The Effect of Price Caps on Pharmaceutical Advertising: Evidence from the 340b Drug Pricing Program*

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Abstract

We study the effect of price caps on the provision of costly effort by pharmaceutical firms using variation in drug discounts generated by a price regulation program that allows eligible hospitals to purchase outpatient drugs at steep discounts. These discounts directly affect drug manufacturers' markups, and may change firms' incentives to exert promotional effort targeted towards physicians at these hospitals. We find that the effects of price regulation on pharmaceutical firm effort depend crucially on the design of the regulations. Using detailed data on marketing payments from pharmaceutical firms to physicians, we observe that physicians receive 12% fewer promotional payments after their hospitals take up the program. The design of the price caps imply that discounts tend to increase with a drug's age. Consistent with theoretical predictions, we find that pharmaceutical firms shift promotional payments away from older drugs and towards newer drugs, which are less affected by the price caps.

JEL Codes: L51; L65; M37; M38; I18; I11.
Keywords: advertising; pharmaceutical industry; 340b drug pricing program; price caps; firm effort.

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1 Introduction

The United States relies on private firms to develop, dispense, and pay for prescription drugs through a market system. Concerns over the costs of, and patient access to, prescription drugs have led the federal government to launch programs aimed at regulating pharmaceutical prices. For example, the Medicaid Drug Rebate Program established price ceilings for most drugs reimbursed by Medicaid and the Inflation Reduction Act aims to set price caps for certain drugs. While regulated prices may increase affordability for consumers and other payors, they may also reduce incentives for firms to innovate or to provide high-quality products and services (Garthwaite et al. (2022); Yurukoglu et al. (2017)). The challenge for policymakers is to balance the benefits of increased access with the costs of reduced innovation or effort. Despite the importance of this trade-off in the pharmaceutical industry, empirical evidence on how firm effort responds to government price interventions is scarce. One challenge for inferring the effect of price regulations on effort (assuming effort is measurable) is that many forms of effort are inflexible in the short run. For example, it may take years to see the effects of reductions in R&D on new product introductions. Alternatively, effort may be chosen at earlier or more aggregated stages than a price intervention, frustrating efforts to empirically identify a causal effect of the policy.

In this paper, we tackle these empirical challenges by studying how caps on the prices of drugs affect an important margin of effort: advertising. Advertising provides a good setting for analyzing the effects of price interventions on effort because advertising is a measurable dimension of effort that may be flexibly adjusted in response to market or regulatory changes. Our analyses focus on firm effort in promotional "detailing" relationships, which we track as in-kind transfers to physicians, typically in the form of a meal. In 2016, pharmaceutical firms spent nearly $10 billion on in-kind transfers to physicians (Centers for Medicare and Medicaid Services). Using granular data on promotional payments, we can study both the overall response of promotional effort to price regulation, and how this response varies across drugs within the firm.

The price regulation we study is the 340b Drug Pricing Program. The 340b program entitles qualifying hospitals to purchase drugs at steep discounts.[1] Manufacturers are not compensated by the government for revenues lost to the discounts mandated by the 340b program. Since its inception in 1992, the 340b program has grown into an economically relevant feature of the US prescription drug market, with participating healthcare providers benefiting from $50 billion in cost savings through the program in 2021 alone (Fein (2020)). Our empirical strategy exploits changes in 340b accreditation across hospitals between 2014 and 2019 in a difference-in-differences framework. We focus on small, regionally dispersed expansions of the program due to voluntary take-up by eligible hospitals. We find that pharmaceutical firms reduce promotional payments to physicians at 340b hospitals by 12% relative to non-340b hospitals following take-up of the 340b program.[2] A placebo exercise examines changes in promotional payments related to medical

[1] Qualifying for the 340b program requires that a hospital serve a large share of low-income patients. While the discounts granted to 340b hospitals are confidential, they reportedly range from 23-99% of the average price paid by wholesalers.

[2] Drug prices are typically negotiated nationally between manufacturers and insurers; hence, they are unlikely to adjust in response to the relatively small and geographically dispersed expansions of the program analyzed in this paper. Instead, physician detailing and in-kind transfers stand out as one of the few localized and flexible margins of adjustment available to firms as a response to the price caps of interest. Overall, our setting allows us to isolate the effect of changes in markups on the marginal promotional incentives of pharmaceutical firms.

devices or supplies, which are not subject to discounts under the 340b program. Reassuringly, we do not find any changes in promotional payments related to these products following take-up of the 340b program by hospitals.

These drops in advertising are expected, as the program reduces the markups earned by drug manufacturers on prescriptions written by physicians at 340b hospitals. An important additional feature of the 340b program is that discounts vary across drugs, which should cause firms to adjust promotional effort differentially across drugs. While we do not observe the full discount mandated by the 340b program for each drug, we are able to approximate one important portion of the discount that varies across drugs: a penalty for raising prices faster than inflation. Typically, prescription drug prices rise faster than inflation, implying that the difference between the current price and the inflation-adjusted launch price widens over a drug's lifecycle. This suggests that the 340b discounts tend to increase as drugs age.[3]

If multi-product firms face different price caps across their drugs, they should re-allocate promotional effort across drugs. Even though one expects that firms will decrease their provision of costly effort on average in response to the price caps, they may *increase* effort for some drugs. We develop a theoretical model to show that a multi-product firm that produces substitute drugs may shift effort towards drugs that face smaller 340b discounts. If the disparity in discounts between two drugs is large enough, a firm will increase promotional effort for the drug facing a lower discount in order to reduce its exposure to the larger mandated discount on the other drug. Combining this prediction with the inflation penalties described above, we expect that firms would decrease effort for older drugs and may increase effort for newer ones.

Consistent with this prediction, we observe heterogeneous responses of promotional effort across drugs. We observe the largest decreases in effort for drugs that have been on the market for more than five years, while most of the drugs that increase effort were within their first five years of FDA approval. To better understand these responses, we examine firms' responses for drugs that treat diabetes, a condition that affects roughly 10% of Americans and accounts for 21% of promotional payments to physicians. This case study allows us to clearly document that within a given pharmaceutical firm, effort adjusts away from older drugs and towards new drugs in the same drug category. At the hospital level, it is unlikely that structural changes after the take-up of the 340b program would produce both increases and decreases in effort within this therapeutic area; thus, we attribute heterogeneity in the responsiveness of effort across drugs to differences in the discounts set by the 340b program.

In-kind transfers to physicians are an important but controversial form of pharmaceutical effort. During detailing visits, pharmaceutical sales representatives inform physicians about their products, including proper use cases, adverse drug reactions, and side effects. Thus, they may allow firms to better inform physicians about their products and lead to quicker and safer adoption of new and existing therapies (e.g., Shapiro (2018); Huang et al. (2019)). However, physician advertising may also lead to over-prescribing of drugs (e.g., Alpert et al. (2022); Grochowski Jones and Ornstein (2016); DeJong et al. (2016)). While we

[3]Relatedly, the design of the 340b program may give hospitals incentives to steer physician prescription volume towards drugs with higher rebates, because hospitals typically do not adjust the price charged to patients or insurers who purchase the price protected drugs, and so enjoy higher markups of their own on drugs with steeper discounts. Although potential changes to physicians' prescribing behavior are of obvious importance for patients, we cannot explore this here because we do not have detailed data on prescriptions.

do not take a stance on the welfare effects of advertising, we briefly speculate on the potential effects of the estimated changes in advertising. Our empirical analyses show that physicians at newly-designated 340b hospitals received fewer promotional payments related to older drugs, for which the informational content of advertising is likely to be relatively lower. In contrast, for some new drugs, those physicians receive more payments than do physicians at non-340b hospitals. Thus, the 340b program may reduce incentives for effort that is likely to be less socially valuable (the promotion of old drugs) and increase incentives for more valuable effort (the promotion of new drugs).[4] A common argument against drug pricing regulations (such as those introduced by the Inflation Reduction Act) is that they may reduce incentives for pharmaceutical firms to develop new cures and provide valuable effort. Our results suggest that the design of price regulations is an important determinant of pharmaceutical firm effort.

Prior work has analyzed the strategic responses of pharmaceutical firms to regulations (Scott Morton (1997); Feng et al. (2023); Dubois et al. (2022); Yde (2023)) and to changes in formularies by health insurers (Agha et al. (2022)).[5] We provide new evidence that the effects of price regulation on upstream firm effort depend on the design of price caps. Our work is closest to Yurukoglu et al. (2017), who find that decreases in Medicare reimbursement rates for sterile injectable drugs led to supply shortages. Our data allow us to infer changes in effort across hospitals for the same drug; hence, we may examine how firms re-optimize promotional effort in response to price caps.

There is an extensive literature in marketing and economics examining the process by which pharmaceutical firms determine their advertising strategies or how profit incentives affect targeted advertising (e.g., Azoulay (2002); Ching and Ishihara (2010); Sood et al. (2014); Ching et al. (2016); Larkin et al. (2017); Guo et al. (2021); Agha and Zeltzer (2022); Lawler and Skira (2022)).[6] Our paper is closest to Lawler and Skira (2022) and Shapiro (2018), who show that drug manufacturers increase their advertising after positive informational shocks. We expand on these works by also considering the process by which pharmaceutical firms determine targeted promotional effort across drugs.

Finally, we contribute to the growing literature on the effects of the 340b drug pricing program. Research in this area has typically focused on how the 340b program affects hospitals, particularly their finances (Han (2018)) and organizational structure (Desai and McWilliams (2018)). A few papers also explore how the 340b program affects the provision of care (Berger (2023); Bond et al. (2023); Desai and McWilliams (2021)) and insurance premiums (Gray (2023)). To the best of our knowledge, we are the first paper to consider how this program affects the incentives facing and behavior of pharmaceutical firms. Our finding that pharmaceutical firms respond strategically to the design of the 340b program parallels the findings in these papers that hospitals respond strategically to the program.

[4] We acknowledge that, from a welfare perspective, advertising of old drugs may be more valuable than advertising of new drugs if it improves physicians' prescribing decisions. This is an important welfare consideration that is outside the scope of this paper.

[5] Prior work has also analyzed how firms change behavior at the time of patent expiration (Scott Morton (2000); Shapiro (2016); Van Der Schans et al. (2021); Regan (2008); Frank and Salkever (1992); Kwong and Norton (2007)). Patent expiration results in greater competition but need not decrease prices (as found by Regan (2008)); thus, price regulations and patent expirations are intrinsically different.

[6] Prior work has also analyzed the effects of advertising to physicians on their prescription patterns (Mizik and Jacobson (2004); Manchanda et al. (2008); Dong et al. (2009); Ching and Ishihara (2010); Montoya et al. (2010); Dong et al. (2011); Chintagunta et al. (2012); Datta and Dave (2017); Guo et al. (2020); Carey et al. (2021); Everhart et al. (2022); Grennan et al. (2022); Marquardt and Ryan (2023)).

We proceed as follows. Section 2 provides an overview of the regulatory setting and direct-to-physician advertising. Section 3 describes our data. Section 4 outlines our empirical strategy. Section 5 presents our main results, and Section 6 presents our model of optimal advertising allocation with an application to the market for the treatment of diabetes. Section 7 concludes.

2 Background

2.1 The 340b Drug Pricing Program

The 340b Drug Pricing Program was enacted by Congress in 1992. The intention of the program was to create a new revenue stream for safety-net healthcare providers, which would then allow them to expand service lines and handle a greater volume of patients. Hospitals qualify for the 340b program if they (a) are either non-profit or government-owned, and (b) serve a large share of low-income patients.[7] The second condition requires that hospitals have a disproportionate share adjustment percentage (DSH %) greater than 11.75% on their most-recently filed cost report. This threshold is relaxed to 8% for rural referral centers and sole community hospitals. The DSH % measures the hospital's share of total patient volume that is either covered by Medicaid or covered by Medicare and receiving supplemental security income.

