The ACA Medicaid Rebate Rule Change: Impact on Pricing and Innovation*

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Abstract

We study how Medicaid drug procurement rules affect private markets, leveraging new data and changes to rules implemented in the Affordable Care Act (ACA). Using a stylized model, we illustrate how the rules of the Medicaid Drug Rebate Program (MDRP) qualitatively distorts pricing and innovation outcomes. Consistent with previous literature, the model predicts that larger mandatory rebates cause firms to set higher initial list prices. However, after factoring in the MDRP's inflation penalty and "best price" provisions, the model predicts that higher Medicaid rebates reduce list price growth, increase private market rebates, and can even encourage higher quality line extensions. We test these predictions using a difference-in-difference analysis that exploits an increase in the minimum Medicaid rebate implemented as part of the ACA. Our empirical results are consistent with the predictions of the model and provide a more nuanced view of the impact of mandatory rebate size on private drug market outcomes.

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1 INTRODUCTION

The impact of government-set prices and subsidies on private market outcomes has been documented empirically in a variety of settings.[1] Medicaid reimbursement for prescription drugs is set as a fraction of private market list price, which Duggan and Scott Morton (2006) show leads firms to set higher list prices. They also show that manufacturers mitigate the effect of provisions that decreases Medicaid prices over the life-cycle of drugs by introducing reformulations of existing products. Their results suggest that the lowering of the reimbursement fraction implemented as part of the Affordable Care Act (ACA) would exacerbate these distortions. List prices however, do not fully capture private market outcomes because they do not incorporate rebates. Private market rebates are referenced through a "most-favored nation" clause in Medicaid. Having a better grasp of how these Medicaid rules interact can help us better assess and understand the impact of the ACA reform on private market outcomes.

In this paper, we use novel data on net prices to study the impact of the ACA on private market outcomes. We find that the change led to lower list price growth, and higher private market rebates, all while having a negligible effect on initial launch prices. Furthermore, our results suggest that firms started introducing higher-quality line extensions after the reform took effect.

The Medicaid price is determined by two components: an initial reimbursement that state programs remit to pharmacies, and a quarterly rebate that manufacturers must send to the federal government. The initial payment is generally at the level of wholesale prices, though small differences exist across states. The rebate is calculated as a percentage of wholesale price. The sum of the two components implies that the effective payment from Medicaid to drug manufacturers is a fraction of the wholesale price.

The actual size of the rebate depends on a set of rules listed under the name of Medicaid Drug Rebate Program (MDRP). The MDRP has three key provisions. First, it sets a mandatory minimum rebate, which is a fixed percentage of the wholesale price. Second, it enforces a "best price" provision, which kicks in if any private payer receives a rebate greater than the mandatory minimum rebate. Third, it imposes an additional inflation-adjusted rebate which effectively anchors the Medicaid price of any drug to its inflation-adjusted launch price.

In order to analyze how the MDRP affects drug prices, we develop a stylized model dynamic pricing model and rebate decisions for a firm pricing to consumers in both the private and Medicaid market. Through the model, we uncover three previously unidentified insights. First, we find that the higher the mandatory rebate percentage, the lower the

[1] See for example Morton (1997); Duggan and Scott Morton (2006, 2010); Clemens and Gottlieb (2017); Maini and Pammolli (2017); Dranove and Ody (2019); Dubois et al. (2019); Ridley and Lee (2019); Blume-Kohout and Sood (2013) for healthcare; **???** for federal aid for college students, Susin (2002); Eriksen and Ross (2015) for housing vouchers, and Jaravel (2018) for food stamps.

subsequent list price growth. This is due to additional rebate canceling out any list price growth plus a greater mandatory rebate from the higher list price. Second, we find that a higher mandatory rebate percentage leads to higher private market rebates. A higher Medicaid rebate lowers the threshold at which Medicaid's "best price" clause kicks in, thereby allowing for lower private net prices. Third, we show that under some additional assumptions, an increase in the mandatory rebate leads higher quality line extensions. This is due to the fact that resetting the rebate involves getting demand to shift from the original drug to the line extension, and a greater rebate increases the marginal returns to quality.

To test the predictions of our model we leverage a change in the MDRP implemented in January 2010 as part of the Affordable Care Act (ACA), which increased the mandatory rebate percentage from 15.1% to 23.1%. We set up a difference-in-difference around the ACA rule change and exploit drug-level heterogeneity in exposure to the Medicaid market — which arises because certain drugs are naturally more likely to be prescribed to Medicaid patients.

Our findings broadly confirm the predictions of the model. We find that the mandatory rebate change increases private market rebates by 4% per year. Second, we find that the additional rebate generally reduces list price growth by 2% per year, with the effect increasing after the ACA change. Finally, we find that an increase in Medicaid rebates leads to an increase in both number and quality of line extensions.

Our work is particularly indebted to Duggan and Scott Morton (2006) — who first examined the impact of the MDRP on drug prices and launch of line extensions — but presents a more nuanced picture of the effects of the ACA change on private market outcomes. On the one hand, based on evidence in Duggan and Scott Morton (2006) and more recent work by Ridley and Lee (2019) in the context of Medicare Part B, the ACA change likely led to higher list prices for drugs launched after 2010, and further product proliferation. On the other hand, the higher Medicaid rebates lead to higher-quality line extensions, higher private market rebates, and reduced list price growth — a growing issue in drug markets highlighted by "buy-and-raise" strategies executed by Martin Shkreli and Horizon Pharmaceuticals. Taken together, these outcomes paint a relatively positive picture of the impacts of the ACA rule change.

Our analysis contributes to several related literatures. First, we contribute to the literature on the impact of Medicare and Medicaid rules on prescription drug markets. This includes work looking at the launch of Medicare Part D (Duggan and Scott Morton, 2010), changes to Medicare Part B price regulation (Ridley and Lee, 2019), and the emergence of Medicaid Managed Care (Dranove et al., 2017). Our paper takes a different approach to other papers in the literature by leveraging a very specific change to Medicaid rules to better model and estimate the impact of the Medicaid drug rebate program on drug markets. More generally, we contribute to the literature on price regulation in prescription drug

markets. First, it contributes to the literature on the impacts of reference pricing. Maini and Pammolli (2017) and Dubois et al. (2019) both study the impact of richer countries referencing the prices of poorer countries, finding distorted entry patterns and prices in the referenced market. In our case, we study referencing going from a market with inelastic demand to a market with more elastic demand, and find a more nuanced impact on prices.

The results also speak to the literature on innovation in the pharmaceutical industry. Specifically, it adds to the growing literature on quality of innovation . Krieger et al. (2018) develop novelty measures for new drug compounds, and leverage the introduction of Medicare Part D to show that more cash-on-hand increases subsequent innovation novelty. We find evidence that firms also respond along the quality dimension to the incentives created by the Medicaid drug rebate program, albeit within the general context of line extensions versus entirely new compounds studied by Krieger et al. (2018). More generally, our results contribute to the long literature on the responsiveness of pharmaceutical innovation to economic returns (Acemoglu and Linn, 2004; Dranove et al., 2014; Dubois et al., 2015). Our results highlight the idea that some changes to market rules or effective market size can alter the marginal incentives for developing higher quality drugs, while others may not.

The rest of the paper proceeds as follows. Section 2 provides an overview of the MDRP and the ACA changes. Section 3 provides a model of how Medicaid rules impact drug manufacturer pricing and line extension decisions. Section 4 provides empirical evidence supporting the model's predictions. Section 5 concludes.

2 Overview of the Medicaid Drug Rebate Program

2.1 Medicaid Drug Benefits

The Medicaid program provides health insurance benefits to a diverse disadvantaged population. The exact requirements for Medicaid coverage vary across states, but the program covers many children, pregnant women, and individuals with disabilities. Since January 2014, in states that expanded the program using federal funds from the Affordable Care Act, the only requirement has become having an income below 133% of the federal poverty line.[2] Though it is technically an optional program, and states have a lot of latitude in determining its characteristics, all states offer drug coverage as part of Medicaid, and most drugs are covered by Medicaid.

Pharmacies that dole out prescriptions to Medicaid beneficiaries are reimbursed by state governments. Reimbursement rates for pharmacies are set through regulatory formulas and have varied quite a bit both over time and across states. The amount is usually

[2] 24 states expanded Medicaid on January 1st, 2014. Since then, 9 more states have also expanded coverage or passed resolutions to do so in the future.

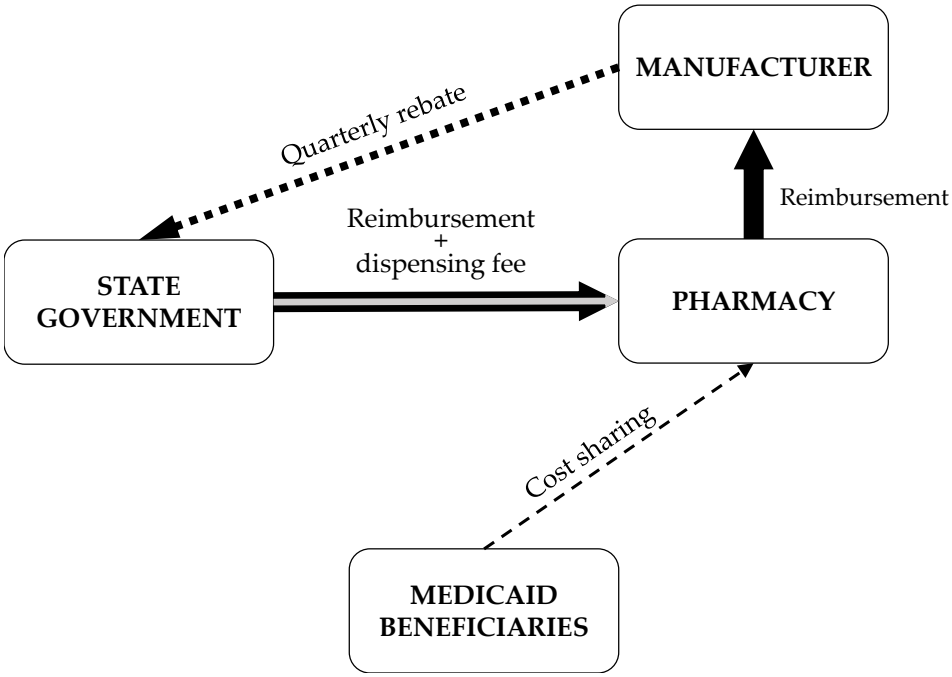

Figure 1: Flow of Medicaid drug payments

expressed as a function of one of two publicly available price points: the Average Wholesale Price (AWP), or Wholesale Acquisition Cost (WAC). AWP is defined as the average price at which wholesalers sell drugs to pharmacies. WAC is defined as the price paid by wholesalers when they acquire the drug from the manufacturer. Both prices are not based on actual transactions, but rather published by the manufacturer. However, while AWP is generally known for being inflated, WAC is usually thought to be fairly accurate, at least for brand drugs (DHHS, 2005).

Medicaid spending accounts for approximately 12.5% of overall drug spending at invoice prices ($59 billion out of $479 in 2018). Among the branded drugs in our sample (which represent 70% of total Medicaid spending), the proportion is slightly lower, peaking just above 11% in 2017. This makes sense since Medicaid tends to be more prevalent among generics.

