\beta_0} + \widehat{\beta_1})]}$$

$$= \frac{\widehat{\beta_7}}{E(y|treat = 0, Hshare = 1, post = 1) + \widehat{\beta_2} + \widehat{\beta_4}}$$

To evaluate the parallel trends assumption between the treat vs control difference of the high share hospitals and the treat vs control difference of the low share hospitals, I use the event study specifications below:

$$(3.4)\quad y_{ijt} = \beta_0 + \beta_1 Hshare_{j,2009} + \beta_2 treat_j + \beta_{3t}\tau_t + \beta_4 Hshare_{j,2009} * treat_j + \beta_{5t} Hshare_{j,2009} * \tau_t + \beta_{6t} treat * \tau_t + \beta_{7t} treat_j * Hshare_{j,2009} * \tau_t + \beta_8 \boldsymbol{X}_{ijt} + \varepsilon_{ijt}$$

If the parallel trends assumption holds, β_{7t} are expected to be insignificant prior to 2010. Post-2010, if the program is influential, β_{7t} is expected to be significantly different from zero.

Finally, since the DDD regression merely focuses on the relative difference in the impact of the program without visually showing the trends of the outcome variables among the newly eligible hospitals with different market shares, I complement the DDD estimation with graphs plotting the raw data trends and the simple difference-in-difference (DID) estimation in model (3.5) below:

$$(3.5)\quad y_{ijt} = \beta_0 + \beta_1 treat_j + \beta_2 post_t + \beta_3 treat_j * post_t + \beta_4 \boldsymbol{X}_{ijt} + \beta_5 \tau_t + \varepsilon_{ijt} \mid if\ Hshare_{j,2009} == 1\ or\ 0$$

All the variables in model (3.5) have the same definition as in model (3.3), the DID parameter of interest, β_3, measures the impact of the 340B program on the newly eligible hospitals with different market shares separately.

3.5. Results

3.5.1. Nationwide CMS State Aggregate Data

Table 3.4 presents the estimation results for model 3.1, using natural log of the state hospital service spending per thousand residents as the dependent variable. The estimate of the interaction term, 0.123, implies that compared to the states with low

average hospital market shares, in the states with high average hospital market shares, a 1 percentage point increase in the state 340B hospital share raises its state hospital service spending by additional 12.3%. The estimate is statistically significant at the 0.1% significance level.

This finding suggests that the positive relationship between the state's 340B hospital share and the state hospital service spending is stronger when the state's average hospital market share is higher. To complement this nationwide state aggregate overview, I use patient visits data to Florida hospitals from 2005 to 2015 in the next section, to examine the impact of market power on Florida 340B hospitals' prescribing behavior, quality of care and patient mix.

3.5.2. Florida AHCA Hospital Visit Data

Table 3.5 summarizes all the estimates of β_1 from running Model 3.2 with different outcome variables to test the association between market power, measured by hospital's market share and market concentration (HHI), and various outcome variables. The estimate for medication cost in Column (1), shows that in Florida, there is a strong positive correlation between hospital's market shares and their medication costs among the newly eligible hospitals. On average, one percentage point increase in market share leads to an average per-visit medication cost increase of $685.01 in the sample. Additionally, with more market power, the newly eligible 340B hospitals also reduce the composition of their Medicaid and Medicaid managed care patients to treat more commercially insured patients. Estimates of quality improvement measured by PO Adverse, length of stay and nonroutine discharge rates are not statistically significant.

When the market HHI is used to measure hospitals' market power, most estimates become insignificant. This could suggest that unlike market share, the average newly eligible hospital does not adjust its medication cost, patient mix, and quality of care as sensitively to competition. It is also likely that the allocation of the 11 newly eligible hospitals in 8 HRR markets (Table 3.2) does not provide enough inter-market variation to produce significant estimates.

Table 3.6 presents all the DDD estimates using market share and market HHI to measure market power in the respective columns. The estimates for the triple interaction term test whether the 340B program have different impacts on the newly eligible hospitals with high market power vs. the ones with low market power.

On medication cost, relative to hospitals with low market shares, the 340B program induces an additional average per-visit medication cost of $167 among the ones with high market shares. This difference represents an additional 378% increase when compared to the counterfactual post-policy mean per-visit medication cost of the high share newly eligible hospitals as if they have not been exposed to the treatment.[54] The estimate is significant at 0.01% significance level when standard errors are robust to heteroskedasticity.[55] Event study in Figure 3.2.1 shows the parallel trends assumption is likely to be satisfied. After the eligibility expansion, the program induces substantially

[54] Refer to the $\widehat{\Delta\%}$ formula in 3.4.2: the post-policy mean medication cost of the high-share control group is $96.99. The pre-policy mean difference between the high-share treatment and the high-share control group is -$52.80 ($\widehat{\beta_2} + \widehat{\beta_4}$), which leads to counterfactual post-policy average per-visit medication cost of the high-share newly eligible hospitals if without treatment as $96.99-$52.80=$44.19. $\widehat{\Delta\%} = \frac{167}{44.19} = 378\%$.

[55] Again, the cluster-robust standard errors in my specific DID / DDD settings are inappropriate due to few treated cluster groups in my sample, so I use SCM to provide inference in the subsequent DID analysis.

higher medication costs among the newly eligible hospitals with high market shares relative to the ones with low market shares.

The raw data trends plot in Figure 3.2.2 shows the newly eligible hospitals with low market shares only have a mild increase in per-visit medication cost, from the pre-policy mean of $39.49 to the post-policy mean of $43.95, while the ones with high market shares have a substantial increase from the pre-policy mean of $52.53 to the post-policy mean of $231.82. Additionally, refer to the DID and SCM estimates in Table 3.7, the 340B program may enable the newly eligible hospitals with low market shares to even reduce per-visit medication cost moderately after the expansion, while the program induces hospitals with high market shares to significantly raise their average per-visit medication cost by $142.02 in the DID analysis. SCM produces a similar significant estimate of increase by $128.36 (Figure 3.2.3) with p-value = 0.014, produced by the SCM permutation test (Figure 3.2.4). These findings suggest the 340B program may affect the newly eligible hospitals with different market shares very differently: the ones with high market shares exercise their market power to raise medication cost per visit, while the program may allow the hospitals with low market shares to make treatments more accessible to patients by lowering their medication cost. On the other side, when market power is measured by market HHI (Column (2) Table 3.6), the estimate of relative increase, 2.94, is small in magnitude for every 1,000 points increase in HHI, and statistically insignificant. The insignificant estimate may suggest that unlike market share, competition may not lead to significant difference in the impact of the 340B program on the newly eligible hospitals' prescribing behavior, but lack of inter-market variation could also be the reason of getting the insignificant estimates.

In terms of patient mix, average uninsured patient ratios among all Florida hospitals monotonically decreased from 3.1% in 2005 to 1.7% in 2015.[56] Part of the reduction could be due to the increase in insurance due to the extensive outreach of the ACA navigator program (Louise Norris 2018) that provides education, and enrollment assistance to consumers eligible for marketplace and Medicaid coverage. Graphically, raw data trends in Figure 3.3.2 show that both the newly 340B-eligible hospitals with high and low market shares have decreasing uninsured ratios over time, while Figure 3.5.2 and Figure 3.6.2 imply part of such decrease in the uninsured ratios is due to the increasing enrollment in Medicaid and Medicaid managed care in Florida over time. To counter statewide Medicaid spending increasing, Florida applied for and received federal approval for an 1115 waiver for its Medicaid Reform pilot, which led to the Statewide Medicaid Managed Care (SMMC) in 2011 and eventually, in 2013, the federal government approved the state's request to move nearly all Medicaid beneficiaries and services into managed care, starting in 2014 on a phased-in schedule.[57] This may explain the sharp drops in Medicaid patient ratios and rises in Medicaid managed care patient ratios since 2014 observed in Figure 3.5.2 and Figure 3.6.2.

Despite these specific changes in the insurance market in Florida, both the DDD estimates (Table 3.6) and the DID / SCM estimates (Table 3.7) suggest that after 2010, compared to the newly eligible 340B hospitals with low market shares that have substituted significant proportion of their commercially insured patients (-9.93%, SCM) to

[56] Even if dividing all hospitals into high and low market-share groups, both have the general monotonic decreasing trends and the ratios are similar.
[57] Medicaid.gov (https://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/managed-care/downloads/florida-mcp.pdf)

treat more Medicaid, Medicaid managed care patients (13.5%, SCM), and provide more charity (0.12%, SCM, insignificant), the ones with high market shares manage to treat more commercially insured patient (7.39%, SCM), but less Medicaid managed care patients (-1.56%, SCM, insignificant). The reason we observe a sharp reduction in uninsured patient ratios among hospitals with low market shares since 2008 (Figure 3.3.2) is likely because they started to enroll more uninsured patients under Medicaid (Figure 3.5.2) or Medicaid managed care (Figure 3.6.2) since then. The positive DDD estimate for uninsured patient ratio in Table 3.6 (0.0086) is due to the larger reduction in the uninsured patient ratios among the hospitals with low market shares than the hospitals with high market shares (Figure 3.3.2), so the DDD estimate captures the relative difference between these two groups of hospitals. With the same possible reasons as I explained before, when I use market HHI to measure market power, these patient-mix-related estimates have the same signs but smaller in magnitude.

For quality of care, both groups of the newly eligible hospitals seem to have reduced their post-operative complication rates to a similar extent after 2010 (Table 3.7, Figure 3.8.2), so that the DDD estimate does not show any significant relative difference (Table 3.6).[58] In addition, refer to Column (1) Table 3.6 and Table 3.7, compared to the newly eligible hospitals with low market shares, the ones with high market shares seem to have reduced length of stay and fewer nonroutine discharges to inpatient or other health care facilities. The shorter length of stay among high market share hospitals may be due to these hospitals treating more privately insured patients who are likely in better health

[58] Compared to the post-policy mean PO Adverse rate of the control group with high market shares, 0.010, the DDD estimate, 0.0001 represents a relative difference of 1%, which is economically insignificant as well.

conditions while the longer length of stay among low market share hospitals may be driven by increased treatment of Medicaid and Medicaid managed care patients who tend to be less healthy than privately insured patients.

3.6. Summary

Using the nationwide CMS state aggregate data from 2003 to 2014, I use state fixed effects model to find that, nationwide, the positive relationship between the state's 340B hospital share and state hospital service spending is stronger when the state's average hospital market share is higher.

Based on the actual patient flows to Florida hospitals from 2005 to 2015, I find strong positive correlations between the newly eligible hospitals' market share, and their medication costs and commercially insured patient ratios. On the other hand, it finds negative correlations between 340B hospitals' market share and their patient ratios that are covered by Medicaid and Medicaid managed care.

Evaluating the impact of the 2010 340B hospital eligibility expansion, I find that the 340B hospitals with low market shares may reduce medication cost moderately while treating more low-income patients and providing more charity to the communities. On the contrary, high market share hospitals significantly increase their medication cost, treat more privately insured patients, treat fewer patients covered by Medicaid managed care, and provide less charity.

I find signs of quality improvement, measured by post-operative adverse reaction rates, among both high and low market share hospitals. However, after the expansion, there is

a possible treatment pattern change so that the newly eligible hospitals with high market shares treat more patients in their own outpatient facilities with a shorter length of stay. Hospitals with low market shares have increased length of stay, possibly due to worse health conditions among the additional Medicaid and Medicaid managed care patients they treat.

Conclusion

This dissertation finds the 340B Drug Pricing Program induces the average 340B hospital to increase medication cost, treat fewer low-income patients but take in more well-insured patients. Though I find some signs of quality improvement among all the 340B hospitals, I am limited by the available measures of quality of care in the AHCA dataset. Future studies could examine the impact of the program on other outpatient quality measures such as readmission rates or patient satisfaction rates to better understand whether the rise in medication cost due to the program is cost-effective, as well as the welfare effects of the reduction in medication cost among certain hospitals. It is also worthwhile to study more heterogenous hospital responses by hospital type as this study does not have data on sole community hospitals and has only one cancer hospital.

Additionally, the study identifies some important heterogenous responses to the 340B program. Hospitals that treat the most uninsured patients, provide the most charity, and have small market shares seem to pass on some of the drug discounts by reducing medication cost to make medical care more accessible for the vulnerable population. These findings shed lights on the potential angles (such as pro-competition policies, requirements on low-income outpatient patient ratio) that policy makers could work with to adjust the design of the program to make it function more effectively and efficiently.

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Appendix A: Tables

Table 1.1 – Summary Statistics

VARIABLES	N	Mean	SD	Min	Max
Id (state)	612	26	14.73	1	51
Year	612	2,009	3.455	2,003	2,014
Retail Drug Expenditure	612	4,677	5,061	246	29,270
Retail Drug Expenditure Per Resident	612	784.2	181.9	379.1	1,343
Log (Retail Drug Expenditure Per Resident)	612	6.637	0.241	5.938	7.203
Hospital Service	612	14,778	16,214	824	107,074
Hospital Service Per Resident	612	2,661	982.8	1,386	9,159
Log (Hospital Service Per Resident)	612	7.840	0.287	7.234	9.123

Table 1.2 – CE Shares by Hospital Types

SHARE VARIABLES	N	Mean	SD	Min	Max
All Six Types of the 340B Hospitals	612	0.219	0.181	0	1
DSH Hospitals	612	0.138	0.108	0	0.434
Children's Hospitals	612	0.00434	0.0156	0	0.143
Free Standing Cancer Hospitals	612	5.91e-05	0.0005	0	0.006
Sole Community Hospitals	612	0.00788	0.0215	0	0.214
Rural Referral Centers	612	0.00304	0.0093	0	0.071
Critical Access Hospitals	612	0.0671	0.132	0	0.619

Table 1.3 – Other Covariates under Control

VARIABLES	N	Mean	SD	Min	Max
Median Household Income	561	59,965	10,117	39,928	93,166
Insurance Rate	612	0.866	0.0402	0.745	0.966
Unemployment Rate	612	0.0347	0.0111	0.0120	0.081
Senior Residents Rate	612	0.170	0.0232	0.0820	0.232
Male	612	0.491	0.00800	0.466	0.516
Bachelors and Beyond	612	0.266	0.0598	0.138	0.568
White	612	0.806	0.138	0.178	0.972
Black	612	0.117	0.114	0.00100	0.599
Asian	612	0.0367	0.0594	0.00100	0.478

Table 1.4 – Effects of 340B Participation on Drug Spending Per Capita

VARIABLES	(1) Ln (Hospital Service Per)	(2) Ln (Retail Prescription Drug Per)
State 340B Hospital Share	0.128***	0.0587
	(0.0281)	(0.0490)
Ln (Income)	0.0970*	0.137
	(0.0561)	(0.0840)
Insured	-0.00860	0.172
	(0.130)	(0.261)
Unemployment	-0.418	-0.0653
	(0.415)	(0.876)
White	0.285	-0.640*
	(0.235)	(0.353)
Black	1.589***	-2.176***
	(0.248)	(0.550)
Asian	0.410	-1.359**
	(0.290)	(0.533)
Senior Ratio	0.263	-0.241
	(0.191)	(0.371)
Male	0.517	-0.101
	(0.474)	(0.807)
Bachelor+	-0.0227	0.0852
	(0.167)	(0.263)
Constant	5.832***	5.711***
	(0.569)	(1.051)
Observations	561	561
Number of Clusters	51	51

Robust standard errors in parenthesis, clustered at state level: *** p<0.01, ** p<0.05, * p<0.1.
Regressions also include year fixed effects and state fixed effects.

Table 1.5 – Random Trend Model

VARIABLES	(1) Ln (Hospital Service per)	(2) Ln (Retail Prescription Drug per)
State 340B Hospital Share	0.153*	0.0482
	(0.0879)	(0.0965)
Ln (Income)	-0.231	0.557***
	(0.274)	(0.182)
Insured	3.001***	1.073**
	(0.643)	(0.494)
Unemployment	2.511*	0.222
	(1.254)	(1.232)
White	-2.033**	0.555
	(0.843)	(0.646)
Black	-1.355*	1.064
	(0.728)	(0.648)
Asian	-3.399***	-0.0788
	(1.121)	(0.783)
Senior Ratio	0.101	2.111***
	(0.955)	(0.774)
Male	2.777	-11.12***
	(3.036)	(2.709)
Bachelor+	1.637*	-1.397***
	(0.876)	(0.408)
Observations	561	561
Number of Clusters	51	51

Robust standard errors in parenthesis, clustered at state level: *** p<0.01, ** p<0.05, * p<0.1.
Regressions also include year fixed effects and state fixed effects.

Table 1.6 – Frequency of Participation by Month

Month of Participation	Freq.	Percent	Cum.
1	665	22.38	22.38
2	6	0.20	22.58
4	625	21.03	43.61
5	4	0.13	43.74
7	641	21.57	65.31
8	79	2.66	67.97
9	294	9.89	77.86
10	580	19.52	97.38
11	10	0.34	97.71
12	68	2.29	100.00
Total	2,972	100.00	

Table 1.7 – Effect of 340B Participation on Spending Per Capita (Lagged-Share)

VAR	(1) Ln (Hospital Service Per)	(2) Ln (Retail Prescription Drug Per)	VAR	(3) Ln(Hospital Service Per)	(4) Ln(Retail Prescription Drug Per)
State 340B Hospital Share_ Lagged (1 Year)	0.097***	0.081*	State 340B Hospital Share (No Lag)	0.128***	0.059
	(0.024)	(0.045)		(0.028)	(0.049)
Observations	561	561		561	561
Number of Clusters	51	51		51	51

Robust standard errors in parenthesis, clustered at state level: *** p<0.01, ** p<0.05, * p<0.1

Table 1.8 – Random Trend Model (Lagged-Share)

VAR	(1) Ln (Hospital Service per)	(2) Ln (Retail Prescription Drug per)	VAR	(3) Ln (Hospital Service per)	(4) Ln (Retail Prescription Drug per)
State 340B Hospital Share_ Lagged (1 Year)	0.084	0.093	State 340B Hospital Share (No Lag)	0.153*	0.048
	(0.106)	(0.118)		(0.088)	(0.097)
Observations	561	561		561	561
Number of Clusters	51	51		51	51

Robust standard errors in parenthesis, clustered at state level: *** p<0.01, ** p<0.05, * p<0.1

Table 2.1 – Summary Statistics of Ambulatory Visits

VARIABLES	Mean	SD
Medication Charges	821.24	2,742
Medication Cost-to-Revenue Ratios (CRR)	0.102	0.055
Medication Charges (CRR Adjusted)	76.48	355.77
Uninsured	0.025	0.157
Charity	0.012	0.110
LOS (In Days)	0.074	0.262
Nonroutine Discharge	0.013	0.115
Post-Operative Adverse Reaction	0.011	0.105
Infection	0.002	0.039
Wound	0.007	0.081
Urinary	0.000	0.019
Pulmonary	0.000	0.021
Cardiovascular	0.000	0.018
GI (Gastrointestinal)	0.000	0.021
CNS (Central Nervous System)	9.88E-06	0.003
Systemic	0.001	0.025
During	0.001	0.034
DSH	0.419	0.493
PED	0.014	0.116
CAN	0.017	0.130
RRC	0.015	0.123
CAH	0.003	0.051
Participation	0.288	0.453
For-Profit	0.259	0.438
Government Owned	0.139	0.346
Nonprofit (as base)	0.571	0.495
Unknown (ownership)	0.031	0.173
Teaching	0.150	0.357
Licensed Beds	572	535
Unemployment (county)	6.865	2.819
Uninsured (county)	23.25	4.909
Male	0.431	0.495
Senior (65+)	0.374	0.484
American Indian	0.002	0.041
Asian	0.009	0.092
Black	0.119	0.324
White (as base)	0.756	0.430
Hispanic	0.129	0.335
Other (Race)	0.045	0.207

Table 2.1 (Continued)

VARIABLES	Mean	SD
Unknown (Race)	0.015	0.120
Traditional Medicaid (as base)	0.065	0.246
Medicaid Managed Care	0.041	0.198
Traditional Medicare	0.314	0.464
Medicare Managed Care	0.089	0.284
Commercial	0.406	0.491
Worker's Compensation	0.010	0.101
Federal Gov (TriCare, etc.)	0.017	0.130
Veteran's Affairs	0.002	0.046
Local Gov	0.011	0.102
Kid Care	0.002	0.048
Commercial Liability Coverage	0.001	0.024
Charlson Comorbidity Index	0.471	1.161
Integumentary Surgery	0.171	0.376
Microbiology Procedure	0.031	0.173
Organ Pathology	0.143	0.350
Hematology	0.200	0.400
Injection	0.198	0.398
Office	0.048	0.214
Surgical Pathology	0.175	0.380
Cardiovascular Medicine	0.086	0.281
Infusion	0.054	0.227
Radiology	0.055	0.227
Chemistry	0.028	0.164
Transfusion Medicine	0.040	0.196
Observation	0.014	0.118
Wound Care	0.001	0.029
Mortality	8.78e-05	0.009
Observations	15,177,275	
Number of Hospitals	184	

Table 2.2 – Main Difference-in-Difference Regressions

VARIABLES	(1) Participation	(2) Estimated Medication Cost
Treat	-0.262***	-33.47***
	(0.000272)	(0.457)
Post	0.320***	60.50***
	(0.000533)	(0.478)
Treat * Post	0.598***	111.3***
	(0.000718)	(1.563)
Licensed Beds	0.000223***	-0.0323***
	(3.58e-07)	(0.000248)
Teaching	0.0924***	24.94***
	(0.000558)	(0.298)
For-Profit	-0.231***	-43.18***
	(0.000193)	(0.193)
Government Owned	-0.0132***	-15.09***
	(0.000334)	(0.221)
Unknown (owner)	-0.265***	38.37***
	(0.000213)	(0.567)
Unemployment (county)	-0.0690***	-4.682***
	(0.000102)	(0.0708)
Uninsured (county)	0.00311***	1.226***
	(2.72e-05)	(0.0229)
Male	0.00276***	1.454***
	(0.000195)	(0.186)
Senior	-0.0470***	3.144***
	(0.000200)	(0.200)
American Indian	-0.0260***	-11.12***
	(0.00230)	(1.936)
Asian	0.0220***	4.257**
	(0.00109)	(1.100)
Black	0.0721***	-5.133***
	(0.000323)	(0.254)
Hispanic	0.0804***	-0.930*
	(0.000351)	(0.316)
Other (race)	-0.0728***	-0.0436
	(0.000476)	(0.468)
Unknown (race)	0.0637***	7.688***
	(0.000852)	(1.015)
Constant	0.323***	69.62***
	(0.000790)	(0.624)
Observations	15,177,275	15,177,275
R-squared	0.309	0.007

Robust standard errors in parenthesis (*** p<0.0001, ** p<0.001, * p<0.01)
Regressions also include year fixed effects.

Table 2.3 – Synthetic Control Estimates Medication Cost

YEAR	_Y_treated	_Y_synthetic	Gap	Mean
2005	37.99	36.41	1.59	
2006	40.88	44.82	-3.94	
2007	44.63	53.06	-8.43	-0.49
2008	67.78	55.24	12.54	
2009	50.78	55.00	-4.22	
2010	160.72	80.90	79.83	
2011	148.43	83.32	65.10	
2012	144.99	83.13	61.86	92.85
2013	165.30	84.86	80.44	
2014	235.71	91.98	143.73	
2015	226.25	100.09	126.16	
Synthetic Control Method DID Estimate				93.35

Table 2.4 – Quantile Regression DID Interaction Estimates

Quantile	QR Estimates	95% Conf. Interval	
		Lower	Upper
0.15	-0.10***	-0.13	-0.08
0.2	-1.52***	-1.63	-1.41
0.3	0.03	-0.17	0.22
0.4	1.47***	1.19	1.75
0.5	4.10***	3.70	4.50
0.6	6.93***	6.43	7.42
0.7	12.61***	11.97	13.26
0.8	25.66***	24.72	26.59
0.9	58.44***	56.54	60.33
0.95	160.62***	154.76	166.48
0.96	232.83***	224.96	240.71
0.97	451.32***	429.16	473.49
0.98	1454.57***	1391.40	1517.00
OLS Mean Reference	110.88***	105.13	116.63
Observations	1,482,709		

Estimates Significance Level (*** p<0.0001, ** p<0.001, * p<0.01)
Regressions also include year fixed effects.