The 340b program requires drug manufacturers that participate in Medicaid to provide outpatient drugs to 340b hospitals at discounted prices. For each drug, the program defines a uniform ceiling price, which sets a cap on the price that firms can charge to 340b hospitals. The ceiling price for each drug is the average price paid by wholesalers as reported to the Centers for Medicare and Medicaid Services (CMS), reduced by a unit rebate amount. The unit rebate amount is set as the sum of a basic rebate and an additional rebate. The basic rebate grants participating hospitals most-favored-nation status: they receive the largest discount granted by the manufacturer to any purchaser.[8] The additional rebate penalizes drugs for raising list prices faster than inflation: each drug must pay an additional rebate equal to the difference between the list price reported to CMS and an inflation-adjusted version of the list price at the time of the drug's initial release.

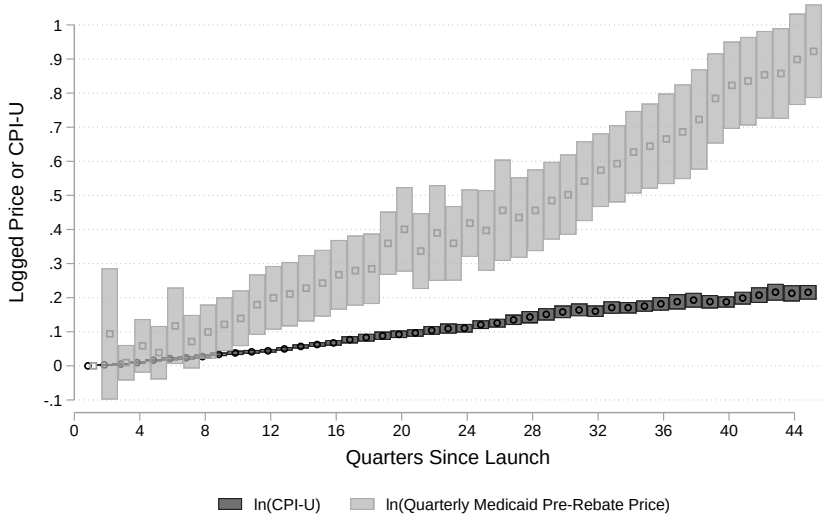
We do not have access to data on the 340b ceiling prices or list prices, which are confidential. However, we can approximate how the inflation penalty evolves over the life-cycle of a drug using the Medicaid State Drug Utilization Data maintained by CMS, which reports quarterly pre-rebate spending and prescriptions by drug for each state.[9] In Figure 1, we show the evolution of pre-rebate prices paid to pharmacies and other providers for 36 diabetes drugs that we observe in our advertising data, which we use as proxy for list prices. Pre-rebate prices increases by roughly 80% on average ten years after launch. In contrast, the Urban Consumer Price Index increased by 20% on average over the same ten-year period. These divergent price series imply that the inflation penalties increase over a drug's lifetime. For example, these series imply that

[7] Qualifying providers also include federally qualified health centers and other specialized clinics. We focus our attention on hospitals, because the other provider types account for a much smaller share of patient volume.

[8] The basic rebate is implemented as the maximum of (1) the difference between the average manufacturer price (AMP) and the lowest price available from the manufacturer during the period to any other purchaser in the US and (2) 23.1% of AMP. The AMP is the average price paid by wholesalers for a given drug, as reported to CMS each quarter. We refer to the AMP as the list price throughout, as we understand that wholesalers play a limited role in determining the prices of branded drugs.

[9] These pre-rebate prices include dispensing fees and any additional pharmacy markups, and thus represent an approximation of the AMP used to determine 340b rebates.

Figure 1: **Evolution of Medicaid Prices and CPI-U for Diabetes Drugs**



Sources: Medicaid State Drug Utilization Data; OpenPayments Data; FDA NDC Database.
Notes: analysis was limited to the diabetes drugs that we identified in the OpenPayments data. Both panels show changes in outcomes relative to the drug's launch quarter. The level of observation in the SDUD is an drug-quarter-year, where the drug is identified based on their ten-digit National Drug Code (NDC). Drugs can have different NDCs for different package sizes. We define a price per unit rather than per prescription to account for different package sizes across NDCs within a drug.

for the average drug, the inflation penalty adds up to nearly $12 per unit (e.g., per dose or pill) five years after a drug's launch, or 19.2% of the average pre-rebate price.

Kakani et al. (2020) use proprietary data on average rebates from 2012-2017 and find that rebates (and thus 340b basic rebates) typically increase over a drug's life-cycle. Combining their findings with the patterns in Figure 1, we expect that overall 340b discounts grow over a drug's life cycle and we use these patterns to interpret our empirical results. In principle, drug manufacturers could adjust their list prices in response to major expansions of the 340b program. We believe it is unlikely that either list prices or negotiated rebates would change in response to the relatively small, regionally-dispersed expansions of the program that we exploit in the empirical analysis. Yet, as we are unable to observe the full 340b discount, we interpret our results as suggestive rather than prescriptive.

The scale and scope of the 340b program have grown rapidly since its inception. In 2019, more than 2,500 hospitals participated in the program and, combined, made nearly $30 billion in outpatient drug purchases through the program (Fein (2020)). In order to take advantage of the program, hospitals must sell drugs to patients either at their facilities or through "contract pharmacies." Contract pharmacies partner with hospitals to dispense drugs purchased through the 340b program. Before 2010, 340b providers were limited to working with a single contract pharmacy. In 2010, the government permitted 340b hospitals to use an unlimited number of contract pharmacies, which enabled them to obtain 340b discounts for more fills of self-administered drugs.[10] The number of retail pharmacies working as a contract pharmacy for 340b

[10]Prior to the change in contract pharmacy policy, many hospitals may have been limited to obtaining 340b discounts on provider-administered drugs, such as cancer treatments that are infused under supervision of a healthcare professional. After the contract pharmacy expansion, hospitals could take advantage of the program for more prescriptions of self-administered drugs, which

providers has grown from fewer than 5,000 in 2010 to nearly 30,000 in 2020 (Mulligan (2021)). 49.9% of Medicare Part D prescriptions written by 340b providers were filled at a contract pharmacies in 2020 (Dickson et al. (2023)); thus, 340b hospitals obtain discounts on a significant share of prescriptions written by their affiliated physicians.

Anecdotal evidence suggests that 340b drug discounts are large and affect producers' markups directly. Drug manufacturers have advocated for reforms of the 340b program, particularly the use of contract pharmacies. Since 2020, at least twelve pharmaceutical firms have announced that they would no longer provide 340b-discounted products to contract pharmacies, leading to litigation between the government and drugmakers (King (2022); Pierson (2023)). These actions suggest that the design of the 340b program significantly reduces the profits earned by pharmaceutical firms. Therefore, the program is likely to change the incentives of pharmaceutical firms to provide effort. We measure effort using data on in-kind transfers from pharmaceutical firms to physicians.

2.2 Physician Payments from Pharmaceutical Firms

Physician detailing constitutes the vast majority of pharmaceutical marketing expenditures: in 2012, more than 85% of the $27 billion spent by pharmaceutical firms on marketing was targeted to physicians (The Pew Charitable Trusts (2013)). As part of their detailing relationships, pharmaceutical firms often make targeted, in-kind transfers to physicians to promote their products. These transfers often take the form of a meal, although pharmaceutical firms may also cover physician expenses for travel, lodging, and professional development. These payments offer an opportunity for pharmaceutical firms to inform physicians about their drugs. As such, we view changes in promotional payments as consistent with changes in the incentives of pharmaceutical firms to provide targeted effort.

From an empirical standpoint, these data on promotional payments, combined with variation in the 340b program across hospitals and time, allow us to infer how profit incentives determine pharmaceutical firms' provision of effort. Notably, we observe differences in promotional effort for the same drug across physicians. Therefore, our setting allows us to contribute to earlier studies of nationally-implemented regulatory or market changes (such as patent expirations), which often involve making comparisons across potentially very different drugs, or studying changes to pharmaceutical firm markups that are correlated with demand shocks.

3 Data

In 2010, Congress enacted the Physician Payments Sunshine Act (hereinafter "the Sunshine Act") as part of the Affordable Care Act. The Sunshine Act required manufacturers of pharmaceuticals and medical devices to disclose all transfers made to physicians and teaching hospitals to CMS. CMS publishes all such records in the publicly available Open Payments (OP) dataset, which we use in our analysis. For every transfer, the OP data identify the firm who made the payment, the physician who received the payment, the dollar amount of the transfer, all products discussed during the meeting, the form of payment (e.g., cash or

consumers obtain through a retail pharmacy. These self-administered drugs are the largest advertisers to physicians in our data.

cash equivalent, in-kind items and services), nature of payment (e.g., food and beverage, travel and lodging), and the date of the payment.

We combine the OP data with information on drugs, physicians, and hospitals. To identify the release date of each drug, we combine the information in the OP data with the National Drug Code database maintained by the US Food and Drug Administration. Our universe of physicians comes from the CMS National Downloadable File data for 2014 to 2019, which includes information on physicians' practice specialties and hospital affiliations. We assign each physician to a hospital in each year based on their first listed hospital affiliation in the National Downloadable File for that year, which we understand represents their "primary" hospital affiliation. In most of our analyses, we exclude physicians who were not affiliated with a hospital, and aggregate payments up to the hospital-level to be consistent with the variation in 340b participation.

Our hospital information comes from three sources: (1) the CMS Hospital Cost Reporting Information System, (2) the CMS Provider of Services data, and (3) the Health Resources and Services Administration Office of Pharmacy Affairs Covered Entity and Contract Pharmacies data. The first dataset details the facility type, disproportionate share percentage (DSH %), beds, rural status, program participation, and tax status (for-profit vs. non-profit). The second dataset provides information on the hospital's location. The third dataset contains information on 340b program participants (commonly referred to as "covered entities") separately for each hospital, including participation history and the identities of all contract pharmacy relationships. We define a hospital as participating in the 340b program in a given quarter if the hospital or any of its affiliated outpatient clinics were participating in the program.

3.1 Sample and Summary Statistics

The OP data are available from January 2014 through December 2019. Consistent with prior research, we focus on records of food and beverage payments, which capture over 90% of payments in the data (Lawler and Skira (2022); Grennan et al. (2021)).[11] We restrict our sample to physicians who were affiliated with hospitals, and to hospitals that appear in the data in every year 2014-2019 in order to avoid detecting changes in physician payments due to closures. The treatment variation is at the hospital level so our analyses aggregate the data across physicians to the hospital level. Our analyses focus on short-term general acute care hospitals, sole community hospitals, and rural referral centers. We provide more information in the data appendix.

Table 1 summarizes physician payments from pharmaceutical firms separately for 2014q1 and 2019q1. Roughly 92% of the 2 million promotional payments per quarter came in the form of a meal, worth an average of about $20 per meal. Pharmaceutical representatives may discuss multiple drugs during a single detailing visit: 27% of the transfers in our data list more than one product. For our analyses at the hospital level of observation, we count a payment only once, regardless of the number of products associated with the payment. For our product-level analyses, we count a payment once for each product associated with the payment.

[11] Other papers, such as Agha and Zeltzer (2022), include non-meal payments because they study industry relationships beyond product promotion.