2.2 *Overview of the Medicaid Drug Rebate Program*

In order to have their drugs covered by Medicaid, drug manufacturers have to enter into a national rebate agreement with the Department of Health and Human Services. The terms of the agreement, which is known as the Medicaid Drug Rebate Program, require

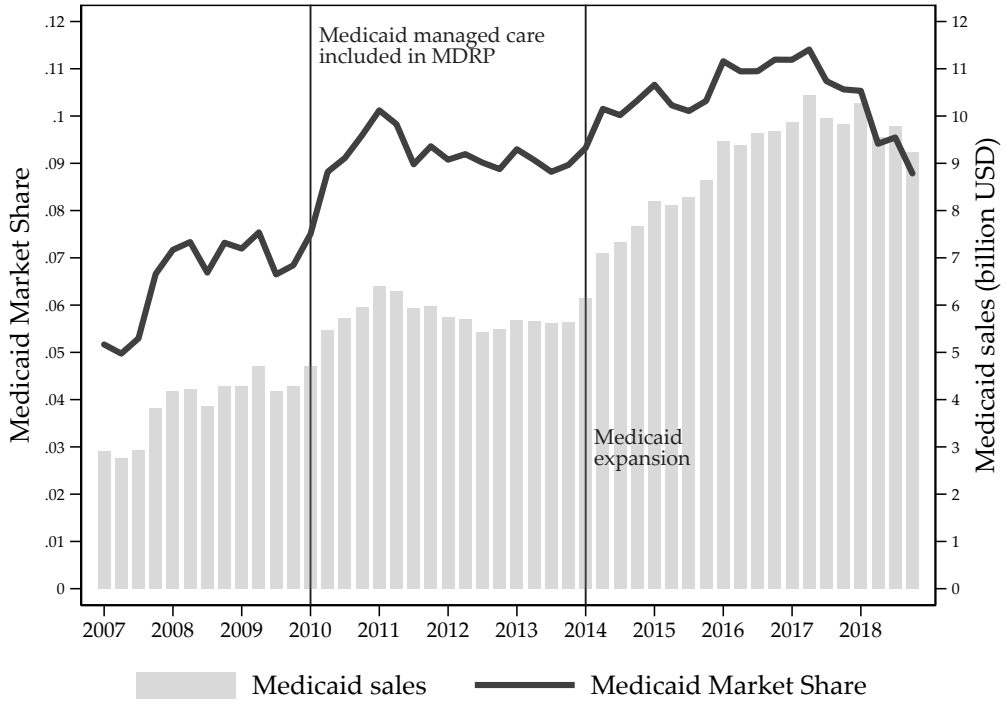

Figure 2: Medicaid sales and market shares, 2007-2018

that a manufacturer submit product and pricing data for all of its drugs to the Center for Medicare and Medicaid Services. That data is then used to determine a rebate for drugs reimbursed under a state plan, which manufacturers have to pay out on a quarterly basis.[3]

The amount of rebate due for each unit of drug is based on a statutory formula that varies depending on whether the drug is (i) an innovator drug (i.e. a branded drug), (ii) a blood clotting factor, (iii) a drug approved only for pediatric use, or (iv) a non-innovator drug (i.e. a generic). Our paper focuses on innovator drugs, so in this section we describe only the formula used for those drugs.

Before the ACA (up until 2009q4)

Rebates in the MDRP are tied to Average Manufacturer Price (AMP). The AMP is defined statutorily as the average price paid by manufacturers to wholesalers for a unit of drug.[4] It is best understood as an invoice price, as it only incorporates prompt payment and other

[3]Manufacturers are also required to enter into a pricing agreements with Section 340B Drug Pricing Program and Veterans Affairs.

[4]The way units are defined is not always consistent, but generally refers to either a pill/tablet, or a fixed volume of chemical for liquids.

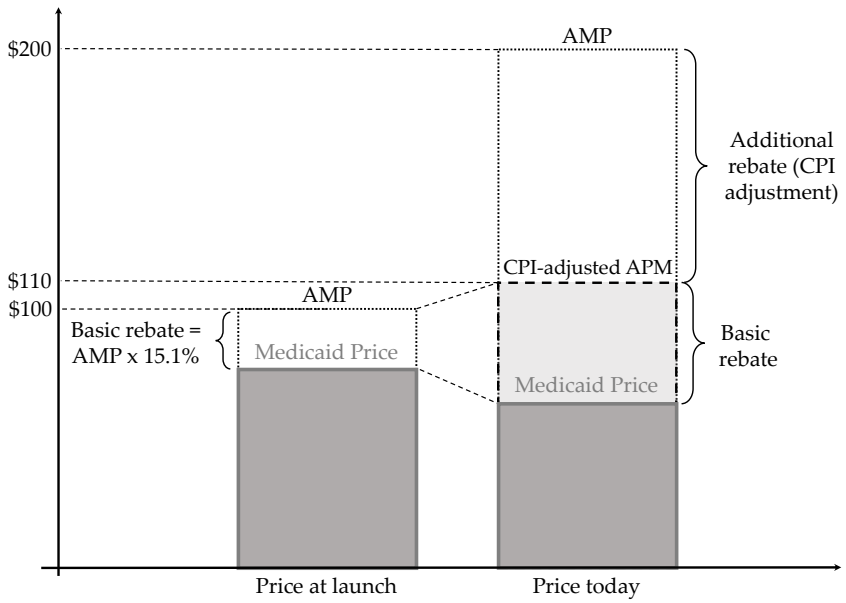

Figure 3: Cross-sectional analysis of a rebate change

small discounts to wholesalers, but not the larger rebates granted to large commercial payers. AMP data is considered proprietary and is only available to the federal government.

The rebate for innovator drugs is split in two parts. Prior to the ACA, the first part, called *basic rebate*, was equivalent to the greatest of 15.1% of the current AMP per unit, or the difference between the AMP and the best price per unit granted to any commercial payer (Medicare Part D, and some other exclusions apply). Before 2010, this basic rebate was capped at 50% of AMP. The second part, called *additional rebate*, applies to drugs whose current AMP is greater than its initial AMP, adjusted for inflation, and is equal to the difference between the two. Virtually all drugs experience price growth above the rate of inflation, so the additional rebate makes up a significant fraction of the overall rebate.

As Figure 3 shows, the is formula has some counterintuitive implications. The basic rebate is expressed as a fraction of the *current* AMP, but the additional rebate anchors the price to the AMP *at launch* (adjusted for inflation). As a result, increases in AMP above the rate of inflation actually lower the effective per-unit price that Medicaid pays. Figure 4 shows that over time, for drugs whose invoice prices increase quickly, the effective Medicaid price could actually become negative. [5]

[5]This is not just a theoretical possibility. Eli Lilly executives told the House Energy and Commerce Committee that some of its insulin products had 100% Medicaid rebates. See page 8 of testimony transcript. More recently, HHS secretary Alex Azar claimed that over 2,300 drugs are at the 100% cap on rebate while making remarks at a policy conference at the American Enterprise Institute.

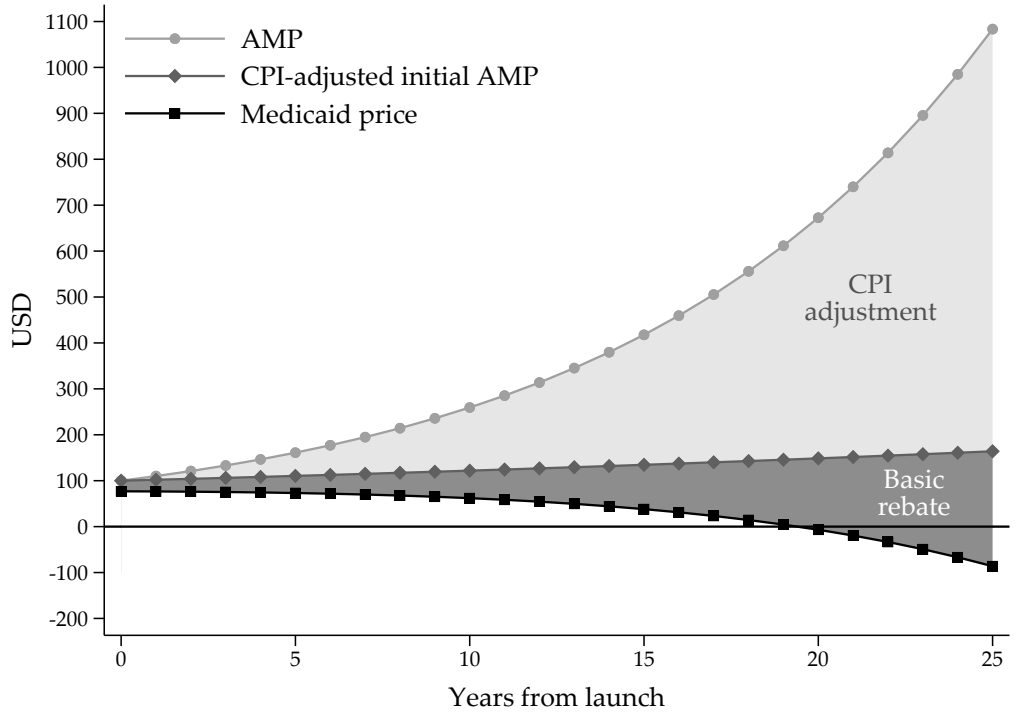

Figure 4: Possible Medicaid price path of a drug over time

The only way firms can increase the Medicaid price after launch is to introduce a line extension of an existing product, i.e. a new version that shares the same active principle, but has a different form, or strength. Line extensions are considered like an entirely new product for the purposes of the MDRP, so the manufacturer can set a new initial price, erasing all the accumulated additional rebate. The existence of this loophole is well-known, and the government recently passed legislation to close it, though it has not been implemented yet.

Changes implemented by the ACA (post 2010q1)

On July 7th, 2009, the government held closed-door negotiations with drug manufacturers over changes to the MDRP in the ACA. The outlines of the agreement were leaked to the media on September 13th, 2009, and contained the following changes to the rebate formula:[6]

1. The minimum basic rebate was increased from 15.1% to 23.1% of AMP.

[6]See Huffington Post article "Internal Memo Confirms Big Giveaways In White House Deal With Big Pharma," available at https://www.huffpost.com/entry/internal-memo-confirms-bi_n_258285.

2. The provision capping the basic rebate at 50% of AMP was removed.

3. A new provision, capping the *overall* rebate (basic plus additional rebate) at 100% of AMP was introduced.

Other relevant changes to Medicaid

Over the past few years the Medicaid program has undergone several changes, that have affected its overall impact on the market. First, starting in January of 2006, dual eligibles, who used to receive drug coverage from Medicaid, were switched to the newly introduced Medicare Part D. Second, in January 2010, on top of changing the formula for the MDRP, the ACA extended MDRP rebates to privately administered plans under Medicaid Managed Care. This lead to a slow increase in the size of the market directly affected by provisions of the MDRP. There was no sudden change because most states carved out drug benefits from Medicaid Managed Care (precisely because they could get better terms under the MDRP). Third, starting in January 2014 Medicaid coverage in several states was expanded to include any individual or family unit with a yearly income at or below 133% of the federal poverty line. Since this expansion occurred at the same time as the introduction of health exchanges, it's important to notice that the expansion did not necessarily expand the Medicaid market relative to the commercial market.

