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Profiting from Most-Favored-Customer Procurement Rules: Evidence from Medicaid†

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Using a difference-in-difference approach, we find that an increase to Medicaid's minimum drug rebate under the Affordable Care Act in 2010 lowered non-Medicaid drug spending by 2.5 percent. A stylized bargaining model shows that this is likely driven by the interaction of this reform with Medicaid's "most-favored customer" clause (MFCC). By examining the response of drugs that faced a change in incentives equivalent to the removal of Medicaid's MFCC, we estimate that removing the Medicaid MFCC would have reduced overall 2010 non-Medicaid drug spending by an additional 3.5 percent, though it would have likely also increased Medicaid spending. (*JEL* C78, H51, I18, I38, L65)

> Our concept of best-price [*sic*] for Medicaid—now incorporated into federal law—was supported by our long[-]standing policy of avoiding deep discounts.
>
> —Roy Vagelos, CEO, Merck (Brandenburger and Nalebuff 1996)

Most-favored-customer clauses (MFCCs) guarantee that a customer will receive the best price offered to anyone. Governments often use these clauses as a way to reduce procurement costs. A large body of theoretical research argues that MFCCs lead to higher equilibrium prices by reducing a firm's incentive to reduce price. These effects, however, are hard to identify empirically, especially in markets with firm-to-firm bilateral bargaining, because the prices that could trigger an MFCC are rarely observed.

This article uses a novel dataset on net prescription drug prices to evaluate the impact of a reform of Medicaid drug reimbursement rules and then leverage the reform to show that MFCCs can lead to higher prices and revenue in the commercial

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market. Medicaid rules require that drug manufacturers provide it with a rebate, which is calculated as the maximum of a statutory minimum rebate and the largest discount offered to a commercial payer (an MFCC, referred in statute as the "best price").[1] A 2010 reform increased the statutory minimum rebate, making the MFCC less likely to be triggered. We start by generating predictions of how the reform affected commercial market outcomes, adapting a model by Cooper and Fries (1991) to our empirical setting. The model predicts that the commercial discount response will be positive and will increase with exposure to the Medicaid market. In addition, it predicts that drugs whose largest commercial discount is at or just above the rebate floor will have the strongest reaction to the policy change. Conceptually, this group faces a change in incentives equivalent to removing the MFCC. Next, we evaluate the impact of the reform using a difference-in-difference approach based on the exposure of drugs to the Medicaid market. We estimate that the reform increased commercial discounts by an average of 2.2 percentage points and reduced overall non-Medicaid spending by 2.5 percent.[2] Breaking out the response by the pre-reform discount of each drug, we find evidence that the most exposed group exhibits the largest response, consistent with the model's predictions. Combining these estimates with our model, we estimate that removing the Medicaid MFCC would have decreased overall spending in non-Medicaid markets by an additional 3.5 percent in 2010. Such a policy change would likely also have resulted in higher drug prices for the Medicaid program.

The setting of this article is the Medicaid Drug Rebate Program (MDRP), which exhibits two features that aid our analysis. The first helpful feature of the MDRP is the 2010 reform mentioned above, which was part of the Affordable Care Act (ACA). The reform increased the statutory minimum rebate from 15.1 percent of list price to 23.1 percent, effectively decreasing the scope of the MFCC. This rebate change is conceptually equivalent to an exogenous decrease in the initially contracted price in a contract containing an MFCC. We use this variation as a natural experiment to evaluate the impact of the policy change and analyze the effects of MFCCs. A second useful feature of the MDRP is its "inflation penalty" provision, which adds any list price growth above inflation to the rebate. This provision prevents firms from increasing their list prices to mitigate the impact of the policy and allows us to focus on commercial discounts as the primary strategic response channel of drug manufacturers.

We embed the rules of the MDRP in a stylized model of price negotiations, based on Cooper and Fries (1991), to predict how manufacturers would respond to the reform. In the model, a monopolistic drug manufacturer engages in Nash bargaining with a representative commercial payer over discounts to an exogenously set list price. The manufacturer earns revenue from the commercial payer and Medicaid, with the price in the latter market determined by a function that incorporates the commercial discount. Specifically, the manufacturer triggers the Medicaid MFCC

[1] To maintain clarity throughout, "rebate" refers to the discount to the list price given to Medicaid while "discount" refers to the discount to the list price in non-Medicaid segments.

[2] Our data only allow us to observe average outcomes across all non-Medicaid segments of the market—including the commercial market, but also Medicare Part D and other institutional payers that are exempt from the MFCC.

whenever the equilibrium discount rate exceeds the statutory minimum rebate. The model highlights two response channels to the increase in the statutory minimum rebate. First, the rule change allows some manufacturers to offer higher discounts in equilibrium without triggering the MFCC. Second, it lowers the threat point of the manufacturer (i.e., the revenue earned if the negotiation fails and Medicaid becomes the sole customer), which also results in a higher equilibrium discount. Both channels are more likely to affect drugs with a higher share of sales from the Medicaid market.

We also use the model to isolate the impact of the reform on a group of drugs that effectively switch from facing an MFCC to not facing one at all. The intuition behind this result is that not all drugs are equally affected by a change in the rebate floor. We distinguish three groups based on their response per unit of Medicaid market share (MMS). First, drugs whose discount rate is below the initial rebate floor do not trigger the MFCC either before or after the reform, so we do not expect to see a change in their commercial market outcomes. Second, drugs whose discount rate is already above the postreform rebate floor will trigger the MFCC both before and after the reform. Despite the consistent exposure to the MFCC, they will still be marginally affected because their outside option (i.e., selling to Medicaid only) becomes less attractive, which implies a higher discount in the Nash bargaining game. Finally, drugs whose discount rate is between the initial rebate floor and the postreform rebate floor trigger the MFCC clause in the pre-period but are potentially free of its influence in the postperiod. Therefore, their discount rate should experience the largest change and approximate the response to a hypothetical removal of the Medicaid MFCC.

Turning to empirics, a key challenge in studying the US pharmaceutical market is the lack of reliable data on discounts, which we address by using a new data source. Published price data such as the Average Wholesale Price (AWP) or the Wholesale Acquisition Cost (WAC) do not reflect the acquisition costs of payers but, more commonly, represent starting points for negotiating discounts.[3] Available evidence on discounts suggests that they average around 20–30 percent market wide and can be as high as 60 percent (Aitken et al. 2016). As a result, there is limited evidence on the impact of policy on drug prices and revenue. We address this challenge using a novel dataset maintained by SSR Health, which contains net sales data from SEC filings of publicly traded drug manufacturers. By comparing net sales to invoice sales and prices from more traditional sources, we can estimate the average market-level discount for each drug. We then use publicly available Medicaid spending data to estimate Medicaid net sales and rebates separately from non-Medicaid net sales and discounts.

Our empirical analysis is divided into two parts. In the first part, we estimate the overall impact of the 2010 reform on the non-Medicaid market. For drugs with high exposure to the Medicaid market, we find that the rule change led to higher discounts and lower revenue in the non-Medicaid market. The average drug experienced a 2.2 percentage point increase in non-Medicaid discounts, equivalent to a 2.5 percent

[3] For example, a 2005 ASPE report found that, on average, the Average Sales Price—a more accurate measure of net price after private sector rebates but available only for drugs covered under Medicare Part B—is 49 percent lower than AWP (Department of Health and Human Services 2005a).

decrease in overall non-Medicaid drug spending, holding units fixed. There is no apparent effect from the reform on units sold on the non-Medicaid market.

We verify the validity and robustness of the results through two primary tests.[4] First, we check that secular trends related to variables correlated with MMS (such as sales, years since launch, or discount level) are not driving our findings. We find similar estimates when allowing for differential trends based on observables and when using a matching estimator. Second, we check that manufacturers affected by the reform did not increase list prices, which would negate the discount response we uncover. The threat point in the bargaining model is a function of both the list price and the statutory minimum rebate. If firms could freely adjust list prices, they could raise them to mitigate the effect of the rule change. We show that firms do not engage in this type of behavior. High-MMS drugs generally exhibit a 1 percentage point lower annual list price growth rate, a novel finding consistent with the incentives generated by the inflation penalty clause of the MDRP.

In the second part of our empirical analysis, we examine the heterogeneous per unit MMS impact of the reform, and we use our estimates to calculate the impact of removing the Medicaid MFCC. We divide drugs into three groups based on their non-Medicaid discount rate in 2009 (pre-policy) and estimate the impact of the reform on each group separately. Consistent with the model's predictions, we find that drugs with an initial discount rate between 15.1 and 23.1 percent (the statutory minimum rebates before and after the reform) exhibit the strongest response. Drugs with an initial discount above 23.1 percent have the second-largest reaction, and drugs with an initial discount below 15.1 percent have the smallest reaction, although these last two coefficients are not statistically significant. The estimates are noisy for two reasons. First, each group has a reduced sample size. Second, and more importantly, our model defines groups of drugs based on their highest discount. However, we observe an average discount measure that also includes some payers exempt from the MFCC, such as the VA and Medicare Part D. We use the estimates from our heterogeneity analysis to perform a back-of-the-envelope calculation of the impact of removing the Medicaid MFCC altogether. Our calculations suggest that removing the MFCC would have resulted in an additional 3.5 percent reduction in 2010 non-Medicaid spending. Sensitivity analysis using alternative methods and specifications return estimates in the 2–4 percent range.

This article contributes to three strands of economic literature. First, we contribute to the theoretical and empirical literature on MFCCs. Our theoretical framework adapts models in Cooper and Fries (1991) and Neilson and Winter (1994) to incorporate the specific features of Medicaid drug rebate rules. Our main contribution is to derive formulas for responses to the increase in statutory minimum rebate, which allows us to isolate the impact of the MFCC from a more general policy change. The formulas can also serve as the basis for structural estimation in settings with available contract-level data. The empirical literature on MFCCs is more limited and less conclusive. Most papers that have examined MFCCs in commercial markets have been unable to detect an impact on prices

[4] Section IIIE provides several additional robustness tests, including one that addresses the potential underestimation of the Medicaid rebate by SSR Health due to the Medicaid MFCC.