Table 1: **Physician Payments Summary Statistics**

	2014q1	2019q1
Total Number of Payments	2,019,870	1,912,232
Total Meal Payments	1,847,479	1,769,174
$ per Meal	19.56	20.37
Number of Advertising Drugs	1,154	1,189
Avg. # of Payments per Drug	2,260.5	1,925.9
	(7,566.5)	(5,721.1)
% of Payments by Top 207 Drugs	0.780	0.732
Avg. # of Payments per Top Drug	12,960.4	8,872.0
	(16,673.5)	(11,905.2)
Number of Advertising Firms	225	292
% of Payments by Top 70 Firms	0.954	0.903
Avg. Number of Drugs in Top Firm Portfolio	12.47	12.64
	(13.7)	(12.7)

We observe payments related to 1,154 drugs in the first quarter of 2014; however, the vast majority of payments come from a subset of high-advertising drugs in the data. When looking at heterogeneous effects across drugs, we focus on a sample of 207 "top" drugs, which account for around 75% of payments.[12] The average "top" drug made 12,960 payments in 2014q1. The vast majority of these top drugs are branded drugs that enjoy patent protection during our study period: based on online research, we identified 36 of our top drugs that lost a patent in 2019 or earlier.[13] We observe 225 pharmaceutical firms making payments in 2014q1, and we focus on the top 70 firms, which account for over 90% of food and beverage payments. These firms promote roughly 12 different drugs in a given quarter.

4 Empirical Strategy

4.1 Estimation

We exploit variation in 340b participation across time and hospitals in a difference-in-differences framework to examine how pharmaceutical firms adjust their advertising strategies in response to drug pricing regulations. We perform analyses at three levels of aggregation. Our hospital-level estimating equation is

$$Payments_{ht} = \beta 340b_{ht} + \alpha_h + \alpha_t + \varepsilon_{ht}, \tag{1}$$

[12] We subset the data in this manner because we may not be able to identify an effect of the 340b program on advertising for drugs that either do not advertise regularly during our data sample or make few payments. Our sample consists of the top 200 drugs based on average quarterly promotional payment volume, plus all diabetes drugs regardless of their level of advertising. This definition left us with 207 drugs - the top 200 drugs plus seven additional diabetes drugs.

[13] In these 36 drugs we also include drugs that continued to enjoy some degree of patent protection or launched a new reformulation.

where $Payments_{ht}$ is the number of payments from pharmaceutical firms received by physicians at hospital h in quarter t, $340b_{ht}$ is an indicator variable equal to one in all quarters in which hospital h participated in the 340b program, and α_h and α_t are hospital and time fixed-effects. We also estimate an event study version of Equation (1):

$$Payments_{ht} = \sum_{l=-8}^{8} \beta^l D_{ht}^l + \alpha_h + \alpha_t + \varepsilon_{ht}, \tag{2}$$

where D_{ht}^l is an indicator that is equal to one if and only if hospital h is l quarters from taking up the 340b program at time t. We estimate Equation (1) and Equation (2) using the estimator from Callaway and Sant'Anna (2021) to account for staggered timing in the adoption of the 340b program.

To control for firm-specific trends, we also estimate versions of Equation (1) and Equation (2) at the hospital-firm-level:

$$Payments_{hft} = \beta 340b_{ht} + \alpha_{hf} + \alpha_{tf} + \varepsilon_{hft}, \tag{3}$$

$$Payments_{hft} = \sum_{l=-8}^{8} \beta^l D_{ht}^l + \alpha_{hf} + \alpha_{tf} + \varepsilon_{hft}, \tag{4}$$

Finally, to control for drug-level trends, we estimate these regressions at the hospital-drug level:

$$Payments_{hfdt} = \beta 340b_{ht} + \alpha_{hfd} + \alpha_{tfd} + \varepsilon_{hfdt}, \tag{5}$$

$$Payments_{hfdt} = \sum_{l=-8}^{8} \beta^l D_{ht}^l + \alpha_{hfd} + \alpha_{tfd} + \varepsilon_{hfdt}, \tag{6}$$

Given the design of the inflation penalties described in Section 3, we expect that firm responses to the 340b program will vary across drugs. Therefore, we examine the potential heterogeneity in responses across drugs by estimating Equation (5) separately for each drug. We use these drug-specific estimates in a case study of the diabetes market, where we compare the responses of firms across drugs in the same treatment area.

4.2 Selecting Treatment and Control Hospitals

Our treatment group includes 115 hospitals that began participating in the 340b program for the first time between January 2016 and March 2018. We focus on hospitals gaining status during this period because the OP data cover 2014-2019, and we want to observe a hospital for at least two years before and after treatment. There are 1,575 hospitals that did not participate in the 340b program at any point between 2014-2019. In order to study hospitals with roughly similar patient populations, our main control group focuses on the 287 hospitals that were eligible for the 340b program in at least one quarter but never participated during this time period.[14] We check that our results are robust to alternative control group definitions in Table A.2.

[14] We exclude hospitals that were in the 340b program for the entirety of our sample ("always-treated" hospitals). Table A.1 presents the same summary statistics from Table 2 but for the 890 always-treated general acute care (GAC) hospitals that are active in all quarters 2014-2019. The always-treated hospitals are slightly larger than our treatment hospitals, but write fewer Part D prescriptions and serve lower-income patient populations as measured by the DSH %. We also exclude hospitals that experienced a lapse in 340b participation ("sometimes-treated" hospitals). There are 228 hospitals that we manually identified as experiencing a lapse in 340b participation, likely because they were unable to meet the qualification criteria.

Table 2 displays summary statistics for the first quarter of 2014 for treatment and control hospitals. Hospitals that gain the 340b status during our sample period tend to be larger in terms of the number of beds and the number of employed medical professionals relative to the set of control hospitals. After controlling for size, our treatment and control hospitals are roughly similar in terms of the amount of detailing payments and prescriptions. In addition, our empirical analyses control for differences in levels using hospital fixed effects.

Table 2: **Hospital-Level Summary Statistics, 2014q1**

	(1) Treatment		(2) Control		(3) Difference		
	Mean	SD	Mean	SD	Difference	SE	P-Value
# of Professionals	237.91	283.68	99.73	148.47	-138.18	21.71	0.000
# of Beds	246.44	283.26	104.86	126.12	-141.57	20.42	0.000
# of Part D Prescriptions per Professional	3835.88	3422.18	3405.16	2475.52	-430.71	306.63	0.161
# of Detailing Payments per Professional - Drugs	2.87	2.07	2.43	2.42	-0.44	0.26	0.088
# of Detailing Payments per Professional - Device	0.43	0.28	0.37	0.48	-0.07	0.05	0.168
DSH %	0.15	0.41	0.15	0.18	-0.01	0.03	0.854
Rural Hospital	0.30	0.46	0.38	0.49	0.09	0.05	0.098
Observations	115		287		402		

4.3 Identification

Our primary identifying assumption is that advertising to physicians at treatment hospitals would have followed the same trend as control hospitals absent their take-up of the 340b program.[15] We also make the standard assumptions from Callaway and Sant'Anna (2021) that treatment is irreversible and that it does not affect outcomes in periods before the hospitals join the 340b program. We face three potential threats to identification. First, take-up of 340b may be correlated with other important changes at the hospital that independently affect the advertising incentives of pharmaceutical firms. Second, take-up of the 340b program may have spillover effects on firms' advertising incentives at non-340b control hospitals. Finally, pharmaceutical firms may anticipate the uptake of the program by a hospital and adjust their effort in advance. We describe each of these concerns below.

Take-up of the 340b program may be correlated with factors that affect both hospital selection into the program and the advertising intensity of pharmaceutical firms at those hospitals. For example, hospitals may join the program due to financial distress or after a restructuring, which may independently lead to a change in payments from pharmaceutical firms. Conversely, newly-designated 340b hospitals may strategically adjust their patient mix or use the revenue generated by the 340b program to acquire more physician practices and expand healthcare offerings, which could lead to changes in promotional payments.[16] The first scenario challenges our identifying assumptions, while the second scenario primarily changes the interpretation of our results from the effects of price regulation on promotional effort to the effects of the 340b program more broadly.

[15] Analogously, for the firm- and drug-level specifications: we assume that payments for a given firm (drug) would follow parallel trends at newly 340b hospitals and control hospitals absent the treatment.

[16] For example, Desai and McWilliams (2018) shows that 340b participation is associated with ownership of more outpatient oncology clinics, and Han (2018) shows that the 340b program allows hospitals to better meet operating expenses.

We evaluate these concerns in several ways. First, we use payments from medical device manufacturers as a placebo group. These products are not covered by the 340b program and medical device firms do not sell drugs. If hospitals take up the 340b program because they are in financial distress or, conversely, because they plan to expand their operations, we should observe that medical device manufacturers will adjust their promotional activity at treated hospitals, because those changes will affect their returns to advertising as well. Changes in the advertising strategies of medical device manufacturers would suggest that take-up of the 340b program was correlated with other important changes at the hospital.

As mentioned above, treated hospitals may change their physician and patient mix after taking up the program, which may change firms' returns to advertising separately from the pricing regulation. We repeat our analyses with added controls for time-varying hospital level covariates using the estimator from Sun and Abraham (2021) and confirm that our results do not change when we control for changes in a hospital's patient mix (using the DSH %), the size of the hospital (using total hospital beds), and the number of physicians affiliated with the hospital.[17]

The concerns above imply that hospital-level changes may be correlated with take-up of the 340b program, leading to possible changes in advertising. However, these structural changes should imply similar adjustments by a pharmaceutical firm within the same drug class. Therefore, we also conduct a case study that focuses on a single drug category: drugs used to treat diabetes. This case study allows us to evaluate strategic reallocation of effort across drugs within a narrowly defined treatment area for which confounding hospital-level changes should have similar effects for firms' advertising strategies.[18]

The second potential threat to identification is that firms may respond to 340b take-up by reallocating advertising effort across hospitals, causing expansions of the 340b program to have spillover effects on non-340b hospitals and violating the identification assumptions of our difference-in-differences estimator. If pharmaceutical firms shift payments from newly-designated 340b hospitals to non-340b control hospitals, then our coefficients would be biased away from zero. If they adjust advertising in the same direction at both newly-designated 340b hospitals and non-340b control hospitals, then our coefficients would be biased towards zero. To evaluate this possibility, we re-run our regressions after excluding control hospitals in the same Hospital Service Area as treatment hospitals.[19] If there are any spillover effects of 340b participation, they are most likely to affect hospitals located near newly designated 340b hospitals. The third concern relates to pharmaceutical firms anticipating take-up of the 340b program by hospitals. The event study specifications provide graphical evidence that that trends in physician payments were similar for treated and

[17] The Callaway and Sant'Anna (2021) estimator does not allow for time-varying covariates, but it does allow for heterogeneity in the treatment effects. We rely on the Callaway and Sant'Anna (2021) for our main analysis because we believe the treatment effects to be heterogeneous across drugs, and we use the Sun and Abraham estimator for robustness checks.

[18] We acknowledge that we may not completely dismiss unobservable changes after the 340b take-up. For example, if changes in patient mix influence physicians' demands in way that increases returns to physician payments for newer diabetes drugs and decreases returns for diabetes drugs that have been on the market for more than 4-5 years, then these unobservables may also be driving our results separately from the price cap mechanisms described in this paper.

[19] Hospital Service Areas are sets of zipcodes whose Medicare residents receive most of their hospitalizations at hospitals located in that area (Dartmouth Atlas). It is possible that the spillover effects of 340b participation may be more geographically dispersed. For example, a pharmaceutical firm may decide to shift advertising from one region to another in response to growth in the 340b program. This adjustment would violate the parallel trends assumption of our difference-in-difference analysis. We cannot confirm whether these cross-geography re-optimizations of marketing effort affect our results because we do not observe the identity of the pharmaceutical marketing reps that make each payment (only their firm).

control hospitals in the quarters prior to the adoption of the program.