3 Optimal Pricing and Launch for Medicaid and the Commercial Market

We continue our analysis by presenting a simple model of optimal entry and pricing. The model is not meant to realistically capture all the relevant aspects of the US pharmaceutical market, but rather to illustrate in intuitive terms the incentives generated by the Medicaid Drug Rebate Program. In the model, a monopolistic firm sets a list price and a discount for the commercial market. These two choice variable are then used by the government as inputs into a pricing formula that applies to the Medicaid market. Since firms know the formula in advance, they will take into account when making strategic decisions that maximize profits across both markets.

To simplify exposition we separate the pricing and launch decision and tackle them separately, starting with price.

3.1 Optimal Dynamic Pricing in Response to the Medicaid Drug Rebate Program

Consider a monopolist selling a product in two markets, indexed by j. Demand in each market is denoted as $D_{j,t}(\cdot)$. The price in market 2 — representing Medicaid — is set through a formula based on the the price in market 1. Let $p_{j,t}$ denote the invoice price in

market j in period t, and assume that the firm can also set a discount d_t, which applies to market 1 only. Then, the net price in market 1 is

$$p_{1,t}^{\text{net}} = p_{1,t} \times (1 - d_t)$$

while the price in market 2 is

$$p_{2,t}^{\text{Med}} = \min(p_{1,0}, p_{1,t}) - p_{1,t} \times \max(r, d_t)$$

where r is a statutory rebate rate.[7] Finally, assume that $D_{2,t}(p_{2,t})$ is perfectly inelastic, so $D_{2,t}(p_{2,t}) = D_{2,t}(0)$.[8]

Optimal pricing in the commercial market

Let's start by characterizing the optimal effective unconstrained price path in market 1, $\left\{p_{1,t}^{\text{unc}}\right\}$. This price path comes from a simple maximization problem:

$$\max_{\left\{p_{1,t}^{\text{net}}\right\}} \left(p_{1,t}^{\text{net}} - c\right) \cdot D_{1,t}(p_{1,t})$$

where we assume a constant marginal cost of production c.[9] We can treat each period separately, so the solution for any t is simply given by the standard FOC

$$p_{1,t}^{\text{unc}} = c - \frac{D_{1,t}(\cdot)}{\frac{\partial D_{1,t}(\cdot)}{\partial p_{1,t}}}$$

Notice that we have eliminated the discount d, since in this model it does not serve any purpose.[10]

[7] The exact Medicaid formula also adjusts the initial price for inflation. Since accounting for inflation would not change the predictions of the model, we do not include it in our model.

[8] In 2018, only 7 states had a copay dependent on drug cost. The range of those copays across those states was between \$0 and \$3.90. Another 7 states have copays that can vary across brand drugs depending on a variety of factors, including preferred status, which might depend on drug cost. All other states have fixed copays by brand status, including 15 states that have no cost-sharing at all (source: Kaiser Family Foundation, https://www.kff.org/medicaid/state-indicator/prescription-drugs/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D, retrieved on 11/14/2019).

[9] This assumption can easily be relaxed with virtually no impact on the predictions of the model.

[10] With d in the model there are an infinite number of solutions, which can be expressed as a set of couples $\left\{(p_{1,t}, d_t) : p_{1.t} \times (1 - d_t) = p_{1,t}^{\star} \wedge d \in [0, 1]\right\}$.

Optimal pricing in the commercial and Medicaid markets

Now consider the overall problem of the firm

$$\max_{\{p_{1,t},d_t\}} \sum_{t=0}^{T} \left(p_{1,t}\left(1-d_t\right)-c\right)\cdot D_{1,t}\left(p_{1,t}\left(1-d_t\right)\right)+\left(p_{2,t}^{\text{Med}}-c\right)\cdot D_{2,t}$$
$$\text{s.t.} \qquad p_{2,t}^{\text{Med}}=\min\left(p_{1,0},p_{1,t}\right)-p_{1,t}\times\max\left(r,d_t\right)$$

Here, firms are choosing both the invoice price $p_{1,t}$ and the discount rate d_t for market 1. We cannot treat the problem as a series of static problems because of the presence of $p_{1,0}$ in the formula for $p_{2,t}$.

We start the analysis of the problem by stating a proposition that will help simplify the analysis of the first-order conditions.

Proposition 1. *$d_t^\star \leq r$ for all $t>0$*

We provide a formal proof of this statement in the Appendix. Intuitively, increasing the discount rate above the minimum mandatory threshold r can never be optimal. Lowering both the list price and the discount rate proportionally leaves the effective price in the commercial market unchanged, and increases the Medicaid price, which yields strictly higher profits.

Thanks to the result in Proposition 1 we can rewrite the problem as having the following two constraints:

$$p_{2,t}^{\text{Med}}=\min\left(p_{1,0},p_{1,t}\right)-p_{1,t}\times r$$
$$d_t\leq r$$

There are four FOCs. After some simplifications, they can be written as

$$[p_{1,0}]: p_{1,0}\left(1-d_0\right)=c+\frac{D_{1,0}}{-\frac{\partial D_{1,0}}{\partial x}}+\frac{\left(1-r\right)D_{2,0}+\sum_{t=1}^{T}\frac{\partial p_{2,t}^{\text{Med}}}{\partial p_{1,0}}\cdot D_{2,t}}{-\frac{\partial D_{1,0}}{\partial x}\left(1-d_0\right)}$$
$$[d_0]: p_{1,0}\left(1-d_0\right)=c+\frac{D_{1,0}}{-\frac{\partial D_{1,0}}{\partial x}}-\frac{\frac{\partial p_{2,0}^{\text{Med}}}{\partial d_0}\cdot D_{2,0}}{-\frac{\partial D_{1,0}}{\partial x}p_{1,0}}$$
$$[p_{1,t}]: p_{1,t}\left(1-d_t\right)=c+\frac{D_{1,t}}{-\frac{\partial D_{1,t}}{\partial x}}+\frac{\frac{\partial p_{2,t}^{\text{Med}}}{\partial p_{1,t}}\cdot D_{2,t}}{-\frac{\partial D_{1,t}}{\partial x}\left(1-d_t\right)}$$
$$[d_t]: p_{1,t}\left(1-d_t\right)=c+\frac{D_{1,t}}{-\frac{\partial D_{1,t}}{\partial x}}$$

Consider first the conditions on $p_{1,t}$ and d_t. It should be immediately obvious that they cannot be satisfied at the same time. $\frac{\partial p_{2,t}^{\text{Med}}}{\partial p_{1,t}}$ is either equal to $(1-r)$ — if $p_{1,t} < p_{1,0}$ — or $-r$ — if the opposite is true. The following proposition characterizes the optimal price for $t > 0$.

Proposition 2. *$p_{1,t}^{\star}(1-d_t^{\star}) \leq p_{1,t}^{unc}$ if and only if $p_{1,0}^{unc} < p_{1,t}^{unc}$.*

The proposition states that Medicaid rules will tend to push prices down in all periods except the initial one. We include a formal proof of this result in the Appendix. Intuitively, if the optimal unconstrained price path in the commercial market is increasing, then the optimal price when taking into account Medicaid rules will tend to push the price down, because charging a list price above the launch price has a negative impact on the Medicaid price. Conversely, if the price path is decreasing, the Medicaid rules will push to increase the price, as that will increase the overall Medicaid price. Notice that the first case is much more likely to be empirically relevant as the price path of virtually all drugs is increasing over time.

Now consider the first period.

Proposition 3. *In the absence of constraints, $p_{1,0}^{\star}$ is unbounded. If the Medicaid price is bounded above by some threshold $\bar{p}^{Med}$, then $p_{1,0}^{\star}$ and d_0 are such that $\bar{p}^{Med} \geq p_{1,0}^{\star}(1-d_0) \geq p_{1,0}^{unc}$.*

Once again, the result of this proposition is intuitive (formal proof in the Appendix). Regardless of the relative market size of Medicaid, one can always find a price high enough that catering only to that market is optimal. This is a straightforward consequence of the fact that $D_{2,t}$ is price inelastic. In practice however, manufacturers likely face practical constraint that prevent them from charging such high prices. This is why we incorporate the second result in the proposition. We discuss some possibilities for these constraints in the next section.

Discussion and predictions

From the propositions, we can derive several predictions about the behavior of firms in the pharmaceutical market. Some of these

Prediction 1: *Drugs with high Medicaid market share should have higher launch prices.* This prediction comes from Proposition 3. Since Medicaid demand is inelastic, firms should in theory charge infinitely high prices. In practice this doesn't happen because the Medicaid price is probably implicitly constrained. The amount that Medicaid pays has to be based on actual transactions with wholesalers. If the price is high enough, wholesalers might face liquidity constraints that will prevent them from actually purchasing the product. Alternatively, firms might fear regulatory action if they are seen exploiting federal regulation in

an obvious manner. Finally, since Medicaid does not have an infinite budget, firms might be concerned that Medicaid might become insolvent.

Firms might also face some constraints on the commercial market. Propositions 3 and 2 combined suggest that the price should drop right after launch. However, price drops could be seen as a negative sign from the market, and could negatively damage the reputation of the company. In these situations, a firm would still have an incentive to charge a higher-than-normal price in the first period, but would take into account how the initial price would affect the future price path.

Increasing r has two effects on the initial launch price. On the one hand, it mechanically lowers the Medicaid price, which creates an incentive to increase the list price to make up the difference. We call this the *price effect.* On the other hand however, it reduces the size of the Medicaid market relative to the commercial market. We call this the *market size effect*. At low values of r, the price effect will dominate, but as r gets close to 1 (i.e. Medicaid prices are close to 0), the market size effect will dominate, and firms will simply disregard the Medicaid market and revert to pricing only for the commercial market. Our expectation is that the current r is probably low enough that the price effect should dominate.

Prediction 2: *Drugs with a high Medicaid market share should experience lower list price growth.* This prediction comes from Proposition 2, and from observing that the price of virtually all drugs increases over time. Proposition 2 states that, as long as the optimal price path in the commercial market is increasing over time, the profit-maximizing price in the commercial and Medicaid market is lower than the profit-maximizing price in the commercial market alone. Intuitively, whenever a drug increases its price above the rate of inflation, their Medicaid price falls, so it makes sense that drugs with a large Medicaid market would refrain from raising their price excessively. As with Prediction 1, here too the impact of r is theoretically uncertain due to the combination of the price effect and the market size effect. In practice, we expect that the price effect should dominate, so price growth should be even lower after the 2010 reform.

Prediction 3: *Drugs with a high Medicaid market share should have lower discounts on the commercial market. These discounts should increase after r is raised in 2010.* This result comes from Proposition 1, which states that the optimal discount rate for drugs that have sales on the Medicaid market should be bounded above by r. We don't expect this rate to be actually bounded above by r in our data for two reasons. First, in our model d_t only matters because it allows the firm to "hide" its real commercial price, which in turn can lead to a higher price on the Medicaid market. In the real world however, d_t matters for much more. Manufacturers can set different rates of d_t to price discriminate across various commercial payers. d_t also determines the earnings of PBMs, which earn a fraction of overall rebates. Hence, a higher d_t can help in negotiations with PBMs. Second, several buyers —

for example Medicare Part D plans and the department of Veteran Affairs — are excluded from the best price rule. Since our data aggregates across all these buyers, our aggregate measure could record a discount above the Medicaid threshold even if the threshold held strictly.

Unlike with the previous three predictions, the effect of r here is unambiguous. Raising r will have a weakly positive effect on the commercial market discount rate.