Table 2.5 – DID by High / Low Charity and Uninsured Groups

VARIABLES	Low Charity Estimated Medication Cost	High Charity Estimated Medication Cost	Low Uninsured Estimated Medication Cost	High Uninsured Estimated Medication Cost
Treat	-40.13***	-7.140***	-33.41***	-34.01***
	(0.539)	(0.405)	(0.469)	(0.408)
Post	60.45***	53.50***	60.43***	63.23***
	(0.477)	(0.430)	(0.478)	(0.738)
Treat * Post	134.2***	-7.158***	112.1***	-31.89***
	(1.851)	(0.599)	(1.574)	(0.832)
Licensed Beds	-0.0323***	-0.0280***	-0.0324***	-0.0281***
	(0.000249)	(0.000229)	(0.000248)	(0.000229)
Teaching	24.65***	20.74***	25.04***	20.74***
	(0.298)	(0.282)	(0.299)	(0.282)
For-Profit	-43.26***	-41.60***	-43.20***	-41.70***
	(0.193)	(0.192)	(0.193)	(0.192)
Government Owned	-15.26***	-14.12***	-15.02***	-14.27***
	(0.221)	(0.221)	(0.221)	(0.221)
Unknown (owner)	38.61***	38.19***	38.37***	38.27***
	(0.567)	(0.566)	(0.567)	(0.566)
Unemployment (county)	-4.805***	-4.182***	-4.630***	-4.085***
	(0.0721)	(0.0679)	(0.0712)	(0.0681)
Uninsured (county)	1.311***	0.833***	1.230***	0.904***
	(0.0232)	(0.0194)	(0.0230)	(0.0196)
Male	1.578***	3.548***	1.446***	3.556***
	(0.188)	(0.170)	(0.187)	(0.171)
Senior	2.752***	3.118***	3.138***	3.107***
	(0.201)	(0.184)	(0.200)	(0.184)
American Indian	-11.14***	-8.459***	-11.12***	-8.489***
	(1.946)	(1.959)	(1.937)	(1.968)
Asian	4.225**	4.636***	4.244**	4.538***
	(1.112)	(1.000)	(1.100)	(1.010)
Black	-5.038***	-4.910***	-5.121***	-4.898***
	(0.255)	(0.226)	(0.254)	(0.227)
Hispanic	-0.156	0.290	-0.943*	0.604
	(0.320)	(0.242)	(0.316)	(0.246)
Other (race)	-0.190	3.307***	-0.0814	3.398***
	(0.474)	(0.410)	(0.468)	(0.415)
Unknown (race)	10.40***	14.00***	7.628***	15.41***
	(1.036)	(0.978)	(1.015)	(1.002)
Constant	68.08***	73.84***	69.33***	71.86***
	(0.630)	(0.607)	(0.627)	(0.612)
Observations	15,053,961	14,559,931	15,165,667	14,448,225
R-squared	0.008	0.006	0.007	0.006

Robust standard errors in parenthesis (*** p<0.0001, ** p<0.001, * p<0.01)
Regressions also include year fixed effects.

Table 2.6 – Quantile Regression DID Estimates by Charity

	Low Charity			High Charity		
Quantile	Estimates	Lower Bound	Upper Bound	Estimates	Lower Bound	Upper Bound
0.10	-0.05***	-0.07	-0.03	-1.51***	-1.94	-1.09
0.20	-2.81***	-2.91	-2.72	-6.83***	-7.24	-6.42
0.30	-1.19***	-1.37	-1.01	-5.95***	-6.60	-5.30
0.40	1.24***	1.01	1.48	-5.55***	-6.09	-5.02
0.50	3.30***	2.96	3.63	-3.32***	-4.13	-2.50
0.60	7.01***	6.59	7.44	1.82***	0.70	2.93
0.70	12.07***	11.50	12.64	11.74***	10.52	12.97
0.80	25.13***	24.24	26.03	16.19***	14.56	17.82
0.90	72.35***	70.30	74.39	4.34***	1.66	7.02
0.95	240.14***	232.05	248.24	-11.09***	-16.01	-6.17
0.96	390.55***	374.83	406.26	-17.74***	-23.72	-11.75
0.97	806.17***	739.33	873.01	-24.78***	-31.80	-17.76
0.98	2166.83***	2120.52	2213.15	-37.19***	-46.69	-27.69
OLS Mean	138.76***	135.13	142.40	4.64***	3.01	6.26
Observations	1,359,395			865,365		

Estimates Significance Level (*** p<0.0001, ** p<0.001, * p<0.01)

Table 2.7 – Quantile Regression DID Estimates by Uninsured

	Low Uninsured			High Uninsured		
Quantile	Estimates	Lower Bound	Upper Bound	Estimates	Lower Bound	Upper Bound
0.10	-0.05***	-0.07	-0.03	4.38***	3.68	5.08
0.20	-1.47***	-1.57	-1.37	2.27***	1.76	2.78
0.30	0.35***	0.18	0.52	0.47	-0.36	1.30
0.40	2.38***	2.14	2.63	1.84***	0.82	2.85
0.50	4.71***	4.37	5.05	1.29	-0.04	2.63
0.60	7.03***	6.62	7.45	-0.85	-2.23	0.52
0.70	12.75***	12.20	13.31	-1.42	-3.37	0.54
0.80	25.34***	24.51	26.17	-3.56***	-5.52	-1.60
0.90	57.47***	55.70	59.25	-14.65***	-17.77	-11.53
0.95	160.08***	154.64	165.53	-36.25***	-43.74	-28.75
0.96	233.60***	224.75	242.46	-46.33***	-52.56	-40.11
0.97	458.31***	439.67	476.94	-55.63***	-63.29	-47.96
0.98	1473.96***	1356.10	1591.82	-84.74***	-100.09	-69.39
OLS Mean	113.85***	110.87	116.84	-11.43***	-13.51	-9.34
Observations	1,471,101			753,659		

Estimates Significance Level (*** p<0.0001, ** p<0.001, * p<0.01)

Table 2.8 – Medicaid Only in the Treatment

VARIABLES	(1) Estimated Medication Cost
Treat	-23.66***
	(0.650)
Post	53.83***
	(0.432)
Treat * Post	35.14***
	(1.802)
Observations	14,591,445

Robust standard errors in parenthesis: *** p<0.0001, ** p<0.001, * p<0.01
Same covariates are controlled in the regression but not shown in this table for conciseness.

Table 2.9 – Synthetic Control Method for Length of Stay

YEAR	Y_treated	Y_synthetic	Gap	Mean
2005	0.051	0.052	-0.002	
2006	0.051	0.050	0.001	
2007	0.037	0.036	0.001	0.000
2008	0.037	0.033	0.004	
2009	0.040	0.044	-0.004	
2010	0.036	0.087	-0.051	
2011	0.050	0.095	-0.045	
2012	0.051	0.106	-0.055	-0.053
2013	0.054	0.114	-0.060	
2014	0.058	0.110	-0.052	
2015	0.051	0.105	-0.054	
Synthetic Control Method DID Estimate				-0.053

Table 2.10 – Robustness Check DID for Medication Cost

	(1)	(2)	(3)
	Only DSH in the Control	Patient Acuity in Control	Unadjusted Charges
VARIABLES	Estimated Medication Cost	Estimated Medication Cost	Unadjusted Medication Charges
Treat	-3.150***	-35.87***	-178.7***
	(0.451)	(0.461)	(3.981)
Post	67.33***	63.65***	799.7***
	(0.733)	(0.474)	(3.750)
Treat*Post	112.2***	107.4***	611.2***
	(1.540)	(1.534)	(11.15)
Charlson Index		49.86***	
		(0.273)	
Observations	6,918,363	15,177,275	15,177,275

Robust standard errors in parenthesis: *** p<0.0001, ** p<0.001, * p<0.01
Same covariates are controlled in the regression but not shown in this table for conciseness.

Table 3.1 – Summary Statistics

VARIABLES	N	Mean	SD	Min	Max
CMS State Average Hospital Market Share	612	2.2%	0.027	0.002	0.167
CMS State 340B Hospital Share	612	21.9%	0.181	0	1
AHCA Newly Eligible 340B Hospital Market Share	740,658	25.3%	0.247	0.0001	0.733
AHCA Newly Eligible 340B Hospital HHI	740,658	3165	2216	510	8791

Table 3.2 – Distribution of 340B Newly Eligible Hospitals by HRR

HRR	HHI09	Concentration Level	Newly Eligible Hospital MPN (Type)	
118	531	L		
127	596	L	100079 (CAN)	103301 (PED)
130	1172	L	100109 (RRC)	103304 (PED)
141	1672	L		
119	1791	L	101309 (CAH)	
123	1852	H		
134	1884	H		
139	1927	H	103300 (PED)	
122	2272	H		
129	2912	H		
115	3580	H		
131	3731	H		
120	3817	H	101301 (CAH)	101310 (CAH)
116	4338	H		
137	4577	H		
133	4816	H	101305 (CAH)	101308 (CAH)
124	5182	H	100157 (RRC)	
140	5804	H		
2	6323	H	101307 (CAH)	

Table 3.3 – Market Shares of the Newly Eligible Hospitals in 2009

Hospital's Market Share in 2009	Freq.	Percent	Cum.
1.0%	9,050	1.25	1.25
1.3%	5,468	0.75	2
1.9%	51,150	7.05	9.06
1.9%	9,478	1.31	10.36
2.7%	6,982	0.96	11.33
2.9%	91,340	12.6	23.92
9.8%	262,796	36.24	60.16
24.3%	7,313	1.01	61.17
25.4%	100,002	13.79	74.96
68.1%	181,561	25.04	100
Total	725,140	100	

Only 10 entries of the share09 (instead of 12) are listed because the remaining two newly eligible hospitals were not in business prior to 2010. The threshold of .098 I use is at the 49th percentile among all sample distribution.

Table 3.4 – State Fixed Effects with Market Share Interaction

VARIABLES	(1) Ln (Hospital Service per)
State CE Share	0.0324
	(0.0391)
High Share	-0.0912***
	(0.00962)
State CE Share * High Share	0.123***
	(0.0365)
Observations	561
Number of Clusters	51

Standard errors are clustered at state level in parenthesis: *** p<0.01, ** p<0.05, * p<0.1 Regressions also include year fixed effects, state fixed effects, gender, race, median household income, insurance coverage, unemployment rate, senior resident's ratio and education.

Table 3.5 – Impact of Market Power on the Newly Eligible 340B Hospitals

Outcome Variables	(1) Reg y on Hospital Market Share	(2) Reg y on Hospital HHI/1000
Medication Cost	685.01***	-4.5
Uninsured	1.9%	0.5%
Charity	-0.3%	0.2%
Medicaid	-25.8%*	0.5%
Medicaid MC	-57.4%**	-4.3%*
Commercial	97.2%***	1.1%
PO Adverse	-1.1%	-0.1%
Length of Stay	-0.13	-0.02**
Nonroutine Discharge	-2.5%*	0.02%
Observations	740,658	477,862
Number of Clusters	12	8

Standard errors are clustered at hospital level for Market Share, at HRR level for HHI: *** p<0.01, ** p<0.05, * p<0.1. Regressions also include year fixed effects, and all other covariates.

Table 3.6 – DDD Estimates for the Treat * Post * High Market Power Variable

Outcome Variables	(1) Estimates for Treat * Post * High Market Share	(2) Estimates for Treat * Post * High Market HHI
Medication Cost	167.0***	2.94
Uninsured	0.0086***	0.0020
Charity	-0.0020***	-0.0108***
Medicaid	-0.0098***	-0.0311***
Medicaid MC	-0.136***	-0.121***
Commercial	0.176***	0.103***
PO Adverse	0.0001	0.0008
Length of Stay	-0.0300***	-0.0437***
Nonroutine Discharge	-0.0130***	0.0077***
Observations	15,100,824	14,914,479

Heteroskedasticity-robust standard errors in parenthesis: *** p<0.0001, ** p<0.001, * p<0.01.
Regressions also include year fixed effects, and all other covariates explained in the paper.

Table 3.7 – DID Estimates for Treat * Post among the Newly Eligible Hospitals with High and Low Market Power

Outcome Variables	(1) DID Estimates among High Market Share	(2) DID Estimates among Low Market Share	(3) SCM Estimates among High Market Share	(4) SCM Estimates among Low Market Share
Medication Cost	142.02***	-13.18***	128.36**	-6.43
Uninsured	-0.68%***	-1.32%***	-1.31%	-1.00%
Charity	0.10%***	0.56%***	-0.45%	0.12%
Medicaid	1.2%***	1.57%***	2.17%	3.0%
Medicaid MC	-1.74%***	11.88%***	-1.56%	13.5%***
Commercial	6.58%***	-11.32%***	7.39%*	-9.93%**
PO Adverse	-0.31%***	-0.35%***	-0.33%	-0.33%
Length of Stay	-0.021***	0.0034***	-0.025	0.045
Nonroutine Discharge	-1.01%***	0.16%***	-0.39%	-0.16%
Observations	15,100,824	15,100,824	1,551	1,551

Heteroskedasticity-robust standard errors for DID estimates: *** p<0.0001, ** p<0.001, * p<0.01.
SCM permutation test one-sided p-value for SCM estimates: *** p<0.01, ** p<0.05, * p<0.1
Regressions also include year fixed effects, and all other covariates explained in the paper.

Appendix B: Figures

Figure 1.1– Purchases by Covered Entities Under the 340B Drug Pricing Program

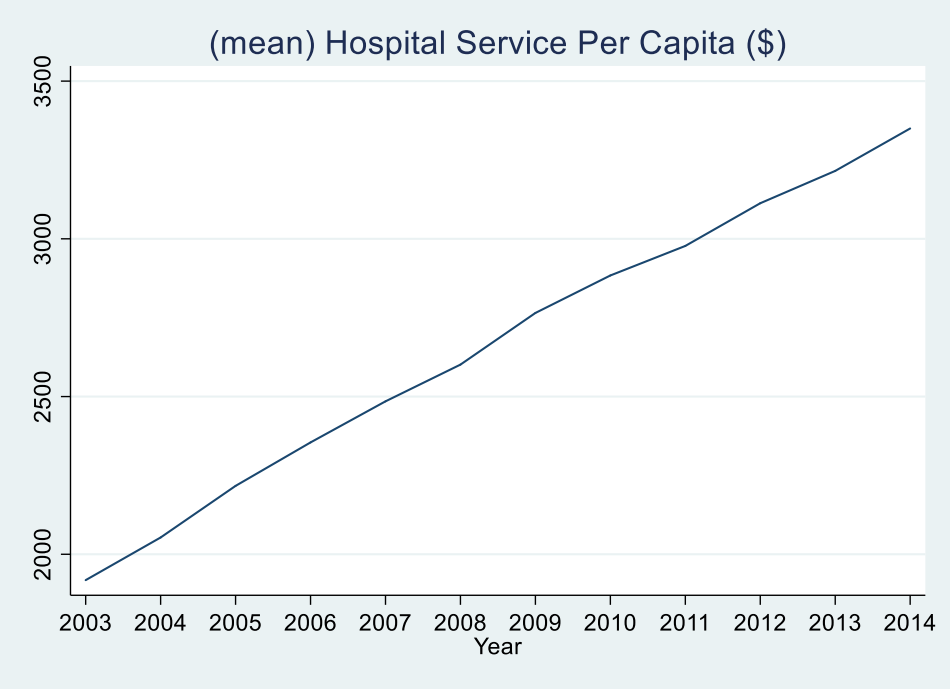

Figure 1.2 – Hospital Service Spending Per Capita

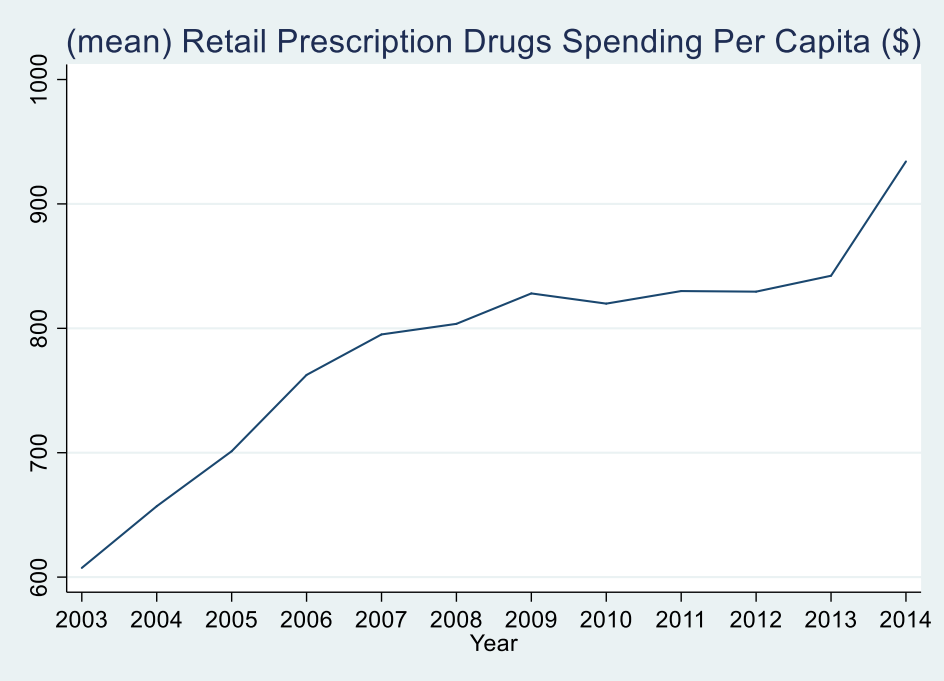

Figure 1.3 – Retail Prescription Drugs Expenditure Per Capita

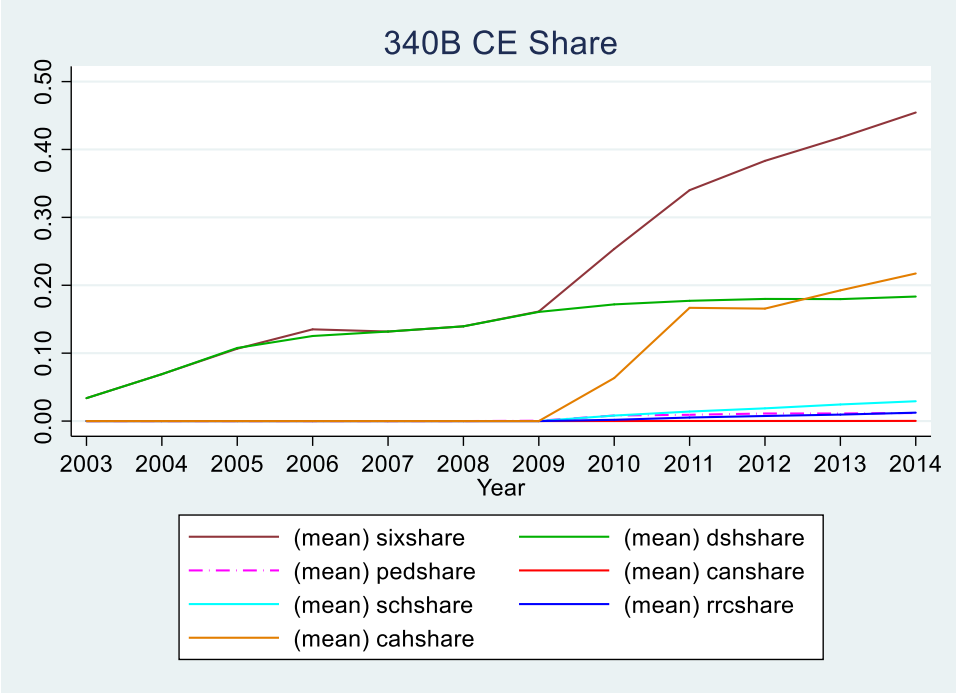

Figure 1.4 – 340B Covered Hospital Share Over Time

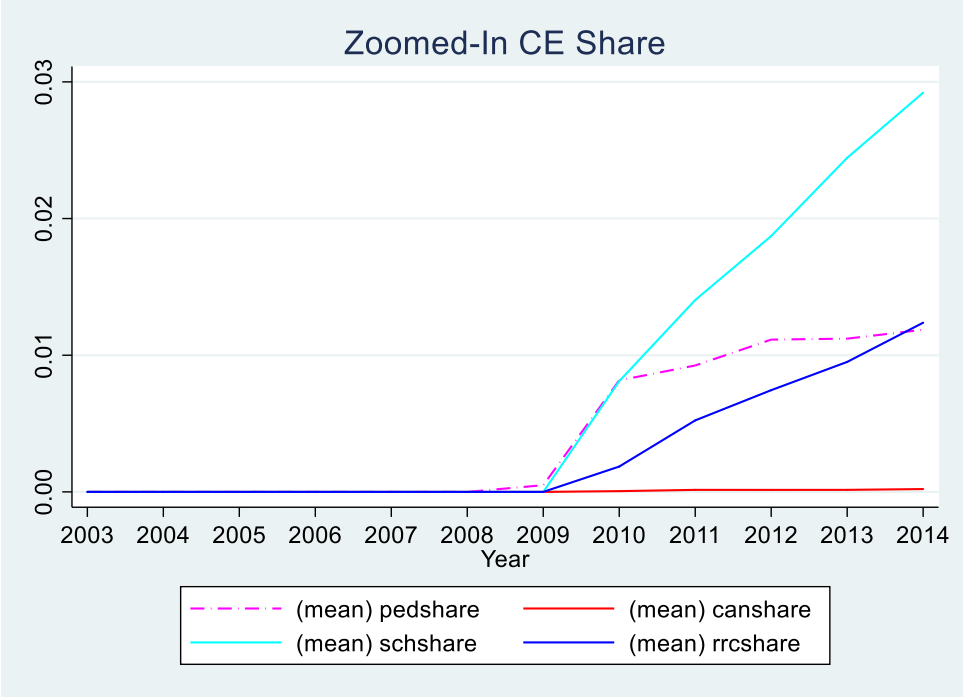

Figure 1.5 – 340B Covered Hospital Share (Zoomed In)