A limitation of our data is that we do not observe firms' advertising efforts to physicians that are not connected to an in-kind transfer. Thus, one may worry that pharmaceutical firms may substitute away from physician payments at newly 340b hospitals to other, non-payment forms of detailing, such as mailing, phone calls, or free samples. While other papers have more complete data on the detailing relationships between certain drug manufacturers and physicians that capture non-payment advertising, such data are typically restricted to one class of drugs or to physicians practicing outside of the United States (e.g., Manchanda et al. (2008); Dong et al. (2009); Narayanan and Manchanda (2009); Ching and Ishihara (2010); Dong et al. (2011); Ching and Ishihara (2012); Liu et al. (2016)). These detailed data are important for understanding the effects of promotion to physicians on their prescription patterns. The OP dataset is ideal for our study because it spans all drugs and allows us to make comparisons both across *and* within drugs and manufacturers. If the decrease in in-kind payments is associated with a substitution to non-payment forms of detailing, our results would still present evidence of pharmaceutical firms shifting effort towards (presumably) lower-value forms of advertising. We do not expect the adoption of the program by the hospitals in our sample to affect untargeted physician advertising, such as direct-to-consumer advertising. We understand that these marketing choices are typically made on a national rather than regional scale.

5 Results

5.1 Effects of 340b on Advertising

Table 3 presents the hospital-level regression results for Equation (1). We observe that physicians receive about 44 fewer drug advertising payments per quarter from pharmaceutical firms after their affiliate hospital joins the 340b program, a 12% decrease off of the sample mean. The second column excludes control hospitals in the same HSA as treatment hospitals to account for potential spillovers. The estimate is nearly unchanged between the two columns, which suggests that any spillovers have a minimal effect on our results. We continue to detect decreases in advertising as we loosen our control group definition to include all non-340b hospitals, reported in Table A.2.

A concern for interpreting our results is that selection into 340b may be correlated with other changes at the hospital (e.g., financial distress, merger, or changes in the physician or patient mix after the take-up) that affect pharmaceutical firms' advertising. We use a placebo exercise to assess whether the decrease in promotional payments for drugs may have been driven by these structural changes. Medical devices and supplies are not subject to 340b discounts. If 340b discounts are driving our main results, we would not expect changes in promotional activities for these products at newly-designated 340b hospitals. Column 3 of Table 3 reports results of estimates for this placebo regression. Reassuringly, we find no effect of 340b participation on advertising by medical device and supply manufacturers.

Table 4 presents the firm- and drug-level regression results from Equation (3) and Equation (5). We estimate the firm-level regressions for a sample of the 70 largest pharmaceutical firms, and estimate the drug-level regressions for the sample of 207 top drugs in the OP sample. On average, pharmaceutical firms reduce payments by 0.72 per quarter when a hospital takes up the 340b program, corresponding to a 11.8%

decrease. The effects are slightly larger for our sample of top drugs: firms make 0.452 fewer payments per drug per quarter to physicians affiliated with newly 340b hospitals relative to physicians affiliated with non-340b hospitals, which corresponds to a 18.2% decrease.

Table 3: **Effect of 340b Participation on Quarterly Physician Payments, Hospital-Level**

	Drugs	Drugs, No Spillovers	Medical Devices and Supplies
340b	–43.9***	–46.7***	2.37
	(16.7)	(16.7)	(3.13)
Observations	9,648	9,168	9,648
Sample Average	353	354	64.3

Notes: Standard errors in parentheses are clustered by hospital. Regressions were estimated using Callaway and Sant'anna (2021) to account for staggered treatment timing. We report the average treatment effect on the treated for all treatment cohorts across all treatment periods. * p<0.10, ** p<0.05, *** p<0.01

Table 4: **Effect of 340b Participation on Quarterly Physician Payments, Drug- and Firm-Level**

	Firm-Level	Drug-Level
340b	–0.724***	–0.452***
	(0.130)	(0.0524)
Observations	518,594	1,517,725
Sample Average	6.09	2.49

Notes: Standard errors in parentheses are clustered by hospital-drug for drug-level regressions and hospital-firm for firm-level regressions. Regressions were estimated using Callaway and Sant'anna (2021) to account for staggered treatment timing. We report the average treatment effect on the treated for all treatment cohorts across all treatment periods. * p<0.10, ** p<0.05, *** p<0.01

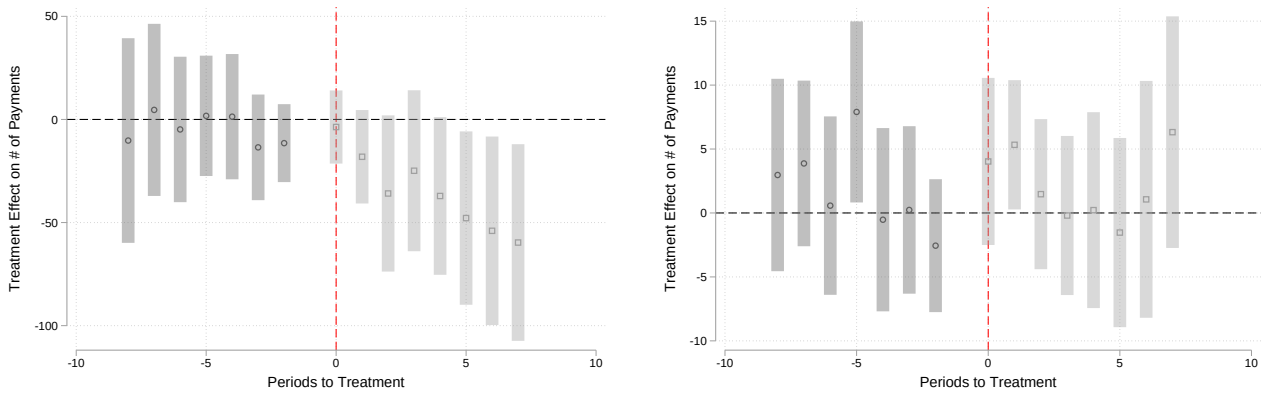
5.2 Event Studies

Figure 2 presents the event study versions of the hospital-level regressions from Equation (2). The event studies demonstrate that promotional payments for both drugs and devices/supplies were trending similarly at treatment and control hospitals prior to the treatment.[20] Promotional payments gradually decline following take-up of the 340b program. These gradual adjustments may be explained by the increased use of contract pharmacies after becoming a 340b hospital. Hospitals can take advantage of the steep discounts if they sell the drugs to patients either at their facility or through contract pharmacies. Developing a network of contract pharmacies to dispense prescription drugs takes time. For example, we observe that our treated hospitals gradually increase their number of contract pharmacy relationships after joining the 340b program.[21] Figure 3 shows the average number of contract pharmacy relationships in each quarter

[20] Figure A.1 reports estimates from Equation (2) using the Sun and Abraham (2021) estimator, which also allows us to confirm the robustness of our estimates when accounting for time-varying hospital covariates.

[21] Some hospitals may already have "in-house" retail pharmacies when they join the 340b program, which would allow them to scale up their utilization of the program immediately after take-up. We do not have access to data that would allow us to determine whether a hospital had an in-house pharmacy. However, less than 5% of 340b covered entities had an in-house pharmacy when the 340b program launched in 1992 (Mulligan (2021)).

Figure 2: **Event Study of 340b Participation on Quarterly Physician Payments, Hospital-Level**

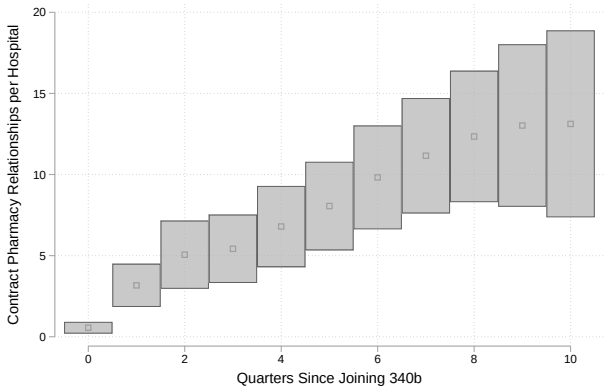


(a) Drugs (b) Medical Devices and Supplies Placebo

Notes: Standard errors are clustered by hospital. All specifications include hospital and year-quarter fixed effects. Regression was estimated using Callaway and Sant'anna (2021) to account for staggered treatment timing. We report the average treatment effect on the treated across all treatment cohorts relative to the quarter before treatment.

following take-up of the 340b program for our treatment hospitals. As hospitals expand their contract pharmacy network, one expects that a larger share of prescription fills are shifted towards the discounted price, decreasing the average margin for drugs prescribed by 340b physicians. Therefore, the increase in contract pharmacies over time implies a decrease in average margins at 340b hospitals over time, which explains the gradual decrease in effort towards our set of treated hospitals.

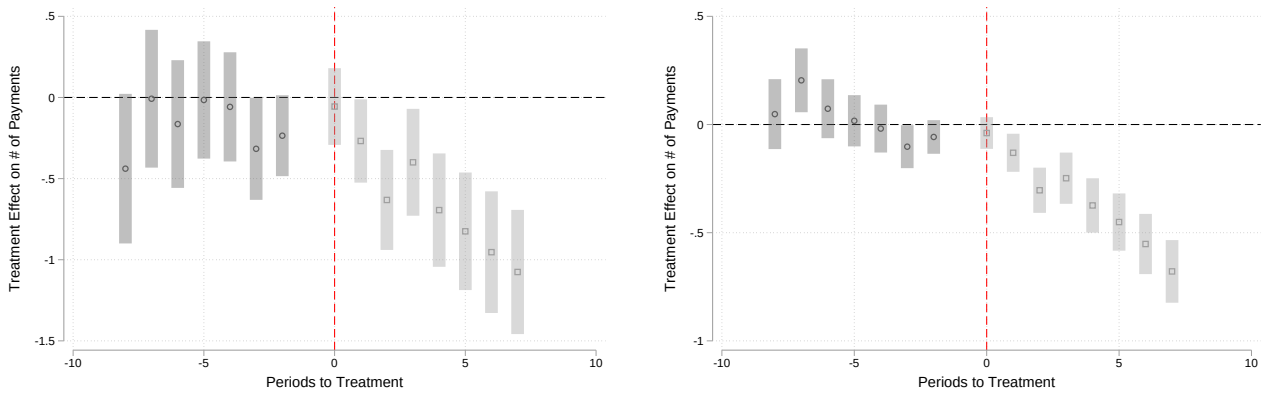
Figure 3: **Utilization of Contract Pharmacies by Treatment Hospitals**



Sources: HRSA OPAIS data. Notes: this graph shows the average number of contract pharmacy relationships in each quarter following take-up of the 340b program for our treatment hospitals. The grey bars represent 95% confidence intervals.