3.2 Optimal introduction of line extensions

One way to regain pricing flexibility in the Medicaid market is to launch a line extension — a product with the same active ingredient of an existing product, but with a different formulation. Line extensions cater to the same pool of patients as the original product. Because of how Medicaid rules work, they also allow manufacturers to set a new initial price, thus erasing most of the discounts that have been accumulating since the original product launched. In this section, we extend our model from the previous section to examine the firm's decision to develop and launch a line extension.

In order to simplify exposition, we make two assumptions. First, we assume that line extensions are not market-expanding, so they will simply replace the older originator product for a fraction of the patients who are taking it.[11] Second, we assume that line extensions only last one period. Modeling the dynamic evolution of line extensions earning is not as relevant in our case, because pricing of line extensions behaves almost identically to pricing of the originator product. Hence, collapsing the profits they generate to one period is inconsequential for our purposes.

Not all line extensions are created equal: higher quality line extensions will attract more patients away from the original product. To model differences in line extensions , we denote s as the fraction of patients that switch from the original product to the new one. Then, we let $c(s)$ be a cost function indicating how much the firm has to invest to create a product that will convince a fraction s of patients to switch. We assume that $c(s)$ is increasing and convex.

We assume firms can choose s, and decide whether to launch a line extension if the additional profit from doing so are greater than 0. Because we care mostly about how the MDRP affects the incentives to launch a line extension we simply write the difference in profit in the commercial market as a reduced-form function $\Delta\pi\left(p_1, p^{\text{le}}\right)$, where p_1 and p^{le} are the prices of the original product and the line extension respectively.

The additional profit from launching a line extension is

$$\Delta\Pi = \Delta\pi\left(p_1, p^{\text{le}}\right) + sD_2\left(p^{\text{le}}(1-r) - (p_{1,0} - p_{1,t} \times r_t)\right) - c(s)$$

[11] The number of new patients that the product will attract is very important to decide whether or not to launch a line extension. We expect that this number will be strongly correlated with the fraction of switchers, so the analysis should not be affected too much by this simplification.

The manufacturers launches a line extension if and only if

$$\max_{p_1, p^{\text{le}}, s} \Delta\Pi\left(p_1, p^{\text{le}}, s\right) > 0$$

Discussion and predictions

Optimal pricing of the line extension is virtually identical to optimal pricing of the originator product, because the Medicaid pricing rules are applied identically to both. In the first period, it is optimal to charge a higher-than-normal price, and in later periods it is more profitable to charge lower-than-normal prices.

The choice of which line extension to develop, and whether or not to launch it is more interesting. We derive two additional predictions.

Prediction 4: *Drugs with a high Medicaid market share will launch line extensions at a higher rate.* The additional term due to Medicaid — $sD_2\left(p^{\text{le}}\left(1-r\right)-\left(p_{1,0}-p_{1,t}\times r_t\right)\right)$ — will be positive if the price of the line extension is higher than the price of the original product. The Medicaid price of the originator will decrease over time, but the line extension gets to set a new price. Therefore, as the originator drug progresses in the life-cycle, Medicaid will generate stronger and stronger incentives to launch a line extension.

Prediction 5: *Drugs with a high Medicaid market share who experience an unexpected increase in r will launch higher "quality" line extensions.* Intuitively, the optimal s increases if the spread between the price of the original product and the line extension goes up, because the marginal benefit of switching over an additional patient goes up. When r increases in the middle of the lifecycle of a drug, that almost certainly happens. However, drugs that do not undergo a regime change are not necessarily affected because they can manipulate list prices to avoid the effect.

To see that more formally, consider the first order condition of $\Delta\Pi\left(\cdot\right)$ with respect to s:

$$c'\left(s\right) = D_2\left(p^{\text{le}}\left(1-r\right)-\left(p_{1,0}-rp_{1,t}\right)\right) \tag{1}$$

As r changes, the term $p^{\text{le}}\left(1-r\right)-\left(p_{1,0}-rp_{1,t}\right)$ — i.e. the difference in the Medicaid price between the originator price and the line extension — will determine how s is likely to change.[12]

$p^{\text{le}}\left(1-r\right)$ is unlikely to change very much. The pricing problem that determines p^{le} is very similar to the pricing problem we examined in the previous section. Since D_2 is inelastic, the optimal price is unbounded, and so what sets the price of the line extension

[12]We assume that any change to $\pi\left(\cdot\right)$ from s is a second-order effect from changes in p_1 and p^{le} that is small enough to be ignored.

is some other constraint to the Medicaid price. Unless the constraint affects the actual list price p^{le} though, there is no reason to believe that moving r would affect the initial list price: the manufacturer can simply increase p^{le} by a proportional amount to leave $p^{le}(1-r)$ unchanged.

Whether or not r affects $p_{1,0} - rp_{1,t}$ may depend on how much the firm knows about r. In the long run, both $p_{1,0}$ and $p_{1,t}$ are set under the new r regime. In these circumstances the manufacturers might be able to adjust prices to avoid any negative impact of r. However, if r changes after a product has been launched, the manufacturer can only react by changing $p_{1,t}$. As a result, an increase in r would probably decrease $p_{1,0} - rp_{1,t}$. In this case, the spread between the price of the line extension and the price of the original product should increase, which in turn means the RHS will become larger. Since $c'(s)$ is concave, when the RHS of 1 goes up, so does s.

4 The Impact of Medicaid Rebates on Drug Prices and Line Extension Development

4.1 Data – Prices, Line Extensions, and Medicaid Sales

We have data on invoice sales, volume sales, net sales, and Medicaid sales for a set of approximately 1,000 brand drugs that were marketed at some point between 2007 and 2018.[13] Additionally, we have data on strength and form for each NDC associated to any of the products in our data. Strength is a variable that refers to the quantity or density of active ingredient contained in a unit of drug. Form refers to the physical manifestation of a drug as a pill, tablet, injection, etc.

Volume sales come from SSR Health, which in turn obtains them from Symphony Health, a company that reports sales data on the pharmaceutical market. Volume sales data is considered to be fairly accurate for drugs that are sold mostly through the retail channel. However, data on drugs sold through other channels, such as hospitals and specialty pharmacies, is more noisy, and therefore subject to underreporting. Symphony Health records sales when prescriptions are distributed to patients. Invoice sales are calculated by multiplying volume sales by the Wholesale Acquisition Cost (WAC), a price published by the manufacturer that is supposed to reflect the cost of the drug to the wholesalers who distribute it to pharmacies and hospitals.

Net sales data, which also comes from SSR Health, is collected on a quarterly basis

[13] Not all drugs are available in all periods. Over time, as more firms have started reporting drug-specific earnings on their SEC filings, the sample has expanded. Occasionally, drugs are also dropped, mainly because of patent expiration. While the data obviously does not provide full coverage of the US pharmaceutical market, it does cover virtually all high-selling brand drugs. The only exception is for drugs that belong to privately owned companies. Since these companies are not required to disclose financial documents to shareholders, no data is available for them (most notably, this means we do not see drugs from Boehringer Ingelheim). In percentage terms, our data covers 85% of US invoice sales, and ~75% of US net sales.

from SEC filings of public firms. In these filings, firms usually disclose net sales by drugs for a handful of their largest sellers. These sales are recorded when the drugs are picked up by wholesalers from the manufacturer. Since wholesalers can sometimes keep an inventory, the lag between the loading dock and the pharmacy sale can vary. Both invoice and net sales are reported at the product level (e.g. Abilify), and therefore are potentially aggregated across many different forms, strengths, and drug package types.

Medicaid sales come from CMS and are publicly available. CMS reports national totals at the NDC level for all prescriptions filled by Medicaid beneficiaries. Overall spending on each NDC is also listed, though this amount only represent the payment disbursed from the state to the pharmacy and does not take into account any additional rebates received by the state from the manufacturer.

Finally, the data on NDC form and strength also comes from SSR Health (but is also publicly available from a variety of sources, including the FDA). We use the information on strength and form to determine whether a new NDC can in fact be considered a line extension or not. Examples of new NDCs that are not considered line extensions include new packages for already approved drugs.

In addition to these variables, SSR Health also calculates the Medicaid rebate. To perform this calculation they take into account: a drug's initial WAC, the current WAC, and the rate of inflation since the launch date of the drug. SSR Health performs this calculation at the product-strength-form level to take into account the line extension loophole and then aggregates the result at the product level in the data that we received. Unfortunately, since SSR Health does not have access to payer-level price and rebate data, it does not know if a drug has triggered the Medicaid "best price" clause. Therefore it simply uses the base Medicaid rebate in its calculations.[14]

Variable calculation

Using the data described above, we construct a series of variables for our analysis.

non-Medicaid discount: This variable is the average discount of a drug to payers other than Medicaid. This includes discounts to commercial payers, like PBM and insurers, government-sponsored programs like Medicare Part D and Medicare Advantage, and government-funded programs like VA and 340B. It also includes discounts that accrue to patients, such as copay assistance programs, and to other actors in the supply chain, such as wholesalers.

[14]The MDRP does not use WAC as a basis for its calculation of rebates. Instead, it uses the Average Manufacturer Price (AMP). The AMP is statutorily defined as the average price paid to the manufacturer for the drug in the United States by wholesalers and retail community pharmacies. WAC and AMP have near identical definitions. Both are best interpreted as list prices, and do not include most discounts and rebates. The difference is that AMP is based on actual transactions. Not much is known about the difference between the two. An ASPE brief from 2005 that compared AMP to WAC found that AMP was about 4% lower than WAC for single-source brand drugs (DHHS, 2005).

To calculate this variable we first calculate net Medicaid sales by multiplying Medicaid sales by 1 minus the Medicaid discount. Then, we calculate the non-Medicaid discount for drug j in period t as

$$d_{jt}^{\text{non-Med}} = 1 - \frac{\text{Net sales}_{jt} - \text{net Medicaid sales}_{jt}}{\text{WAC sales}_{jt} - \text{Medicaid sales}_{jt}}$$

Medicaid Market Share: This variable measures the fraction of a firm's revenue that comes from Medicaid. Ideally, we would like to calculate this number as a market share in terms of units sold. Unfortunately, SSR Health and CMS record units in a different way, meaning that we cannot compute this directly. Instead, we measure a revenue market share at list prices. The idea is that since both Medicaid and invoice sales are reported at list prices, the price component will cancel out when we take the ratio.[15] For any given drug j and period t,

$$MMS_{jt} = \frac{\text{Medicaid sales}_{jt}}{\text{WAC sales}_{jt}}$$

Number of line extensions: To identify line extensions we rely on information on the form and strength of each NDC code. First, we define the set of all forms and strengths included in the initial approval by looking at NDCs with positive Medicaid sales in the first year since the drug's original launch date.[16] NDCs that appear for the first time more than one year after the initial launch are all possible candidates for a line extension. We assign line extension status to a drug if either the form or the strength variable were not previously available in the set of drugs from the original launch, plus all line extensions launched before the drug in question. We then create two additional indicators for each line extension to signal whether it was a new form line extension, or a new strength line extension (or both).

Data issues and core sample

Volume and invoice sales, net sales and Medicaid sales are reported by three different sources: Symphony Health, firm SEC filings, and CMS. Differences in the timing of these records lead to two possible errors in the variables listed above.

First, the two different sources report sales at different points in the supply chain. Manufacturers (who are the source of net sales, through their SEC filings), record sales when the drugs are picked up by wholesalers. Symphony (who provides gross sales and units sold) records sales to patients. Hence, any fluctuation in drug inventories will generate

[15] In practice, we will still have some residual measurement error that comes from the fact that Medicaid generally reimburses at prices that are slightly higher than WAC. Furthermore, each state uses a different formula for reimbursements, which can generate some additional noise.