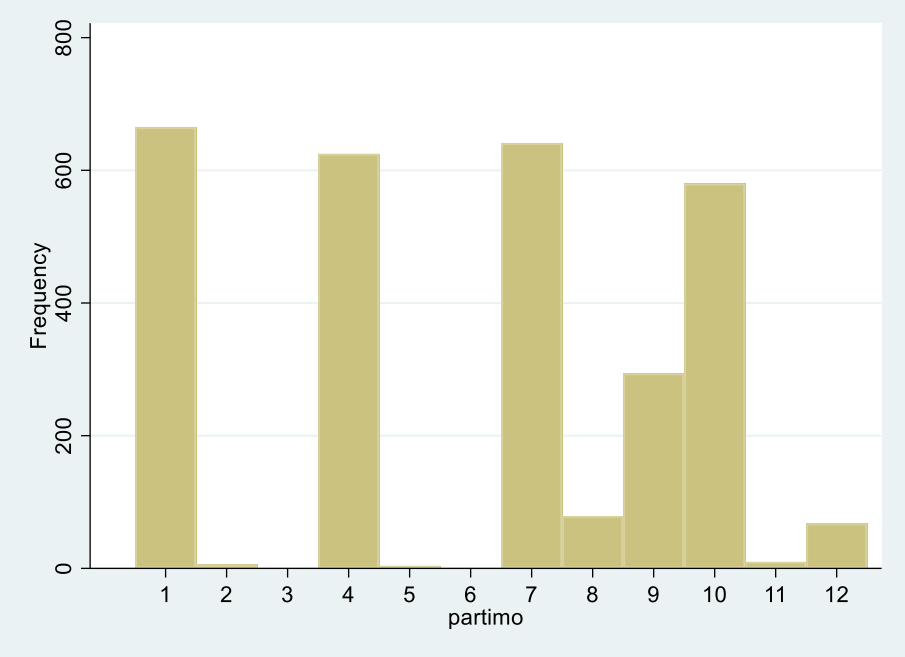

Figure 1.6 – Histogram of Participation Start Month

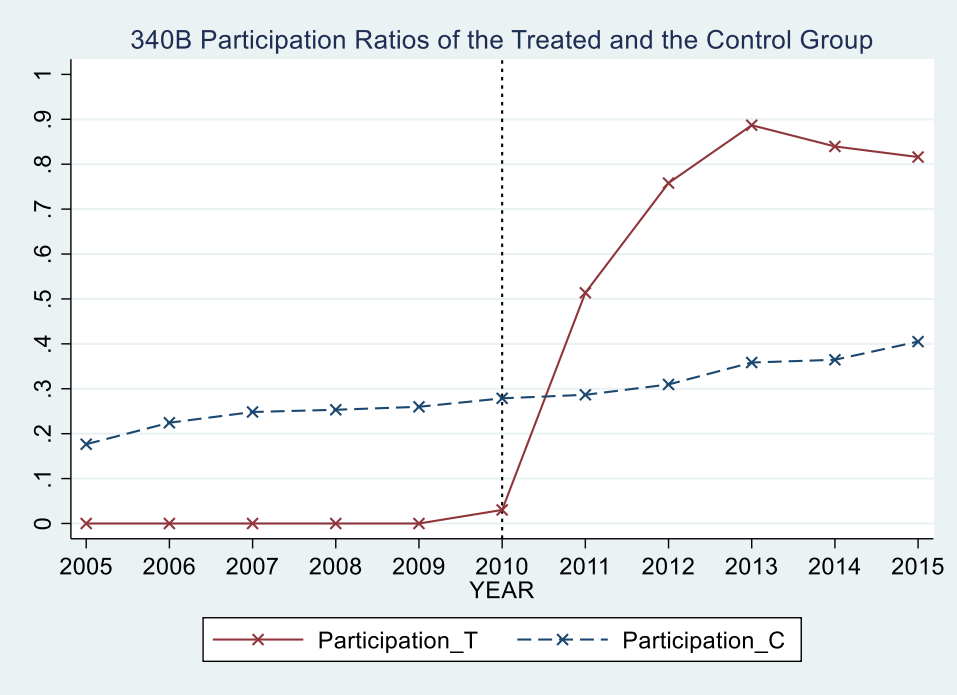

Figure 2.1.1 – Raw Data Trends Plot for Hospital 340B Participation

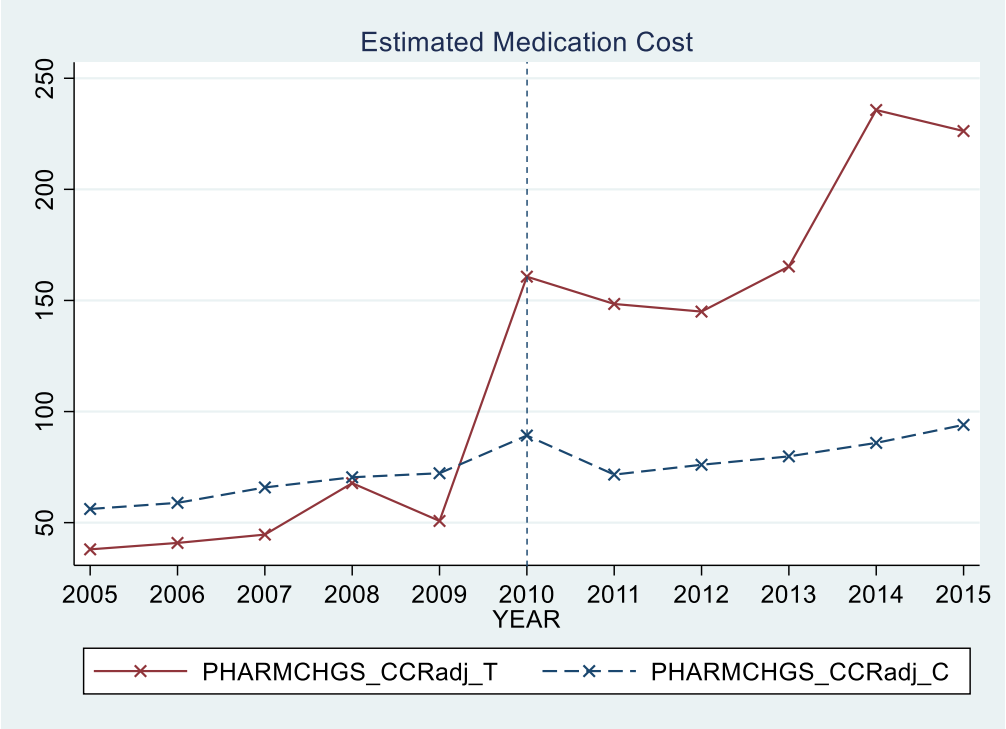

Figure 2.1.2 – Raw Data Trends Plot for Outpatient Medication Cost

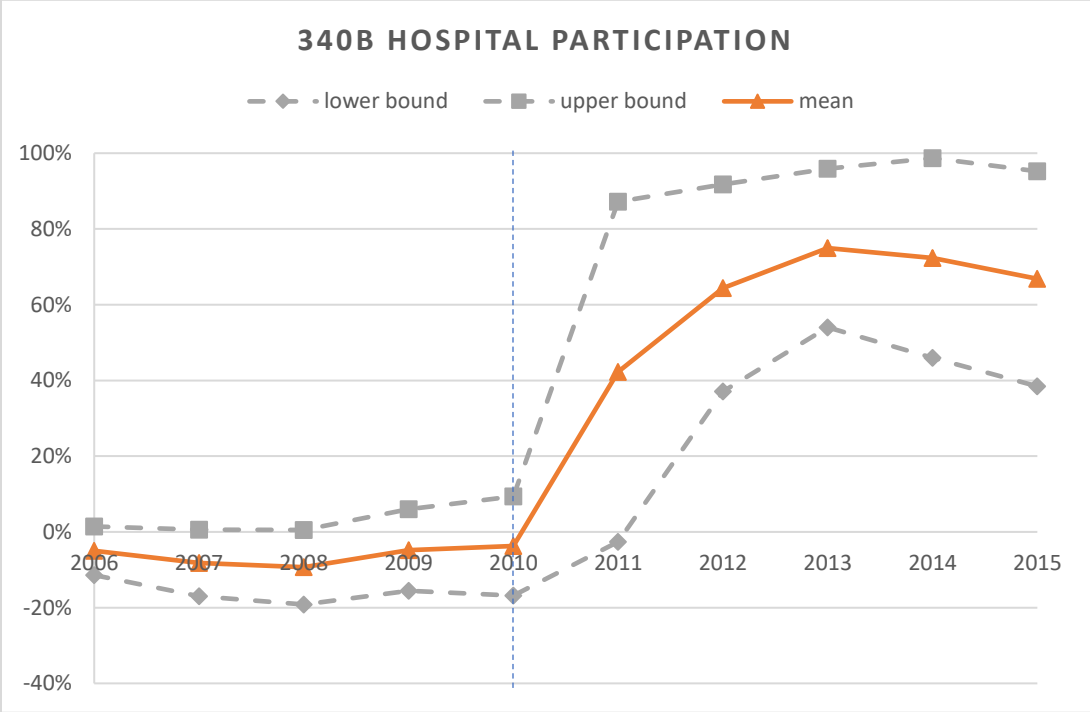

Figure 2.2.1 – Event Study for DID on 340B Hospital Participation

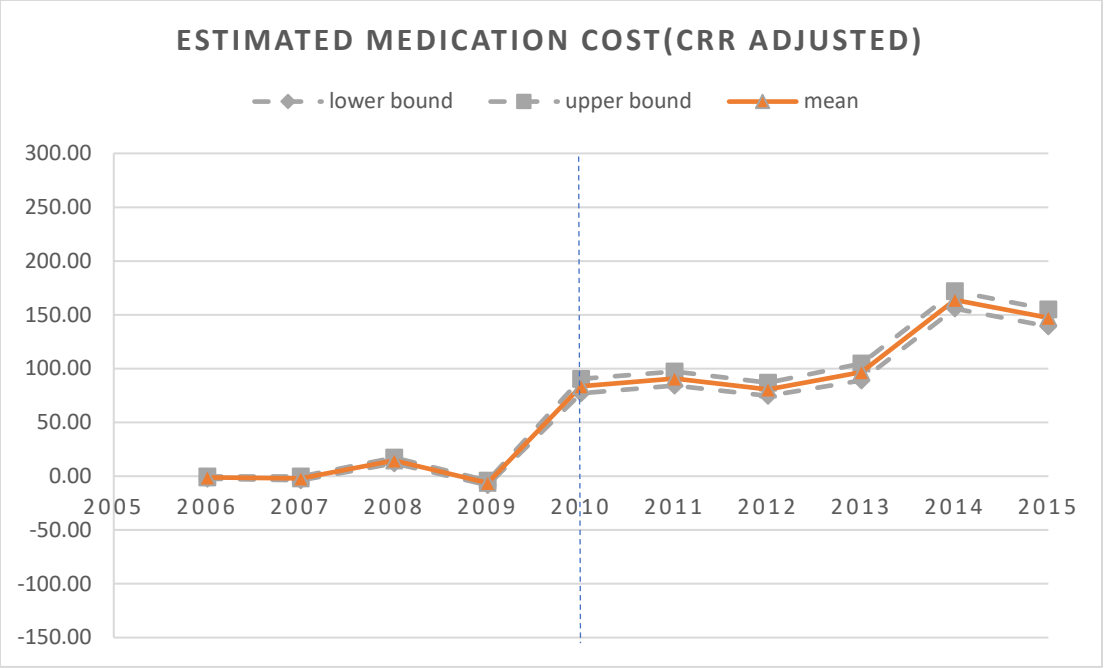

Figure 2.2.2 – Event Study for DID on Medication Cost

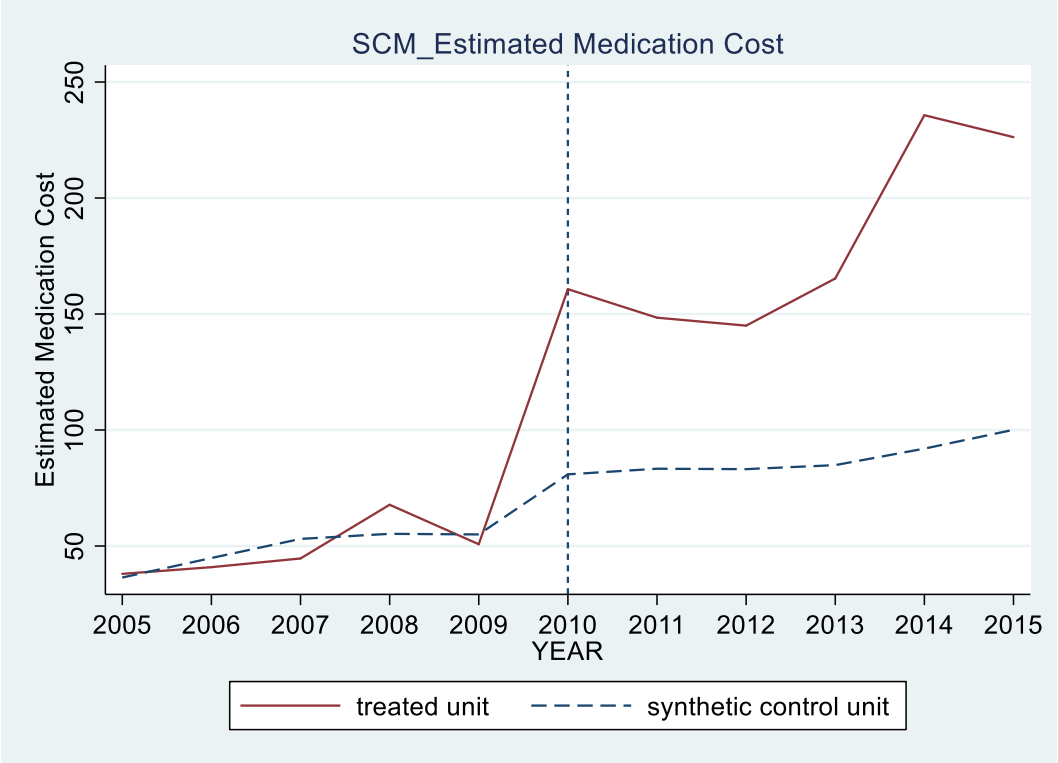

Figure 2.3.1 – Synthetic Control Method for Medication Cost

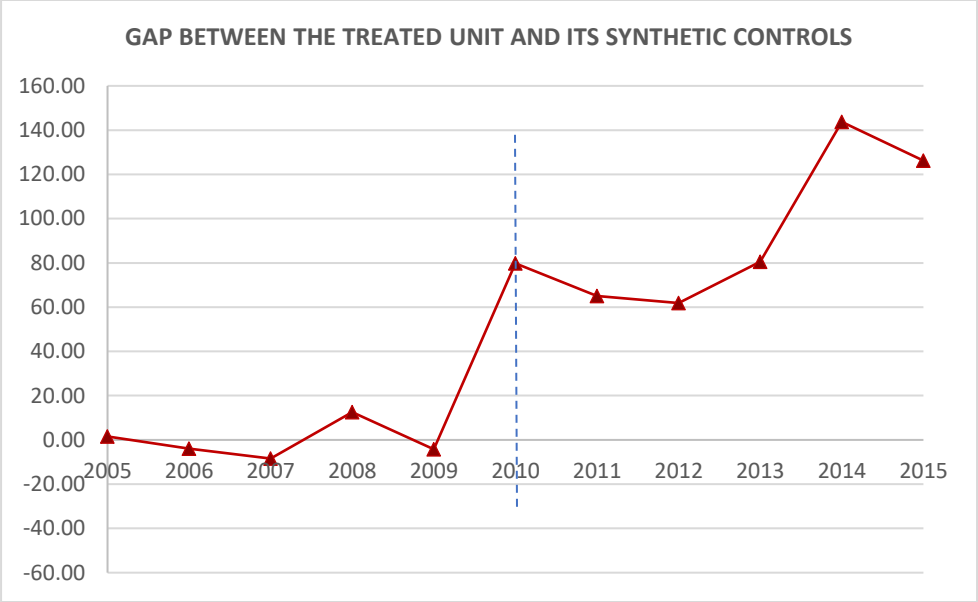

Figure 2.3.2 – Difference Between the Treated Unit and the Synthetic Unit

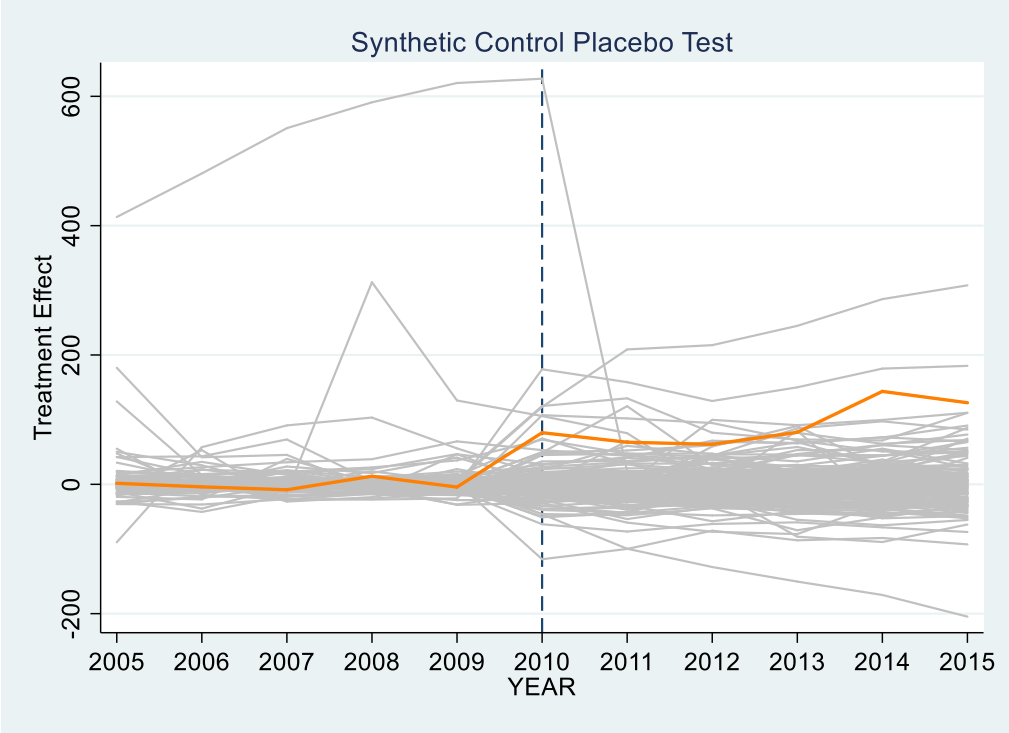

Figure 2.3.2 – Synthetic Control Permutation Test at Hospital Level

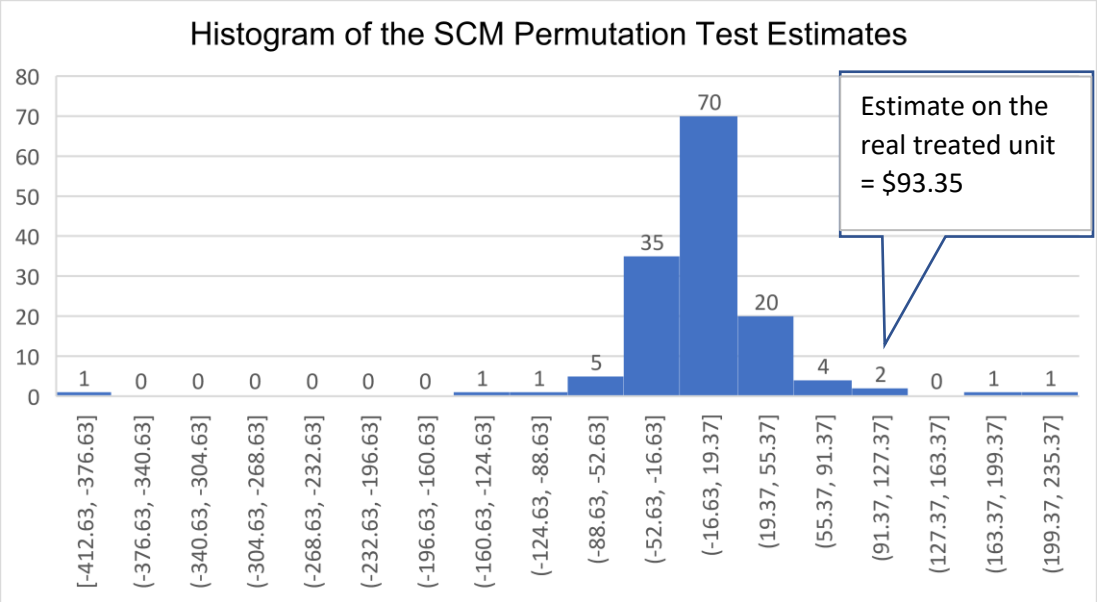

Figure 2.3.3 – Histogram of the SCM Permutation Test Estimates*

*3 out of 140 estimates are larger than the estimate of the real treated estimate, -0.053, one-sided p-value=2.14%