For completeness, Figure 4 presents the firm- and drug-level event studies from Equation (4) and Equation (6), which again demonstrate that payments were trending similarly at treatment and control hospitals prior to 340b take-up, even within a pharmaceutical firm or drug. One concern may be that the decreases in promotional payments for older drugs are driven by the entry of generic competitors. The vast majority of the drugs in our top drug sample are branded drugs that enjoyed patent protection for the entirety of our

Figure 4: **Event Study of 340b Participation on Quarterly Physician Payments**



(a) Firm-Level (b) Drug-Level

Notes: Standard errors are clustered by hospital-firm or hospital-drug. Firm-level specifications include hospital-firm and year-quarter-firm fixed effects. Drug-level specifications include hospital-drug and year-quarter-drug fixed effects. Regression was estimated using Callaway and Sant'anna (2021) to account for staggered treatment timing. We report the average treatment effect on the treated across all treatment cohorts relative to the quarter before treatment.

study period. Regardless, generic entry should not drive our results as long as that entry has similar effects on promotional payments for the same drug across our treatment and control hospitals, because our regression has drug-hospital and drug-quarter fixed effects. To confirm that our results are not driven by changes in patent protection for our sample of drugs, Figure A.2 shows the same drug-level event study but excluding the 36 drugs for which we identified a patent expiration in 2019 or earlier based on online research. The results are virtually unchanged, providing further confidence that 340b take-up and not confounding drug-specific events drive our findings.

5.3 Drug-Level Heterogeneity

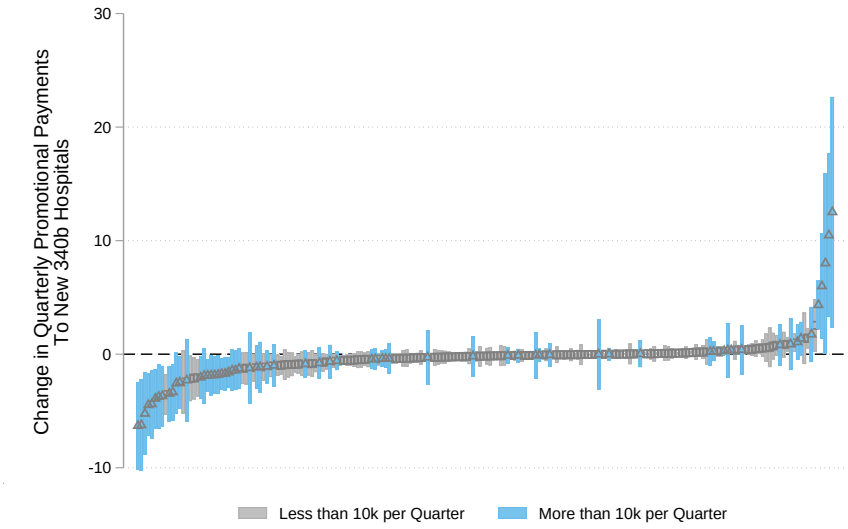
The 340b program reduces the markups pharmaceutical firms receive for outpatient drugs dispensed by participating physicians; hence, a drop in firm effort is expected. However, the size of the discounts mandated by the 340b program vary across drugs (e.g., due to the inflation penalties), which suggests that advertising responses to the 340b program may also vary across drugs. For example, drugs facing large discounts should respond by reducing advertising, but drugs facing smaller discounts may want to maintain or increase advertising.

Figure 5 presents the distribution of drug-level treatment effects from Equation (5).[22] While many drugs reduce their promotional payments, a few drugs increase payments to newly designated 340b hospitals. We highlight drugs with more than 10,000 quarterly promotional payments on average in blue to demonstrate that many of the null effects come from drugs that do not make many promotional payments during our sample period.

In Section 2, we noted that the 340b program should prompt the greatest reductions in advertising effort for older drugs because they are subject to the largest discounts due to the inflation penalty built into the 340b

[22]Figure A.3 presents the distribution of firm-level treatment effects from Equation (3).

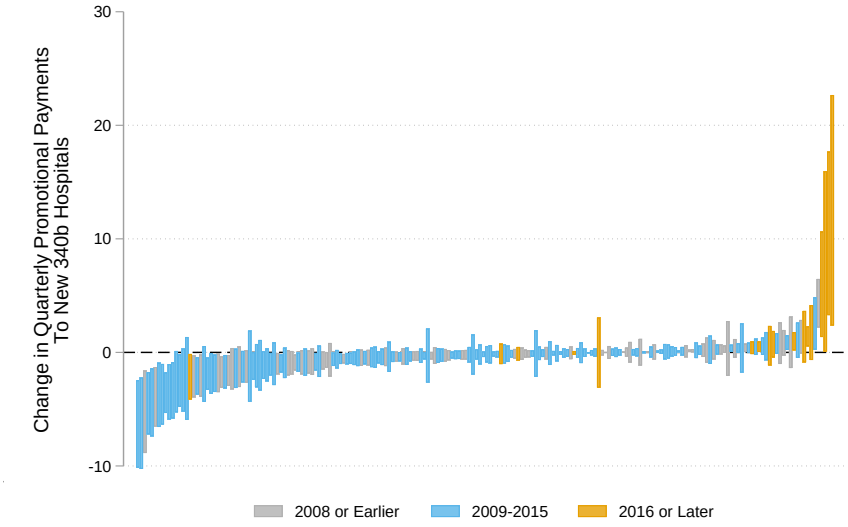
Figure 5: **Distribution of Drug-Level Treatment Effects**



Note: the bars represent 95% confidence intervals.

program. In Figure 6, we highlight drugs based on their FDA release date. Consistent with our prediction, the drugs with the largest reductions in promotional payments were all launched before 2015. Importantly, most of the drugs with *increases* in advertising to physicians at newly accredited 340b hospitals are new drugs that were launched in 2016 or later.

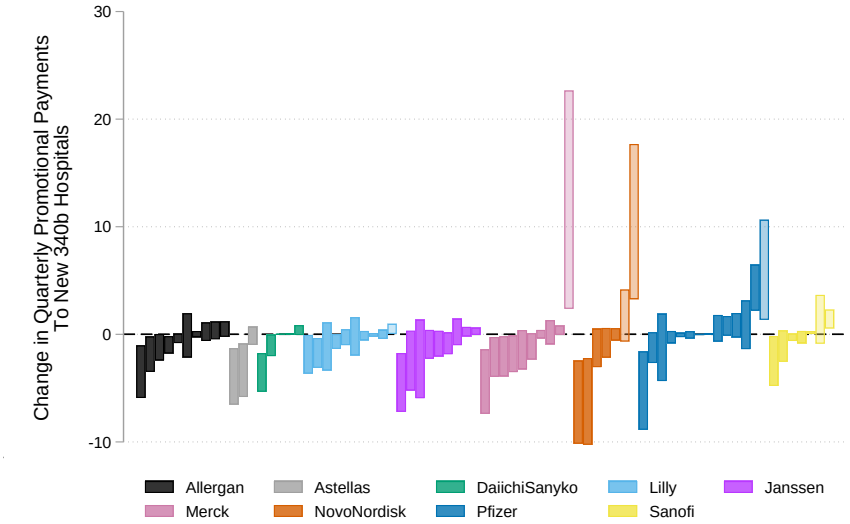
Figure 6: **Distribution of Drug-Level Treatment Effects, Highlighting by Release Date**



Note: the bars represent 95% confidence intervals. We determine each drug's release date using the FDA NDC Database.

We next show how these adjustments differ within multi-product firms. Figure 7 presents the drug-level estimates grouped by firm for the nine largest pharmaceutical firms. Consistent with our earlier findings,

Figure 7: **Within-Firm Heterogeneity by Drug**



Note: the bars represent 95% confidence intervals. Transparent bars represent drugs launched in 2016 or later. See Figure A.4 for a version with labels identifying each drug.

pharmaceutical firms typically reduce promotional effort for most of their products. However, we observe increased advertising at 340b hospitals for some drugs, consistent with re-optimization of promotional effort across drugs. We again find that firms shift promotional effort away from older drugs and towards new drugs: Figure 7 denotes drugs launched in 2016 or later using transparent bars.

While our headline finding that firms reduce promotional effort is expected, this reallocative effect is not a consequence of price caps on their own, but is instead a result of variation in the size of the 340b discounts across drugs. To provide a foundation for understanding how the design of the 340b program affects the advertising incentives of firms and illustrate conditions under which price regulation can induce greater promotional effort, we use a stylized theoretical model to show how a multi-product firm would shift effort across its products. Then, we undertake a case study of the market for drugs used to treat diabetes in order to analyze how these incentives can manifest in promotional payments to physicians.

6 Optimal Advertising Effort

6.1 A Model of Firm Advertising Effort

We introduce a stylized model to illustrate how price regulation changes the incentives of pharmaceutical firms to exert effort. Our empirical analysis exploits small, local expansions of the program, while prices are set nationally. As a result, the theoretical model takes prices as given and allows firms to optimize advertising effort in response to mandated discounts. We allow regulation to affect markups differently across drugs and show that this heterogeneity induces corresponding adjustments to advertising across drugs.

Given the patterns in Figure 7, we focus on a simple setting of a single multi-product monopolist. The

firm sells two differentiated drugs $j \in \{1,2\}$ and its profits are defined as:

$$\Pi(\mathbf{p},\mathbf{a}) = \sum_{j=1,2} D_j(\mathbf{p},\mathbf{a})(p_j - c) - A(a_j), \tag{7}$$

where $D_j(\mathbf{p},\mathbf{a})$ is demand for drug j (which depends on the prices and advertising levels of both drugs), c is the marginal cost of production, and $A(\cdot)$ is the firm's advertising cost function. We consider a static one-period game: the firm simultaneously chooses advertising levels a_j for both products, taking prices p_j as given. Maximizing Equation (7) with respect to a_j provides the first order conditions that determine equilibrium advertising levels:

$$\sum_{k=1,2} \frac{\partial D_k}{\partial a_j}(p_k - c) = \frac{\partial A(a_j)}{\partial a_j}. \tag{8}$$

This optimality condition demonstrates that advertising of drug j depends on both its own markup and the markup of the other drug k. When a hospital joins the 340b program, the firm faces mandated discounts that lower the prices for both of its drugs. Given these new prices, the firm would likely re-optimize its advertising intensities. The advertising response of drug j depends on two factors: the post-regulation prices for both drugs and the cross-ad effects $\frac{\partial D_k}{\partial a_j}$. Consider the case where the 340b-mandated discount for drug k is larger than that of drug j. If $\frac{\partial D_k}{\partial a_j} < 0$, then the firm may want to increase advertising for drug j if its markup is sufficiently larger than drug k's. This strategy may be optimal because advertising for drug j can be used to divert sales from the less profitable drug k. In contrast, if $\frac{\partial D_k}{\partial a_j} \geq 0$, such that advertising for drug j has positive spillovers on drug k, then the firm will not increase post-regulation advertising for drug j.