[16] We use appearance in Medicaid as a proxy for the launch date because we do not have that information at the NDC level.

volatility in the quarterly price and discount numbers. Additionally, it is possible that volume-triggered rebates might be incorporate in the filings at different points in time. Timing issues are particularly prominent at the very beginning of a drug's lifecycle — as wholesalers build inventories — and at the very end — as the manufacturers rushes to ship as much product as possible to wholesalers before generic entry.

A second source of bias comes from incompleteness in the sales numbers calculated by Symphony Health. Drug sales through certain channels, such as specialty pharmacies, dentists, and hospitals, are harder to track.[17] This type of measurement error can be very problematic. Drugs with underreported invoice sales appear to have a high Medicaid market share (because Medicaid data does not suffer from the same underreporting problem). As a result, they will mistakenly be included in our treatment group, thus weakening the power of our estimator. In addition, underreporting creates problems for our measures of private market discounts, as net sales sometimes greatly exceed list sales over a long period.

We select our core sample of analysis to minimize measurement error problems in our data. We focus on drugs that launched in 2007 or earlier. This ensures that in 2009 — the year in which we calculate the Medicaid market share (MMS) that we use in the analysis — sales reporting has more or less normalized. This mitigates the timing issue in our data. For the same reason we also calculate our variables at the annual level.

To take care of the underreporting problem, we compare net sales and invoice sales. Net sales are reported by the firm, so they do not suffer from underreporting. By definition, they also must be less than or equal to invoice sales, but because of the timing issue it is possible for net sales to be higher than invoice sales in a given quarter. Over a longer period however, overall net sales must be lower than overall invoice sales. We use this test to exclude drugs from our sample whose lifecycle net sales are greater than invoice sales or whose net sales are fifty percent more than gross sales over an entire year.[18] Appendix B.2 provides additional details on the sample selection procedure and evidence on the unreliability of the excluded sample.

4.2 Summary Statistics

In Table 1, we present the summary statistics for our cross-sectional variables and outcomes.

We find that the Medicaid market share of most drugs is very small. The average drug

[17] For example, Eylea, a leading macular degeneration drug that is typically administered by doctors had annual net sales between 838 million and 4 billion during our sample period, but had recorded gross sales ranging from 3.5 million to 83 million in our data. This leads to a very high implied Medicaid market share, sometimes greater than 1, even though the drug is used mostly to treat older patients.

[18] Here, by lifecycle we mean all quarters for which we have data. We recognize that this approach is not ideal because it is a data-driven selection process. We are looking for an alternative selection mechanism through the construction of a list of drugs that are sold through specialty pharmacies and to dentists.

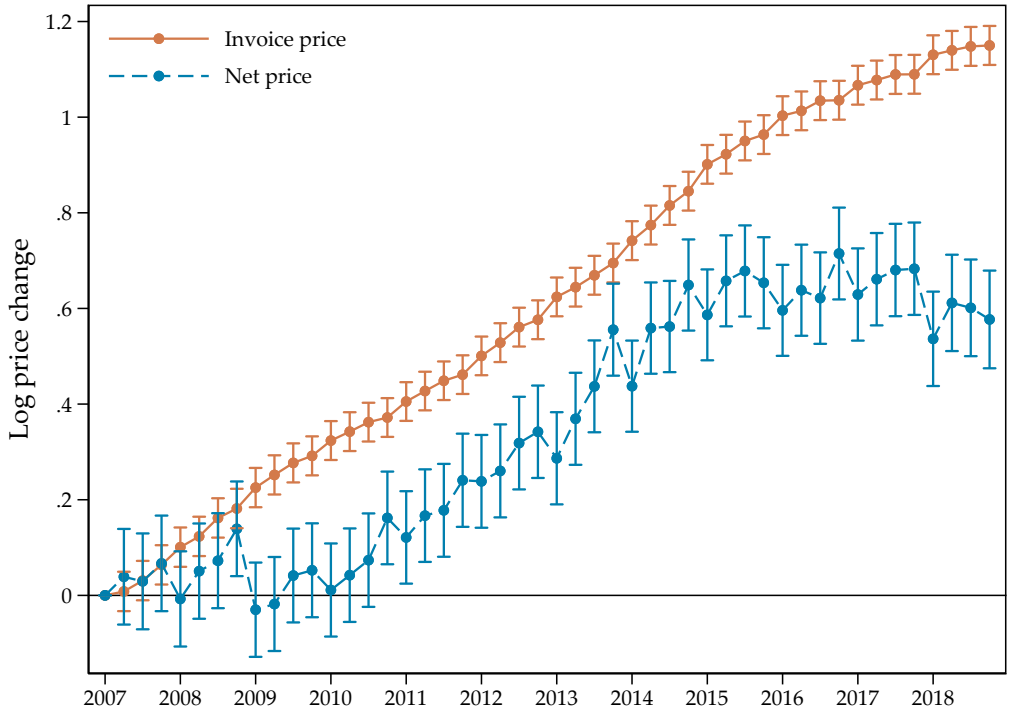

Figure 5: List and Net Price growth, 2007-2018

in our sample has an MMS of 6.98%. This is much smaller than the MMS in Duggan and Scott Morton (2006) — they found an average MMS of 16.5%.The difference is likely due to the implementation of Medicare Part D in 2006. Part D now covers Medicaid-eligible patients over 65, which means that Medicaid is responsible for the drug coverage of a much smaller set of individuals..

Yearly WAC growth is much greater than the rate of inflation, confirming the idea that the additional Medicaid rebate is going to be very relevant for many drugs. The average growth rate is almost 11% a year. The average non-Medicaid discount is around 25%. Both of these numbers are consistent with results published in previous literature (see for example Aitken et al., 2016). We look at both list and net price growth more in detail in Figure 5, where we plot the quarter fixed effect coefficients from a regression of log price on time and product fixed effects.We notice that while list price growth is basically linear, net prices exhibit very different trends, and even seem to diverge after 2013.

Finally, we find that the average yearly probability of launching a line extension is about 5%. This number is also somewhat smaller than the number in Duggan and Scott Morton (2006). The reason is that they focus on top-selling drugs, while we don't filter for sales.

Table 1: Summary Statistics at the Drug Level for Core Sample

	Mean	Median	SD
2009 Medicaid Market Share (%)	6.9	3.8	8.2
2009 Sales to Medicaid ($M)	53.1	14.9	121.2
Yearly WAC Growth (%)	10.89	9.0	16.1
Non-Medicaid Discount (%)	25.3	23.7	20.9
Line extensions probability (yearly)	0.047	0	0.213
New Form probability	0.020	0	0.139
New Strength probability	0.039	0	0.1993

Notes: 261 drugs, 2,309 drug-years.

High-selling drugs are much more likely to launch line extensions because the line extension is more likely to earn back the fixed cost of development.

4.3 Analysis of drug prices

The two dependent variables we analyze in the first part of the analysis are invoice price (as measured by Wholesale Acquisition Cost, or WAC), and non-Medicaid discount. The basic empirical strategy we follow is to compare drugs with a high Medicaid Market Share (MMS) to drugs with a low MMS, before and after January 1st, 2010 — the date when the changes to the Medicaid Rebate Drug Program went into effect. Under the assumption that the two groups have parallel trends (after controlling for observables), this is a standard diff-in-diff regression design. Note however, that we expect these groups of drugs to exhibit different behavior even prior to the reform. The change in the formula exacerbated the incentives of drugs with a high MMS, but these incentives existed already. In order to account for this we separately control for pre- and post-ACA trends.

We run regressions of the form

$$y_{it} = \alpha_i + \beta X_{it} + \gamma Z_{it} + \delta_t + \varepsilon_{it}$$

where i indexes drugs, t indexes year, y_{it} is one of our dependent variables, X_{it} contains measures of exposure to Medicaid markets and any variables interacted with status (such as time trends), and Z_{it} includes any eventual additional controls. In certain specifications we also control for drug and year fixed effects.

Impact of the MDRP on invoice prices

First, we test the predictions of our model for the impact of the MDRP on list price growth, including the impact of the ACA change. We find results generally consistent with the predictions of our model, with generally lower list price growth for drugs with high exposure to Medicaid, which is accentuated by the ACA changes.

Table 2 reports results for the regression with log WAC as dependent variable. In X_{it} we include separate linear trends for high-MMS drugs (our treatment group) before and after the ACA reform was implemented. Specifically, we run regressions of the form:

$$log(WAC_{it}) = \alpha_i + \beta_1 \times MMS_i \times (t - 2007) + \beta_2 \times MMS_i \times PostACA_t \times (t - 2010) + \delta_t + \varepsilon_{it}$$

We do not include trends over time in the control group because the year indicators account for that. Our regressions also account for drug fixed effects, so our identification is based on differences in invoice price growth of high- and low-MMS drugs before and after the reform was implemented.

In the first column of Panel A, we simply compare average price growth of high-MMS drugs to the average price growth of other drugs in the cross section. Consistent with our hypothesis, we find that drugs with high MMS experience lower list-price growth, by about 1.3 percentage points annually for every standard deviation increase in MMS. However, this result could be due in part to other differences in the nature of the drugs in each group.

The second column displays results from our diff-in-diff estimation. We find that there is no significant difference between high- and low-MMS drugs in the pre-period, potentially due to the low number of years of data or other factors correlated with the Medicaid exposure variable. However, we do find that post-ACA, the treatment group has lower invoice price growth relative to the pre-period. The point estimates suggest an effect of approximately 2.0 percentage points per year lower growth in WAC for a one standard deviation increase in MMS.

To check robustness to how we measure Medicaid market share, we repeat the analysis using indicators for quartile. The results are reported in Panel B of Table 2. We find again that drugs in the highest MMS quartile have significantly lower increases in WAC, with effects accentuated after the ACA.

Impact of the MDRP on non-Medicaid rebates

Next, we test the model's predictions for the overall impact of the Medicaid drug program on private market rebates, as well as the impact of the ACA reforms. Again, we find evidence supporting the prediction that private market discounts are lower for drugs with

high Medicaid exposure, with some increase in discounts after the implementation of the ACA.

In our main specification, we look for differences in private market discounts between drugs with different exposure to Medicaid, including differential impacts of the ACA. Specifically, we run regressions of the following form:

$$Discount_{it} = \beta_1 \times MMS_i + \beta_2 \times MMS_i \times PostACA_t + \delta_t + \varepsilon_{it}$$

where $Discount_{ij}$ is the fractional discount in the private market relative to list price. We also run specifications with drug fixed effects, in order to highlight the differential response of private market drug discounts to the ACA:

$$Discount_{it} = \alpha_i + \beta_2 \times MMS_i \times PostACA_t + \delta_t + \varepsilon_{it}$$

In Table 3 we report results from our regressions using non-Medicaid discount as a dependent variable. We focus here on the discounts in the years surrounding the policy change, 2007-2012, in order to isolate the effects of the ACA.[19] Column 1 shows that a one standard deviation increase in MMS is associated with a 2.3 percentage point decrease in private market discounts. In other words, the Medicaid program leads to higher private market *negotiated* prices, as predicted by the model. However, the same caveat applies here in that other factors could be driving this cross-sectional relationship.

We then turn to analyzing the impact of the ACA on this differential. In our diff-in-diff specification, we find evidence that post-ACA discounts for drugs with high Medicaid exposure are higher. The effect is about a 1.6 percentage point increase in discount rate for every standard deviation increase in MMS. This is consistent with the hypothesis that the ACA rebate change relaxed the constraints on private market negotiations. We find similar but statistically weaker estimates using drug fixed effects and breaking out the results by quartile.