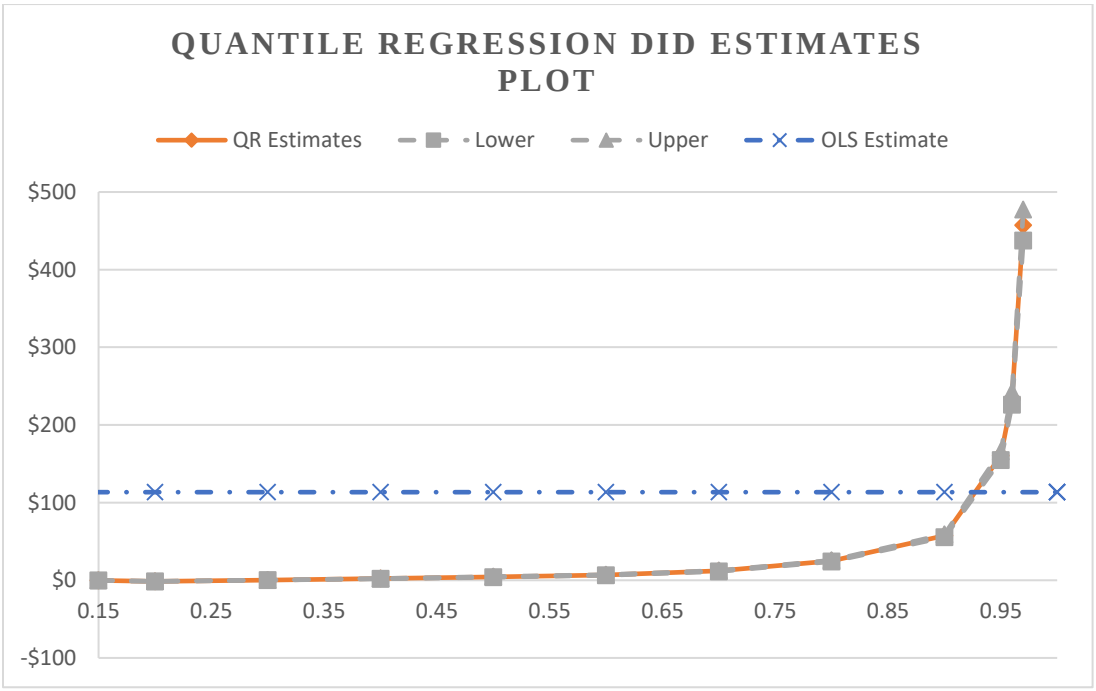

Figure 2.4.1 – Quantile Regression DID Estimates

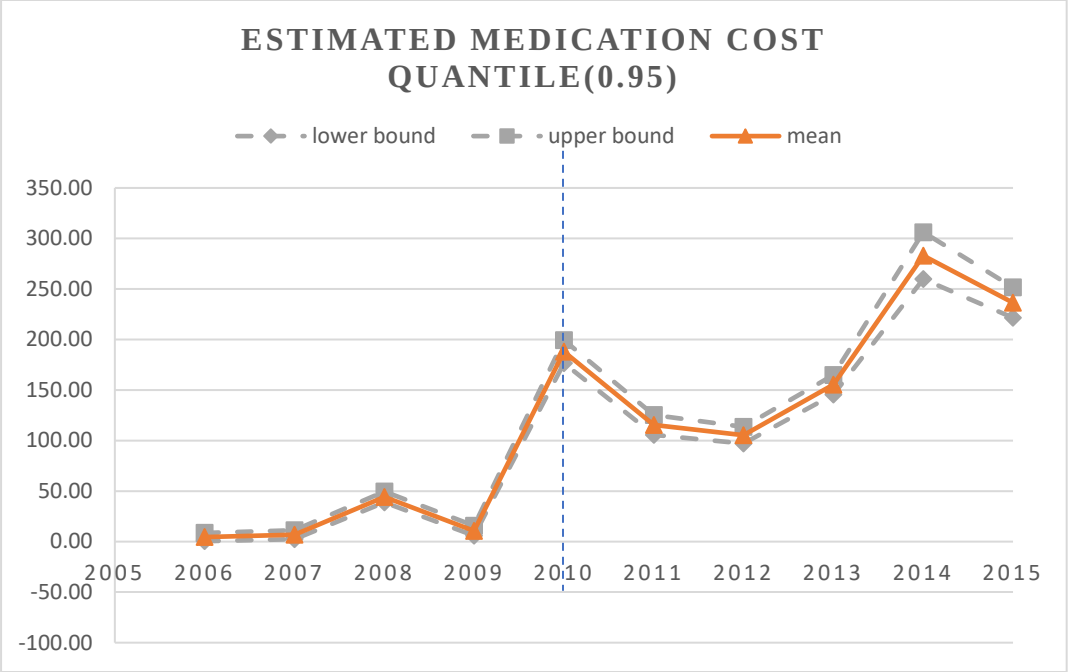

Figure 2.4.2 – Event Study for Quantile Regression at 95th Percentile

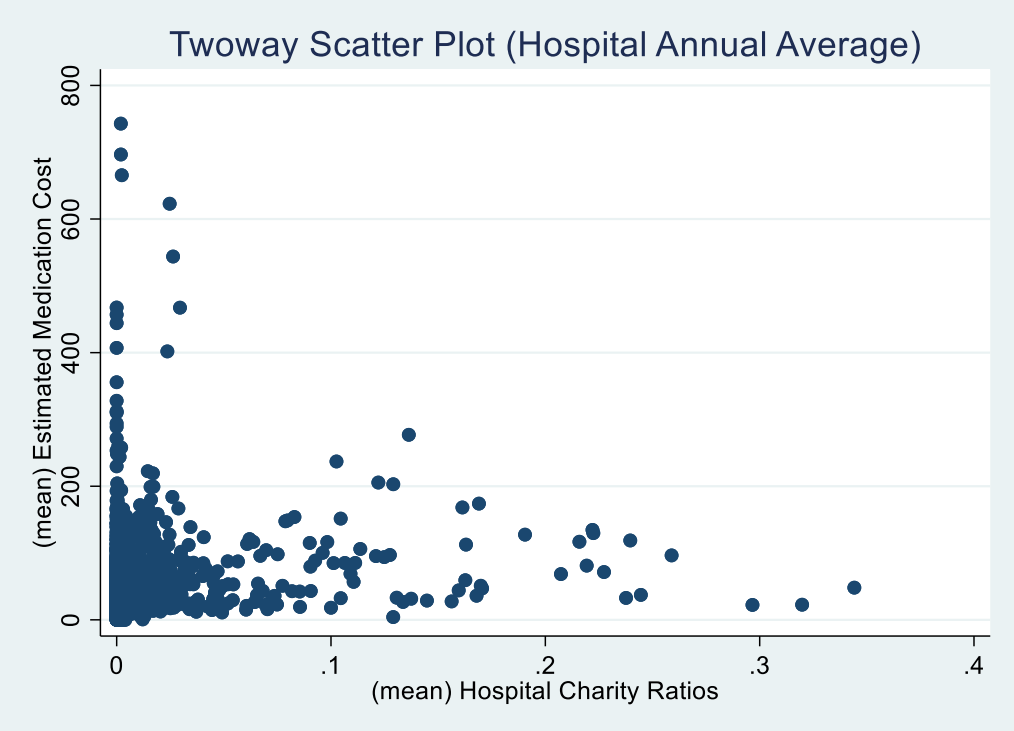

Figure 2.5.1– Raw Data Scatter Plot of Medication Cost and Charity Ratios

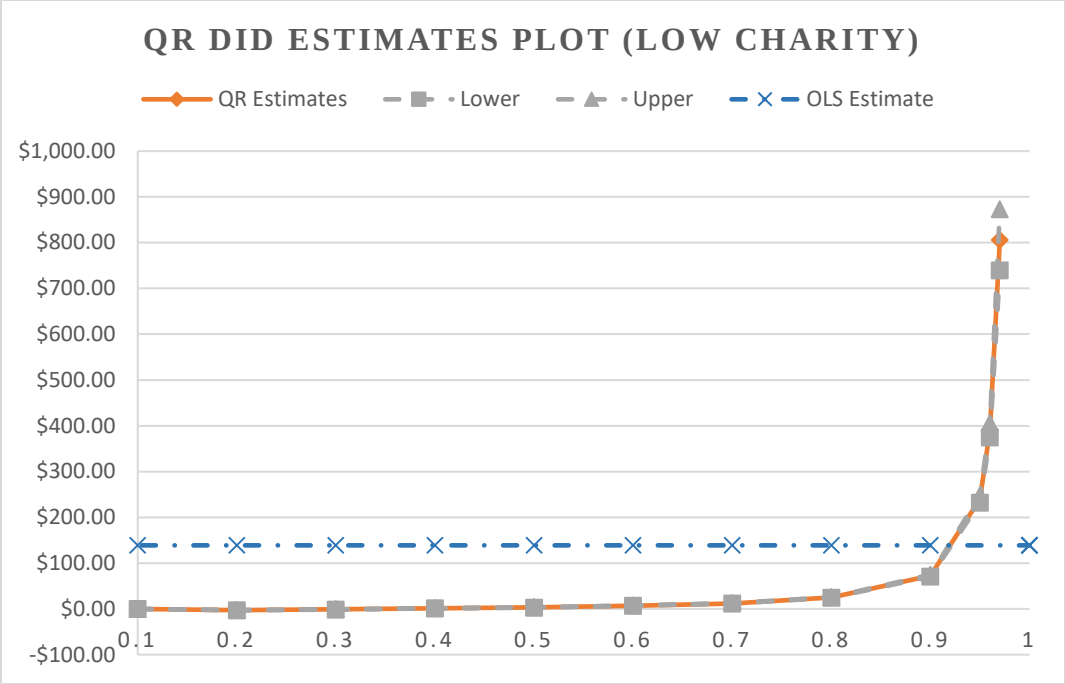

Figure 2.6.1 – Quantile Regression DID Estimates Plot for Low Charity Hospitals

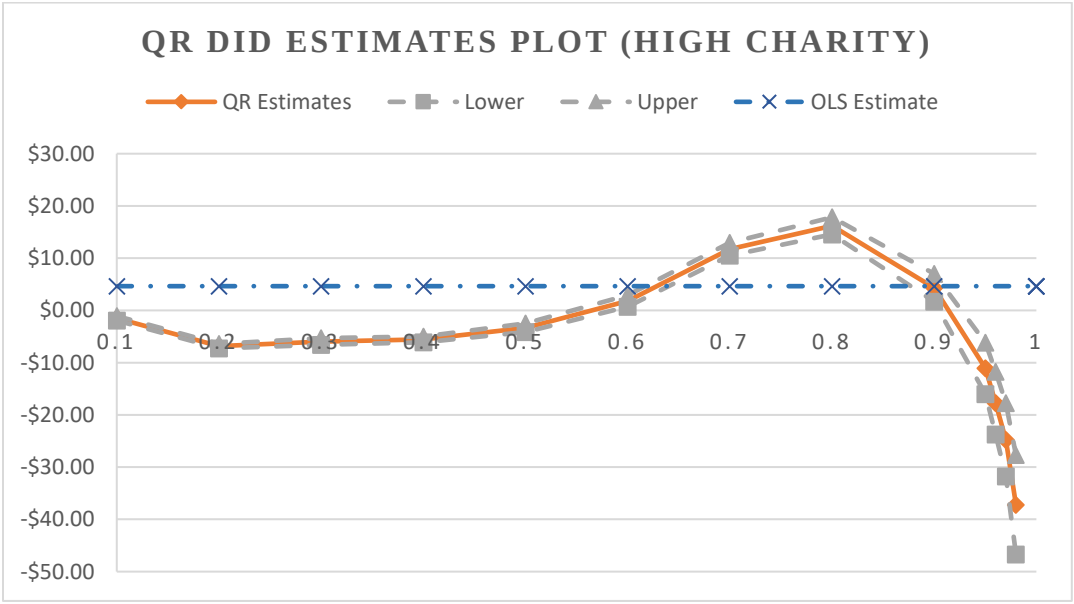

Figure 2.6.2 – Quantile Regression DID Estimates Plot for High Charity Hospitals

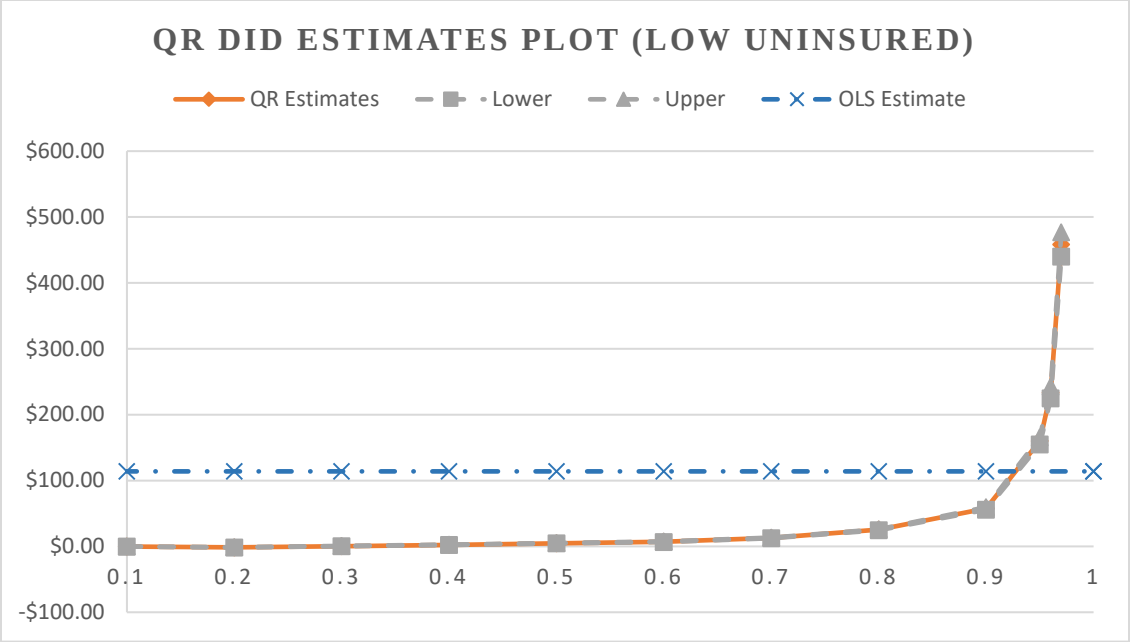

Figure 2.7.1 – Quantile Regression DID Estimates Plot for Low Uninsured Hospitals

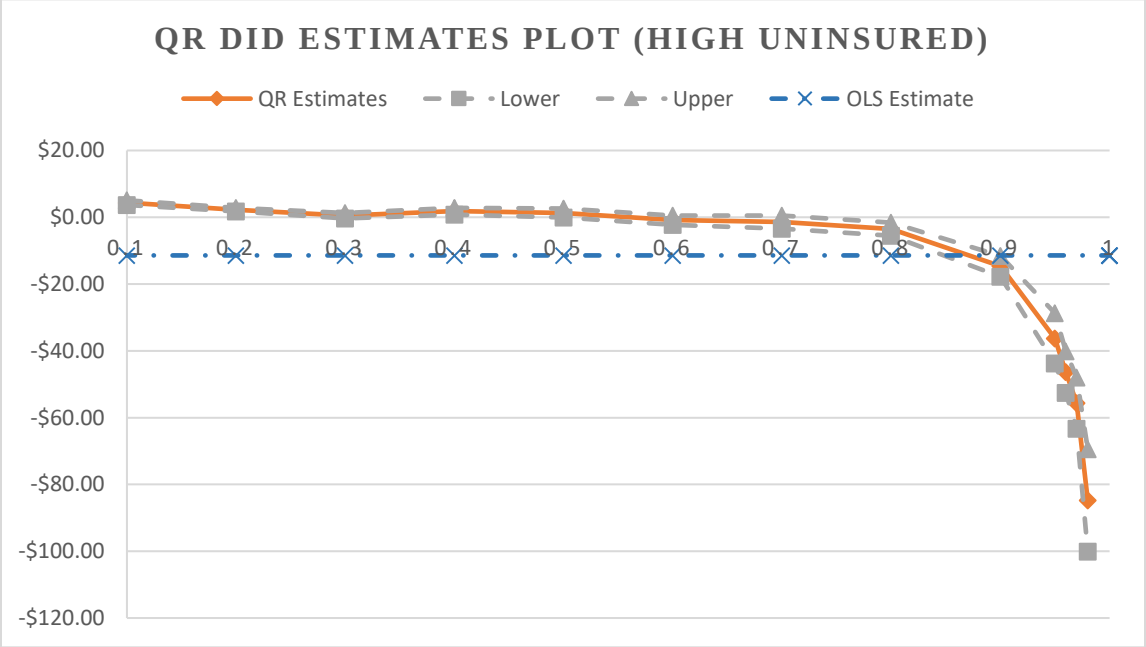

Figure 2.7.2 – Quantile Regression DID Estimates Plot for High Uninsured Hospitals

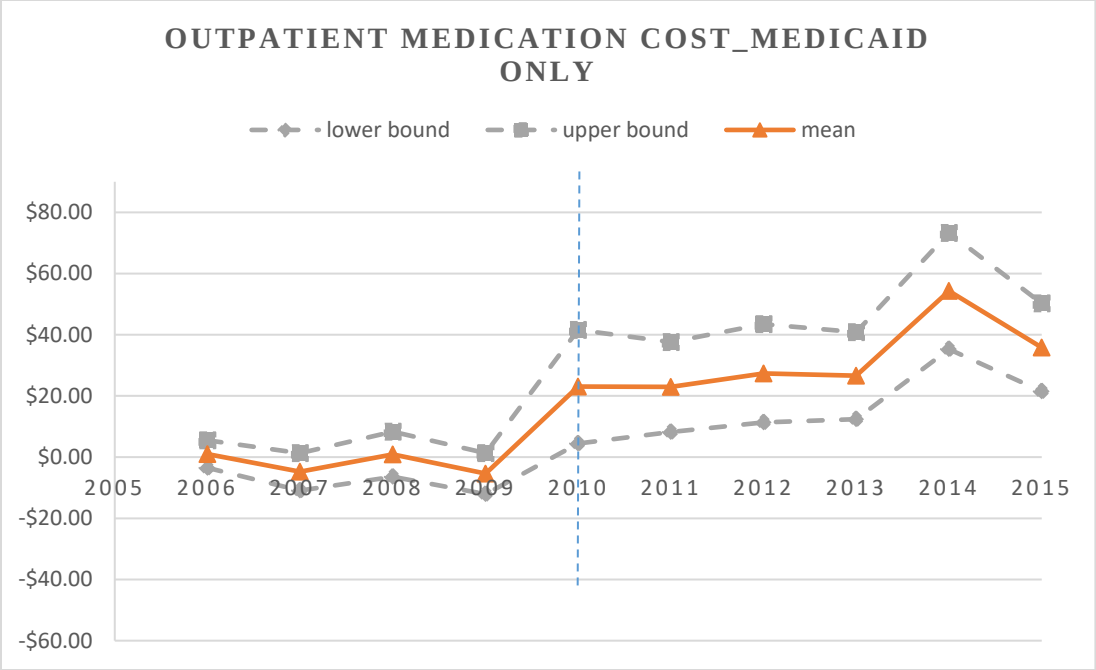

Figure 2.8.1 – Event Study for Medicaid Only DID Regression

Figure 2.9.1 – Patient Mix SCM Trends

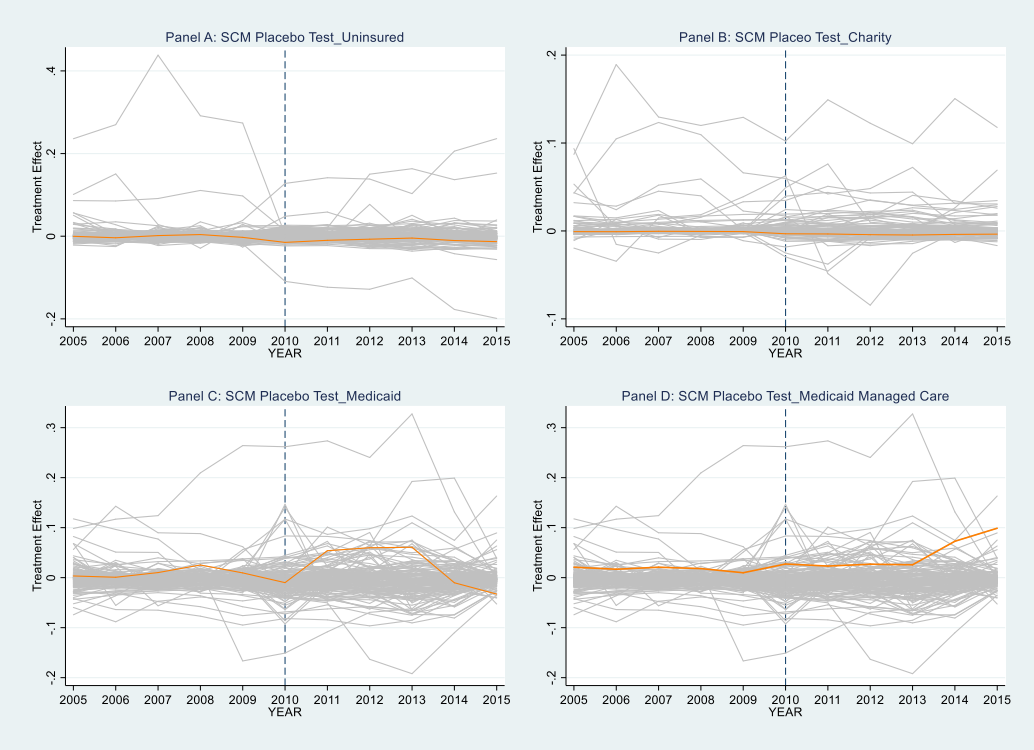

Figure 2.9.2 – Patient Mix SCM Placebo Tests

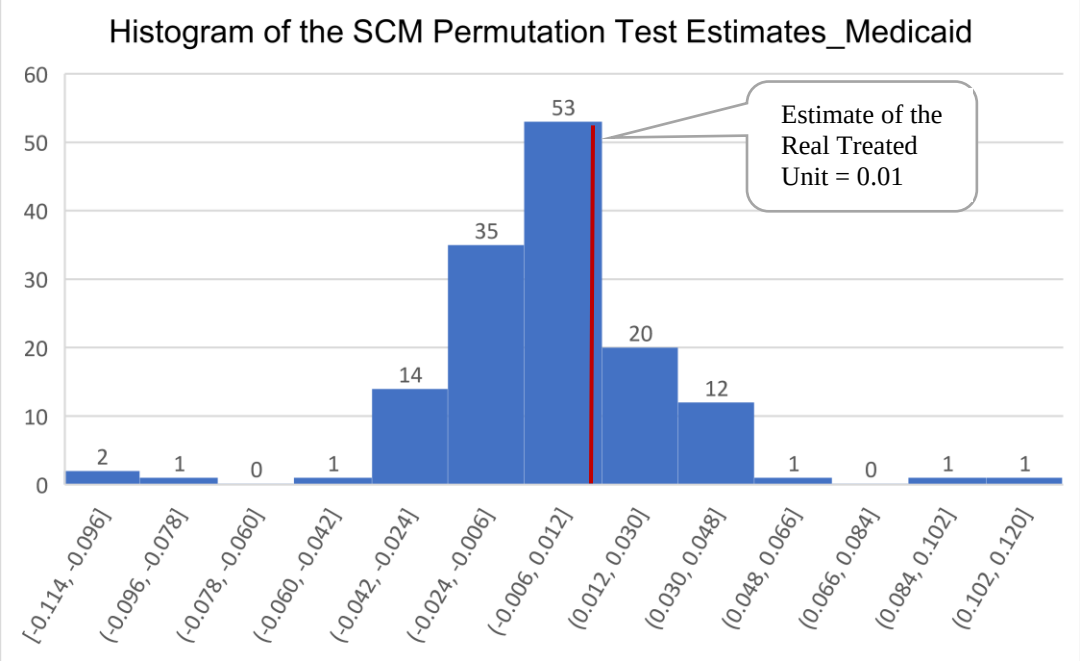

Figure 2.9.3 – Medicaid SCM Placebo Test Histogram*

*36 out of 140 are larger than the estimate of the real treated unit, 0.01, p-value=25.7%

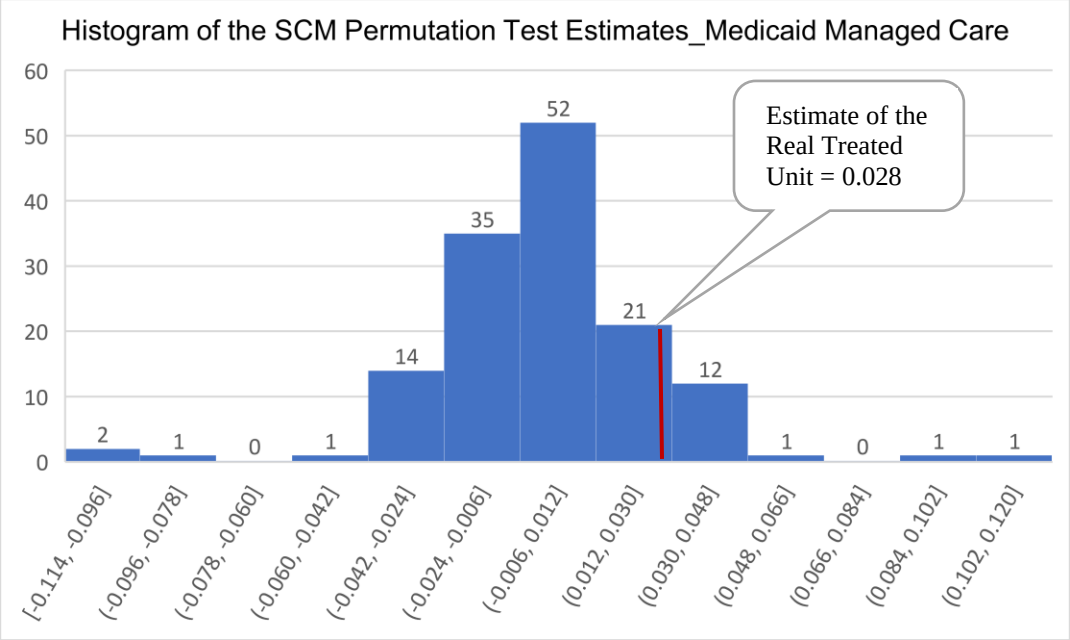

Figure 2.9.4 – Medicaid Managed Care SCM Placebo Test Histogram*

*16 out of 140 estimates are larger than the estimate of the real treated unit, 0.028, one-sided p-value=11.4%

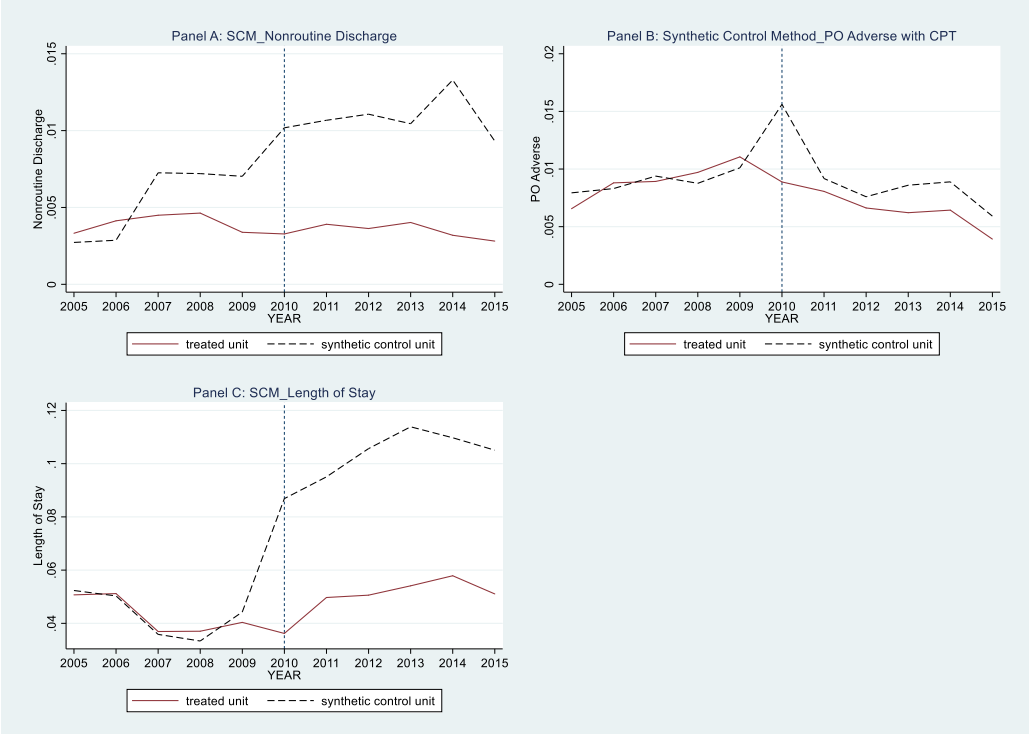

Figure 2.10.1 – Quality of Care SCM Trends

Figure 2.10.2 – Quality of Care SCM Placebo Tests

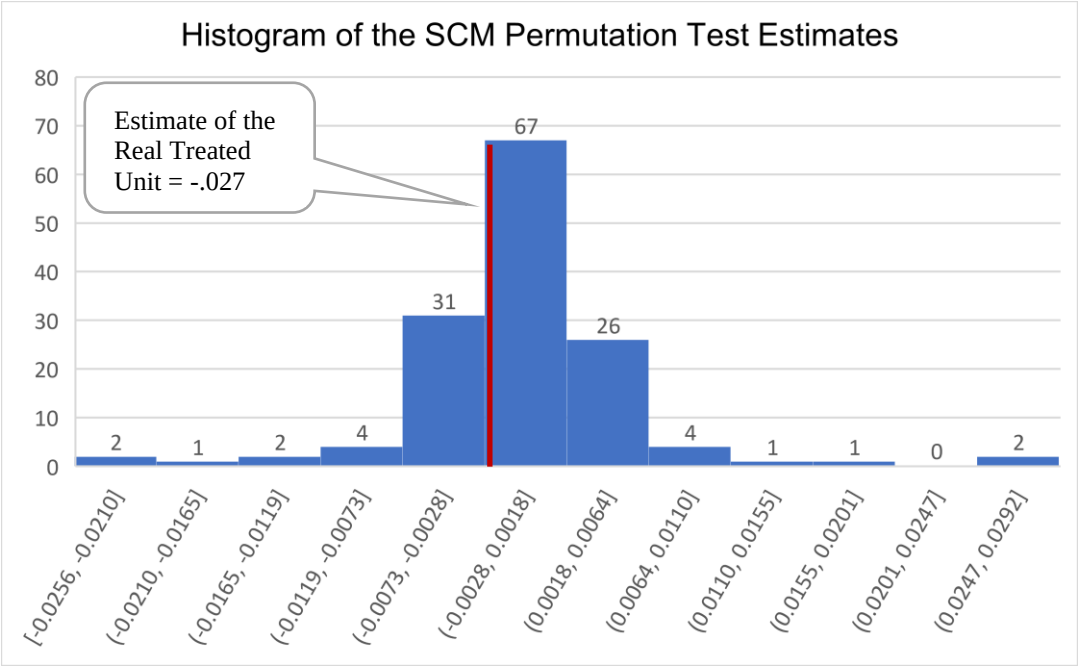

Figure 2.10.3 – PO Adverse SCM Placebo Test Histogram*

*40 out of 140 estimates are smaller than the estimate of the real treated unit, -0.027, one-sided p-value=28.6%