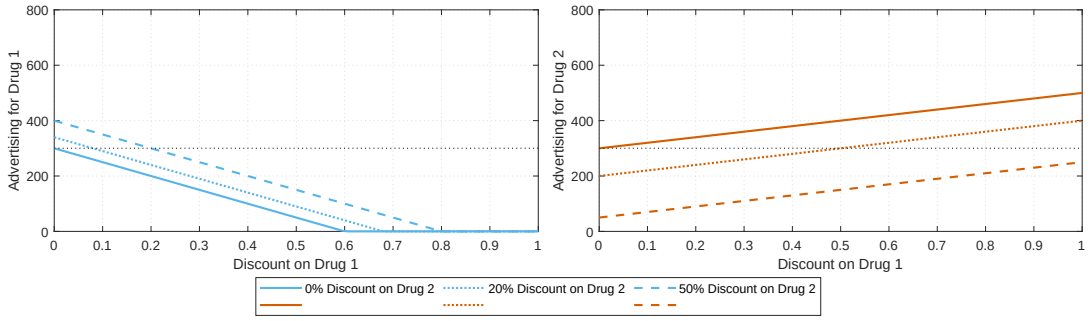
A numerical simulation helps us to illustrate these points. We use a linear demand function described as:

$$q_j = \gamma + \beta_1 p_j + \beta_2 p_k + \beta_3 log(a_j) + \beta_4 log(a_k). \tag{9}$$

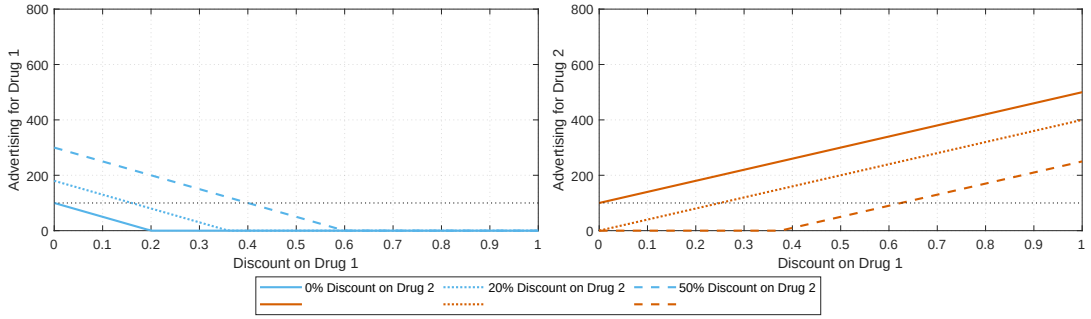
First, we set prices and parameter values for the two drugs such that, absent 340b discounts, the "pre-discount" advertising levels of the two products are symmetric. Then, we plot how optimal advertising changes as the discounts for each drug increase. The graphs in Figure 8 plot the optimal advertising levels (a_1, a_2) plotted on the y-axis and the discount set by the 340b program for drug 1 on the x-axis. In each graph, we plot three lines that vary the discount for drug 2 to be 0%, 20% and 50%. We focus on the response of drug 1, shown in the left panels and optimal advertising for drug 2 is plotted in the right panels for completeness. The horizontal black dotted line denotes the firm's optimal level of advertising absent price regulation; that is, optimal advertising levels above that line indicate an increase in advertising relative to the advertising level chosen without the government mandated discounts. We consider three different cases to illustrate when price regulation may lead to increases or decreases in the advertising levels of both drugs.

The first panel shows the scenario where we set $\gamma = 1000, \beta_3 = 5$, and $\beta_4 = -2$, such that the cross-ad effect $\frac{\partial D_k}{\partial a_j}$ is negative. As expected, we see that advertising decreases as the drug faces higher discounts. We also see the expected increasing relationship between advertising and the discount of the other drug (because $\frac{\partial D_k}{\partial a_j} < 0$). Comparing across the three lines in panel (a), we see that there are values for which

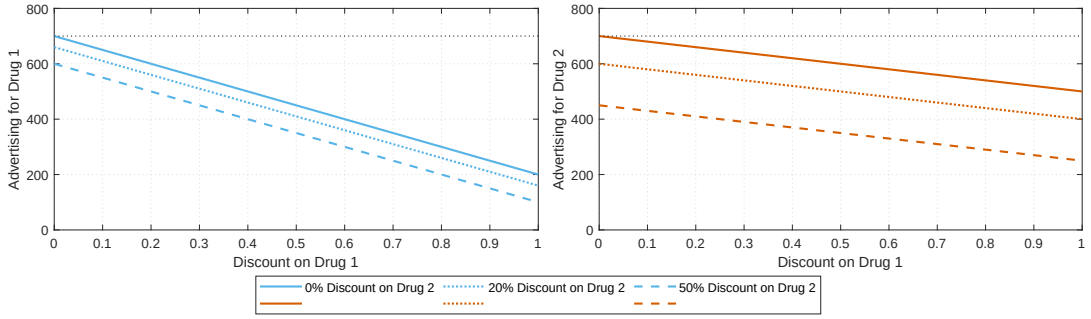
Figure 8: **Model Simulation**



(a) Base Case ($\beta_3 = 5, \beta_4 = -2$)



(b) Increase Cross-Ad Effect ($\beta_3 = 5, \beta_4 = -4$)



(c) Positive Cross-Ad Effect ($\beta_3 = 5, \beta_4 = 2$)

Note: we parameterize demand for good j as $D_j = \gamma_j + \beta_1 p_j + \beta_2 p_{-j} + \beta_3 log(a_j) + \beta_4 log(a_{-j})$. In equilibrium, $a_j = \beta_3 p_j - \beta_4 p_{-j}$. We set $\gamma_j = 1000 \beta_1 = -0.5, \beta_2 = 0.25, p_1 = p_2 = 100$ in all simulations. The left panels depict how advertising for drug 1 depends on the discount on drug 1. The right panels depict how advertising for drug 2 depends on the discount on drug 1.

the advertising for drug 1 is higher than its advertising absent the price caps. These patterns rationalize the increases in advertising estimated in Section 5: when drug 1's discount is sufficiently small relative to drug 2's discount, the firm may prefer to increase advertising for drug 1 in order to divert demand to the more profitable product, even if the level of its markup has decreased. For example, when drug 2 faces a 50% discount, we see that drug 1 increases advertising above pre-cap levels as long as its discount is less than 20%.

The other two panels of Figure 8 show how these reallocation effects change as the substitution between the two drugs changes. In our simple setting, which keeps prices fixed, we capture substitution between the two drugs with $\frac{\partial D_k}{\partial a_j}$. In panel (b), we allow that drugs may be more substitutable by changing the β_4 parameter from -2 to -4, such that the cross-ad effects are stronger. While the stronger cross-ad effect leads to lower levels of optimal advertising regardless of the discounts, we also show that the incentives to shift advertising towards the more profitable drug increase with the substitutability between the two products. For example, when drug 2 faces a discount of 50%, drug 1 increases advertising as long as its discount is less than 40%.

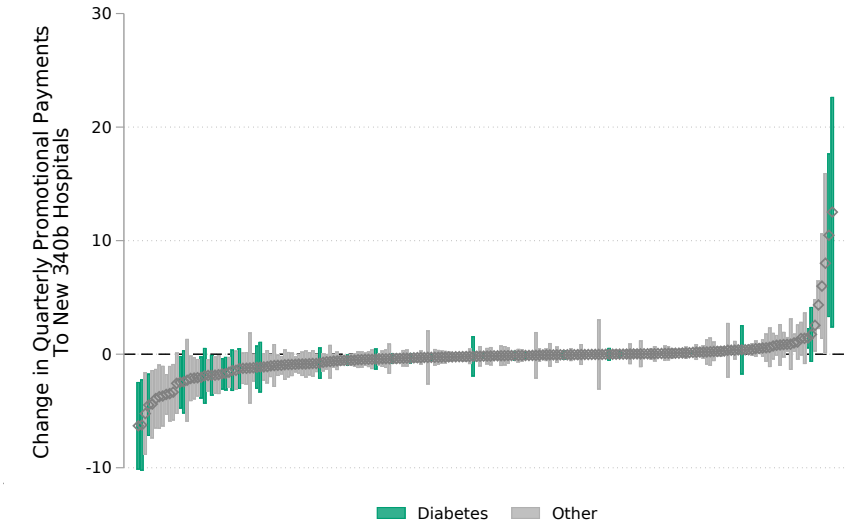
Panel (c) shows the changes in advertising exposure when advertising induces positive spillovers in demand.[23] We set $\beta_4 = 2$ and see that optimal advertising is highest in the case of positive spillovers, regardless of the discounts. As expected, the firm reduces advertising for drug 1 when drug 2 faces a discount, because advertising for drug 1 also increases demand for the less profitable drug 2.

The discussion above showed how differential price caps affect firm effort through their *direct impact* on markups. One may speculate that differences in price discounts may also change the returns to adverting to physicians. For example, differences in discounts may change how physicians substitute across drugs, because, say, hospitals promote the use of the older drugs that are more profitable to them. If these hospital promotion activities act as substitutes to physician payments, then this *indirect mechanism* will also imply a similar pattern of re-optimization in firm effort to the one described above. Building up on this idea, one may also see increased advertising after price regulation that is driven by competition across firms. If two firms face different discounts, then the higher priced drug may find it optimal to increase its advertising to compensate for its price disadvantage from the perspective of the physician (and hospital). That is, both firm competition and optimal advertising choices of a multi-product firm are consistent with our empirical findings.

While highly stylized, this model captures the key incentives faced by pharmaceutical firms when determining their advertising strategies under price regulation. Mandated price caps reduce incentives for firms to provide effort. However, differential exposure to discounts across drugs will sometimes entice pharmaceutical firms to shift promotional effort from less profitable drugs to more profitable ones. This incentive will be strongest when there are large disparities in the discounts and when physicians view the drugs in the firm's portfolio as highly substitutable.

[23] Shapiro (2018) identifies positive spillovers of detailing in the context of anti-psychotic drugs.

Figure 9: **Distribution of Drug-Level Treatment Effects, Highlighting Diabetes Drugs**



Note: the bars represent 95% confidence intervals.

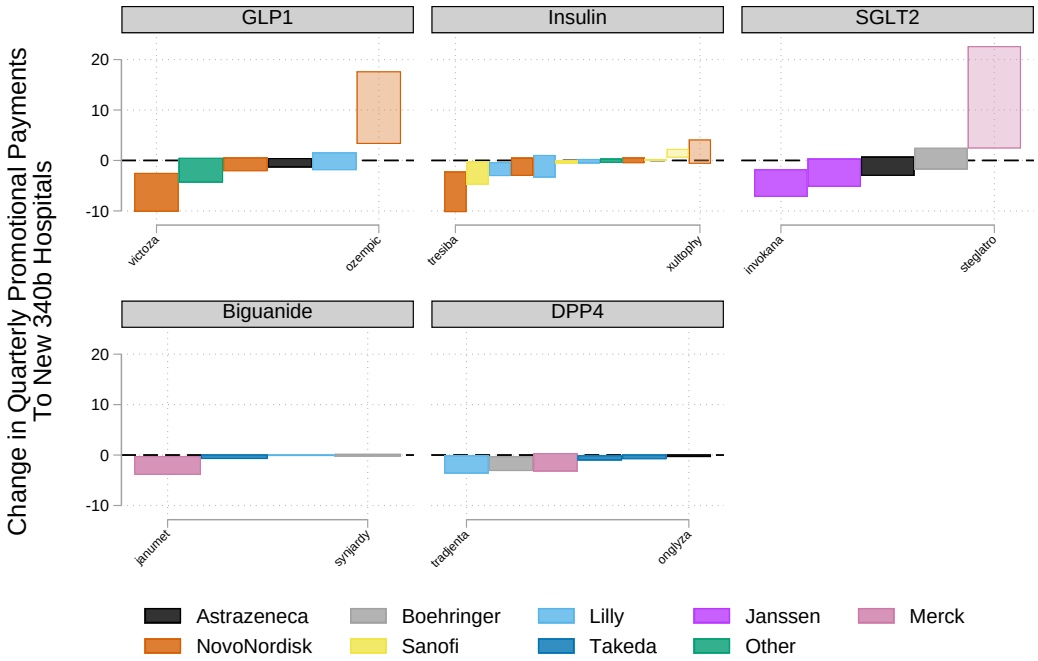
6.2 Diabetes Case Study

We use a case study of the diabetes drug market to explore the responses of pharmaceutical firms to price regulation. The diabetes drug market provides a good setting for a case study for at least three reasons. First, diabetes is one of the most common medical conditions in the United States: one in ten Americans have diabetes, and diabetic patients account for 25% of total healthcare spending (American Diabetes Association). Second, diabetes drugs are among the largest advertisers in the OP data: at least 21% of promotional payments are related to diabetes drugs. Finally, we observe large heterogeneity in the response of diabetes drugs to 340b participation. Figure 9 presents the distribution of drug-level treatment effects, highlighting diabetes drugs in green.