4.4 The Impact of Medicaid Rebates on Line Extensions

As discussed earlier, one way to regain pricing flexibility in the Medicaid market is to launch a line extension. In this section, we use more detailed data on line extensions to build on test the predictions of the model in Section 3.2. First, we establish that new formulation line extensions garner more market share, consistent with

[19] As the sample moves further from the policy change, other factors such as additional entrants and mergers in the PBM industry can have large effects on discounts.

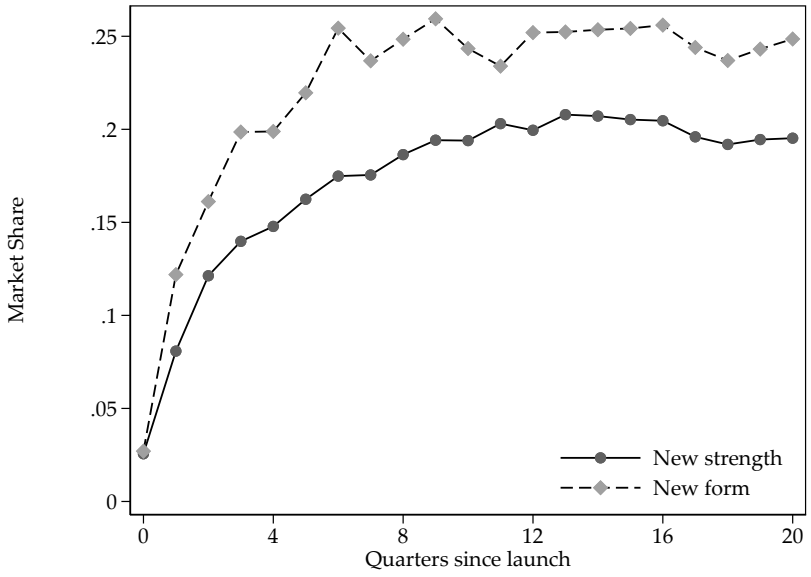

Figure 6: Market Shares within Molecule by Line Extension Type

4.5 Line Extension Penetration by Type

Our model of line extension investment behavior predicts that the ACA rebate change leads to higher quality line extensions (our definition of quality is based on revealed preferences: if more patients switch to the line extension, we interpret that as a signal of quality). However, assessing drug quality is quite challenging in the context of drug development.[20] In the case of line extensions, the conventional wisdom is that new forms can greatly enhance the value of an existing drug, while new strengths are more marginal.[21] We provide empirical evidence that new formulation line extensions garner more market share within a molecule than new strength extensions.

Using demand data from Medicaid, we find evidence consistent with beliefs in the industry. We collect publicly available data on aggregate drug demand by quarter and NDC from the Medicaid program, and identify when line extensions of each type are launched. We then compute the share of the molecule captured by line extensions of each type versus number of quarters since launch. As shown in Figure 6, we find that new form line extensions consistently garner greater market share.

A few caveats exist here. First, our set of line extensions reflect firm investment choices,

[20] Krieger et al. (2018) use chemical similarity measures to assess the novelty of new compounds.

[21] Fowler (2017) discusses this in greater detail. One example mentioned in her paper is Aricept ODT, which is a formulation line extension that dissolves orally instead of coming in tablet form, which helps Alzheimer's patients who have difficulty swallowing.

so we don't observe how line extensions that are not developed would have performed. A related problem is that we are comparing across molecules, so our results may be picking up on inherent differences across markets rather than differences across line extension types. Finally, our demand data comes from the Medicaid segment, which is relevant for our setting, but may not reflect preferences in the broader market. That being said, we believe that looking at Medicaid makes for a cleaner comparison between an original product and its line extensions. Cost-sharing of Medicaid patients constant, so the manufacturer cannot use pricing strategy to affect the switching rate from the original product to the line extension.

4.6 Medicaid Rebate Size and Line Extension Quality

Given the model and descriptive findings on line extension penetration, we would expect that firms responded to the ACA by developing more formulation line extensions. We find evidence consistent with this in the data.

In order to test our hypothesis, we run hazard regressions to see if firms with high Medicaid exposure are more likely to launch more line extensions after the ACA. As analyzed in Fowler (2019), firms are naturally more likely to launch line extensions early and late in a product's patent term, a pattern present in our data as well. To net out this secular trend, we employ a Cox proportional-hazards model. The additional covariates capture whether a line extension launch is more likely to occur at a given age after the ACA, particularly for drugs with high Medicaid exposure.

Formally, we run the following hazard regression:

$$\lambda_{it}\left(\text{age}|\, X_{it}\right) = \lambda_0\left(\text{age}\right) \times \exp\left(HighMedSales_i + HighMedSales_i \times PostACA_{it}\right)$$

where i indexes the molecule that could potentially have a line extension, and t indexes year. The only variable that changes over time in the covariates is the $PostACA$ variable. Intuitively, we are just changing the exposure to the new regulatory regime, and look for deviations from the baseline rate of line extension launches by age.

Unlike earlier, our primary cross-sectional variable here is $HighMedSales_i$, an indicator for whether the drug has above median sales to the Medicaid market. When choosing to develop a line extension, firms need to weigh the potential returns against development costs. Here, the relative exposure to the Medicaid market is less relevant for this kind of decision, because a firm may choose to develop a line extension for a drug with low MMS but high Medicaid sales due to the high absolute returns.[22] Both absolute Medicaid sales and line extensions are less prone to measurement problems, allowing us to include

[22] As robustness checks, we also run specifications with MMS as the predictor variable, and find weaker results.

a larger sample of drugs in our analysis.

We find evidence both consistent with the results in Duggan and Scott Morton (2006) and with the additional predictions from our model. Our results are reported in Table 4, with coefficients representing hazard rates relative to the baseline. First, we find evidence consistent with Duggan and Scott Morton (2006) that having higher Medicaid exposure generally increases the likelihood of launching a line extension. The hazard regressions that use only "High Med Sales" as a covariate capture this effect. Drugs with high Medicaid exposure are twice as likely to have line extension launched.[23] Our result is less noisy relative to those in Duggan and Scott Morton (2006), as we focus on just the new NDCs that are eligible for a rebate reset, while they count all new NDCs.[24]

We then leverage the ACA policy change to test whether it led to more and higher quality line extensions. We find that the ACA does appear to increase the rate of line extensions, with the effects for the high Medicaid exposure group loaded on the "new form" line extensions, as predicted by the model. The hazard rate for "new form" line extensions in the high Medicaid exposure group post-ACA is 3 times higher than the baseline, with a much smaller and statistically insignificant effect for new strength extensions.

In ongoing work, we are working to refine this basic analysis. We have run specifications that allow for multiple line extension introductions (multiple failure models), which reflects the fact that about a third of the molecules have multiple line extensions, conditional on having one line extension. We also are refining our study to deal with cases where both strength and form change, which occurs sometimes with extended release versions of drugs and also account for other types of line extensions such as combinations and enantiomers.

5 Conclusion

In this paper, we leverage changes to the Medicaid Drug Rebate Program in the ACA to study the impact of MDRP rules on firm pricing and innovation decisions. Overall, we find that the ACA reform has generally had positive impacts on outcomes. The increase in mandatory rebate discourages list price growth, lowers negotiated prices, and leads to higher quality line extensions, albeit possibly only in the short-run.

Our results carry important implications for policy design. First, we show that the Medicaid rebate rules are not easy to exploit. The combination of limiting the maximum price to the inflation adjusted price at launch, combined with the best-price provision, make it very hard for firms to extract a high price from Medicaid, despite the fact that the program

[23] One specific concern with the result could be that Medicaid has both a different patient pool and different cost sharing conditions. Line extensions may be profitable for reasons other than the incentives created by the rebates.

[24] For example, new NDCs sometimes represent packaging changes, going from 30 tablets to 90 tablets in one package.

pays for all medication costs (making demand almost perfectly inelastic). Second, we provide further evidence that profit implications matter for firms R&D decisions, not only in terms of quantity, but also in terms of quality. Our analysis is limited in that we only look at line extensions. Future work could ask the questions of whether intensified focus on line extensions comes at the expense of more innovative research.

More broadly, our work speaks to the challenges faced by a government facing regulatory providing a welfare program while at the same time facing regulatory constraints. In the case of Medicaid, the government is prohibited from directly negotiating with manufacturers, so it has to come up with a different way of setting prices. Governments facing this situation using choose one of two approaches: they set prices unilaterally using expert estimates — as in the case of Medicare provider reimbursements — or they use formulas that tie prices to the commercial market. We analyze the latter case, and show the tradeoffs implied by various features of these formulas.

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A PROOFS

A.1 Proof of Proposition 1

Proof. The proof proceeds by contradiction. Assume that $d^\star_{t'} > r$ for some $t' > 0$. Let $p^\star_{1,t'}$ be the optimal choice of list price in the commercial market. Then we can pick $\varepsilon > 0$ to construct a new choice pair $\left(p'_{1,t'}, d'_{t'}\right)$ that satisfies the following:

1. $d'_{t'} = d^\star_{t'} - \varepsilon > r$
2. $p'_{1,t'} = p^\star_{1,t'} \times \frac{1-d^\star_{t'}}{1-d^\star_{t'}+\varepsilon}$
3. $p'_{1,t'} < p_{1,0}$ if and only if $p^\star_{1,t'} < p_{1,0}$

The third condition comes from the fact that $p^\star_{1,t'} \times \frac{1-d^\star_{t'}}{1-d^\star_{t'}+\varepsilon}$ is continuous function that tends to $p^\star_{1,t'}$ from above as ε tends to 0 from above.

The net price in the commercial market is the same for both choice pairs: $p'_{1,t'}\left(1 - d^\star_{t'}\right)$. Therefore, profits in the commercial market remain unchanged.

Next, consider the price in the Medicaid market. Since Medicaid demand is price inelastic, a higher price translates to higher profits. Under the original price pair the price is

$$p^{\text{Med}}_{2,t} = \begin{cases} p^\star_{1,t'}\left(1 - d^\star_{t'}\right) & \text{if } p^\star_{1,t'} \leq p_{1,0} \\ p_{1,0} - p^\star_{1,t'} \cdot d^\star_{t'} & \text{if } p^\star_{1,t'} > p_{1,0} \end{cases}$$

Under the alternative choice pair the price is

$$p^{\text{Med}}_{2,t} = \begin{cases} p^\star_{1,t'}\left(1 - d^\star_{t'}\right) & \text{if } p'_{1,t'} \leq p_{1,0} \\ p_{1,0} - p^\star_{1,t'}\left(\frac{1-d^\star_{1,t'}}{1-d^\star_{t'}+\varepsilon}\right)\left(d^\star_{t'} - \varepsilon\right) & \text{if } p'_{1,t'} > p_{1,0} \end{cases}$$

Combining these expressions, we see that there are two possible cases.

Case 1: $p^\star_{1,t'} \leq p_{1,0}$**.** In this case, $p'_{1,t'} < p_{1,0}$, so the Medicaid price is the same. There are no differences between the two choice pairs.