(see, e.g., Chen and Liu 2011; Mantovani, Piga, and Reggiani 2019). One notable exception is Scott Morton (1997), to which our paper is closely related, which examines the introduction of the Medicaid MFCC in the 1990s. Scott Morton (1997) finds that the introduction of the MFCC led to higher list prices among branded drugs with generic competitors but does not find an effect among patent-protected branded drugs. Our contribution here is to use newly available measures of commercial market discounts to show that the MFCC does affect the net prices of patent-protected brands. This distinction is essential both conceptually and for policy. Conceptually, it provides evidence that MFCCs can matter even in settings where manufacturers have significant market power. From a policy standpoint, more precise estimates of the response of patent-protected brands are useful because they account for the vast majority of pharmaceutical spending.

Second, our work is related to the broader literature on (mostly government-imposed) rules that limit price discrimination. These rules—like MFCCs—also generate spillovers across otherwise separate markets and negotiations. Empirical work on non-MFCC price restrictions includes several structural and reduced-form papers estimating the price, entry, and welfare effects of laws restricting prices (Duggan and Scott Morton 2006; Kyle 2007; Kyle and Ridley 2007; Mortimer 2007; Hastings 2009; Villas-Boas 2009; Grennan 2013; Clemens and Gottlieb 2017; Maini and Pammolli [forthcoming]; Ridley and Lee 2020). A paper of particular interest in this literature is Dubois, Gandhi, and Vasserman (2019), which uses a model closely related to ours to simulate the potential effects of the US referencing Canadian drug prices—essentially, an international MFCC. Our results are consistent with the authors' projection that reference pricing with Canada would increase Canadian prices. The implications of our work also apply to more informal reference structures. For example, recent evidence by Grennan and Swanson (2020) shows that information on peer acquisition prices can lead to lower prices in the context of hospitals' stent acquisitions. Our results suggest that price transparency could potentially lead to overall higher price levels in the long run.[5]

Third, our article contributes to the literature on US prescription drug markets, primarily by addressing the role of discounts. Recent papers have documented significant differences between invoice data and net revenue data from financial filings (Feng and Maini 2023; Kakani, Chernew, and Chandra 2020; Maini et al. 2021).[6] To the best of our knowledge, our paper is the first to show that invoice and net prices exhibit differential responses to a policy change.

The rest of the article is organized as follows. Section I discusses Medicaid procurement rules and the policy change we exploit. Section II presents the model and

[5] Grennan and Swanson (2020) interpret the results as being caused by a reduction in asymmetric information about the manufacturer's marginal cost of production. The two interpretations are not mutually exclusive. Our results merely raise the possibility of an additional effect. In addition, we stress that the transparency of individually negotiated prices is very different from list price transparency or even the transparency of aggregated negotiated rebates, both of which have recently been proposed by legislators and regulators—see, e.g., the final rule requiring disclosure of negotiated drug prices by payers (https://www.federalregister.gov/documents/2020/11/12/2020-24591/transparency-in-coverage, accessed March 28, 2021). Our results do not apply to such policies.

[6] Several recent policy analyses in medical journals also use SSR Health data (see, e.g., Hwang, Jain, et al. 2019; Hwang, Dusetzina, et al. 2019; San-Juan-Rodriguez et al. 2019; Wineinger, Zhang, and Topol 2019; Hernandez et al. 2020).

its predictions. Our empirical analysis consists of two parts: Section III presents our analysis of the ACA policy change, while Section IV breaks down the policy's effect across drugs and contains our estimate of the impact of removing the Medicaid MFCC. Section V concludes.

I. Overview of Medicaid Drug Procurement Rules

The Medicaid program provides health insurance benefits to a broad population. Exact requirements for Medicaid coverage vary across states, but the program covers many children, pregnant women, and individuals with disabilities. In states that expanded the program using federal funds available under the Affordable Care Act (ACA), the only requirement for coverage post-January 2014 is an income below 138 percent of the federal poverty line. All states offer drug coverage as part of Medicaid, and Medicaid is required to cover virtually all drugs approved by the Food and Drug Administration.[7]

A. *Medicaid Drug Procurement*

Medicaid payments for most prescription drugs can be broken down into two steps (see Figure 1 for a simplified schematic). First, state governments reimburse pharmacies that dispense prescriptions to Medicaid beneficiaries. Reimbursement rates vary across states but are generally based on acquisition costs and include a dispensing fee. Medicaid beneficiaries usually pay minimal or no out-of-pocket costs.[8] Then, manufacturers remit a quarterly rebate to states under a program called the Medicaid Drug Rebate Program (MDRP). The rebate size depends on a statutory formula that varies for innovator (i.e., branded) and non-innovator (i.e., generic) drugs. Our article focuses on innovator drugs.

The basic formula for an innovator drug's rebate is

$$R = N \times p \times r,$$

where N is the total number of Medicaid prescriptions in a given quarter, p is a measure of price, and r is the rebate fraction.

The MDRP measures p as the Average Manufacturer Price (AMP). The Code of Federal Regulations (42 CFR § 447.504) defines the AMP as the average price paid by wholesalers to manufacturers for a unit of a drug. AMP data are not publicly available, but it is closely related to Wholesale Acquisition Cost (WAC) for brand

[7] To have their drugs covered by Medicaid, drug manufacturers enter into a national rebate agreement with the Department of Health and Human Services. The terms of the agreement, known as the Medicaid Drug Rebate Program, require manufacturers to submit product and pricing data for their drugs to the Center for Medicare and Medicaid Services (CMS). Manufacturers are also required to enter into pricing agreements for the Section 340B Drug Pricing Program and Veterans Affairs to have their drugs covered under Medicaid. Virtually all manufacturers comply with these terms.

[8] In 2018, the range of Medicaid copays across states was between $0 and $4 everywhere except Montana, where a prescription for a nonpreferred brand drug cost $8. In addition, 15 states have no cost sharing at all (see 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, accessed November 14, 2019).

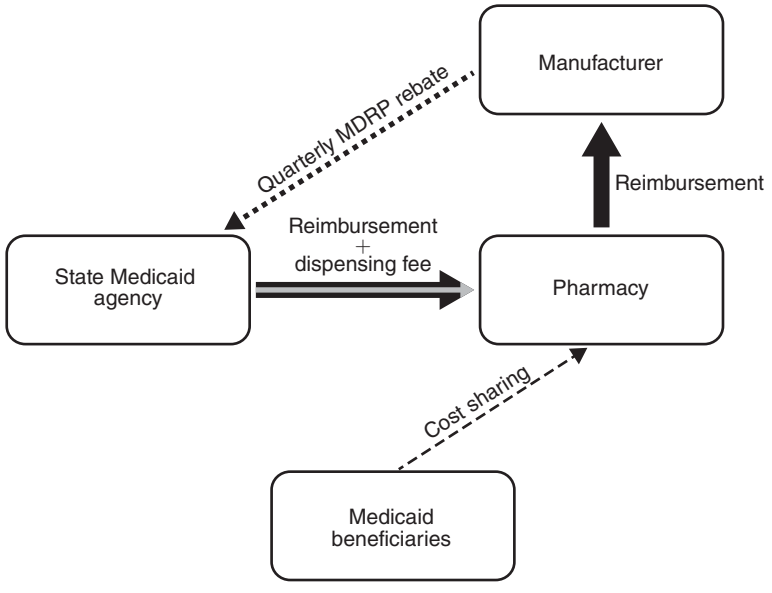

Figure 1. Stylized Flow of Medicaid Drug Payments

drugs—a widely available measure of list price (DHHS 2005b). Crucially, AMP is an invoice price; it does not incorporate discounts provided to commercial and public payers.

The rebate r has two components. The first (known as the "basic rebate") equals the greater of the statutory minimum rebate and the largest discount offered to a commercial payer. Discounts to Medicare Part D plans, the VA, and a few other institutional and public payers are exempt from the calculation of this rebate.[9] The second component, the inflation penalty, is the difference between the current AMP and the inflation-adjusted AMP at launch. Many drugs experience price growth above the inflation rate, so the inflation penalty often makes up a significant fraction of the overall rebate.

As Figure 2 illustrates, this formula entails some counterintuitive implications. The statutory minimum rebate is expressed as a fraction of the current AMP, but the inflation penalty anchors the price to the AMP at launch (adjusted for inflation). As a result, increasing the AMP above the inflation rate decreases the effective per unit price that Medicaid pays.[10]

[9] See the Code of Federal Regulation (42 CFR § 447.509) for more details.

[10] In some cases, drugs that see rapid increases can end up owing Medicaid rebates of 100 percent of AMP (the maximum possible value of the total Medicaid rebate). Eli Lilly executives told the House Energy and Commerce Committee that some of its insulin products have 100 percent Medicaid rebates (see https://docs.house.gov/meetings/IF/IF02/20190410/109299/HHRG-116-IF02-Wstate-MasonM-20190410.pdf, accessed September 10, 2020). More recently, former Secretary of Health and Human Services Alex Azar claimed at an American Enterprise Institute policy conference that over 2,300 drugs are at the 100 percent cap on rebate (see https://pink.pharmaintelligence.informa.com/PS123174/Medicaid-Reform-Trump-Administration-Pursuing-Rebates-Over-100, accessed September 10, 2020).

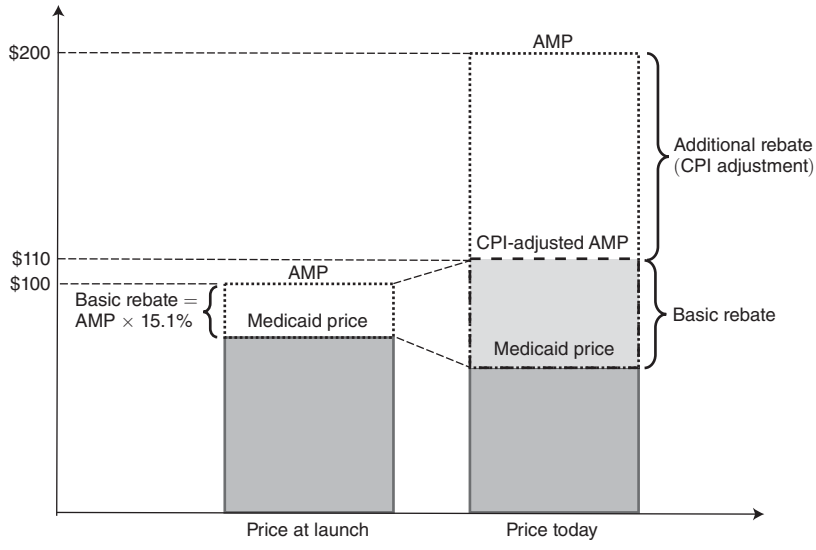

Figure 2. Cross-Sectional Analysis of a Rebate Change

The Medicaid rebate formula can affect the pricing strategies of firms that produce drugs with high exposure to the Medicaid market in three ways. First, to maximize the per unit reimbursement, firms may try to set a high initial list price. Second, firms are generally incentivized to avoid giving discounts above the statutory minimum rebate to private payers. Third, firms should minimize list price growth over time. We note that while the first two effects have been noted at least as early as Duggan and Scott Morton (2006) and Scott Morton (1997), respectively, the third effect remains unexplored in the economic literature, to the best of our knowledge.