We explore adjustments within firms across their set of diabetes drugs and also within more narrowly defined classes of diabetes drugs. We identify drugs that appear in our advertising data for five prominent diabetes drug classes based on online research: biguanides, dipeptidyl peptidase-4 (DPP-4) inhibitors, glucagon-like peptide-1 (GLP-1) receptor agonists, insulin, and sodium-glucose transporter 2 (SGLT-2) inhibitors. This classification allows us to evaluate changes in advertising both for close substitutes (i.e., drugs within the same drug class) and for products in different classes. Figure 10 plots the estimated parameters for the diabetes drugs highlighted in Figure 9 separately for each drug class. We color code each drug by its manufacturer and denote newer drugs (i.e., those released in 2016 or later) with transparent coloring.

Within GLP1 and insulin, we see both an increase and a decrease of promotional effort for the same pharmaceutical firm: Novo Nordisk (dark orange) that match the prediction of our model, because the products with decreased advertising are the older drugs and the products with increases are the newer drugs offered by the same firm. For example, we see that Novo Nordisk reduces payments to physicians at newly 340b hospitals related to Victoza, a GLP-1 approved by the FDA in 2010, but increases payments related to

Figure 10: **Diabetes Drug-Level Treatment Effects by Drug Class**



Note: the bars represent 95% confidence intervals. Drugs were assigned to a treatment category based on online research. Transparent bars represent drugs launched in 2016 or later

Ozempic, a GLP-1 approved in 2017.[24] Similarly, for insulins, we see that Novo Nordisk and Sanofi (yellow) reduced payments to physicians at newly 340b hospitals related to "legacy" insulins and increased payments related to newly developed insulins, relative to physicians at non-340b hospitals. This re-optimization can also occur across the above definitions of drug classes: for example, Merck (pink) reduced payments related to Janumet (a biguanide launched in 2007) and Januvia (DPP4 launched in 2006), but increased advertising for Steglatro (SGLT2 launched in January 2018).

These findings are consistent with our model's prediction: pharmaceutical firms attempt to reduce exposure to the 340b program by shifting promotional effort towards newer drugs. Our analysis suggests a key insight into the likely effects of price regulation: the incentives for firms to provide effort depend crucially on the design of the regulations. It is unlikely that structural changes at the hospital after the 340b take-up would produce both increases and decreases in effort within the drug class; thus, we attribute this heterogeneity in responses across drugs to differences in discounts set by the 340b program.

As expected, pharmaceutical firms reduce their overall promotional effort targeted towards physicians at newly-designated 340b hospitals. However, firms shifted some of that effort away from old drugs (for which the informational effects of advertising are likely lower) to new drugs (about which physicians are less likely to have complete information). Thus, it seems that the 340b program may have (possibly unintentionally) incentivized firms to engage in advertising activities that are, on average, more informative. If physician

[24]Note that our sample period includes data through 2019, which was before recent discoveries about Ozempic's potential as a weight-loss product.

payments are assumed to be wasteful from a societal perspective, then our results imply that the reductions in advertising induced by the 340b program are welfare-improving. Alternatively, if payments provide important information or older drugs are more effective, then the decrease in advertising may decrease welfare. Evaluating the welfare effects of these changes is beyond the scope of this paper.

7 Conclusion

We study how price regulations affect the incentives for pharmaceutical firms to provide costly effort. We exploit changes in participation by hospitals in the 340b drug pricing program to understand how firms adjust their provision of effort when faced with price caps. We measure effort using publicly disclosed physician payments, which represent a measurable and locally determined unit of effort that is likely to respond to changes in markups.

On average, we find that the 340b drug pricing program reduces the incentives of pharmaceutical firms to promote their products. Importantly, we also document increases in advertising for some drugs, typically those that have recently entered the market. 340b discounts typically increase with a drug's age because the 340b program penalizes drugs for raising prices faster than inflation. This design feature seems to have induced pharmaceutical firms to shift advertising away from older drugs and towards new drugs in order to reduce their exposure to the 340b program. Consistent with this theoretical prediction, we find that firms shift advertising towards newer drugs within the diabetes drug class.

Our analysis offers insights into the effects of other regulations in the pharmaceutical industry, such as the drug pricing provisions of the Inflation Reduction Act (IRA). The design of the IRA price regulations contains some similar aspects as the 340b program. The IRA empowers the federal government to negotiate rebates in Medicare, but small-molecule drugs that have been on the market for less than nine years are excluded from this negotiation. The IRA also implements an inflation penalty similar to the 340b additional rebate (Cubanski et al. (2023)). As a result, the IRA will reduce markups mostly for older drugs, with less of an impact on drugs in their first few years on the market. Based on our analysis, we would expect pharmaceutical firms to reduce advertising for older drugs that are subject to the "negotiations" clause of the IRA and potentially increase advertising for some newer drugs in order to reduce their exposure to the IRA.

Future work should examine how price caps may influence other margins of effort, such as research and development. When evaluating the IRA, the Congressional Budget Office estimated that its drug pricing provisions would dampen innovation incentives for pharmaceutical firms, but only slightly: they predicted that 13 fewer drugs would come onto the market over the next 30 years (Cubanski et al. (2023)). Our findings suggest that price regulations can be designed so as to steer investment in specific directions. For example, the IRA gives somewhat preferential treatment to certain categories of drugs by excluding them from the negotiation process. Biological drugs are exempt for their first 13 years on market; "orphan" drugs that treat rare diseases and plasma-derived products are excluded outright. Thus, the IRA may end up incentivizing pharmaceutical firms to *increase* investment in developing products that face less exposure to the IRA's price regulations.

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Data Appendix

Our main dataset is the Open Payments (OP) data for 2014-2019. We focus on meal payments, as identified by the "Nature of Payment" variable. For each payment, the OP data lists the firm that made the payment and the products associated with the payment, including a classification of the product (drug, biologic, device, or medical supply) and the product's National Drug Code (NDC), where applicable. We use the broad product classifications to identify devices and supplies for our placebo analysis. For each payment, there can be up to five products associated with the event. For our hospital- and firm-level analyses, we count each payment only once, regardless of how many drugs were discussed during the visit. For our drug-level analyses, we count each payment once for every drug discussed during the visit.[25]

We link the OP data to the National Drug Code (NDC) database provided by the US Food and Drug Administration (FDA) to obtain more detailed information about drugs. Because the NDC database does not include information on discontinued drugs or discontinued packages of drugs, we obtain this information for some drugs using historical versions of the NDC databases from 2016-2019 using the Wayback Machine. We use the most current information available for each NDC. The dataset contains information on the drug's product type (e.g., vaccine) and its marketing start date. We link databases by the 11 or 10 digit NDC package code, or by 9 digit product code if the package code from OP was not listed in the FDA data. We made some additional merges by manually matching drugs in the OP data to the FDA data when possible. We manually standardized names for the firms and drugs that we include in our sample for all analyses at the firm- and drug-level. In doing so, we aggregate payments for the same drug across different NDCs, which represent different package sizes or formulations of the same treatment. We use the "Product Type Name" field in the NDC database to identify payments related to vaccines, which are not covered under the 340b program, because the classifications in the OP data do not separately identify vaccines.

We use the NDC database to obtain the marketing start date for each drug. A drug's marketing start date is the date that the product entered commercial distribution. A drug may have multiple marketing start dates across NDCs, most likely due to reformulations or different packages of the same product. For each drug, we assign it the earliest start year of any NDC observed in both the OP and FDA data, conditional on at least one percent of that drug's payments in the OP being for NDCs with that start year. Early packages of some drugs have been discontinued, meaning that the marketing start dates listed in the NDC database may reflect newer reformulations and not the date that the legacy product received its initial FDA approval, particularly for drugs that have been on the market for several decades.[26] We manually checked that the marketing start dates for each drug were accurate and made corrections manually when necessary.

We define the universe of active physicians in each year as the doctors who appear in the National Downloadable File (NDF) data. These data contain the set of physician who received any reimbursements from Medicare in that year. In the empirical analyses, we use payments for which the physician/year combination appeared in the NDF data. 65% of physician-year combinations have at least one hospital affiliation listed

[25] For example, if a firm lists drug A and drug B as being discussed during a given meal, we count that payment once towards drug A and once towards drug B.

[26] For example, Oxycontin was approved by the FDA in 1995, but the original formulation of Oxycontin was replaced by a reformulated version in 2010 and the legacy NDCs were discontinued. As a result, 2010 is the earliest marketing start date listed for Oxycontin in the FDA data. In this case, we would manually assign the marketing start date as 1995.

in the National Downloadable File. For physicians with multiple hospital affiliations, we treat the first listed hospital for each professional as their primary hospital affiliation (which we understand to be the norm per correspondence with CMS).[27] We link the OP and NDF datasets by National Provider ID (NPI) using the Physician Profile Supplement data provided along with the OP data.

We link the NDF to CMS hospital-level datasets using the CMS Certification Number (CCN), which uniquely identifies hospitals. We restrict the sample of hospitals to those that appear in the HCRIS data in every year 2014-2019 in order to avoid detecting changes in advertisements due to closures.[28] The empirical analyses focus on short-term general acute care (GAC) hospitals. We exclude critical-access hospitals, which serve remote areas and are automatically eligible for the 340b program. We also exclude specialty hospitals that are also eligible for the 340b program (cancer and children's hospitals), and hospitals for which the facility type indicated it was reserved for demonstration projects. Hospitals in the same system may sometimes report to CMS under independent hospital IDs and other times report together under a single ID. We drop one treatment hospital (330214 - NYU Langone Hospitals) that began reporting jointly with other hospitals in the same system at the same time as 340b take-up, because we are unable to assign physicians to different facilities within the same system when the hospitals report together. Finally, our analysis is restricted to hospitals located in US territories.[29]

We manually calculated DSH %'s for each hospital-year, because the DSH % reported by hospitals are capped at 12% for many hospitals.[30] Hospitals report their annual Disproportionate Patient Percentage (DPP), which is the sum of Medicare Supplemental Security Income Days (divided by Total Medicare Days) and Medicaid, Non-Medicare Days (divided by Total Patient Days). The formula for the DSH that is set by CMS is non-linear. A hospital's DSH % is calculated as $2.5\% + 0.65 * (DPP - 15\%)$ until it reaches 12%, after which it is calculated as $5.88\% + (0.825 * (DPP - 20.2\%))$. We use this re-constructed DSH % for some of our descriptive analyses and to identify hospitals that had at some point been eligible for the 340b program, which we use to define the control group for our empirical analyses.

To identify the hospitals who participate in the 340b program, we rely on publicly available data from the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs Information System. The HRSA data contain detailed information on 340b program participants (commonly referred to as "covered entities"), including information on the dates that they participated. Covered entities include hospitals as well as any affiliated outpatient clinics that participate in the program.[31] For each covered entity, the HRSA data lists its "registration date", "participating start date", "participating approval date", and "last recertification date." We noticed that HRSA frequently overwrites these fields in a manner that made it difficult to ascertain the participation histories of hospitals from snapshot extracts of the HRSA data. As a result,

[27] We are unable to track movements by physicians across hospitals within a given year using the National Downloadable File. It is also possible that the hospital affiliation in these data do not fully capture financial affiliations between outpatient physicians and hospitals. Nevertheless, we believe the National Downloadable File affiliations to be mostly reliable, particularly for physicians who practice in a hospital-owned facility, which are most likely to be affected by the 340b program.