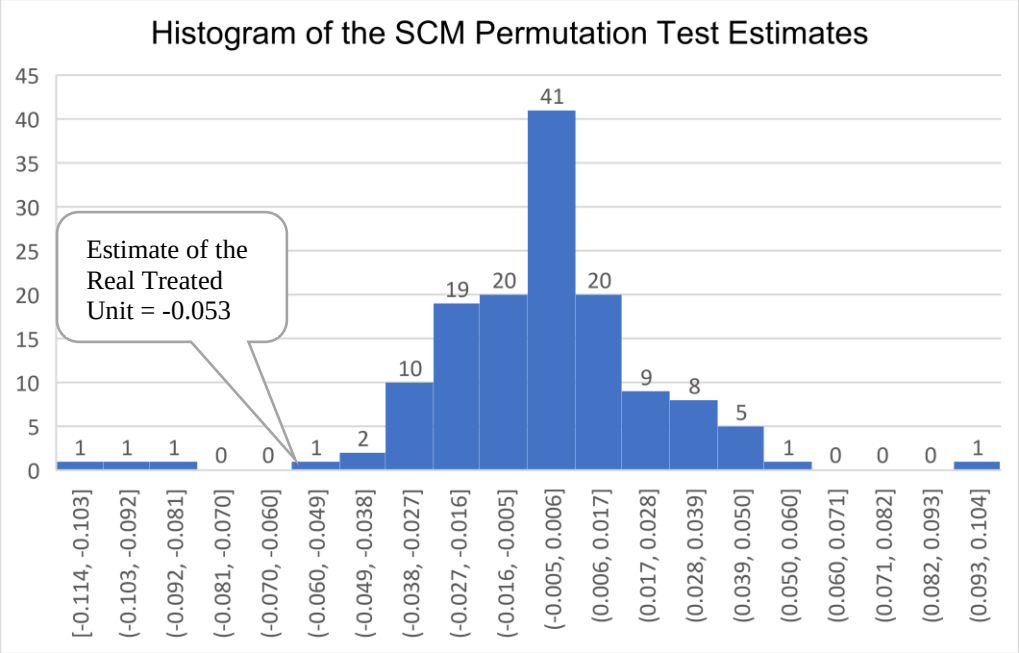

Figure 2.10.4 – Length of Stay SCM Placebo Test Histogram*

*3 out of 140 estimates are smaller than the estimate of the real treated unit, -0.053, one-sided p-value=2.14%

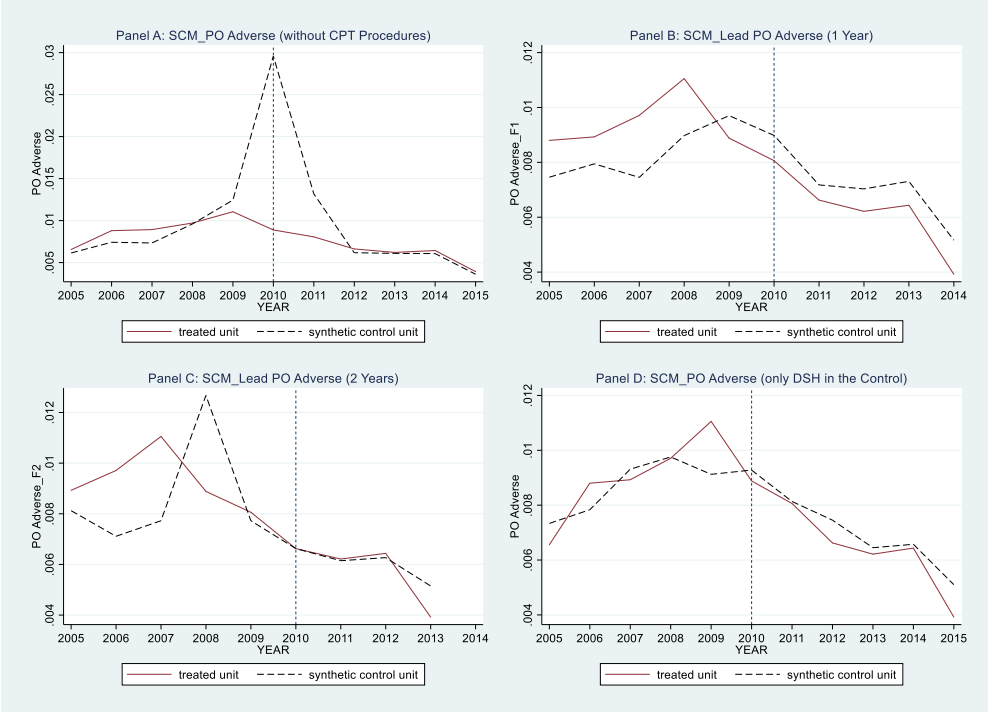

Figure 2.11.1 – SCM PO Adverse Robustness Check

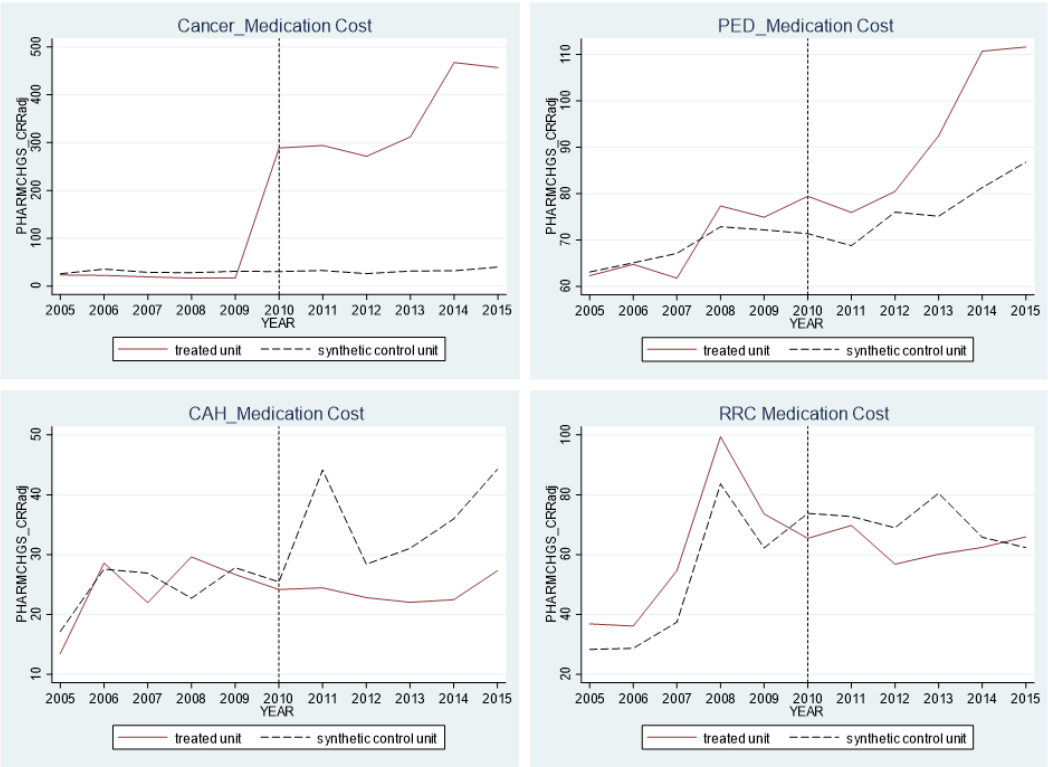

Figure 3.1.1 – SCM Medication Cost Changes by Types of 340B Hospitals

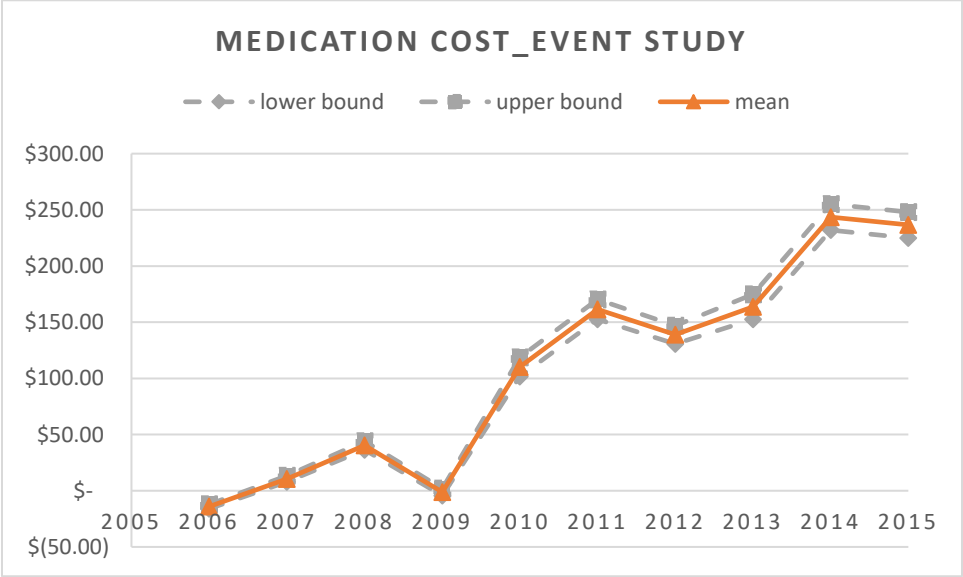

Figure 3.2.1 – Medication Cost Event Study (DDD High Market Share Interaction)

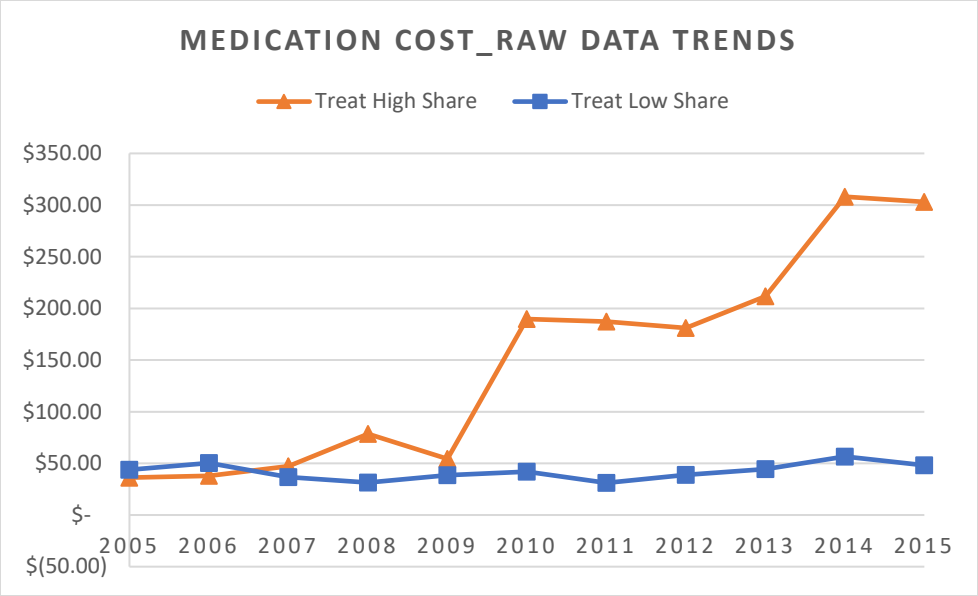

Figure 3.2.2 – Medication Cost Raw Data Trends by Market Share

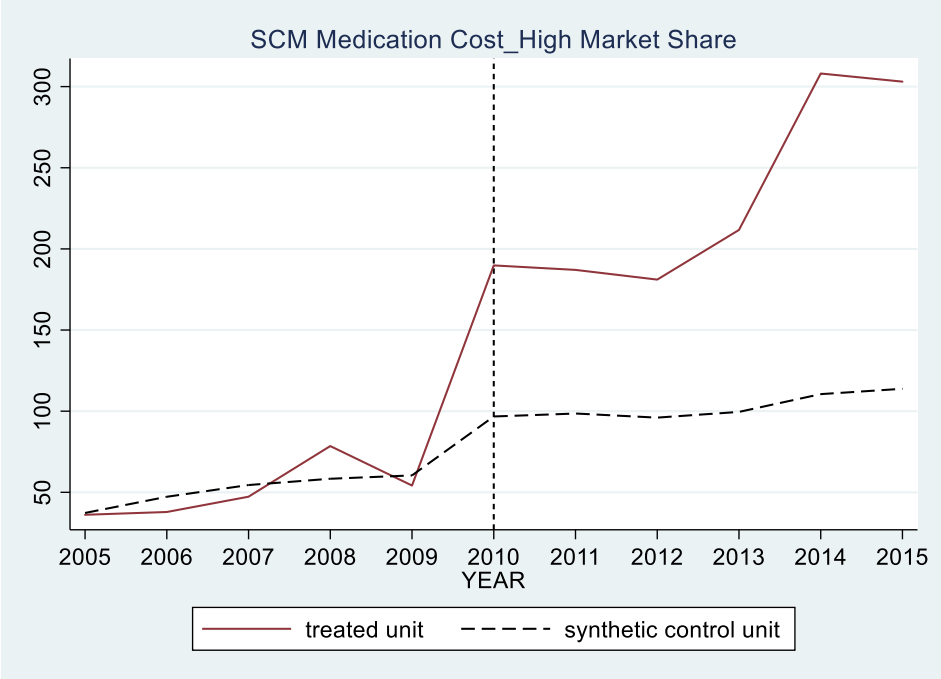

Figure 3.2.3 – SCM Medication Cost (High Market Share)

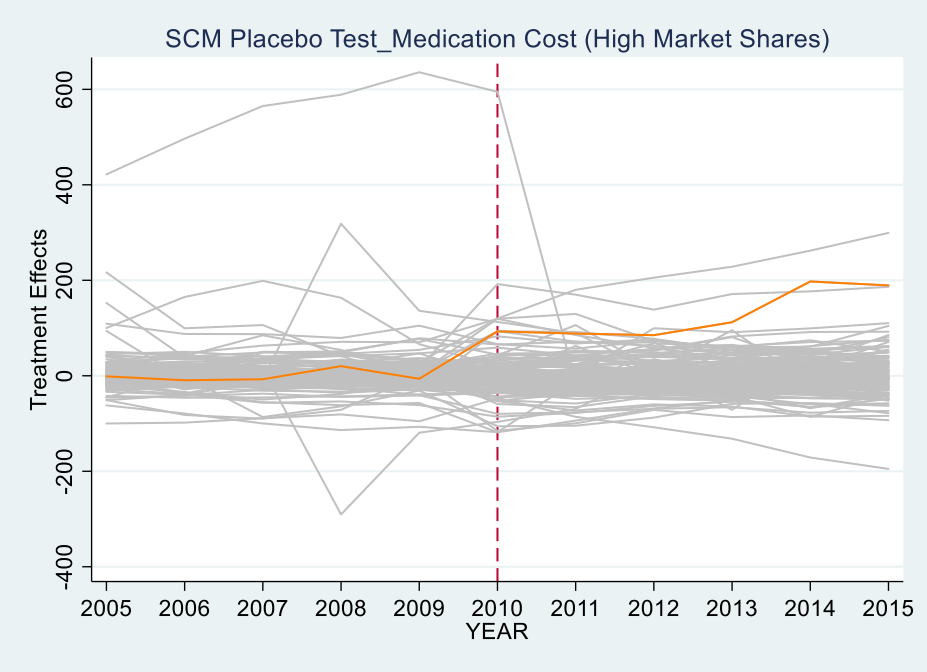

Figure 3.2.4 – SCM Permutation Test (High Market Share)*

*2 out of 140 estimates are larger than the estimate of the real treated unit → one-sided p-value = 0.014

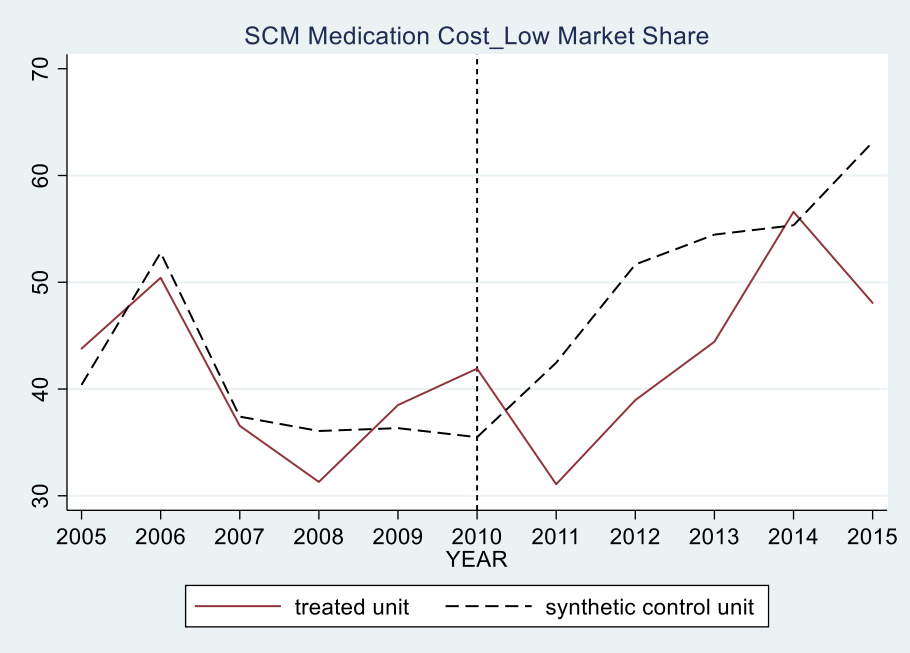

Figure 3.2.5 – SCM Medication Cost (Low Market Share)

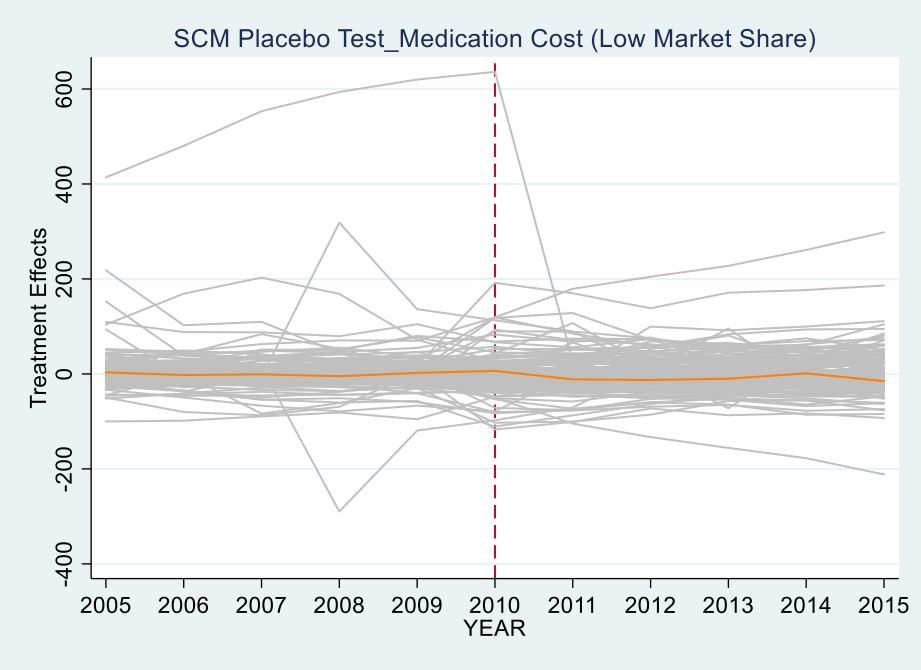

Figure 3.2.6 – SCM Permutation Test (Low Market Share)

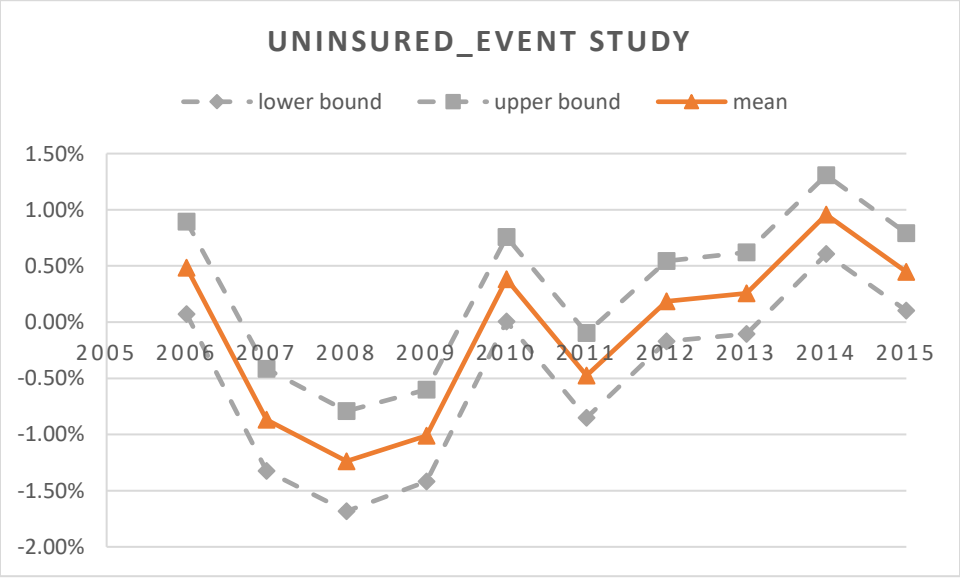

Figure 3.3.1 – Uninsured Event Study (DDD High Market Share Interaction)

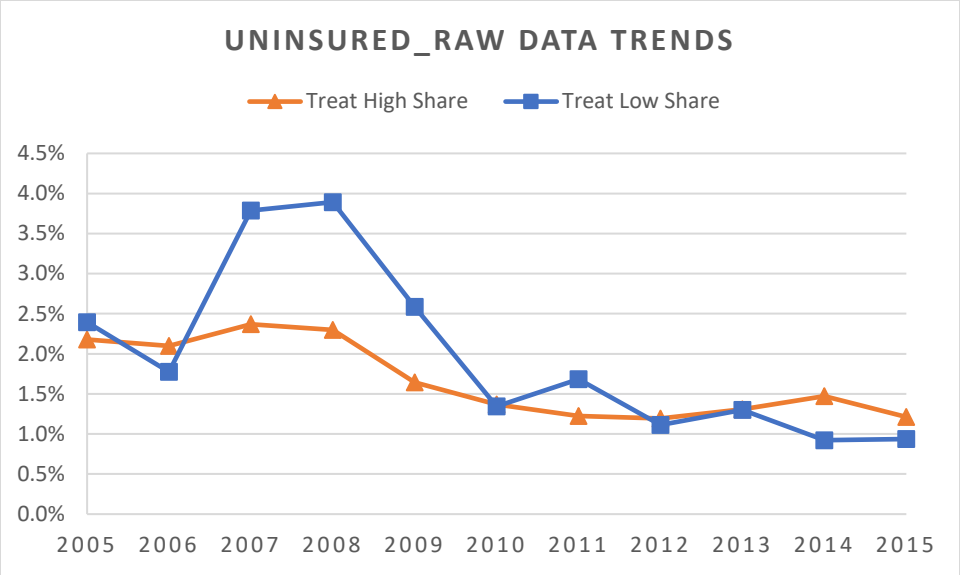

Figure 3.3.2 – Uninsured Raw Data Trends by Market Share

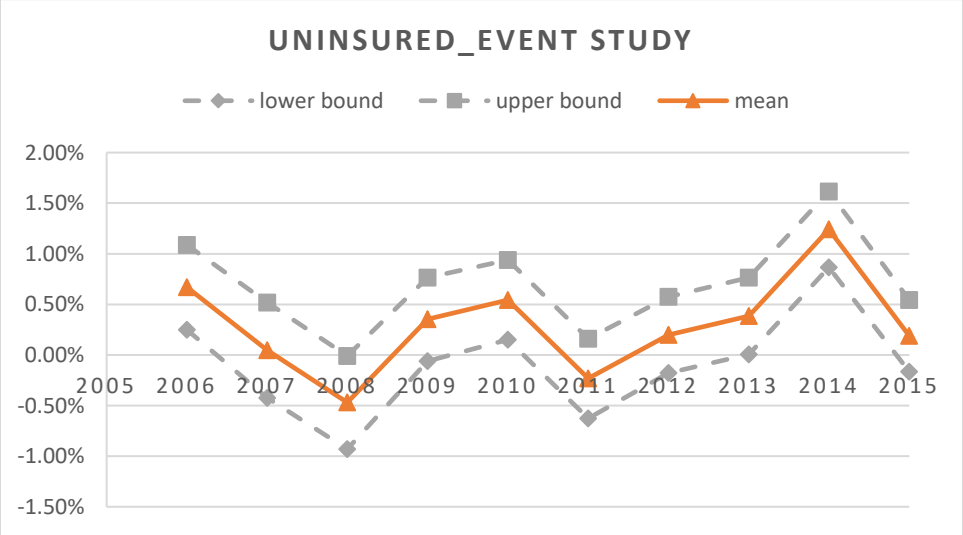

Figure 3.3.3 – Uninsured Event Study (DDD HHI Interaction)