B. *January 2010 Reform*

The MDRP revisions included in the ACA were implemented immediately after the act was signed into law on March 23, 2010, and they retroactively applied to the entire first quarter of 2010. Hence, the law affected Medicaid drug purchases starting on January 1, 2010. Table 1 summarizes how the ACA amended the MDRP. The MFCC provision was in place before the ACA and was not changed by the reform.

For the purposes of this paper, the most consequential aspect of the reform was the increase in the statutory minimum rebate from 15.1 percent to 23.1 percent. Another change under the ACA was the extension of rebates to Medicaid Managed Care (MCO)—the privately managed Medicaid that some states rely upon. This turns out to matter far less because, as noted in Dranove, Ody, and Starc (2021), states that use Medicaid Managed Care carved out prescription drugs before 2010 to take advantage of the MDRP's MFCC rule. Although Medicaid spending grows over time, it does not appear to jump significantly in 2010 due to the Managed Care expansion, suggesting that the reform did not impact the size of Medicaid spending subject to the MFCC.

Table 1—Features of the Medicaid Drug Rebate Program for Innovator Drugs

	Until December 2009	After January 2010
Statutory minimum rebate	15.1 percent of AMP	23.1 percent of AMP
Total rebate	Uncapped	Capped at 100 percent of AMP
Inflation penalty	Anchored to launch AMP	Anchored to launch AMP
Rebate applies to	State Medicaid only	State Medicaid and Medicaid Managed Care

Unlike most instances of the Medicaid expansion, which occurred starting in 2014, the changes to the formula were implemented immediately.[11] Two other provisions of the ACA took effect in the 2010–2011 period, although we do not expect them to affect our results. The first was an expansion of the 340B program, which provides drug discounts to hospitals serving low-income populations. This reform mostly affects drugs administered in or sold through hospitals; these drugs are not a large part of our core sample of analysis. The second change was a 50 percent discount on drugs acquired by patients in the Medicare Part D coverage gap. In response to this reform, drugs with a high Medicare Market Share would be incentivized to increase both their list prices and rebates (leaving effective prices unchanged). In online Appendix C.5 we show that Medicaid and Medicare Market Share are only weakly correlated and that our results are robust to controlling for Medicare Market Share.

Increasing the statutory minimum rebate from 15.1 to 23.1 percent had three effects. First, it may have increased the incentive to launch at a higher price, although other market forces might constrain drug manufacturers' abilities to do so.[12] Second, it reduced the scope of the MFCC, thus relaxing the restrictions on high rebates to private payers. Third, it increased the incentive to reduce list price growth. This last effect occurs because the rebate rate r applies to the current list price. Combined with the inflation penalty, a higher minimum rebate rate increases the rate at which prices fall, thus increasing the implicit penalty on list price increases. Figure 3 illustrates how the Medicaid price path of a drug whose list price increases annually by 10 percent above the inflation rate would appear under pre-ACA and post-ACA rules.

II. Bargaining under Procurement Constraints

We consider a single-product, monopolistic drug manufacturer selling to both Medicaid and commercial patients, and focus on how changing the statutory minimum rebate r affects equilibrium outcomes.

[11] Six states (California, Connecticut, Minnesota, Missouri, New Jersey, and Washington) plus Washington, DC took advantage of an "early opt in" option in the law and expanded Medicaid access between March 2010 and July 2012.

[12] This is not the focus of our paper, but we do test this hypothesis in an analysis reported in online Appendix C.4. We do not find strong evidence supporting this effect, mainly because of the high degree of price variation across drugs. A 2010 CBO analysis estimated that ACA's Medicaid provisions would lead to an increase in the price for new drugs of approximately 4 percent (see https://www.cbo.gov/sites/default/files/112th-congress-2011-2012/reports/04-05-ryan_letter.pdf, accessed September 10, 2020).

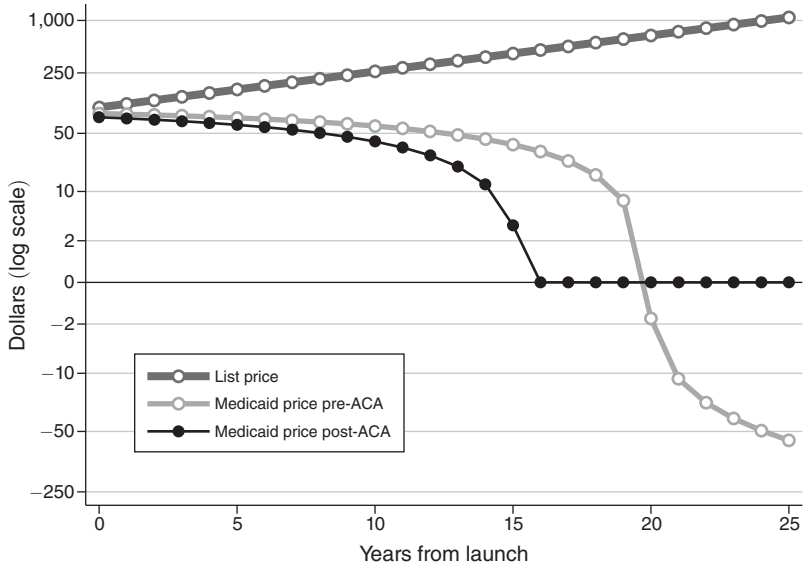

FIGURE 3. SIMULATED MEDICAID PRICE PATH BEFORE AND AFTER THE ACA REFORM

To simplify exposition, we make two assumptions. First, we assume that the manufacturer bargains with a representative commercial payer over a discount rate d off an exogenous list price p_{list}. We make this assumption because firms with a high Medicaid market share, or MMS, have no incentive to reduce list prices and, due to the inflation penalty, have limited leeway to increase list prices for drugs already on the market. Second, we assume that demand from both Medicaid and commercial patients is perfectly inelastic. Medicaid patients face fixed cost sharing that does not depend on the reimbursement price. The demand of commercial patients depends on cost sharing and not on price. Though the two are obviously related, the elasticity with respect to the net price should be relatively small. We also note that while we believe that these two assumptions are good approximations of real market conditions, they are not necessary for any of the key results of the model. We show in online Appendix B how to derive the main results of the model in a generalized setting.

We denote demand in the commercial market as D_C and demand in the Medicaid market as D_M. The Medicaid price p_M is set through a formula:

$$p_M = \min\left\{p_{list}^0, p_{list}\right\} - p_{list} \times \max\left\{r, d\right\}, \tag{1}$$

where p_{list}^0 is the list price of the drug at launch, and r is the minimum Medicaid rebate rate. We treat p_{list}^0 as exogenous, as we are interested in how the reform affects drugs launched before the reform takes place.

We use Nash bargaining to describe the negotiation between the manufacturer and the representative commercial payer. We assume that when parties fail to negotiate, the manufacturer can still sell its drug to Medicaid. In this case, the rebate that applies is simply the statutory minimum rebate r. Hence, Medicaid affects both the

profits from successful negotiations and the outside option. The problem can be stated as

$$(2)\quad \max_{d}\left[p_{list}(1-d)D_C - p_{list}\max\{0,d-r\}D_M\right]^{b} \times \left[\Pi\left(p_{list}(1-d)\right) - \Pi_0\right]^{1-b},$$

where $\Pi\left(p_{list}(1-d)\right)$ represents the net benefit to the commercial payer of acquiring the drug at price $p_{list}(1-d)$, and Π_0 is the benefit of not striking an agreement. We assume that the function $\Pi\left(p_{list}(1-d)\right)$ is concave.

The negative term in the payoff of the drug manufacturer reflects the impact of the MFCC. If the manufacturer agrees to a discount $d > r$, it will lose some of its Medicaid profits, which it could recoup by walking away from the negotiating table. (Of course, this would mean forfeiting any profits from the commercial market.)

The first-order condition yields the following implicit expression for the equilibrium discount rate d^{NB}:

$$(3)\quad 1-d^{NB} = \begin{cases} \dfrac{1}{\frac{1-b}{b}\times\left(-p_{list}\right)\frac{\partial \log\Delta\Pi\left(p_{list}\left(1-d^{NB}\right)\right)}{\partial x}}, & \text{if } d^{NB} \le r; \\ \dfrac{1}{\frac{1-b}{b}\times\left(-p_{list}\right)\frac{\partial \log\Delta\Pi\left(p_{list}\left(1-d^{NB}\right)\right)}{\partial x}} + \left(1-r\right)\times MMS, & \text{if } d^{NB} > r; \end{cases}$$

where $MMS = D_M/\left(D_C + D_M\right)$ is the Medicaid market share of the drug and $\Delta\Pi(x) \equiv \Pi(x) - \Pi_0$. Notice that the two-part FOC implies possible bunching at the r threshold.[13]

This first-order condition has two implications. The first implication regards the relationship between the equilibrium discount rate and the statutory minimum rebate r.

PROPOSITION 1: *The equilibrium discount rate d^{NB} is weakly increasing in r at a rate that is increasing in the Medicaid market share* (*MMS*).

Proposition 1 implies that increasing r will lead to higher discounts in the commercial market but also that drugs with a high MMS will be more affected.[14] We structure our core empirical analysis around this result.

The model also makes predictions about the relationship between the firm's revenue and the statutory minimum rebate r.

COROLLARY 1: *Total firm revenue from the commercial market is weakly decreasing in r at a rate that is increasing in the Medicaid market share* (*MMS*).

[13] This bunching condition would make for the cleanest identification in the empirical analysis. Unfortunately, we cannot exploit it because several non-Medicaid payers (most crucially, Medicare Part D and the VA) are excluded from the MFCC. Therefore, our average estimated discount will not necessarily show any bunching. We also note that because information about rebates is highly protected, a manufacturer could still exploit the r threshold in negotiations with a given payer even if it had already crossed that threshold with another payer, as long as the other party in the negotiation is not privy to this information.

[14] Online Appendix B.1 provides a full proof.

This corollary follows from Proposition 1. When r increases, the equilibrium discount rate (weakly) increases. Combined with fixed list prices, the change will lower the equilibrium net price. Furthermore, because commercial demand is assumed to be inelastic, total revenue will also decrease.