[28] We thank Adam Sacarny for providing his code to clean the HCRIS data (Sacarny (2022)).

[29] This includes the Virgin Islands, Puerto Rico, Mariana Islands, Guam, and American Samoa.

[30] The primary function of reporting the DSH % is to determine Medicare DSH Adjustments, which compensate hospitals for serving a significantly disproportionate number of low-income patients. This DSH payment is capped at 12% for most hospitals.

[31] For example, there are separate entries for "University of Virginia Medical Center" and "University of Virginia Medical Center Outpatient Surgery Center - 2660."

we manually reviewed the history of profile adjustments maintained by the HRSA for each hospital, which allowed us to more accurately determine the dates that each hospital participated in the 340b program.

Some covered entities start and stop participating in the 340b program during the time period. We define a hospital as participating in the program in a given quarter if the hospital or any of its affiliated outpatient clinics were participating in the program. We define a hospital as a treatment hospital if it took up the program between 2016q1-2018q1 and had not been previously participating, and remained in the program through the end of 2019 with no lapses in participation. Our control hospitals are hospitals that did not participate in the 340b program at any point during 2014-2019 but were at some point eligible for the program (e.g., "never-treated" hospitals). We consider alternative control group definitions in the appendix. We exclude two types of hospitals from our analysis: "always-treated" hospitals that were in the program for all of 2014-2019, and "sometimes-treated" hospitals that change 340b status more than once during 2014-2019. 890 hospitals are always-treated, and 228 hospitals are sometimes-treated. Of these 228 sometimes-treated hospitals, 20 hospitals were not participating in the program at the beginning of the sample and were participating at the end of the sample, but experienced at least one lapse in participation. Because it is unclear what triggered these lapses or how pharmaceutical firms would respond to these lapses, we exclude these hospitals entirely from our empirical analyses.

Appendix Tables & Figures

Table A.1 presents summary statistics separately for three sets of the hospitals: the 115 hospitals that comprise our treatment group; the 287 hospitals in our control group; and the 890 always treated hospitals, for comparison.

Table A.1: **Hospital-Level Summary Statistics, 2014q1**

	(1) Treatment		(2) Control		(3) Always-Treated	
	Mean	SD	Mean	SD	Mean	SD
# of Professionals	237.91	283.68	99.73	148.47	258.49	278.55
# of Beds	246.44	283.26	104.86	126.12	283.96	248.78
# of Part D Prescriptions per Professional	3835.88	3422.18	3405.16	2475.52	3109.76	1722.96
# of Detailing Payments per Professional - Drugs	2.87	2.07	2.43	2.42	2.52	1.84
# of Detailing Payments per Professional - Device	0.43	0.28	0.37	0.48	0.41	0.28
$ of Detailing Payments per Professional - Drugs	49.20	31.88	41.25	36.32	45.77	31.56
$ of Detailing Payments per Professional - Device	17.99	13.04	14.97	21.25	17.22	13.00
DSH %	0.15	0.41	0.15	0.18	0.23	0.13
Rural Hospital	0.30	0.46	0.38	0.49	0.31	0.46
Observations	115		287		890	

Table A.2 presents estimates of Equation (1), Equation (3), and Equation (5) where we remove the requirement that control hospitals must be eligible for the 340b program in at least one quarter. The results are qualitatively similar.

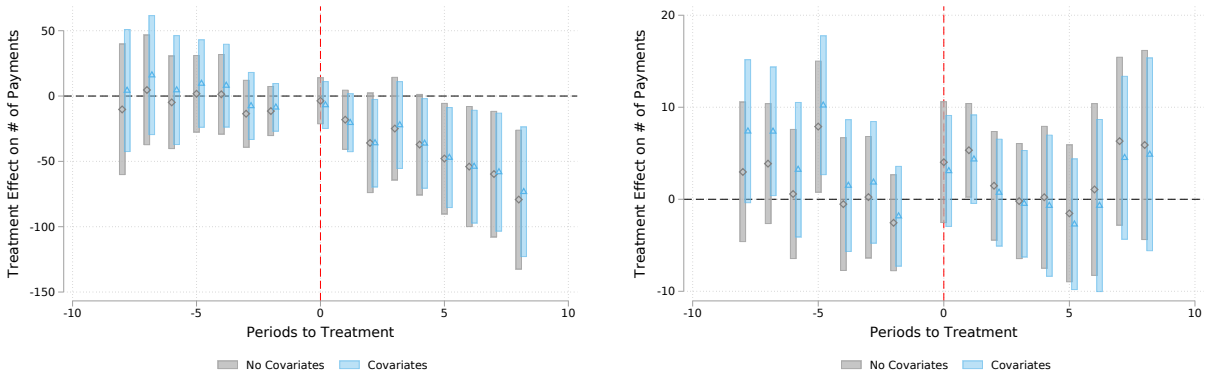
Table A.2: **Robustness to Alternative Control Group Definitions**

	Hospital Level		Firm-Level		Drug-Level	
	(1)	(2)	(3)	(4)	(5)	(6)
340b	–43.9***	–32.6**	–0.452***	–0.290***	–0.724***	–0.579***
	(16.7)	(15.8)	(0.0524)	(0.0493)	(0.130)	(0.123)
Treatment Group	Any Hospitals	Any Hospitals	Any Hospitals	Any Hospitals	Any Hospitals	Any Hospitals
Control Group	Ever Eligible Hospitals	Any Hospitals	Ever Eligible Hospitals	Any Hospitals	Ever Eligible Hospitals	Any Hospitals
Observations	9,648	40,632	1,517,725	6,856,168	518,594	2,336,606
Sample Average	353	427	2.49	2.81	6.09	6.90

Notes: Standard errors in parentheses are clustered by hospital in columns 1+2, by hospital-firm in columns 3+4, and by hospital-drug in columns 5+6. We report the average treatment effect on the treated for all treatment cohorts across all treatment periods. * p<0.10, ** p<0.05, *** p<0.01

Figure A.1 estimates Equation (2) using the Sun and Abraham (2021) estimator, which allows us to confirm the robustness of our estimates and also to account for time-varying hospital covariates. We interpret these results as suggestive evidence that the take-up of the 340b program was not correlated with important unobserved changes at the hospital that would affect physician payments separately from the 340b discounts.

Figure A.1: **Hospital-Level Event Study, Robustness to Sun and Abraham (2021)**

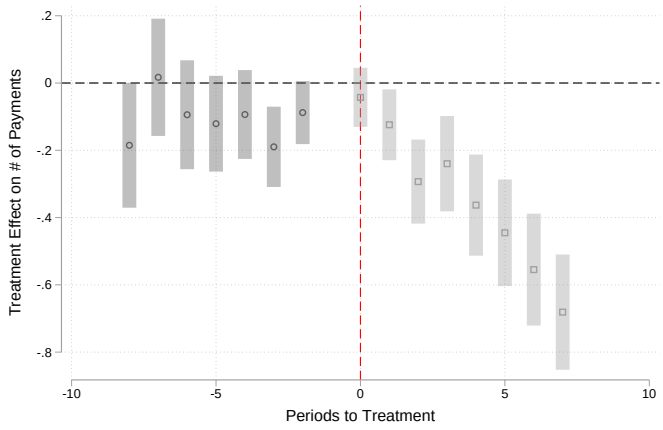


(a) Drugs (b) Medical Devices and Supplies

Notes: Standard errors are clustered by hospital. All specifications include hospital and year-quarter fixed effects. Regression was estimated using Sun and Abraham (2021) to account for staggered treatment timing. The blue bars control for lagged DSH %, total beds, and number of medical professionals, which vary by hospital and year.

Figure A.2 estimates Equation (2) using the Callaway and Sant'Anna (2021) estimator, but excludes the 36 drugs that we identified as losing a patent in 2019 or earlier. The treatment effects are virtually unchanged.

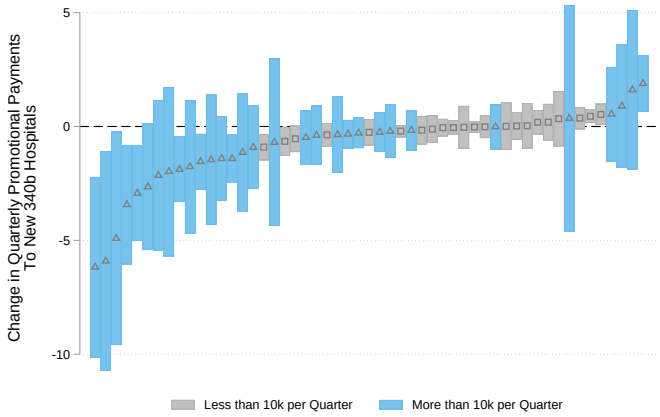
Figure A.2: **Event Study of 340b Participation on Quarterly Physician Payments, Drug-Level, Exclude Drugs with Identified Patent Events**



Notes: Standard errors are clustered by hospital-drug. All specifications include hospital-drug and year-quarter-drug fixed effects. Regression was estimated using Callaway and Sant'anna (2021) to account for staggered treatment timing. We report the average treatment effect on the treated across all treatment cohorts relative to the quarter before treatment.

Figure A.3 presents the estimates from Equation (3), separately for each of our top pharmaceutical firms. The distribution closely resembles the distribution in Figure 5. We highlight firms that made at least ten thousand payments per quarter in blue to demonstrate that many of the null effects are connected to pharmaceutical firms that do not make very many physician payments.

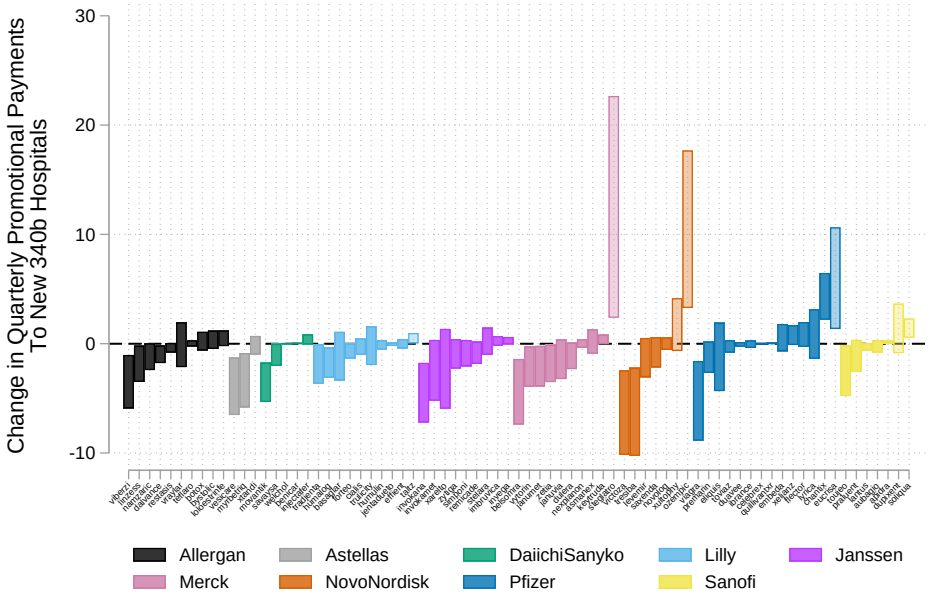
Figure A.3: **Distribution of Firm-Level Treatment Effects**



Note: the bars represent 95% confidence intervals.

Figure A.4 labels each of the drug-level estimates that were presented in Figure 7.

Figure A.4: **Within-Firm Heterogeneity by Drug, With Labels**



Note: the bars represent 95% confidence intervals. Transparent bars represent drugs launched in 2016 or later.