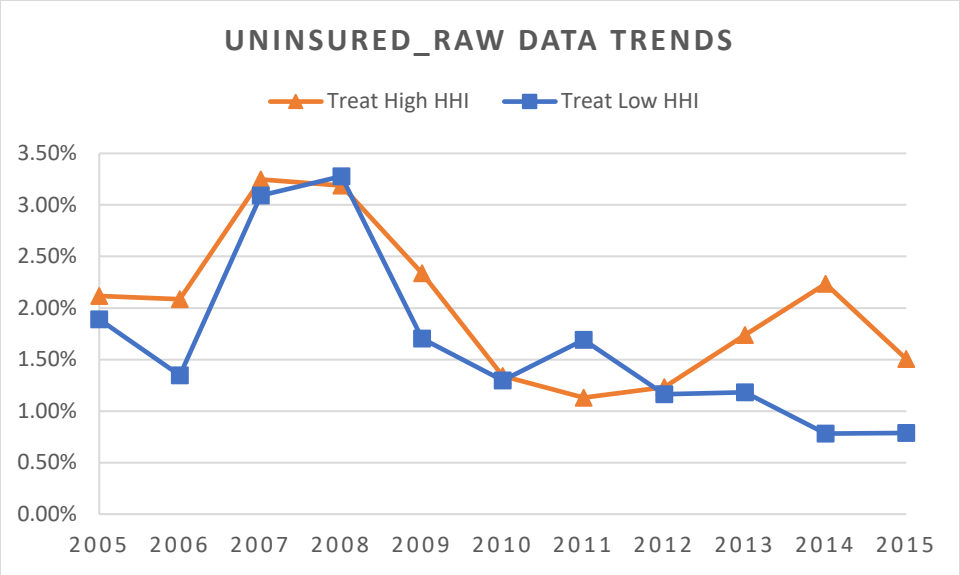

Figure 3.3.4 – Uninsured Raw Data Trends by HHI

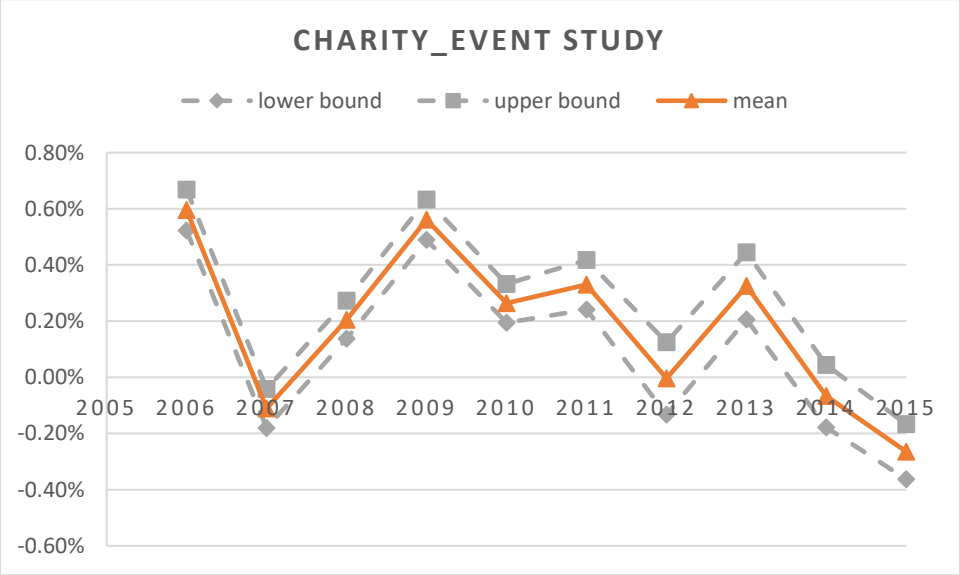

Figure 3.4.1 – Charity Event Study (DDD Market Share Interaction)

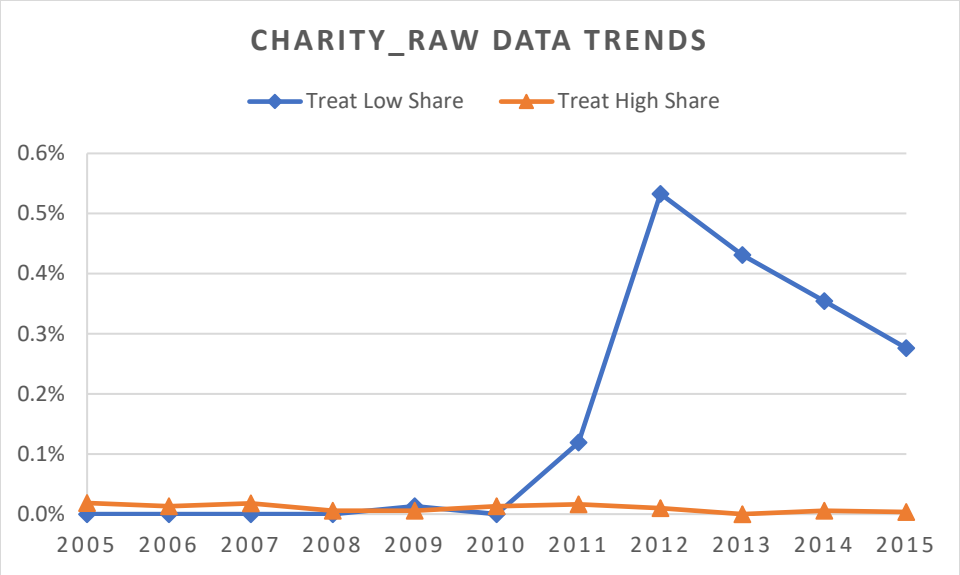

Figure 3.4.2 – Charity Raw Data Trends by Market Share

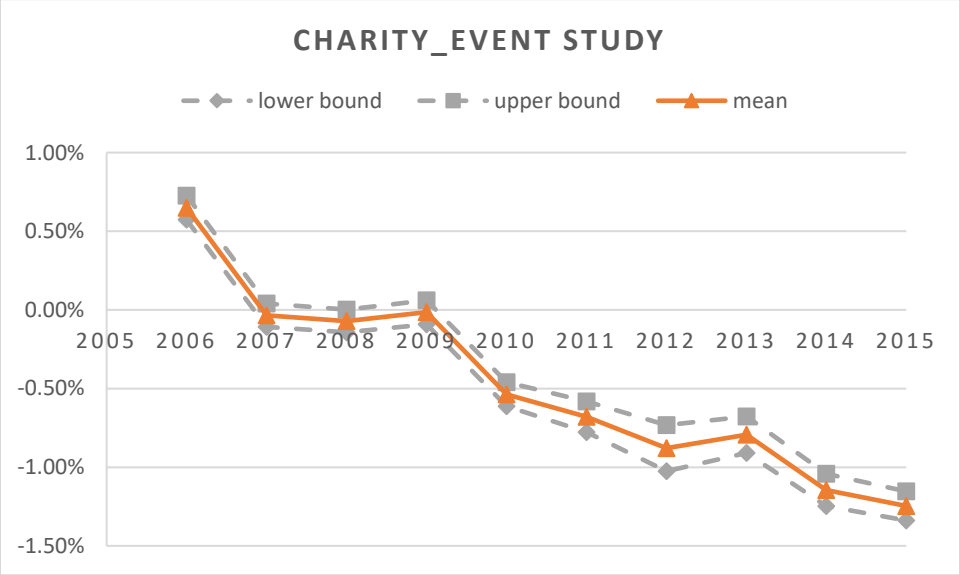

Figure 3.4.3 – Charity Event Study (DDD HHI Interaction)

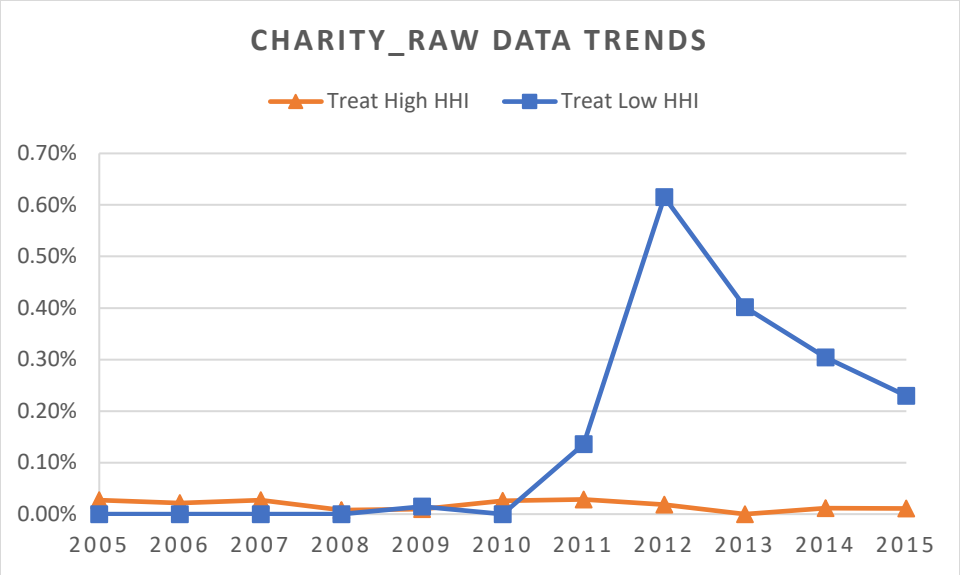

Figure 3.4.4 – Charity Raw Data Trends by HHI

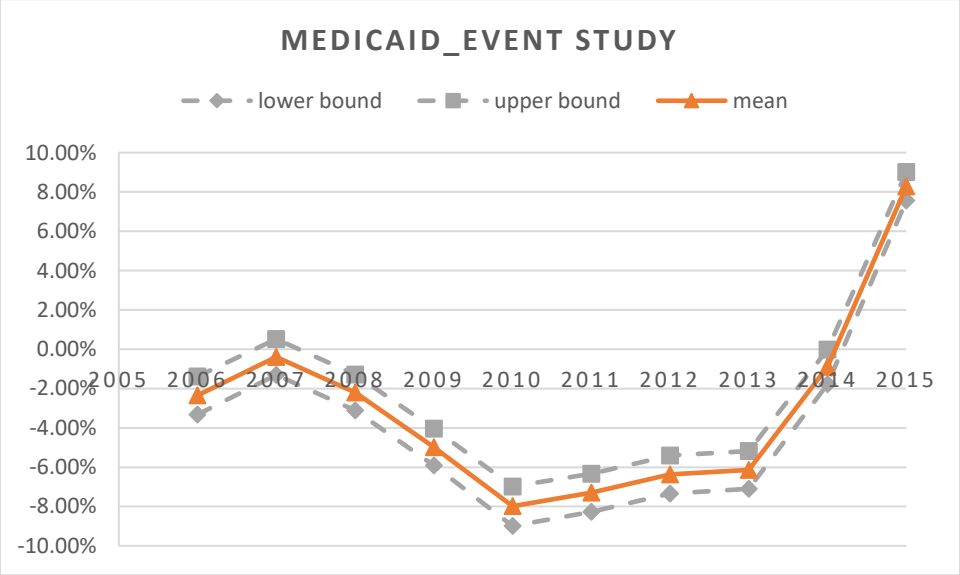

Figure 3.5.1 – Medicaid Event Study (DDD Market Share Interaction)

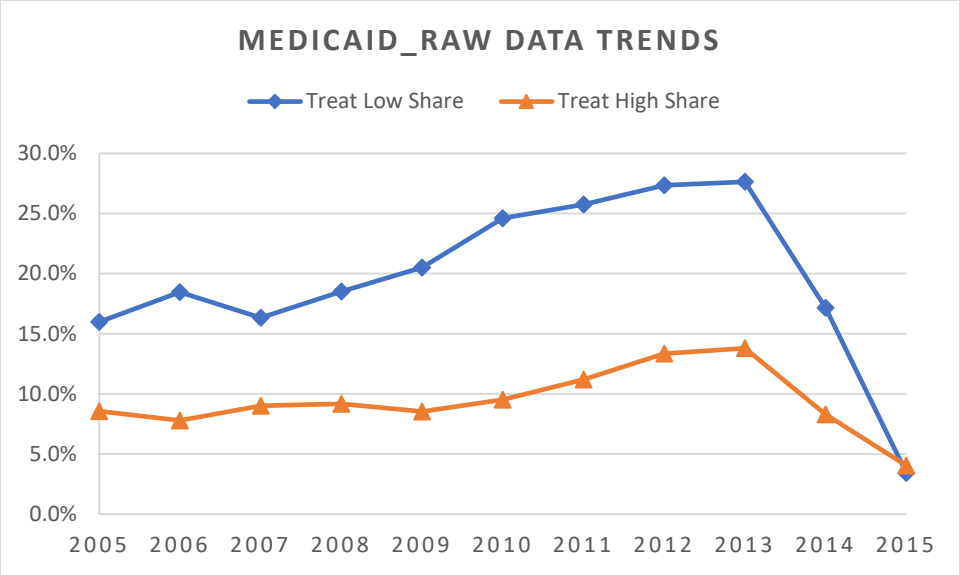

Figure 3.5.2 – Medicaid Raw Data Trends by Market Share

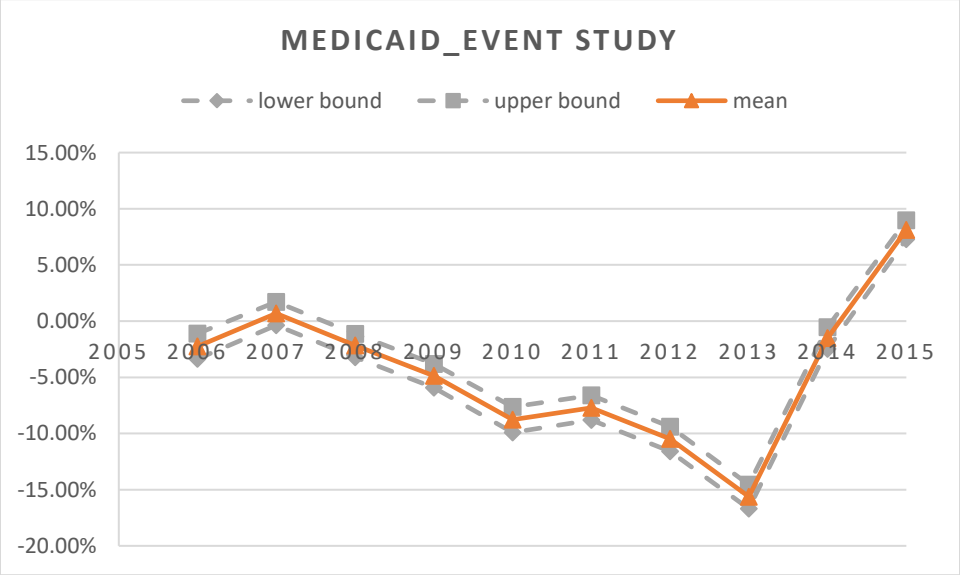

Figure 3.5.3 – Medicaid Event Study (DDD HHI Interaction)

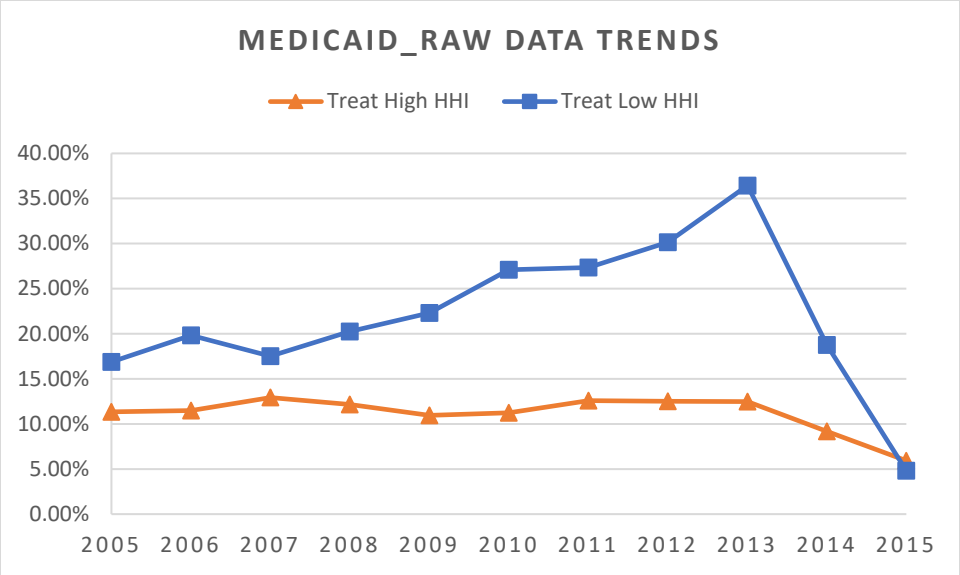

Figure 3.5.4 – Medicaid Raw Data Trends by HHI

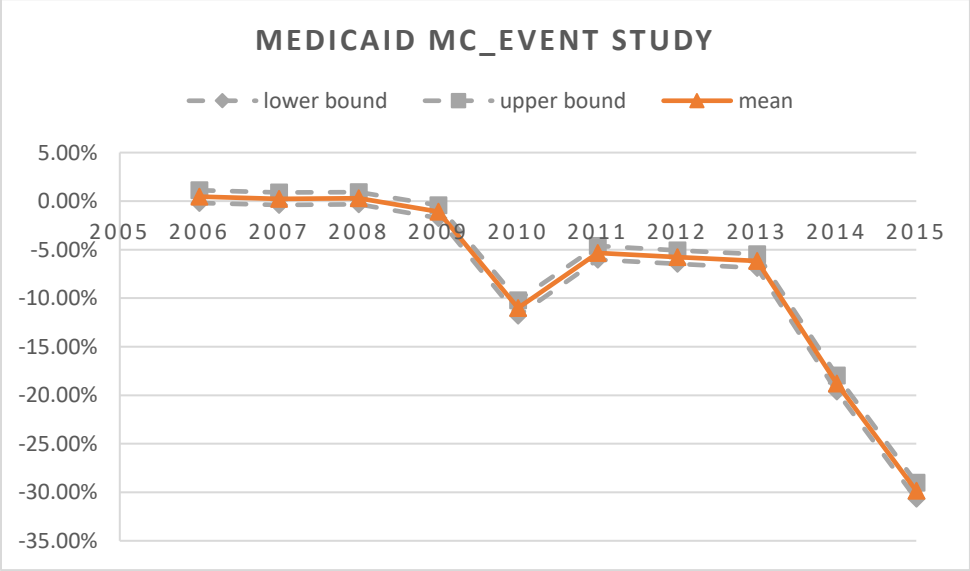

Figure 3.6.1 – Medicaid MC Event Study (DDD Market Share Interaction)

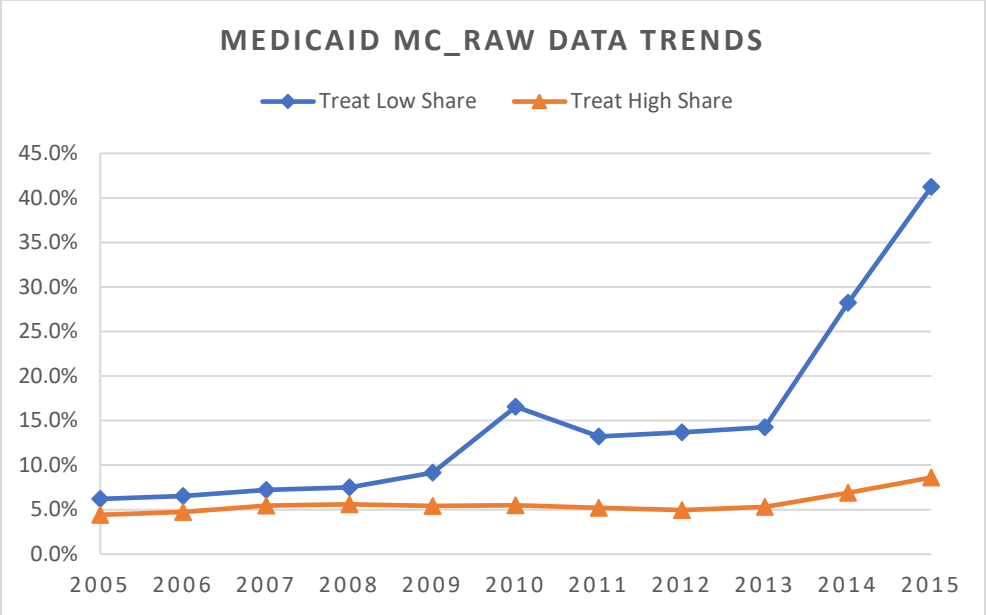

Figure 3.6.2 – Medicaid MC Raw Data Trends by Market Share

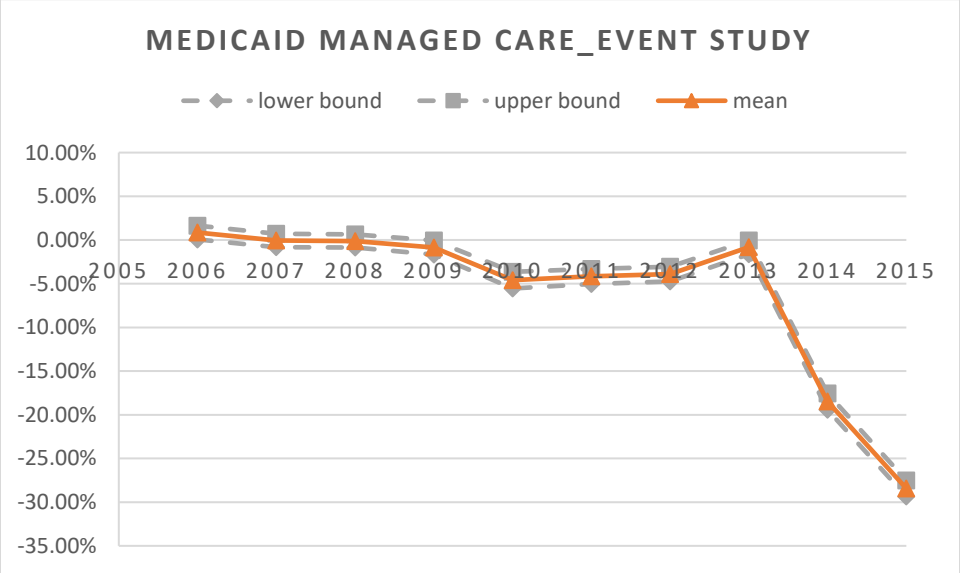

Figure 3.6.3 – Medicaid MC Event Study (DDD HHI Interaction)

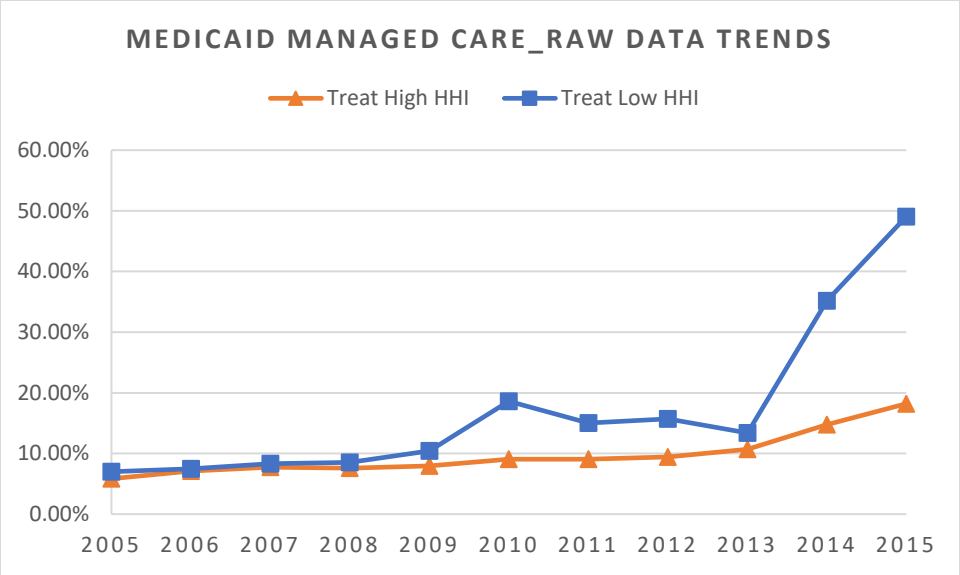

Figure 3.6.4 – Medicaid MC Raw Data Trends by HHI

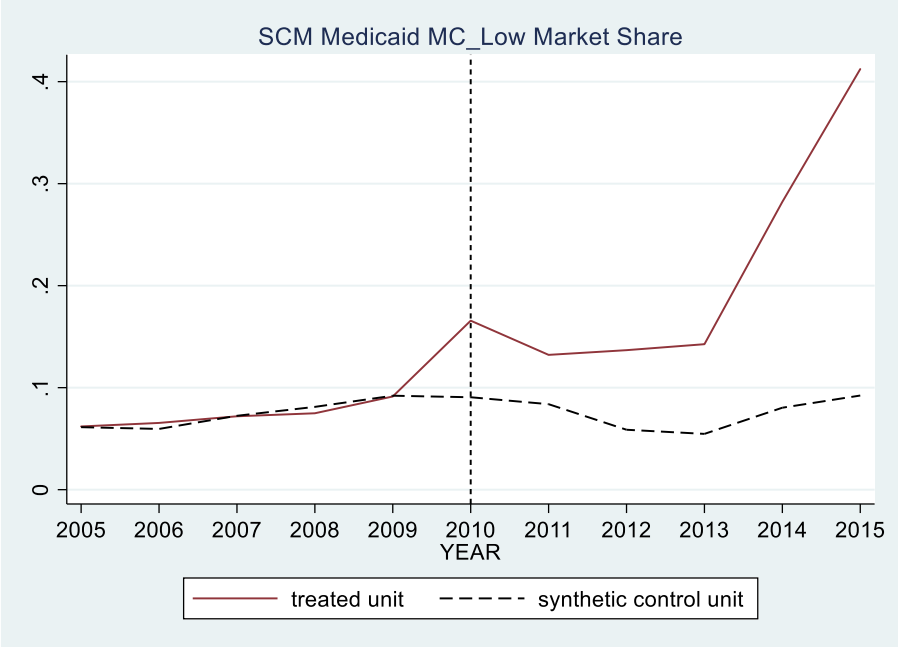

Figure 3.6.5 – SCM Medicaid MC (Low Market Share)