We note that even though the proof of Corollary 1 relies on our assumptions of fixed list prices and inelastic demand, the result extends to a setting with endogenously set list prices and elastic demand. Intuitively, the Medicaid inflation penalty prevents firms from simply increasing the list price in response to an increase in r. Moreover, even with elastic commercial demand, an increase in price will result in higher revenue as long as the price is below monopoly levels (see online Appendix B.3 for a rigorous proof).

This result implies that the Medicaid MFCC works in the firm's favor on the commercial market by making it easier to extract higher prices from commercial payers. If Medicaid were to drop the clause, manufacturers would simply negotiate on the basis of commercial revenue. The relevant first-order condition would be the one currently valid only for $d^{NB} < r$, which implies a higher commercial discount rate in equilibrium.

Decomposing the Effect of the Policy.—We now discuss how a change in the statutory minimum rebate from r to r' affects firms with varying pre-reform discount rates. The results of Proposition 1 and Corollary 1 hold for all firms, but not all firms will respond in the same way. Firms with initial discount $d^{\mathrm{NB}} < r$ are unaffected because their equilibrium price does not trigger the MFCC before or after the reform. Firms with $d^{\mathrm{NB}} \in \left[r < r'\right)$ will lower their discounts because they are no longer affected by the MFCC. Firms with $d^{NB} \geq r'$ will also lower their prices—although by a smaller amount—because their threat point has worsened. We note that this last effect is also a consequence of the MFCC and would not appear under a scenario in which Medicaid lowered its statutory minimum rebate but did not have an MFCC in place.[15]

We can derive more precise formulas for how increasing the statutory minimum rebate affects each firm by imposing a functional assumption on $\Pi(\cdot)$, i.e., the profit function of the commercial payer. We assume that

$$\Pi\big(p_{list}(1-d)\big) - \Pi_0 = \alpha\big(p_{list} - p_{list}(1-d)\big) \times D_C. \tag{4}$$

This functional form implies that commercial payers earn a constant linear fraction of the savings they generate by negotiating rebates on list prices. We make this assumption for two reasons. First, we think it generally reflects the business model of pharmacy benefit managers (PBMs), who usually negotiate drug contracts for

[15] Without the MFCC, a statutory minimum rebate change affects the negotiation payoff and the threat point in the same way. For example, suppose that the rebate increased from 15 percent to 25 percent. Without the MFCC, the payoff of a successful negotiation falls by $0.1 \times D_M$, but so does the threat point. Those two changes cancel out in the objective function of the Nash bargaining problem.

insurance companies and large employers.[16] Second, this assumption is akin to a first-order Taylor expansion that will hold for small changes around the equilibrium discount rate. In this case, α can be interpreted as the slope of the derivative of the profit function at the equilibrium discount rate. Hence, even if the profit function is not linear, the approximation will hold in a neighborhood of the equilibrium discount rate.

This simplification allows us to rewrite the first-order condition of the model as

$$d^{NB} = \begin{cases} 1-b, & \text{if } d^{NB} \leq r; \\ (1-b) \times \left[1-(1-r) \times MMS\right], & \text{if } d^{NB} > r. \end{cases}$$

This new condition, in turn, makes it very simple to compute responses to changes in r at various levels of d^{NB}:

$$d' - d^{NB} = \begin{cases} 0, & \text{if } d^{NB} < r; \\ (1-b)(1-r)MMS, & \text{if } d^{NB} \in [r, r') \text{ and } d' < r'; \\ r' - d^{NB}, & \text{if } d^{NB} \in [r, r') \text{ and } d' = r'; \\ (1-b)(r'-r)MMS, & \text{if } d^{NB} \in [r, r') \text{ and } d' > r'; \\ (1-b)(r'-r)MMS, & \text{if } d^{NB} \geq r'. \end{cases} \tag{5}$$

The response of the middle group (the one with $d^{NB} \in [r, r')$) depends on the exact initial level of d^{NB}. Drugs with d^{NB} either at r or very close to it will experience an increase of $(1-b)(1-r)MMS$ units. These are drugs that switch from being constrained by the MFCC to being unconstrained. Drugs with slightly higher d^{NB} might hit the new rebate threshold and bunch there. Hence, the change will be equal to $r' - d^{NB}$. Finally, drugs already close to the new rebate threshold may move past it. These drugs will experience the same change in discount rate as the group immediately above (the one with $d^{NB} > r'$). Combining these results implies that drugs in the middle group will be the most affected and drugs with very low initial discounts will be least affected.

We can extend this exercise to calibrate the effect of removing the Medicaid MFCC altogether. In the model, this is akin to setting $r' = 1$ because, in this case, the MFCC can never be triggered. Let d^1 denote the equilibrium discount in this scenario. The difference between d^1 and the discount rate under floor rebate r is equal to

$$d^1 - d^{NB} = \begin{cases} 0, & \text{if } d^{NB} < r; \\ (1-b)(1-r)MMS, & \text{if } d^{NB} > r. \end{cases} \tag{6}$$

Note that the formula in equation (6) depends more heavily on the linearity assumption because the assumed change in r is not small.

[16] See, for example, information disclosed by the Senate Finance Committee as a part of its insulin probe at https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf (accessed March 9, 2021).

III. Impact of the Reform on Non-Medicaid Prices and Spending

In this section we evaluate the impact of the 2010 reform to the Medicare Drug Rebate Program (MDRP) using a variable intensity difference-in-difference framework based on exposure to the Medicaid market.

A. *Data*, *Variable Construction*, *and Core Sample*

We combine data from two sources: the Medicaid Public Use Files (PUF) published by CMS and a private pharmaceutical research company called SSR Health.

The Medicaid PUF report national spending totals at the National Drug Code (NDC) level for all prescriptions filled by Medicaid beneficiaries (CMS 2019). Crucially, the amount listed represents the payment disbursed from the state to the pharmacy and does not take into account any rebates provided to Medicaid by the manufacturer.

From SSR Health, we obtain data on invoice sales, volume sales, and net sales for a set of approximately 1,000 branded drugs between 2007 and 2019 (SSR Health, 2019). SSR Health collects net sales on a quarterly basis from SEC filings of publicly traded firms. In these filings, firms disclose net sales by drug for their highest-selling drugs.[17] In 2018, SSR Health covered ∼90 percent of US invoice sales and ∼80 percent of US net sales.[18] The main branded drugs not covered by the data are those belonging to privately owned companies; these companies are not required to file public disclosures on net sales, so no data are available for them. However, the vast majority of pharmaceutical companies are publicly traded, so this restriction should not affect the interpretation of our results.

SSR Health combines net sales data with invoice and volume sales from Symphony Health, a company that reports sales data from the pharmaceutical industry. Symphony data are accurate for drugs sold through the retail channel; however, data on drugs sold through other channels, such as hospitals and specialty pharmacies, may be underreported. We address this potential issue by running our main analysis on a set of drugs sold mostly through the retail channel.

In addition to these variables, SSR Health also estimates the Medicaid rebate of each drug. The calculation takes into account a drug's initial list price (measured using the wholesale acquisition cost, or WAC), the current list price, and the rate of inflation since the launch date of the drug. Because SSR Health does not have access to payer-level price and discount data, it does not know if a drug has triggered the MFCC. Therefore, its calculations simply use the base Medicaid rebate. Crucially, even drugs whose average discount rate exceeds the minimum rebate rate need not have triggered the MFCC. Discounts to Medicare Part D, the VA, and several other

[17] 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.

[18] These numbers are based on a comparison of total spending in the SSR Health data against figures in an IQVIA report on 2018 US drug spending (IQVIA 2019). IQVIA reports invoice sales at $479 billion and net sales at $344 billion. SSR Health data have invoice sales for $439 billion and net sales for $276 billion. The slight discrepancy in invoice versus net coverage is likely driven by generics, which usually offer no rebates.

institutional payers affect the average discount rate in our data but do not trigger the MFCC. This limitation prevents us from running additional analyses such as tests of bunching at the minimum rebate thresholds.

Variable Construction.—For our analysis, we need to construct measures of Medicaid market share, net non-Medicaid revenue, and non-Medicaid discount.

The Medicaid market share (MMS) of a drug is the fraction of a firm's volume sales that comes from Medicaid. SSR Health and CMS record units in different ways, making it difficult to compute the MMS directly. Instead, we compute MMS using invoice sales. As both Medicaid and invoice sales are reported at list price levels, the price component should cancel out when we take the ratio.[19] For any given drug j and period t, we define

$$MMS_{jt} = \frac{Medicaid\ sales_{jt}}{Total\ invoice\ sales_{jt}}.$$

Medicaid sales—which do not incorporate rebates—and total invoice sales both come from our data. One limitation in our dataset is potentially underreported invoice sales in the Symphony invoice sales data for certain categories of drugs—namely, those that are physician administered or distributed through specialty pharmacies.[20] This would lead to potential measurement error in our MMS variable for such drugs. To avoid this issue, we exclude drugs that are likely to be subject to underreporting of invoice sales, as further discussed in the upcoming sample selection section.

Net non-Medicaid revenue is the difference between reported net sales from the SSR Health data and our estimate of net Medicaid sales. To calculate the net Medicaid sales, we multiply Medicaid sales by one minus the estimated Medicaid discount:[21]

$$Net\ Non\text{-}Medicaid\ Revenue_{jt} = Net\ sales_{jt} - Medicaid\ sales_{jt} \times \left(1 - Medicaid\ Discount_{jt}\right).$$

Net sales and Medicaid sales come from the data. SSR Health also estimates the Medicaid discount by adding the statutory minimum rebate and the inflation penalty.

[19] In practice, we might still have some residual measurement error because Medicaid sometimes reimburses at prices slightly higher than WAC. Furthermore, each state uses a different formula for reimbursements, which can generate additional noise.

[20] Similar issues exist in the IQVIA National Sales Perspective data, another commonly used source.

[21] Net non-Medicaid revenue includes sales to commercial payers; government-sponsored programs, like Medicare Part D and Medicare Advantage; and government-funded programs, like those run by the VA and the 340B program. The measure also incorporates firm spending on copay assistance programs and the relatively small discounts offered to other actors in the supply chain, such as wholesalers. Nonetheless, net non-Medicaid revenue is the best available measure of private market response, and we should still be able to identify the impact as long as these other components are not changing in a way correlated with Medicaid exposure.