Case 2: $p^\star_{1,t'} > p_{1,0}$**.** In this case we compare $p_{1,0} - p^\star_{1,t'} \cdot d^\star_{t'}$ and $p_{1,0} - p^\star_{1,t'}\left(\frac{1-d^\star_{1,t'}}{1-d^\star_{t'}+\varepsilon}\right)\left(d^\star_{t'} - \varepsilon\right)$. Since $d^\star_{t'} - \varepsilon < d^\star_{t'}$ and $\frac{1-d^\star_{1,t'}}{1-d^\star_{t'}+\varepsilon} < 1$, the new pair yields a higher Medicaid price.

This concludes the proof. □

A.2 Proof of Proposition 2

TBD

A.3 Proof of Proposition 3

TBD

B Sample of Drugs

B.1 List of Top Selling Drugs by Medicaid Exposure

Here, we show the list of drugs, sorted by MMS quartile (based on 2009 sales) and total gross sales from 2007-2018. The results are generally reflective of the fact that drugs with low Medicaid exposure tend to treat diseases that affect older individuals, such as arthritis and cancer, while drugs with high Medicaid exposure treat diseases more likely to affect younger, more vulnerable populations, such HIV/AIDS, mental health, and breathing conditions.

B.2 Details on Sample and Measurement Issues

The raw sample of drugs comes from data compiled by SSR Health of prescription drugs sold by publicly-traded companies anytime between 2007 and 2018. We focus on this sample so that we have data on private market discounts. To be included in the sample, the drug has to have revenue numbers reported in company financial filings, which corresponds to the top selling drugs for each firm. The raw sample has 1,052 total drugs.

To understand the impact of the ACA, we restrict to drugs launched in 2007 or earlier, so that we have enough pre-ACA data on them. This leaves 552 total drugs, which represents our expanded sample. Next, to address problems with gross sales measures, we exclude drugs with net sales greater than gross sales over the entire data period or with especially high net-to-gross ratio in a given year. This leaves us with our core sample of 261 drugs. The drop in number reflects the prevalence of problems in the gross sales data. Through inspection, the problematic drugs tend to be low-selling drugs, administered by doctors or dentists, or sold through specialty pharmacies because the drugs treat serious conditions such as Alzheimer's and Parkinson's.

We also find that the MMS measures across years are much more stable within our core sample relative to the excluded drugs. We compare MMS measures across years for the different samples and report the findings in Table 2. In the core sample, MMS is very stable from year-to-year, with a high R^2 and coefficient close to 1 whereas the excluded drugs have a much noisier fit.

Table 2: Stability of Medicaid Market Share Across Years

	MMS 2010	
MMS 2009	2.332	1.154**
	(1.619)	(0.019)
Sample	Excluded	Core Sample
R^2	0.253	0.960
N	244	251
	MMS 2009	
MMS 2008	0.011	0.957**
	(0.012)	(0.023)
Sample	Excluded	Core Sample
R^2	0.0379	0.966
N	249	261

Notes: $+p < 0.1$, * $p < 0.05$, ** $p < 0.01$.

C Additional Specifications

In this section, we provide additional robustness checks of our core empirical results.

C.1 Alternative Medicaid Exposure Measures

One major measurement issue affecting our analysis is that gross sales appear to be significantly mismeasured for a large set of drugs. To address this problem we construct the Medicaid exposure measure by dividing Medicaid gross sales by overall net sales. We find that this alternate MMS measure is more more stable for the drugs excluded from the core sample, as the net sales data is more reliable. The main problem with this specification is that drugs with high discount will be classified as high MMS drugs, creating an artificial positive correlation between MMS and private market discounts. However, this should only add noise to our cross-sectional measure and likely does not bias our difference-in-difference estimates.

We report the results in Table 3. We find generally similar results using this net sales-based measure of Medicaid exposure. The only major difference is that MMS and private market discounts are positively correlated, but this is mainly a result of the artificial correlation generated by how we constructed the exposure variable.

Table 3: Robustness Check – Extended Sample, Net Medicaid Measure

Panel A: List Price

	log (WAC)	
MMS	-0.0699**	0.00552
× Year	(0.0163)	(0.0260)
MMS × Year		-0.103*
× Post-ACA		(0.0440)
Product FE	Y	Y
Year FE	Y	Y
N	3,697	3,697

Panel B: Private Market Discounts

	non-Medicaid discount		
MMS	0.0958**	0.0650+	
	(0.0337)	(0.0373)	
MMS		0.0628+	0.0522
× Post-ACA		(0.0340)	(0.0351)
Age FE	Y	Y	Y
Year FE	Y	Y	Y
Drug FE	N	N	Y
N	1,797	1,797	1,797

Notes: Standard errors are clustered at the drug level. $+p < 0.1$, * $p < 0.05$, ** $p < 0.01$.

We also test the robustness of our results to the year in which we measure Medicaid market share. In the main analysis, we use 2009 data to measure MMS, in order to best capture Medicaid exposure right before the policy change. Here, we re-run the results using data from 2007 to measure Medicaid market share. We report the results in Table 4 again find very similar results, with larger magnitudes on the coefficients of interest.

Table 4: Robustness Check – 2007 Medicaid Market Share

Panel A: List Price

	log (WAC)	
MMS	-0.209**	0.0410
× Year	(0.0621)	(0.0786)
MMS × Year		-0.342**
× Post-ACA		(0.108)
Product FE	Y	Y
Year FE	Y	Y
N	2,342	2,342

Panel B: Private Market Discounts

	non-Medicaid discount		
MMS	-0.388*	-0.535**	
	(0.174)	(0.159)	
MMS		0.325*	0.228+
× Post-ACA		(0.143)	(0.126)
Age FE	Y	Y	Y
Year FE	Y	Y	Y
Drug FE	N	N	Y
N	1,474	1,474	1,474

Notes: Standard errors are clustered at the drug level. $+p < 0.1$, * $p < 0.05$, ** $p < 0.01$.

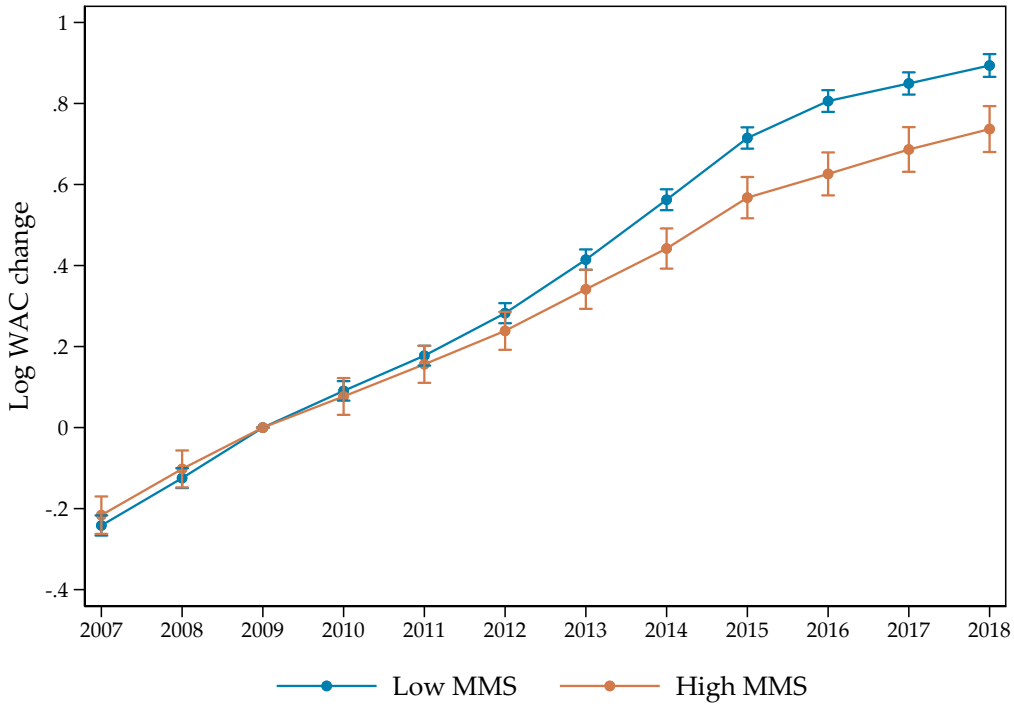
C.2 Launch Prices

In our core analysis, we have focused on drugs launched before the ACA rule change. Here, we test whether launch prices are higher after the ACA rule change, akin to the analysis in Ridley and Lee (2019). To do so, we compare the launch prices of the drugs launched between 2008-2009 and between 2010-2011.

We report the results in Table 5. First, we run the raw comparison, and find evidence that post-ACA launch prices are significantly higher. However, after we restrict to our core sample (reliable gross sales measures) and control for drug class fixed effects, we find little evidence that launch prices for high MMS drugs are differentially affected by the ACA policy change. The caveat here is that we have a very limited sample of drugs, which make it difficult to make systematic comparisons.

In addition to levels, we also test implications from the model regarding initial price increases. We construct two outcomes: the price growth between launch year and the second year, $log\left(\text{WAC}_1\right) - log\left(\text{WAC}_0\right)$, and second derivative of the price path, $[log\left(\text{WAC}_2\right) -$

Figure 1: Change in WAC



$log\,(\text{WAC}_1)]-[log\,(\text{WAC}_1) - log\,(\text{WAC}_0)]$. The model predicts that companies launching high Medicaid exposure drugs after the ACA will set list prices in a way that limits initial growth. We report the results in Table 6. We do not find evidence that initial growth is smaller or an increasing price trajectory for high Medicaid exposure drugs after the ACA, although the estimates are again noisy.