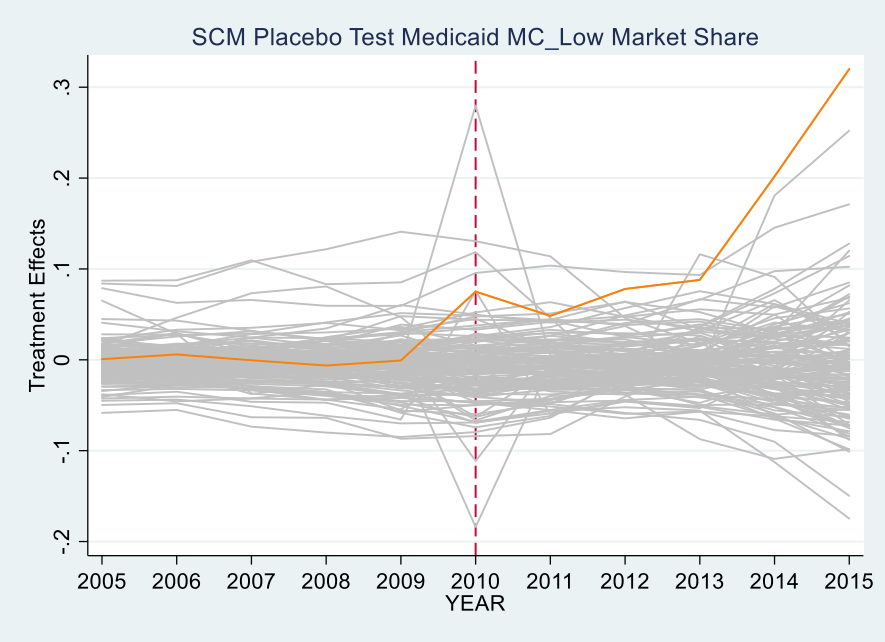

Figure 3.6.6 – SCM Permutation Test (Low Market Share)*

*0 out of 140 estimates are larger than the estimate of the real treated unit, → one-sided p-value = 0.000

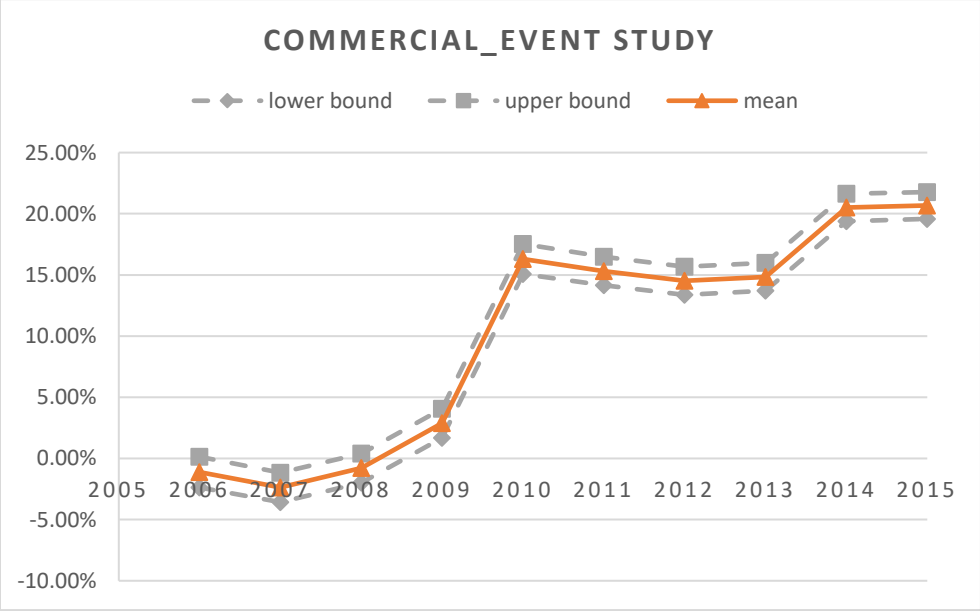

Figure 3.7.1 – Commercial Event Study (DDD Market Share Interaction)

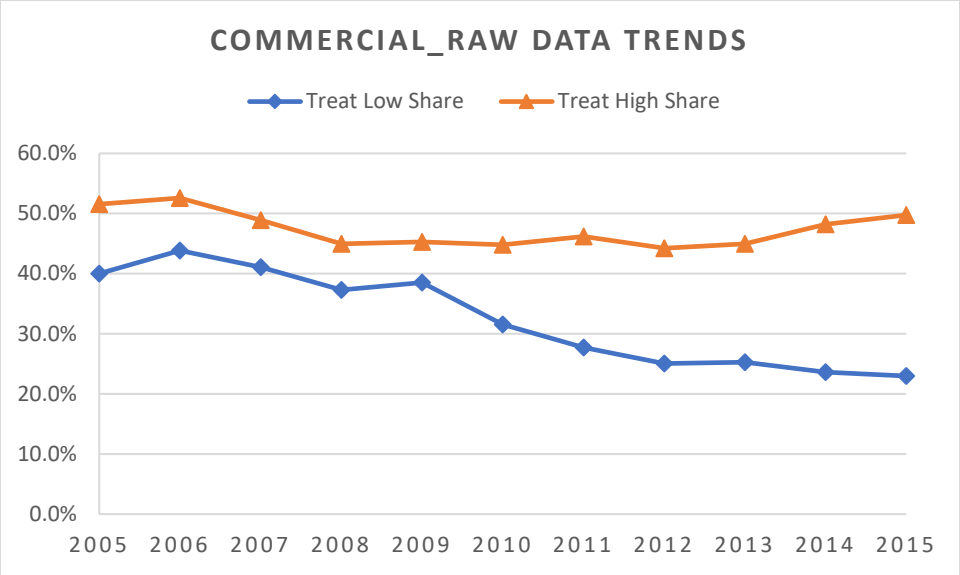

Figure 3.7.2 – Commercial Raw Data Trends by Market Share

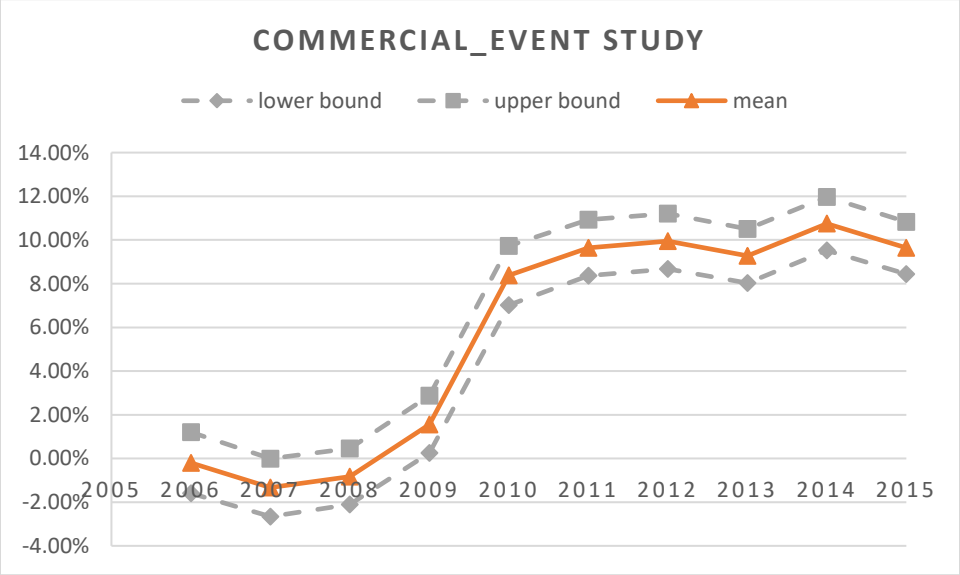

Figure 3.7.3 – Commercial Event Study (DDD HHI Interaction)

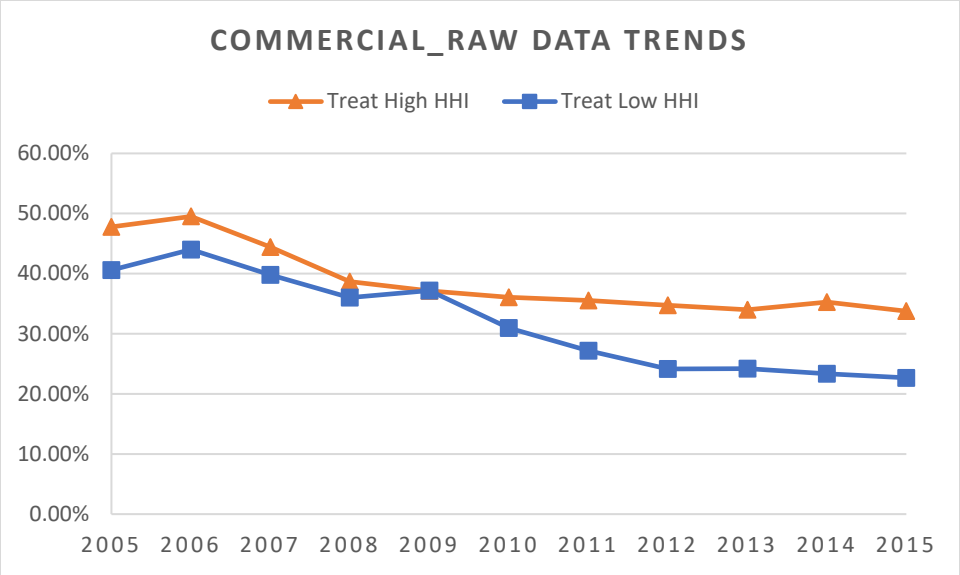

Figure 3.7.4 – Commercial Raw Data Trends by HHI

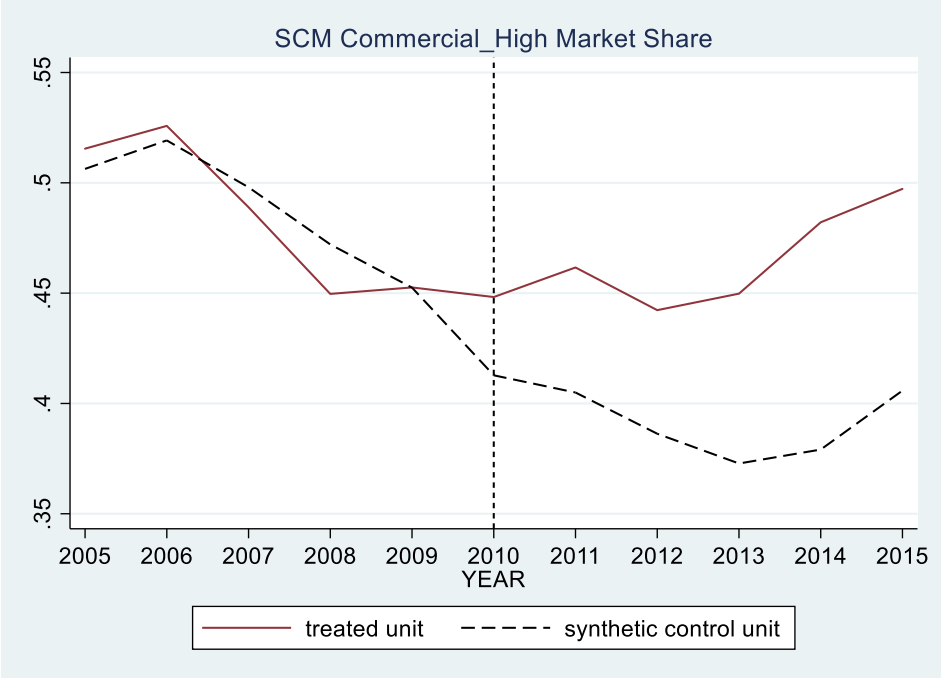

Figure 3.7.5 – SCM Commercial (High Market Share)

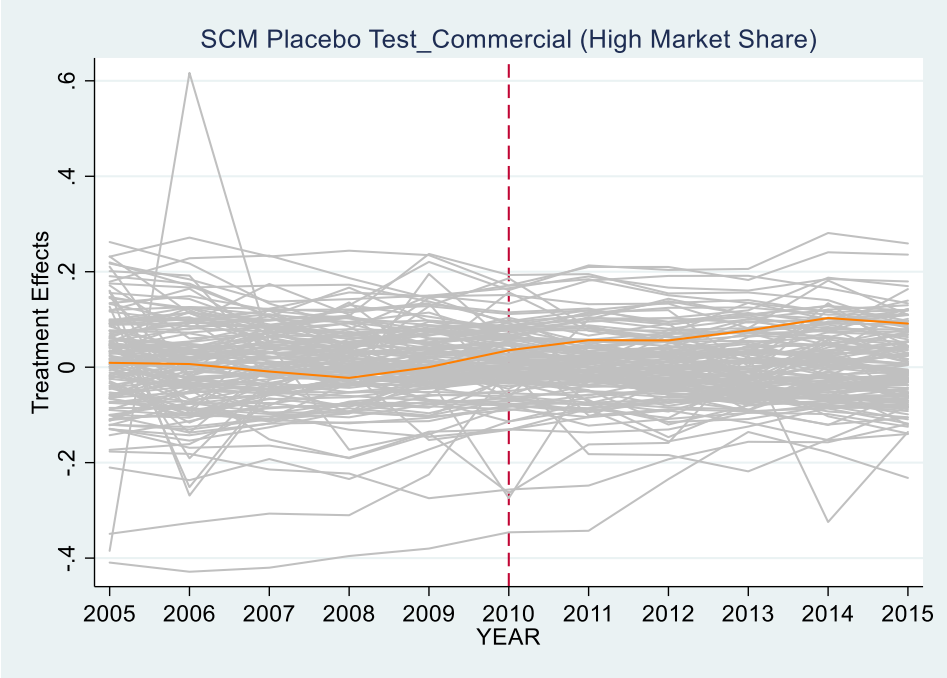

Figure 3.7.6 – SCM Permutation Test (High Market Share)*

*12 out of 140 estimates are larger than the estimate of the real treated unit → one-sided p-value = 0.086

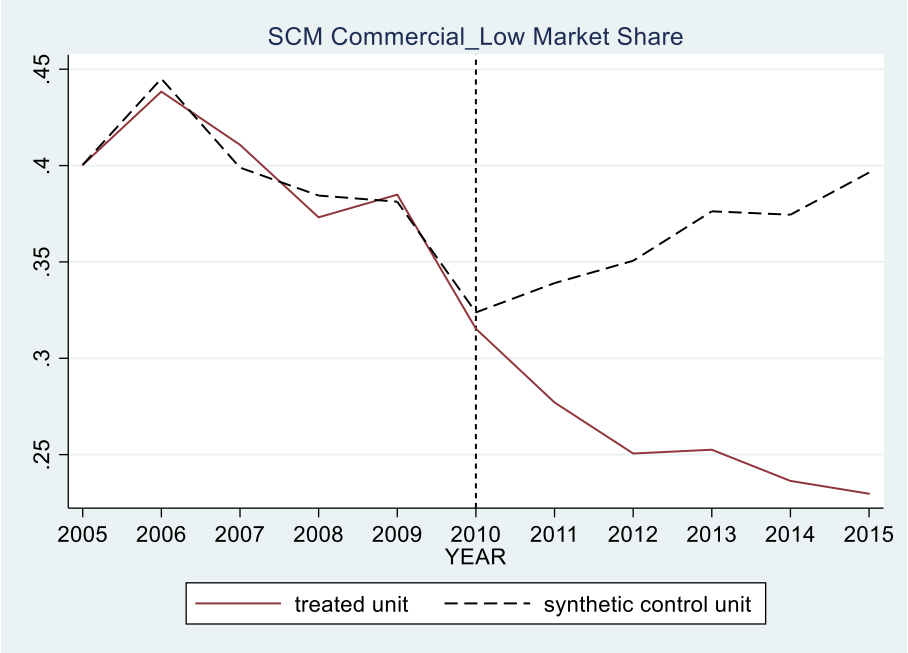

Figure 3.7.7 – SCM Commercial (Low Market Share)

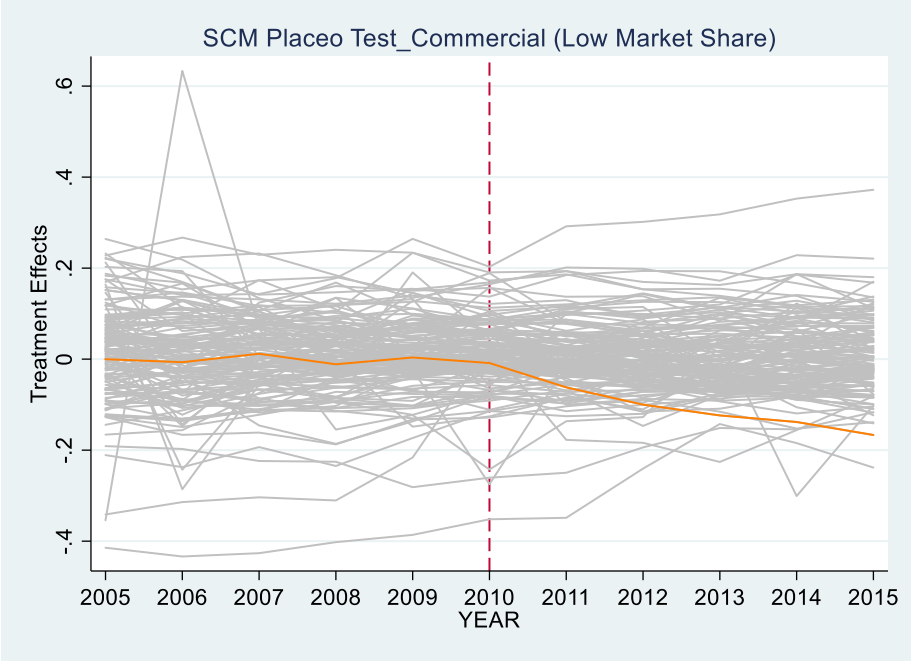

Figure 3.7.8 – SCM Permutation Test (Low Market Share)*

*6 out of 140 estimates are smaller than the estimate of the real treated unit → one-sided p-value = 0.043

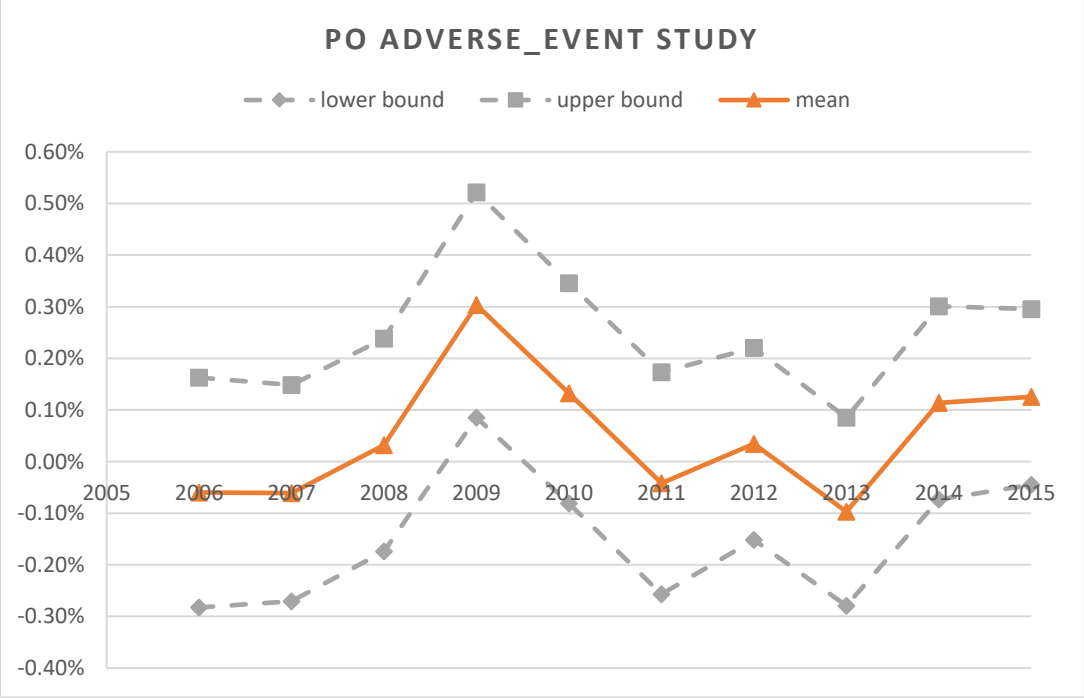

Figure 3.8.1 – PO Adverse Event Study (DDD Market Share Interaction)

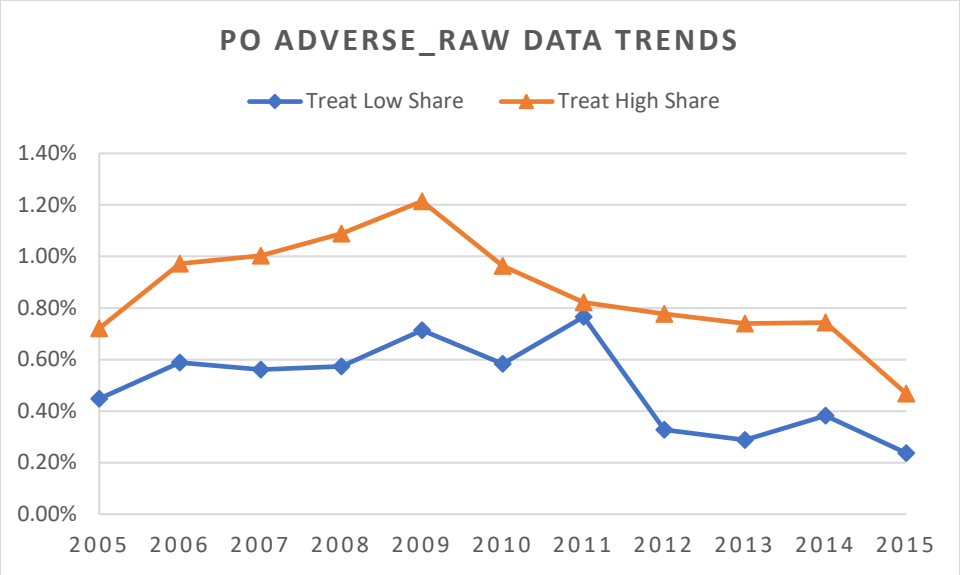

Figure 3.8.2 – PO Adverse Raw Data Trends by Market Share

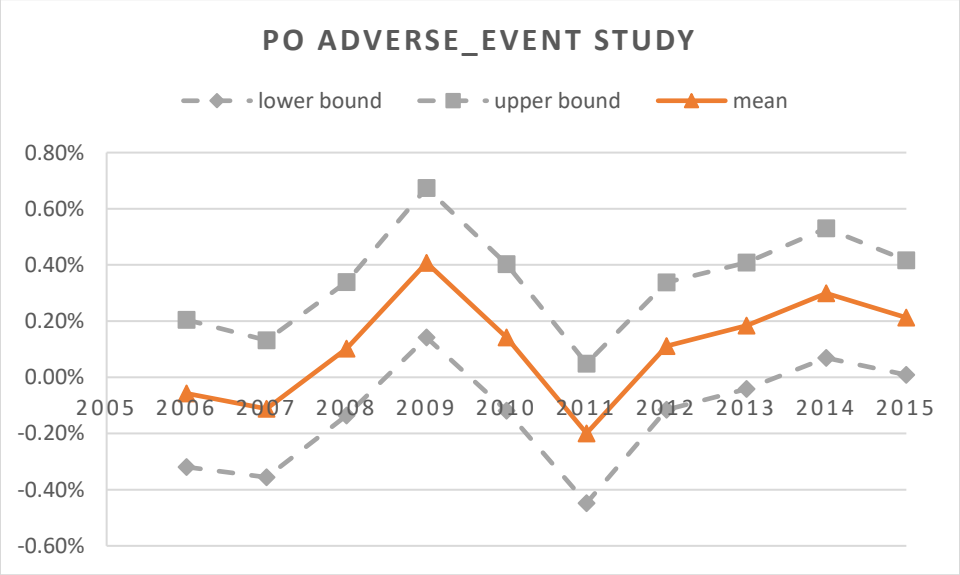

Figure 3.8.3 – PO Adverse Event Study (DDD HHI Interaction)