The non-Medicaid discount is the average discount to payers other than Medicaid. We calculate it as the ratio of net non-Medicaid revenue to gross non-Medicaid revenue:

$$d_{jt}^{non\text{-}Med} = 1 - \frac{Net\ Non\text{-}Medicaid\ Revenue_{jt}}{Invoice\ sales_{jt} - Medicaid\ sales_{jt}}.$$

Both $d_{jt}^{non\text{-}Med}$ and the Medicaid discount in the previous formula are expressed in terms of WAC rather than AMP because AMP data are not publicly available. All elements of the formula come directly from the data except for net non-Medicaid revenue, which includes SSR Health's estimated Medicaid discount. Because SSR Health does not know the drugs for which the MFCC applies (such data are confidential by rule), the SSR Health estimates potentially underestimate the Medicaid rebate, which may, in turn, underestimate net non-Medicaid revenue and overestimate $d_{jt}^{non\text{-}Med}$. The potential underestimation of net non-Medicaid revenue is likely to be higher for drugs with high Medicaid exposure. To address this issue, we conduct robustness checks using an adjusted estimate of the Medicaid rebate (which then flows through to net non-Medicaid revenue and $d_{jt}^{non\text{-}Med}$). We discuss this further in Section IIIE.

Sample Selection.—Next, we turn to sample selection. We focus on drugs launched before 2009. The primary motivation here is that high-MMS drugs launched before the rule change have limited ability to adjust their list prices in response. Therefore, the threat point—a function of list price—changes in a mostly mechanical way, yielding a cleaner test of the hypotheses. In addition, our focus on drugs launched before 2009 allows us to compare outcomes within a drug, helping us control for significant heterogeneity in prices and revenue across drugs.

To mitigate issues surrounding the measurement of invoice sales, we filter out drugs for which the measurement issues are more pronounced. We use two methods. First, we screen out drugs that record net sales higher than invoice sales, which likely reflects underreporting of invoice sales.[22] Second, we directly address the source of underreporting—that is, missing sales from specialty pharmacies and in outpatient settings. To do so, we apply the screening rules used by Kakani, Chernew, and Chandra (2020), who select a sample of drugs primarily sold through retail pharmacies.[23]

After applying the two filters, we end up with a core sample of 198 drugs. In Table 2, panel A, we provide statistics summarizing our core sample. Prices and revenues are adjusted for inflation (BLS 2021), and we winsorize the non-Medicaid

[22] Net sales and invoice sales are recorded at different times, which can lead to some noise in a given year. To be conservative, we apply the filter only if net sales are greater than invoice sales over the entire period in which a drug is in the SSR sample. We also exclude drugs with net sales that are more than 50 percent greater than invoice sales in any given year other than the launch year and year before loss of exclusivity.

[23] We thank the authors of the paper for sharing their detailed methodology with us. We show in online Appendix A.3 that MMS measures are highly consistent across years for the sample using just our filter and the sample using both filters, with excluded drugs exhibiting very low correlation in MMS across years. This suggests that the filters are effective at addressing the problem.

Table 2—Summary Statistics

Variables	Mean	Median	Seventy-fifth percentile	Std. dev.	Observations
Panel A. Overall statistics					
Drug level					
MMS 2009	0.070	0.037	0.100	0.082	198
Age (in 2009)	7.56	7	11	4.97	198
Drug-year level					
WAC	42.77	4.41	13.00	272.54	1,087
WAC growth rate	0.112	0.095	0.141	0.181	889
Non-Medicaid discount fraction	0.213	0.202	0.306	0.185	1,067
Net non-Medicaid revenue ($M)	425.54	160.81	484.24	779.55	1,067

	High MMS		Low MMS	
Variables	Mean	Std. dev.	Mean	Std. dev.
Panel B. 2009 statistics by Medicaid exposure				
Age	8.36	5.14	7.29	4.90
WAC	25.64	85.88	45.63	301.42
WAC growth rate	0.105	0.120	0.143	0.228
Non-Medicaid discount	0.196	0.179	0.191	0.185
Net sales ($M)	396.29	638.95	463.03	860.64
Net non-Medicaid revenue ($M)	342.34	566.94	450.56	837.69
Observations	50		148	

Notes: The table shows summary statistics for the core sample. Both WAC and net non-Medicaid revenue are adjusted to year-2000 dollars. The non-Medicaid discount is winsorized at the fifth and ninety-fifth percentiles. Net non-Medicaid revenue is measured in millions of dollars. "High MMS" refers to drugs above the seventy-fifth percentile in our 2009 MMS measure. The missing entries for the discount fraction occur in years with missing net revenue data. (Fifteen occur in 2007.) In addition, there are three drug-years with negative implied net non-Medicaid revenue: two for the drug Nephro-Vite and one for Loxitane. This leads to null entries for the log transformation of the variable used later. As discussed in Section IIIA, this is likely due to measurement error in Medicaid net revenue.

discount at the fifth and ninetieth percentiles.[24] The average MMS is around 7 percent, with significant variance around the mean. Every outcome variable, including the price growth rate, has a skewed distribution.

In addition, we only track drugs through the year in which they lose exclusivity. The first reason is practical. Companies tend to report net revenues only for their top-selling drugs. After loss of exclusivity (LOE), drug sales typically plummet, which means the data are often missing. Furthermore, post-LOE branded drugs are much less likely to be policy relevant, given their dramatically reduced sales. The second reason is conceptual, as our goal is to show that the MFCC has an impact beyond the set of drugs with generic competition.

Table 2, panel B provides summary statistics by Medicaid exposure. The table provides a breakdown by "High MMS," an indicator of whether the drug is above the seventy-fifth percentile of the MMS distribution in 2009. The statistics are generally similar across the two groups. High-MMS drugs have been on the market

[24] Winsorization is necessary because measurement issues can lead to non-Medicaid discount rates that are large and negative for a handful of drugs with low net sales. We discuss this in online Appendix C.6.

longer and have lower prices and sales.[25] They also exhibit lower list price growth on average, consistent with the predicted effect of the Medicaid rebate formula, as explained in Section IA. Non-Medicaid discounts are virtually identical across the two groups.[26]

B. *Impact of the Rule Change on the Non-Medicaid Market*

We now evaluate the impact of the rule change on non-Medicaid market outcomes using a difference-in-difference framework.

Empirical Strategy.—We compare outcomes for drugs in the 2007–2009 period versus the 2010–2012 period (before and after the ACA rule change was implemented).[27] In order to account for secular trends in drug markets, we test for differential responses by exposure to the Medicaid market. The implicit assumption is that drugs with no exposure to Medicaid are unaffected by the policy and therefore serve as a control group. In addition, the approach assumes that the magnitude of the response increases with MMS, which is consistent with the predictions of the model.

Formally, we run the following regression:

$$(7) \quad Y_{it} = \gamma_i + \beta_1 \times PostACA_t + \beta_2 \times MMS_{i,2009} \times PostACA_t + Age\ FE + \epsilon_{it},$$

where i indexes the drug and t indexes the year. γ_i are drug fixed effects, $MMS_{i,2009}$ represents the Medicaid market share of the drug in 2009, and $PostACA_t$ is an indicator for the year being 2010 or later.[28] β_2 captures the average per unit MMS response. The main set of controls we include is a set of indicators for years since launch (i.e., age) that capture life cycle effects.[29] The main outcomes we focus on are discounts and net revenue in the non-Medicaid market. We use a winsorized measure of discounts in our core results because a few outlier drugs have very large raw discounts that could otherwise have an outsize impact on the estimator.[30] We also run specifications using an indicator for high MMS, defined as MMS in the seventy-fifth percentile or above, in place of the MMS measure.

Table 3 reports the results with non-Medicaid discount as the outcome. We find significantly higher non-Medicaid discounts after the reform for drugs with high Medicaid exposure. Based on the estimate in our preferred specification (column 5), a one-standard-deviation increase in MMS (0.082) equates to about a 2.12 percentage point higher discount in the non-Medicaid market after the rule change

[25] Unit prices are not necessarily representative of annual cost of treatment.

[26] Our empirical strategy, which we turn to next, accounts for potential systematic cross-sectional differences by including drug fixed effects.

[27] Restricting to the 2007–2012 period avoids market-wide changes that could alter the estimation such as the Medicaid expansion and the Express Scripts–Medco merger, which involved two of the largest pharmacy benefit managers and closed in the middle of 2012.

[28] $MMS_{i,2009}$ is constant within drug and is therefore absorbed into the fixed effect.

[29] We do not control for drug-specific or therapeutic class–specific price trends, as doing so would capture most of the useful variation. (MMS is highly correlated within class.)

[30] Figure C.6 in the online Appendix presents a box plot of the raw data. Specifications that do not use winsorization generally lead to larger estimated effects.

Table 3—The Impact of the MDRP Change on Non-Medicaid Discounts

	Non-Medicaid discount					
	(1)	(2)	(3)	(4)	(5)	(6)
Post-ACA	0.0702	0.0507	0.0555	0.00345	−0.0152	−0.0114
	(0.0110)	(0.0149)	(0.0132)	(0.0126)	(0.0140)	(0.0133)
MMS × *Post-ACA*		0.271			0.258	
		(0.133)			(0.127)	
High MMS × *Post-ACA*			0.0546			0.0566
			(0.0224)			(0.0221)
Age FE	N	N	N	Y	Y	Y
Drug FE	Y	Y	Y	Y	Y	Y
Observations	1,067	1,067	1,067	1,067	1,067	1,067

Notes: The table shows estimates of equation (7) with winsorized non-Medicaid discount as the outcome. Age refers to the number of years a drug has been on the market. Standard errors are clustered at the drug level.

relative to a baseline average discount of 21.3 percentage points. Stated in different terms, the estimate implies that the average spending across all drugs, holding units fixed, decreases by approximately 2.5 percent after the reform.[31] Because the non-Medicaid measure includes segments other than the commercial market, our estimates likely understate the true impact of the rule change on commercial market discounts but should still accurately capture the overall revenue effect. Another aspect captured by the results is that, on average, discounts increase over a drug's life cycle.[32] This increase is reflected in our estimate of β_1 in specifications (1–3). Once we account for age fixed effects in specifications (4–6), the baseline pre- and post-ACA discounts are no longer significantly different.

Next, we study the impact of the rule change on net non-Medicaid revenue. Table 4 reports the results. We find that drugs with higher MMS earn lower net non-Medicaid revenue after the rule change. The estimate in our preferred specification (column 5) implies that a one-standard-deviation increase in MMS is associated with a 15 percent decrease in non-Medicaid revenue.