D GRAPHS

D.1 Change in prices around the MDRP ACA change

D.2 Distribution of non-Medicaid discount

Figure 2: Change in Medicaid Price

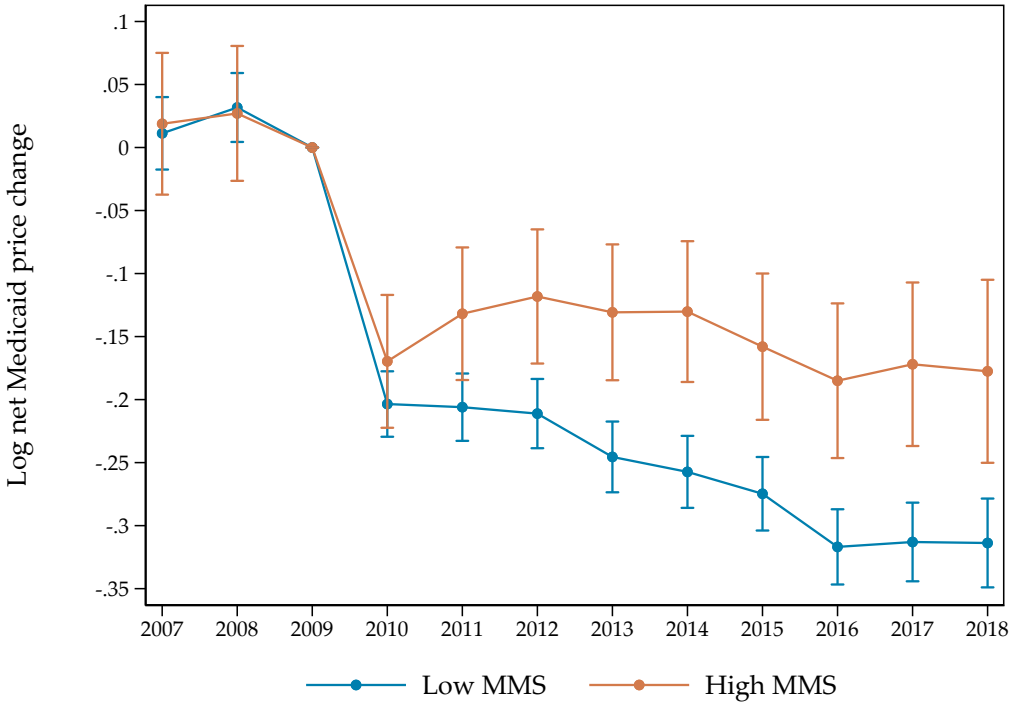


Figure 3: Change in non-Medicaid Price

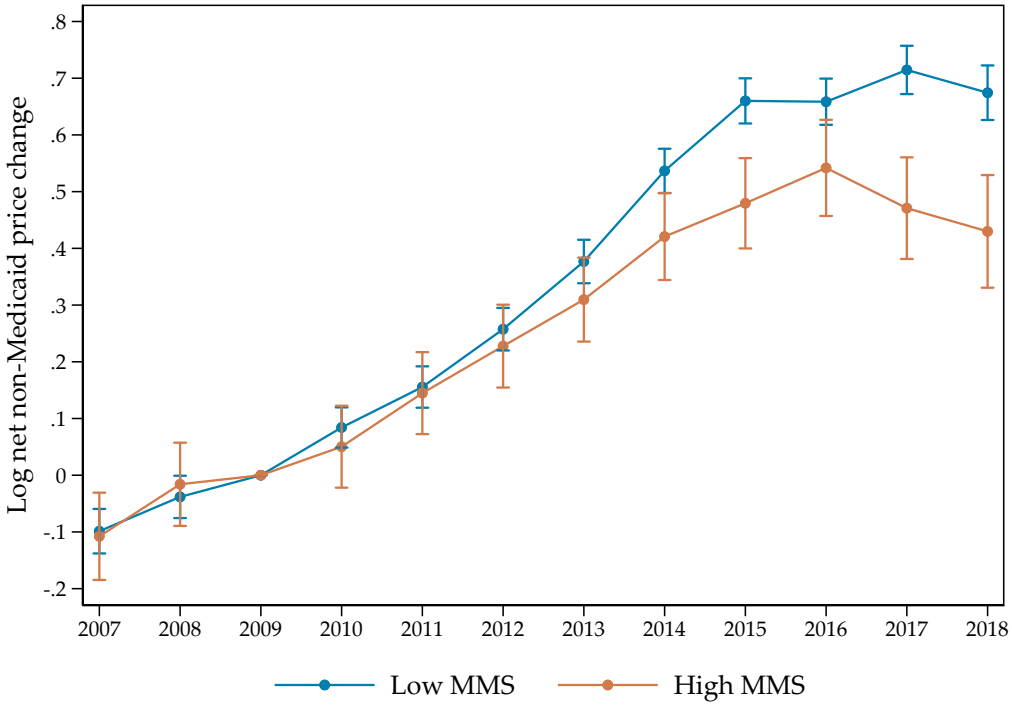


Figure 4: Change in the distribution of average non-Medicaid discount

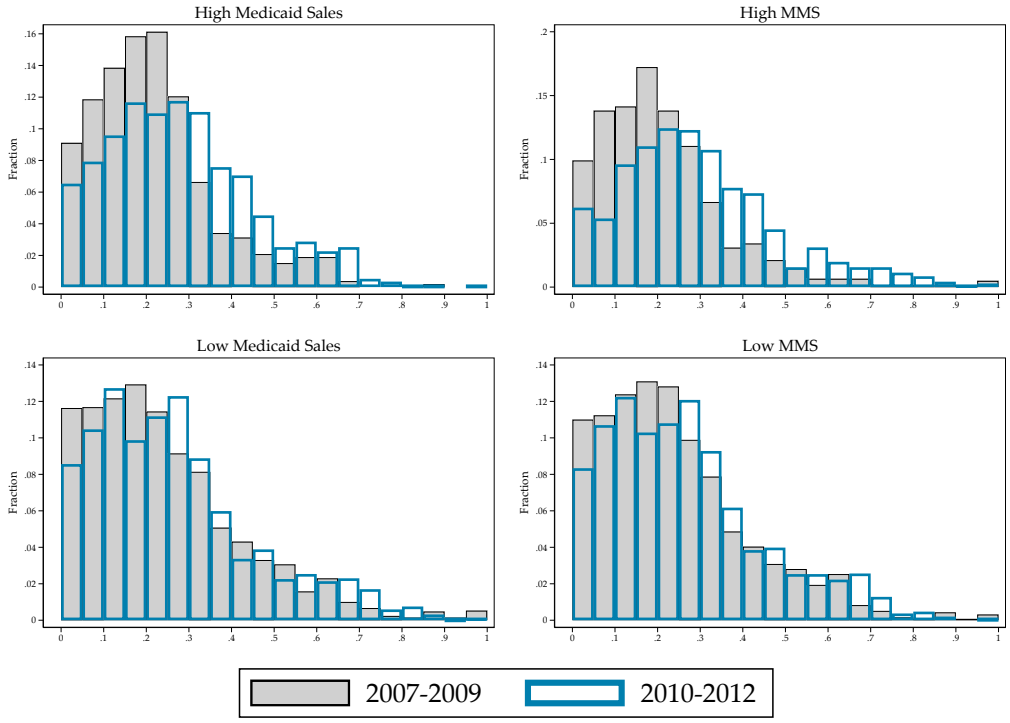


Table 2: Impact of MDRP on WAC

Panel A: Medicaid Market Share

	log (WAC)	
MMS	-0.169**	0.0165
× Year	(0.0532)	(0.0654)
MMS × Year		-0.253**
× Post-ACA		(0.0888)
Product FE	Y	Y
Year FE	Y	Y
N	2,309	2,309

Panel B: Medicaid Market Share Quartiles

	log (WAC)	
MMS Quartile 2	-0.00678	-0.00658
× Year	(0.0154)	(0.0172)
MMS Quartile 3	-0.0234	-0.0158
× Year	(0.0192)	(0.0166)
MMS Quartile 4	-0.0453**	-0.00146
× Year	(0.0146)	(0.0183)
MMS Quartile 2 × Year		-0.000251
× Post-ACA		(0.0254)
MMS Quartile 3 × Year		-0.0103
× Post-ACA		(0.0242)
MMS Quartile 4 × Year		-0.0597*
× Post-ACA		(0.0248)
Product FE	Y	Y
Year FE	Y	Y
N	2,309	2,309

Notes: Standard errors are clustered at the drug level.
$+p < 0.1$, * $p < 0.05$, ** $p < 0.01$.

Table 3: Impact of MDRP on private market negotiated prices

Panel A: Medicaid Market Share

	non-Medicaid discount		
MMS	-0.287*	-0.382**	
	(0.143)	(0.136)	
MMS		0.202+	0.150
× Post-ACA		(0.108)	(0.104)
Age FE	Y	Y	Y
Year FE	Y	Y	Y
Drug FE	N	N	Y
N	1,440	1,440	1,440

Panel B: Medicaid Market Share Quartiles

	non-Medicaid discount	
MMS Quartile 2	-0.0558*	-0.0618**
	(0.0227)	(0.0236)
MMS Quartile 3	-0.0218	-0.0389
	(0.0298)	(0.0309)
MMS Quartile 4	-0.0932**	-0.111**
	(0.0331)	(0.0333)
MMS Quartile 2		0.0124
× Post-ACA		(0.0195)
MMS Quartile 3		0.0362
× Post-ACA		(0.0238)
MMS Quartile 4		0.0384
× Post-ACA		(0.0294)
Age FE	Y	Y
Year FE	Y	Y
Drug FE	N	N
N	1,440	1,440

Notes: Standard errors are clustered at the drug level.
$+p < 0.1$, * $p < 0.05$, ** $p < 0.01$.

Table 4: Impact of MDRP Rebate on Line Extension Development

	All Line Extensions		New Form		New Strength	
High Med Sales	2.278**	1.725**	2.459**	1.439	2.370**	1.939**
	(0.367)	(0.364)	(0.600)	(0.515)	(0.404)	(0.433)
Post-ACA		0.947		0.937		1.110
		(0.246)		(0.348)		(0.304)
High Med Sales		2.078*		3.029*		1.697
×Post-ACA		(0.691)		(1.500)		(0.589)
N	552	552	552	552	552	552

Notes: The coefficients reported are odds ratios. Robust standard errors.
$+p < 0.1$, * $p < 0.05$, ** $p < 0.01$.

Table 1: Top Selling Drugs by Medicaid Exposure

Product	Gross Sales ($M)	Medicaid Market Share	MMS Quartile
HUMIRA	97,327	0.033	1
ENBREL	62,597	0.029	1
REMICADE	61,226	0.015	1
RITUXAN	42,942	0.015	1
LANTUS	71,617	0.065	2
ADVAIR	67,286	0.078	2
NEULASTA	59,060	0.035	2
NEXIUM	58,542	0.057	2
LYRICA	35,278	0.087	3
TRUVADA	30,352	0.169	3
ATRIPLA	30,213	0.116	3
SINGULAIR	23,629	0.129	3
ABILIFY	40,224	0.282	4
SEROQUEL IR	19,254	0.246	4
ZYPREXA	12,286	0.2723	4
VENTOLIN	10,303	0.218	4

Table 5: Analysis of List Prices at Launch for Drugs Launched Between 2008-2011

	$log\,(\text{WAC})$					
Post-ACA	1.118*	1.275*	0.527	0.443	-0.454	-0.363
	(0.436)	(0.531)	(0.652)	(0.788)	(0.508)	(0.695)
MMS		-2.190		-17.81+		1.983
		(6.161)		(10.37)		(14.97)
MMS		-3.865		10.84		-2.743
×Post-ACA		(7.048)		(10.54)		(14.80)
ATC3 FE	No	No	No	No	Yes	Yes
Sample	All	All	Core	Core	Core	Core
N	130	130	62	62	50	50

Notes: Robust standard errors. $+p < 0.1$, * $p < 0.05$, ** $p < 0.01$.

Table 6: List Price Dynamics After Launch

Panel A: List Price Growth in First Year

	$log\,(\text{WAC}_1) - log\,(\text{WAC}_0)$					
Post-ACA	-0.0369	-0.0527	-0.0141	-0.0289	0.0298	0.00712
	(0.0352)	(0.0459)	(0.0444)	(0.0598)	(0.0595)	(0.0764)
MMS		-0.392		-0.592		-2.567
		(0.301)		(0.932)		(1.645)
MMS		0.455		0.628		-0.199
×Post-ACA		(0.338)		(0.933)		(1.627)
ATC3 FE	No	No	No	No	Yes	Yes
Sample	All	All	Core	Core	Core	Core
N	130	130	62	62	50	50

Panel B: List Price Trajectory

	Trajectory					
Post-ACA	0.0830*	0.108*	0.0983	0.112	-0.00880	-0.0653
	(0.0396)	(0.0509)	(0.0626)	(0.0849)	(0.103)	(0.140)
MMS		0.541		0.290		-0.0857
		(0.344)		(1.190)		(3.005)
MMS		-0.712+		-0.460		2.193
×Post-ACA		(0.381)		(1.203)		(2.971)
ATC3 FE	No	No	No	No	Yes	Yes
Sample	All	All	Core	Core	Core	Core
N	130	130	62	62	50	50

Notes: Robust standard errors. $+p < 0.1$, * $p < 0.05$, ** $p < 0.01$.