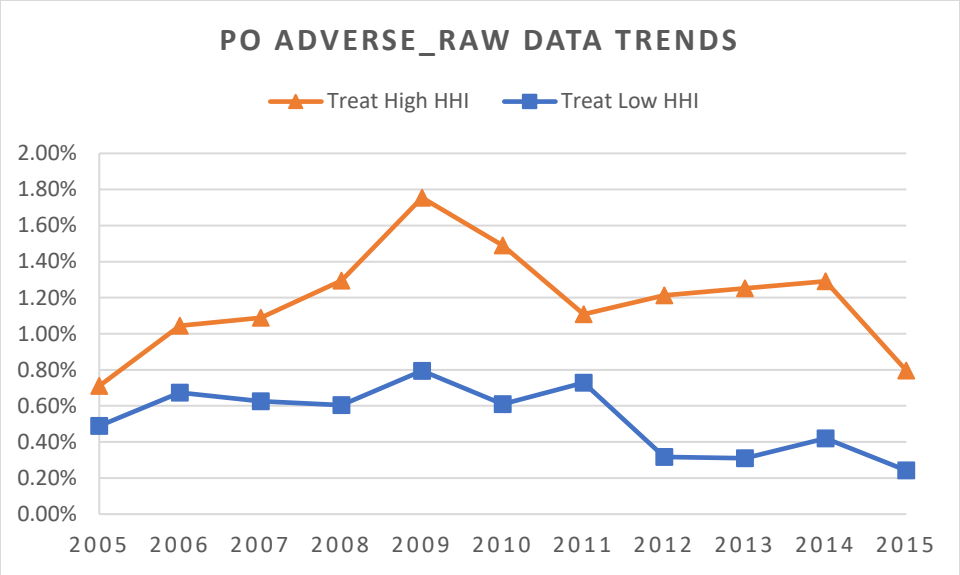

Figure 3.8.4 – PO Adverse Raw Data Trends by HHI

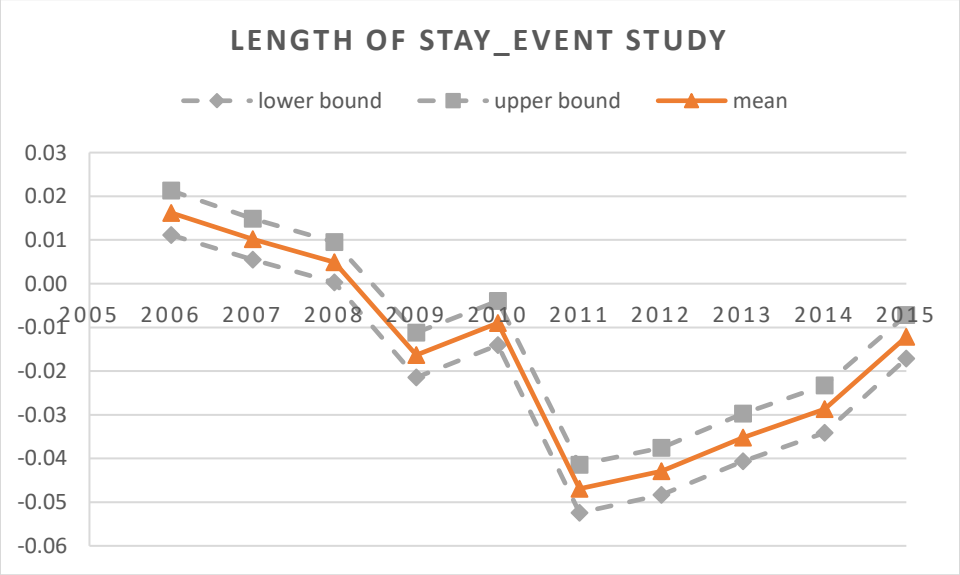

Figure 3.9.1 – Length of Stay Event Study (DDD Market Share Interaction)

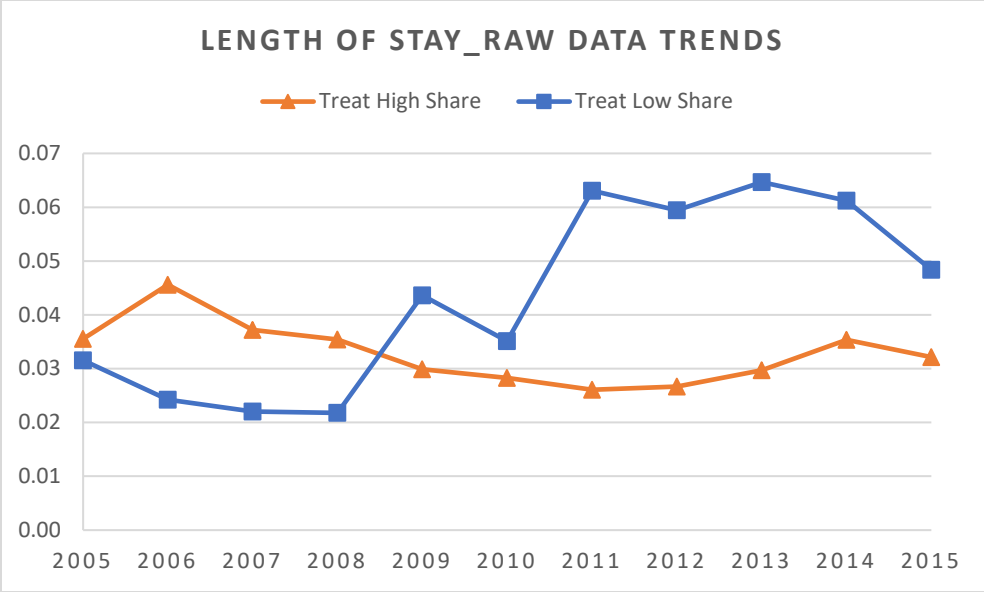

Figure 3.9.2 – Length of Stay Raw Data Trends by Market Share

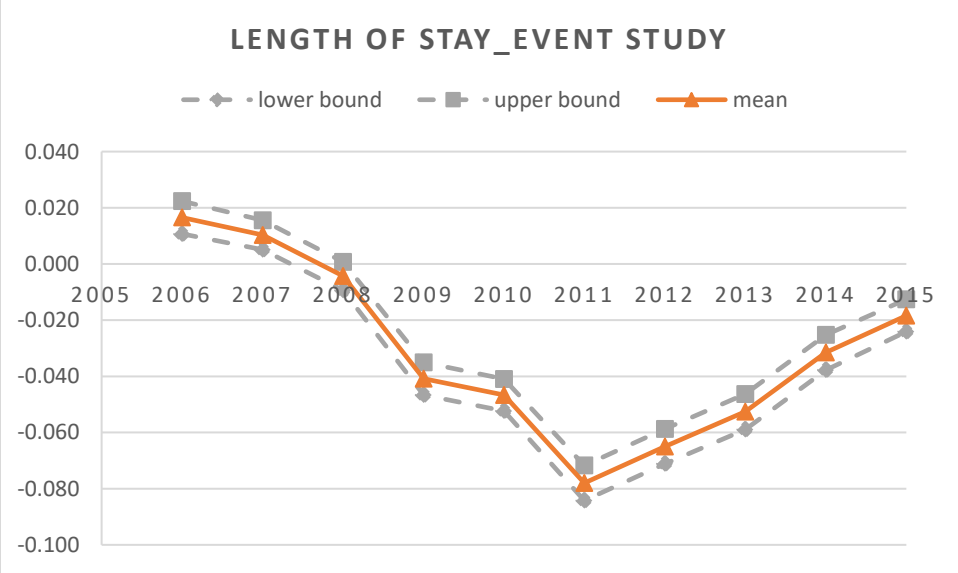

Figure 3.9.3 – Length of Stay Event Study (DDD HHI Interaction)

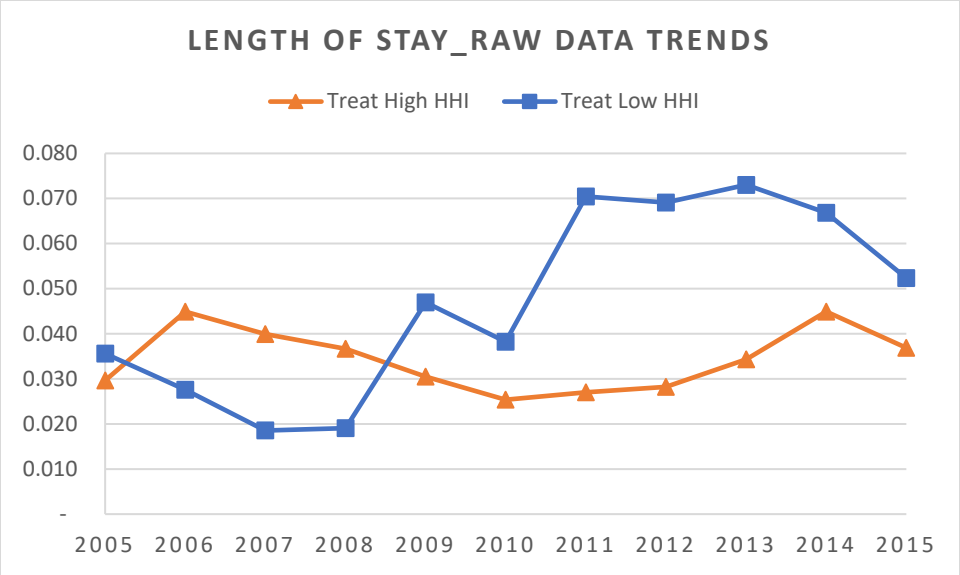

Figure 3.9.4 – Length of Stay Raw Data Trends by HHI

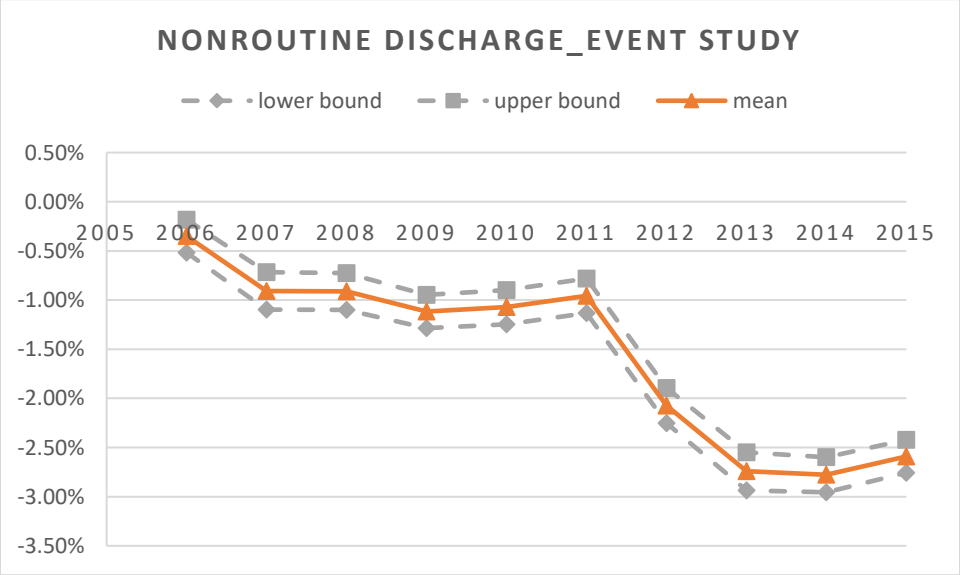

Figure 3.10.1 – Nonroutine Discharge Event Study (DDD Market Share Interaction)

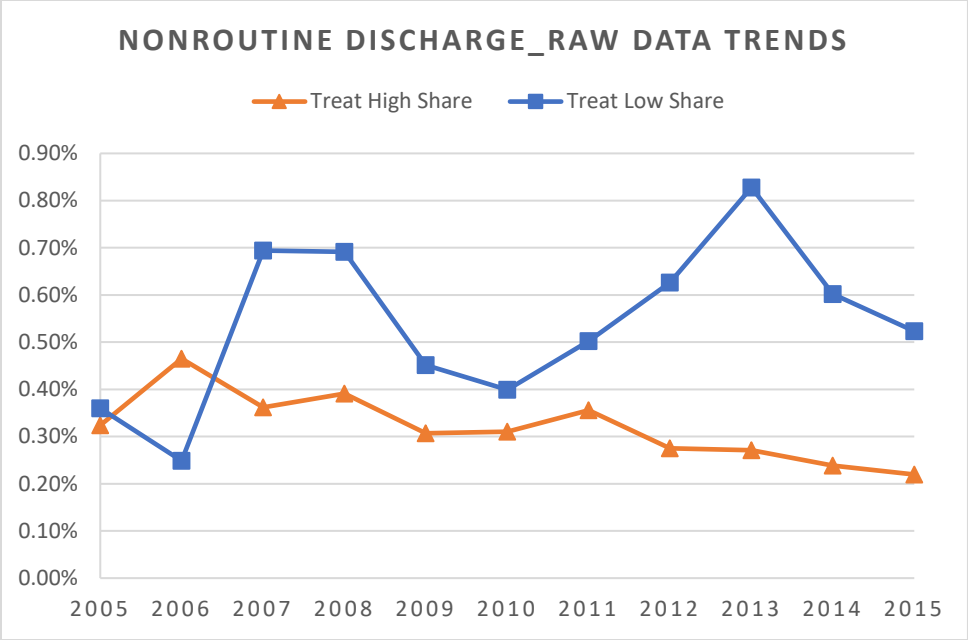

Figure 3.10.2 – Nonroutine Discharge Raw Data Trends by Market Share

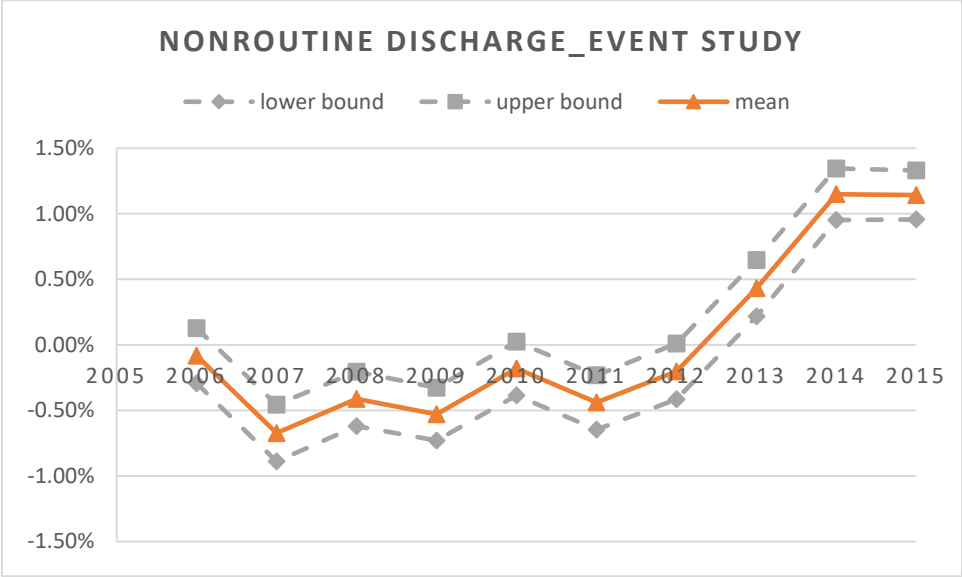

Figure 3.10.3 – Nonroutine Discharge Event Study (DDD HHI Interaction)

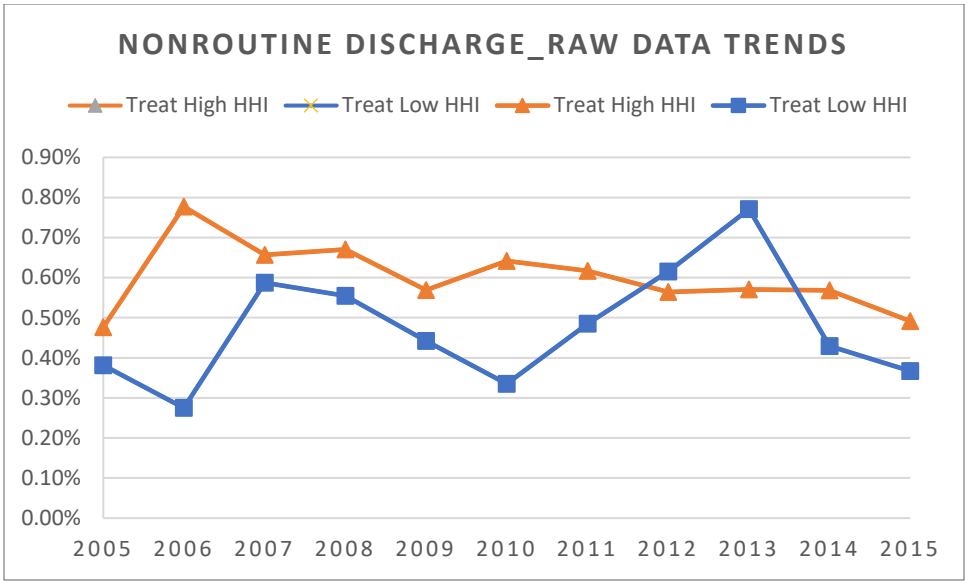

Figure 3.10.4 – Nonroutine Discharge Raw Data Trends by HHI

Appendix C: ICD-9 Codes for Post-Operative Adverse Reactions

Mechanical wound complications
Delayed wound healing: 998.83
Postoperative hematoma: 998.12
Postoperative seroma (noninfected): 998.13
Disruption of operative wound: 998.3
Persistent postoperative fistula: 998.6

Infections
Postoperative infection: 998.5
Postoperative skin abscess: 998.59
Postoperative septic wound complications: 998.59
Postoperative skin infection: 998.59
Postoperative intraabdominal abscess: 998.59
Postoperative subdiaphragmatic abscess: 998.59
Postoperative infected seroma: 998.51
Urinary complications
Postoperative urinary retention: 997.5
Postoperative urinary tract infection: 997.5

Pulmonary complications
Postoperative atelectasis: 997.3
Postoperative pneumonia: 997.3
Mendelson syndrome resulting from a procedure: 997.3
Postoperative acute respiratory insufficiency: 518.5
Postoperative acute pneumothorax: 512.1
Adult respiratory distress syndrome: 518.5
Postoperative pulmonary edema: 518.4

Gastrointestinal complications
Postoperative small bowel obstruction: 997.4
Postoperative ileus: 997.4
Postoperative ileus requiring nasogastric tube: 997.4
Postoperative nausea: 997.4
Postoperative vomiting: 997.4
Postoperative pancreatitis: 997.4
Complication of anastomosis of gastrointestinal tract: 997.4

Cardiovascular complications
Postoperative deep venous thrombosis: 997.79
Postoperative pulmonary embolism: 415.11
Postoperative stroke: 997.02
Phlebitis or thrombophlebitis from procedure: 997.2
Cardiac arrest/insufficiency during or resulting from a procedure: 997.1

Systemic complications
Postoperative shock (septic, hypovolemic): 998.0
Postoperative fever: 998.89

Complications during procedure
Accidental puncture or laceration, complicating surgery: 998.2
Foreign body accidentally left during procedure: 998.4
Bleeding complicating procedure: 998.11

Appendix D: 14 Categories of Procedures Leading to 50% of All Outpatient Post-Operative Adverse Reactions

14 Categories	CPT Procedures	Freq.	Percent	Cum.	Description
Integumentarysurg	11042	54,927	6.2	6.2	Debridement Procedures on the Skin
Microbiology	87070	22,188	2.5	8.7	Microbiology Procedures
Integumentarysurg	36415	19,760	2.23	10.93	Venous Procedures
Organpathology	80048	17,075	1.93	12.86	Organ or Disease Oriented Panels
Microbiology	87205	16,898	1.91	14.76	Microbiology Procedures
Hematology	85025	16,526	1.86	16.63	Under Hematology and Coagulation Procedures
Injection	J2250	16,485	1.86	18.49	Injection, midazolam hydrochloride, per 1 mg
Injection	J3010	16,388	1.85	20.34	Injection, fentanyl citrate, 0.1 mg
Hematology	85610	15,943	1.8	22.14	Under Hematology and Coagulation Procedures
Injection	J2405	14,789	1.67	23.81	Injection, ondansetron hydrochloride, per 1 mg
Hematology	85027	14,022	1.58	25.39	Under Hematology and Coagulation Procedures
Hematology	85730	12,835	1.45	26.84	Under Hematology and Coagulation Procedures
Office	99213	12,548	1.42	28.25	Under Established Patient Office or Other Outpatient Services
Microbiology	87075	12,111	1.37	29.62	Microbiology Procedures
Surgpathology	88305	10,955	1.24	30.85	Surgical Pathology Procedures
Cardiovascularmedicine	93005	10,819	1.22	32.08	Cardiography Procedures
Microbiology	87186	9,681	1.09	33.17	Pathology and Laboratory Procedures
Injection	J0690	8,996	1.02	34.18	Injection, cefazolin sodium, 500 mg
Infusion	J7120	8,763	0.99	35.17	Ringers lactate infusion, up to 1000 cc
Integumentarysurg	10140	8,474	0.96	36.13	Incision and Drainage Procedures on the Skin, Subcutaneous and Accessory Structures
Integumentarysurg	11043	8,440	0.95	37.08	Debridement Procedures on the Skin
Organpathology	80053	8,063	0.91	37.99	Organ or Disease Oriented Panels
Microbiology	87077	7,862	0.89	38.88	Microbiology Procedures
Radiology	71010	7,564	0.85	39.73	Diagnostic Radiology (Diagnostic Imaging) Procedures
Injection	J1170	6,979	0.79	40.52	Injection, hydromorphone, up to 4 mg
Integumentarysurg	17250	6,527	0.74	41.25	Surgical Procedures on the Integumentary System
Chemistry	82962	6,291	0.71	41.96	Chemistry Procedures
Office	99212	6,019	0.68	42.64	Under Established Patient Office or Other Outpatient Services
Integumentarysurg	11041	5,629	0.64	43.28	Debridement Procedures on the Skin
Injection	J1100	5,575	0.63	43.91	Injection, dexamethasone sodium phosphate, 1 mg
Surgpathology	88304	5,496	0.62	44.53	Surgical Pathology Procedures
Office	99214	5,192	0.59	45.11	Under Established Patient Office or Other Outpatient Services
Integumentarysurg	11040	5,143	0.58	45.69	Under Established Patient Office or Other Outpatient Services
Office	99211	5,141	0.58	46.27	Under Established Patient Office or Other Outpatient Services
Transfusionmedcine	86900	4,783	0.54	46.81	Transfusion Medicine Procedures
Injection	J2001	4,697	0.53	47.34	Injection, lidocaine HCl for intravenous infusion, 10 mg
Radiology	71020	4,474	0.5	47.85	Radiology Procedures
Observation	G0378	4,306	0.49	48.33	Hospital observation service, per hour
Transfusionmedcine	86901	4,258	0.48	48.81	Transfusion Medicine Procedures
Woundcare	97597	4,258	0.48	49.29	Active Wound Care Management
Transfusionmedcine	86850	4,163	0.47	49.76	Transfusion Medicine Procedures
Woundcare	97605	3,986	0.45	50.21	Active Wound Care Management

Appendix E: Medicaid Duplicate Discount Prohibition

I. PROVIDER EXCLUSION METHOD (CARVED-IN/CARVED-OUT MEF METHOD)

When registering with HRSA, each participating hospital must notify HRSA if it intends to use 340B drugs for Medicaid beneficiaries (known as carved-in stage), whereby it is listed in Medicaid Exclusion File (MEF) to assist states in excluding all their drug spending from the rebate invoice that the state sends to drug manufacturers for rebates, or if the hospital does not intend to do so (known as carved-out stage). Therefore, when a carved-in 340B hospital treats a Medicaid beneficiary, the Medicaid program will exclude their drug claim from the rebate invoice to drug manufacturer and reimburse this hospital at the ceiling prices. In short, a carved-in hospital will get cheaper drugs, but Medicaid will also reimburse them at low prices, so the incentive to over-prescribe is low.

However, because of the Prime Vendor Program, i.e. a carved-in hospital can still make additional profits from the difference between the ceiling price and the sub-ceiling price. But the discount from PVP is much smaller than URA.

On the other hand, if a 340B hospital opts to be carved-out, it is not supposed to use 340B discounted drugs on Medicaid beneficiaries, so the incentive to over-prescribe due to URA never exists, but the PVP discounts are still available.

II. Claim-Level Method

In addition to provider exclusion method, a state can use claim-level methods to identify and exclude 340B drugs from its rebate invoice. Under this approach, a covered entity indicates on the claim whether the drug was purchased under 340B or not. This approach is more flexible because claim-level methods allow providers that generally use 340B drugs for Medicaid to indicate individual instances when they did not do so; for example, if the provider ran out of a particular 340B drug and had to substitute a drug from general inventory, that could be indicated on the claim.

However, as long as being compliant, since hospitals indicate clearly on the claim to Medicaid whether they use discounted drug or non-discounted drug for every treatment, the main 340B drug discount is not available to them either.