On average, the estimate implies that non-Medicaid drug revenue fell by 13 percent, which is a larger effect than what we would obtain based only on the discount regressions. Because lower prices generally imply higher sales, one might have expected a lower impact on revenue than on price. However, the revenue effect is driven not only by the response of discounts but also by the responses of list prices and units:

$$\log(\textit{non-Medicaid Revenue}) = \log(\textit{list price}) + \log(1 - \textit{non-Medicaid discount}) + \log(\textit{units sold}).$$

[31] This is computed by evaluating the discount effect at the average MMS (0.07) and then translating to a percentage decrease in net price. Estimates are similar when weighting by sales because the correlation between MMS and sales is weak.

[32] Figures C.1–C.3 in the online Appendix presents estimates of age fixed effects.

Table 4—The Impact of the MDRP Change on Net Non-Medicaid Revenue

	log(*Non-Medicaid Revenue*)					
	(1)	(2)	(3)	(4)	(5)	(6)
Post-ACA	−0.0107	0.181	0.0990	−0.0804	0.0559	−0.0208
	(0.0804)	(0.110)	(0.0859)	(0.0756)	(0.108)	(0.0863)
MMS × *Post-ACA*		−2.666			−1.901	
		(1.361)			(1.167)	
High MMS Ind. × *Post-ACA*			−0.412			−0.231
			(0.200)			(0.169)
Age FE	N	N	N	Y	Y	Y
Drug FE	Y	Y	Y	Y	Y	Y
Observations	1,064	1,064	1,064	1,064	1,064	1,064

Notes: The table shows estimates of equation (7) with log net non-Medicaid revenue as the outcome. Age refers to the number of years a drug has been on the market. Standard errors are clustered at the drug level.

We discuss how each component of the RHS of the accounting identity above responded to the reform. As we show in the next section, list price growth is lower for high-MMS drugs, likely driven by the inflation penalty provision. This accounts for about a quarter of the average revenue effect (−2.8 percent). The ACA does accentuate the incentives for high-MMS drugs to avoid list price growth, but most of this effect would have existed absent the rule change. The change in the non-Medicaid discount accounts for another part of the effect (−3.1 percent).[33] However, if we use the raw discount measure without applying any winsorization, the estimate rises to −5.7 percent. Finally, non-Medicaid units sold exhibit a very noisy but negative response for high-MMS drugs, accounting for another −4.8 percent.

Our preferred estimate of the impact of the ACA reform excludes the effect of list price and units sold. The list price effect would have existed in the absence of the reform, and the decline in units sold is very noisy. Hence, our best estimate of the impact of the reform on revenue is a 2.5 percent decline, based on our more robust results on discount from Table 3.

C. *Are Secular Trends Driving the Estimates?*

Our core results establish that the magnitude of the response to the rule change increases with MMS. This finding is consistent with the idea that changes to Medicaid rules drive the observed response, but, nonetheless, it is possible that the MMS variable could be proxying for characteristics of drugs that are, in turn, related to other secular trends in the market. In other words, our research design would lead to a similar estimate even absent the rule change.

There are two possible ways that MMS might proxy for other drug attributes. First, as shown in Table 2, panel B, there are other observable differences between

[33] The discrepancy relative to the 2.5 percent number based on Table 3 stems from differences in functional form assumptions. (Our discount regression is linear, while the revenue breakdown requires the use of logarithms.)

Table 5—Estimates from Adding Controls and Matching

	Non-Medicaid Discount					
	(1)	(2)	(3)	(4)	(5)	(6)
Panel A. Additional controls						
Post ACA	0.127	0.101	0.109	0.0573	0.0344	0.0397
	(0.0455)	(0.0471)	(0.0472)	(0.0580)	(0.0574)	(0.0576)
MMS × *Post-ACA*		0.264			0.223	
		(0.129)			(0.119)	
High MMS × *Post-ACA*			0.0569			0.0538
			(0.0224)			(0.0219)
Controls	*Post-ACA* interacted with *Non-Med Discount*, log(*sales*), log(*WAC*), *Age*, Age^2					
Age FE	N	N	N	Y	Y	Y
Drug FE	Y	Y	Y	Y	Y	Y
Observations	1,061	1,061	1,061	1,061	1,061	1,061

	Non-Medicaid Discount			
	(1)	(2)	(3)	(4)
Panel B. Coarsened exact matching				
MMS	−0.0784	−0.231		
	(0.118)	(0.103)		
MMS × *Post-ACA*		0.323		
		(0.141)		
High MMS			−0.0179	−0.0434
			(0.0159)	(0.0164)
High MMS × *Post-ACA*				0.0541
				(0.0215)
Observations	1,061	1,061	1,061	1,061

Notes: The table shows estimates of equation (8) with winsorized non-Medicaid discount as the outcome. Age refers to the number of years a drug has been on the market. All controls in panel A are measured in 2009 and held constant across years. The discrepancy in data points with Table 3 is driven by missing net sales data for two drugs in 2009, which translates to six drug-year data points that we do not use. Standard errors are clustered at the drug level.

drugs with high and low Medicaid exposure, such as annual sales and age. Our core estimates could thus be picking up on other secular changes occurring during the period, such as shifts in the strategy of PBMs. Second, the 2009 non-Medicaid discount is negatively correlated with MMS, which may lead the core regression to pick up on the heterogeneous effects investigated in Section IVA.[34]

To address these concerns, we first augment the core specification by adding controls interacted with the post-ACA indicator. This allows the change in discounts to depend on observables. The controls we interact with the post-ACA indicator are the 2009 non-Medicaid discount, sales, and WAC (the last two in log form), and linear and squared versions of age in 2009. Table 5, panel A reports the results, with more detailed results available in Table C.18 of the online Appendix. The estimated coefficients are very similar to those reported in Table 3, with generally small and

[34] Online Appendix C.3 presents correlations between MMS and other observables. The coefficients are generally small in magnitude and noisy.

insignificant control coefficients. The results support the idea that the core estimates are not just picking up on secular trends driven by other observables.

In addition, we also use coarsened exact matching to group drugs. We sort drugs into strata based on log sales, log WAC, age, and non-Medicaid discount in 2009. This matching procedure creates 36 strata with 11 unmatched drugs. Once we have the strata, we can then run the following specification:

$$(8) \qquad Y_{it} = \gamma_i + \beta_1 \times MMS_{i,2009} + \beta_2 \times MMS_{i,2009} \times PostACA_t + Strata\text{-}Post\ ACA\ FE + \epsilon_{it}.$$

Essentially, we are comparing responses to the rule change within similar groups of drugs that differ primarily based on MMS, allowing for flexible average responses within each stratum and then pooling the estimates across strata to recover estimates.

Table 5 reports the results. Again, we recover similar if not larger estimates relative to those reported in Table 3. Therefore, both approaches suggest that our core estimates are not picking up on other secular trends driven by observables correlated with MMS.

D. *Medicaid Rules and List Price Growth*

Next, we consider the possibility that drug manufacturers raised list prices in response to the reform. Doing so can improve their bargaining position by increasing the net price necessary to trigger the MFCC. The inflation penalty discussed in Section I makes a positive list price response for high-MMS drugs unlikely. However, we want to verify this empirically.

The inflation penalty discourages list price growth above inflation, which may result in different baseline list price growth rates between high- and low-MMS drugs. Furthermore, the statutory minimum rebate increase creates an additional disincentive for list price increases because a statutory minimum rebate 8 percentage points higher is applied to the increase. To formally test for these trends, we run the following regression:

$$(9) \quad \log(WAC_{it}) = \gamma_i + \beta_1 MMS_{i,2009}(t - 2007) + \beta_2 MMS_{i,2009} \times PostACA_t \times (t - 2009) + Age\ FE + \epsilon_{it},$$

where β_1 represents general differences in list price growth rates and β_2 represents any additional trend after the reform.

The evidence does not support an increase in list prices for high-MMS drugs after the rule change. Table 6 reports the estimates. With only the basic trend included, we find a statistically significant effect that equates to a 1 percentage point lower annual growth rate per each MMS that is one standard deviation higher. When allowing for a baseline trend plus an additional postreform trend, the results align with the theoretical predictions, though the estimates are noisier.

TABLE 6—LIST PRICE GROWTH: CORE SAMPLE

	$\log(WAC)$	
$MMS \times (t - 2007)$	−0.146	−0.0709
	(0.0656)	(0.0914)
$MMS \times Post\text{-}ACA \times (t - 2009)$		−0.122
		(0.101)
Product FE	Y	Y
Age FE	Y	Y
Observations	1,087	1,087

Note: Standard errors are clustered at the drug level.

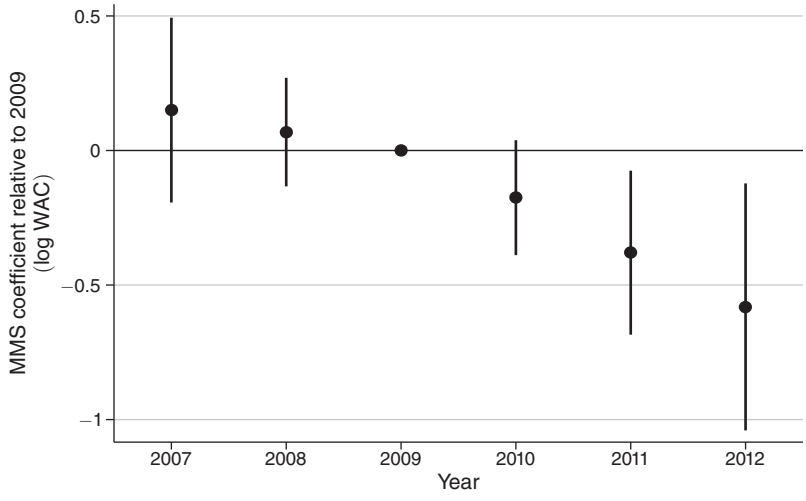

FIGURE 4. LIST PRICE DIFFERENCE BY MMS RELATIVE TO 2009

Notes: The figure displays a plot of the coefficient estimates from equation (10), with log WAC as the outcome. The lines represent 95 percent confidence intervals around each point estimate.

We confirm the same result by estimating a nonparametric regression that interacts year indicators with the MMS variable, using 2009 as the omitted year:

$$\log(WAC_{it}) = \gamma_i + MMS_{i,2009} \times \sum_{y=2007}^{2009} \beta_y \mathbf{1}\{t = y\} + Age\ FE + \epsilon_{it}. \quad (10)$$

Figure 4 plots our estimates. The results do not exhibit a jump in list price for high-MMS drugs between 2009 and 2010. Instead, we see a trend in list price growth consistent with the predicted impact of the inflation penalty.

These results matter beyond providing support for the assumption of fixed list prices in the model. They extend the analysis in Duggan and Scott Morton (2006) by highlighting the dynamic impact of the MDRP. Duggan and Scott Morton (2006) show that MDRP rules encourage firms to set higher list prices, but the presence of the inflation adjustment rule implies that this effect is limited to initial list prices.

The MDRP actually inhibits subsequent list price growth. The overall impact of the rule then depends on the relative magnitude of the initial launch price response and on subsequent price growth. This point is relevant to ongoing drug policy debates, as current proposals in the Senate and the House both include an extension of inflation penalty provisions to Medicare Part B and Part D drugs.[35]

E. *Additional Robustness Checks—Samples, Measurement, and Pre-Trends*

Finally, we investigate the robustness of our core results in five sets of checks in which we (i) test the sensitivity of results to an adjusted measure of the Medicaid rebate, (ii) broaden the sample, (iii) perform pre-trend tests, (iv) control for Medicare market share, and (v) test robustness to functional form assumptions. We provide a brief discussion here and detailed results from these checks in online Appendix C.6. The results generally support the findings from the core analysis.

First, we verify that our non-Medicaid discount results are not mechanically driven by possible underestimation of the Medicaid rebate, as noted in Section IIIA. To do so, we construct an adjusted estimate of the Medicaid rebate by using the average non-Medicaid discount in place of the best commercial price. Rerunning our analysis with the adjusted Medicaid rebate, we find statistically significant estimates with nearly equivalent magnitudes, suggesting that our results are not driven by measurement error.

Second, we rerun our analysis on broader samples. Our core sample combines two filters intended to deal with underreporting of invoice sales data. The first filter (FHM) screens drugs based on a logical test comparing net and invoice sales data. The second filter (KCC) screens drugs based on their presumed sales channel.[36] We rerun the analysis by applying one filter at a time. The FHM sample exhibits the best coverage of top-selling drugs and consistency in MMS across years. In this sample we find qualitatively similar results. The point estimates are smaller in magnitude across the board, potentially reflecting additional measurement error in MMS; however, the net revenue estimate is still statistically significant. We also find qualitatively similar results in the KCC sample, again with smaller magnitudes. The non-Medicaid discount estimates are statistically significant, but the net non-Medicaid revenue estimates are not.

Third, we check that our results are not simply capturing secular differences between high- and low-MMS drugs in discount and revenue trends. We rule out this possibility in two ways. First, we look for obvious pre-trends in outcomes from 2007–2009. Figure 5 plots the estimates from interacting year dummies with the MMS variable with 2009 as the omitted year. Formally, we reestimate equation (10) using non-Medicaid discount and log net non-Medicaid revenue as the dependent variables. Figure 5 plots the estimates from interacting year dummies

[35] See the following summary by the Commonwealth Fund: https://www.commonwealthfund.org/publications/2019/sep/key-provisions-proposals-drug-price-negotiation-inflation-rebates-part-d-redesign (accessed June 30, 2020).

[36] Section IIIA provides details on these filters.

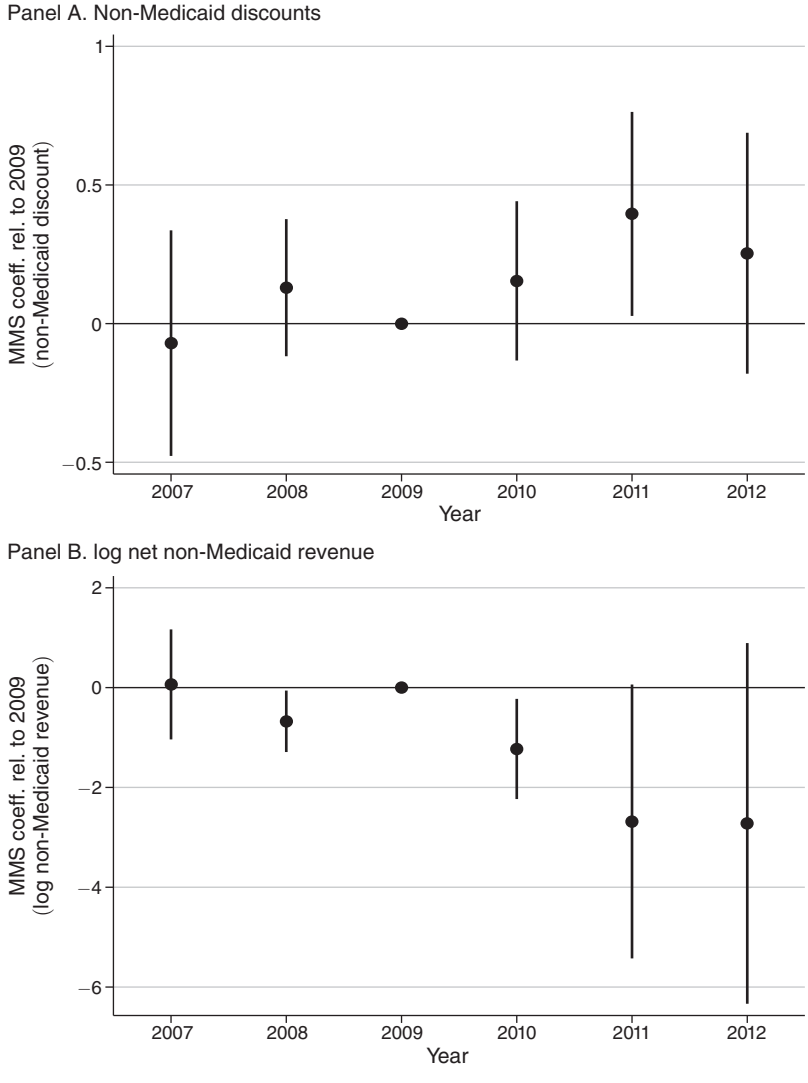

FIGURE 5. MMS COEFFICIENT ESTIMATES BY YEAR RELATIVE TO 2009

Notes: The figure displays a plot of the coefficient estimates from equation (10). The lines represent 95 percent confidence intervals around each point estimate.

with the MMS variable with 2009 as the omitted year. Although the estimates are noisy, there is no obvious trend leading up to the rule change.

Fourth, we verify that our results are not driven by the 2011 changes to Medicare Part D. First, we check that Medicare Part D market share is very weakly correlated with MMS. This suggests that any impact of Medicare reform should be orthogonal to the impact of the Medicaid policy change. We then augment our core specification by adding an interaction term between Medicare Part D market share and "Post-2011," which will absorb any differential effects driven by the Part D changes.

Adding this control reduces the precision of the estimates, but the magnitudes are very similar to those reported above.

Finally, we verify the robustness of our results to functional form assumptions. First, we estimate responses to the rule change by MMS quartile and again find that drugs in the higher quartiles end up with higher discounts and lower revenue after the rule change. Second, by adding year fixed effects to our main specification and dropping the post-ACA variable, we also show that our results are not driven by differential composition of drugs across years. Third, we also allow MMS to vary within a drug over time. Our core specification uses MMS measured in 2009, a pre-reform measure. However, average MMS increases over time, and MMS also fluctuates within a drug, both changes to which firms can respond. Allowing for varying MMS, we find similar, if not larger, estimates for the impact of the reform.

IV. Decomposing the Average Effect of the Reform: Implications for MFCCs

In this section we empirically investigate heterogeneity in the per unit MMS response to the policy. We then combine our estimates with the model to assess the impact of removing the Medicaid MFCC on non-Medicaid spending.

A. *Heterogeneous Effects by Pre-ACA Discount*

As discussed in Section II, our model predicts that the per unit MMS response to the rule change varies by pre-ACA outcomes. In particular, the model predicts that the largest per unit MMS response come from drugs that had commercial market discounts in the (r, r') range pre-ACA. The average response of drugs in the $(0, r)$ range should be zero, while the response of drugs in the $(r', 1)$ range will be positive but much smaller.

Although we do not perfectly observe the pre-ACA commercial best price due to price dispersion and exemptions for Medicare Part D and others, we can still conduct an approximate test of these predictions. We introduce a binary *High Exposure* variable indicating whether a drug's average non-Medicaid discount in 2009 falls into the (r, r') range. In addition, we create a *Low Exposure* variable for drugs whose average non-Medicaid discount in 2009 falls in the $(r', 1)$ range. Using these definitions, 73 drugs had a 2009 non-Medicaid discount below 15.1 percent, 49 had discounts between 15.1 percent and 23.1 percent, and 76 had rebates greater than 23.1 percent.

We then interact these indicator variables with the core specification to estimate a triple difference regression:

$$
\begin{aligned}
(11)\quad Y_{it} = {} & \gamma_i + \beta_1 \times MMS_{i,2009} \times PostACA_t + \beta_2 \times PostACA_t \\
& \times Low\ Exposure_i + \beta_3 \times MMS_{i,2009} \times PostACA_t \times Low\ Exposure_i \\
& + \beta_4 \times PostACA_t \times High\ Exposure_i + \beta_5 \times MMS_{i,2009} \\
& \times PostACA_t \times High\ Exposure_i + Age\ FE + Year\ FE + \epsilon_{it}.
\end{aligned}
$$

Table 7—Differences in Response by Exposure to MFCC

	Non-Medicaid discount	
	(1)	(2)
MMS × *Post ACA*	0.112	0.0863
	(0.188)	(0.153)
Post ACA × *Low Exposure*	−0.0399	−0.0350
	(0.0304)	(0.0308)
MMS × *Post ACA* × *Low Exposure*	0.147	0.201
	(0.277)	(0.276)
Post ACA × *High Exposure*	−0.124	−0.116
	(0.0415)	(0.0460)
MMS × *Post ACA* × *High Exposure*	0.543	0.575
	(0.374)	(0.386)
Fixed effects	Drug, Year	Drug, Year, Age
Low exposure range	$(0.231, 1]$	$(0.231, 1]$
High exposure range	$[0.151, 0.231]$	$[0.151, 0.231]$
$\beta_1 + \beta_5 = 0$ (p-value)	0.044	0.058
Observations	1,067	1,067

Notes: The table shows estimates of equation (11) with winsorized non-Medicaid discount as the outcome. "Exposure range" refers to the drugs we classify as high exposure and low exposure based on the 2009 average non-Medicaid discount. $\beta_1 + \beta_5$ refers to the sum of the *MMS* × *Post ACA* coefficient and the *MMS* × *Post ACA* × *High Exposure* coefficient. Standard errors are clustered at the drug level.

The specification allows for flexible level changes by group and aims to isolate different per unit MMS effects for each group. Table 7 reports the results, which are generally consistent with the model's predictions.

The patterns of this regression are consistent with the predictions of our bargaining model, although it is difficult to precisely identify heterogeneous per unit MMS effects because of the limited number of data points, noise in the underlying data, and sensitivity to the linear specification. Columns 1 and 2 present the estimates with and without age fixed effects and show similar results. Focusing on column 2, our preferred specification, the baseline per unit MMS effect is 0.086, which is small and statistically insignificant. On top of this baseline, the *Low Exposure* group has an additional per unit MMS effect of 0.201, though the difference is not statistically significant. The *High Exposure* group has an additional effect of 0.575. This is, again, statistically indistinguishable from the baseline group, but the total per unit MMS effect, which we would recover if we restricted our analysis to just the *High Exposure* group, is weakly significantly different from zero (p-value $= 0.058$).

B. *Policy Analysis: Removing the Medicaid MFCC*

We can combine the results of our analysis of heterogeneous effects with our model to estimate the Medicaid MFCC's impact on commercial market spending. Recall that equation (5) in Section IIA gives the change in equilibrium discount rate

as a result of the policy. In particular, the predicted change for drugs in each of the groups can be written as

$$d_0' - d_0 = 0,$$

$$d'_{High\ Exposure} - d_{High\ Exposure} = (1-b)(1-r) \times MMS,$$

$$d'_{Low\ Exposure} - d_{Low\ Exposure} = (1-b)(r'-r) \times MMS,$$

where d_g' is the postreform discount and $g \in \{0, High\ Exposure, Low\ Exposure\}$ denotes the three groups in our heterogeneity analysis.[37] Moreover, we know from equation (6) that the impact of removing the MFCC is equal to

$$d^1 - d^{NB} = (1-b)(1-r)MMS$$

for all drugs with d^{NB} at or above the rebate threshold.

Using this setup, we can use two approaches to calculate the impact of the Medicaid MFCC on commercial market spending. The first approach looks only at the response of the high exposure group. The model suggests that drugs in this group switch from being exposed to the MFCC before the reform to not being exposed after the reform. Therefore, the per unit MMS effect of 0.575 can serve as a direct estimate of the impact of removing the MFCC on discounts.[38] Applying this estimate to the broader sample of drugs that the removal of the Medicaid MFCC would affect implies a reduction in non-Medicaid revenue of 3 percent.[39]

A second approach is to calibrate the parameters of the underlying theoretical model using information from all of the estimates in Table 7 and then to use the model to calculate the impact of removing the MFCC. This approach allows us to more carefully consider how deviations from the model can influence the final revenue numbers. Our data give a direct measurement of *MMS* and *r* but not *b*. The best way to estimate *b* would be from changes in contract-level discounts before and after the reform. This would provide clean identification of the bargaining parameters at the drug level. Unfortunately, these data are not publicly available. Instead, we calibrate *b* using the coefficients from Table 7.

There are two discrepancies between the model predictions and the coefficients from Table 7. First, the baseline group, which is predicted to have a coefficient of zero, has a positive coefficient. Second, the coefficient for the low-exposure group is implausibly high relative to the model's prediction, which implies that, holding MMS fixed, the per unit MMS effect cannot be higher than $r' - r = 0.08$ because the bargaining parameter $b \in [0,1]$. These two facts suggest that both of these

[37] To be precise, drugs in the high-exposure group can experience effects of three possible magnitudes (see Section IIA for more details). We abstract from these differences and assume that all drugs in the group experience a change of magnitude $(1-b)(1-r) \times MMS$. Because this change is the largest of the three, doing so leads us to underestimate the impact of the reform.

[38] This calculation does not incorporate the 0.086 baseline per unit MMS effect.

[39] To calculate this number, we simply multiply $0.575 \times MMS_{2010} \times$ *non-Medicaid Invoice Sales*$_{2010}$ and sum across all drugs with a 2010 discount rate above 23.1 percent.

groups may include some additional drugs from the high-exposure group. We are not too concerned about the second possibility, given that drugs in both the high- and low-exposure groups would react in the same way to removing the MFCC. However, the possibility that some drugs in the baseline group could be in the high-exposure group matters for our counterfactual.

To reconcile data and model, we allow for the possibility that some fraction of drugs in the baseline group may in fact be high-exposure drugs. This leads us to the following system of equations with two unknowns:

$$\hat{\beta}_1 = \alpha(1-b)(1-r),$$

$$\hat{\beta}_1 + \hat{\beta}_5 = (1-b)(1-r),$$

which leads to $b \approx 0.22$ and $\alpha \approx 0.13$.

Once we have a calibrated b and α, we can calculate the effect of removing the MFCC when $r' = 0.231$:

$$d^1 = d_{2010} + (1-b)(1-0.231)MMS_{2010}$$

for all drugs with $d_{2010} > 0.231$, plus about 13 percent (e.g., a fraction α) of drugs with $d_{2010} < 0.231$.

We use 2010 data because the interpretation of this discount is as the incremental discount relative to what was achieved with the 2010 reform. To calculate the change in revenue as a result of these savings, we simply take the change in discount for each drug and multiply it by non-Medicaid invoice sales.[40] We find that removing the Medicaid MFCC would have reduced non-Medicaid spending by 3.5 percent. Non-Medicaid net sales in 2010 on our sample of 198 drugs amount to slightly over $100 billion, so this represents almost exactly a $3.5 billion spending decline (in 2010 dollars). Drugs with $d_{2010} < 0.231$ contribute about $400 million to the total, so if we wanted to be conservative and remove them from the calculation, we would still end up with a 3.1 percent decrease in spending.

Because our classification of drugs into groups is imprecise, the main concern with our calculation is that we could mistakenly include some drugs in the unaffected group. We ran several alternative specifications to assess the impact of using different group assignments. The general pattern that emerges from these checks—which we report in online Appendix C.6—is the same as our main specification: drugs with a non-Medicaid discount between 13 and 25 percent tend to exhibit the strongest response to the reform, and drugs with very high discounts respond more strongly than drugs with very low discounts. The implied impact of removing the MFCC across these alternative specifications ranges between 1.7 and 2.7 percent.

There are other possible caveats. First, we are implicitly assuming that the bargaining parameter of all firms is the same, which is unlikely. In general, we may expect drugs with higher discounts to have less bargaining power. If this is the case, we are

[40] For drugs with $d_{2010} < 0.231$, we apply the discount to all drugs and then multiply by α.

likely underestimating the impact of the reform, given that we are calibrating b using drugs with the lowest discount among those that would be affected by the reform. We can obtain an upper-bound estimate by assuming $b = 0$. This yields savings of 4.5 percent in our sample of 198 drugs. Second, our model does not account for competition on either the payer's or the manufacturer's side. Competition on the payer's side is probably not a significant concern unless there are large changes in the market structure that we are not explicitly modeling.[41] Competition on the manufacturer's side could matter if part of the effect that we measure is driven by competitive responses of low-MMS drugs to changes in the prices of high-MMS drugs. In practice, this effect is probably of second-order concern because competing drugs have similar Medicaid market shares. Third, lower commercial prices may result in higher sales volume, which would partially offset the number we calculated (which holds units constant). However, we did not find any evidence of a volume effect in response to the lowering of discounts following the 2010 policy change. This suggests that such volume adjustments would probably be small.

V. Conclusion

This article evaluated the effects of a 2010 reform under the Affordable Care Act to the Medicaid Drug Rebate Program (MDRP) and used it to study the impact of MFCCs in procurement on firm behavior and outcomes. The empirical results suggest that MFCCs increase drug manufacturer profits in the commercial market by allowing these firms to negotiate drug prices more effectively.

Our results have implications for both theoretical industrial organization and public policy. In terms of theory, our research makes two main points. First, we confirm that MFCCs significantly impact markets where firms already wield significant market power, an intuition dating back to Cooper and Fries (1991). Previous work has noted the effect of these clauses in oligopoly markets with homogeneous goods (Scott Morton 1997), but we show that their impact extends to markets where firms do not face identical competitors and can exert significant market power. Second, our analysis of list price dynamics furthers our understanding of how Medicaid rules impact commercial prescription drug markets. Drugs with high MMS exhibit slower growth in list prices, likely in response to the incentives created by the inflation penalty clause.[42]

Our research also yields two implications for policy. First, our results suggest that the 2010 reform of the MDRP reduced overall prices for drugs already on the market. Our evidence speaks primarily to reduced prices in commercial markets, but the combination of lower list price growth, higher commercial discounts, and higher statutory minimum rebates imply savings for Medicaid as well. Second, our results suggest that removing the MFCC may decrease non-Medicaid prices, most likely for large commercial payers and for drugs in competitive therapeutic classes. However, it is crucial to note that any such savings in the commercial

[41] The 2012 Express Scripts–Medco merger would qualify as such a change, partly motivating our focus on pre-2013 data.

[42] Given the current concern over rising list prices resulting in higher out-of-pocket costs for patients, this could be interpreted as a positive spillover of this specific clause.

market from repealing the MFCC would need to be carefully weighed against potentially higher prices for Medicaid and other payers (namely, the 340B program) that use Medicaid's MFCC.[43] Nonetheless, our results caution against implementing policies that may mimic the effect of MFCCs, such as requiring public disclosure of individually negotiated prices. Although this kind of transparency may hold intuitive appeal, our results show that it could produce unexpected market outcomes.

We conclude by noting that while our study uses a novel dataset of drug prices and revenues to extract theoretical and policy insights, it still faces some limitations. Our inability to observe confidential contract-level data prevents us from running more explicit model tests. If contract-level data does become available, future work could examine whether the policy change affects contracts whose prices are already below the threshold, which would further support the bargaining model. Contract-level data would also open the door to structural estimation of our theoretical model.

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[43] The cost of removing the Medicaid MFCC is likely higher today than at the time since the passage of the ACA because rebates have increased in recent years. Policy makers seeking to remove the MFCC would probably need to increase the statutory minimum rebate under the MDRP to prevent an increase in Medicaid drug spending. However, note that the benefit may also have increased because higher discounts mean that more drugs are affected by the MFCC and would respond to its removal.

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