Restrict the Middleman?

Quantitative models of PBM regulations and their consequences

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This paper provides the first quantitative economic models of pharmacy benefit management (PBM) regulation. Indeed, few economic models of the pharmaceutical industry even acknowledge that drug benefits are managed and that companies specialize in benefit management. The models in this paper project a rich variety of consequences of rebate rules in Medicare Part D, commercial, and insulin markets. They also estimate the economic effects of contract transparency rules and restrictions on pharmacy Direct and Indirect Remuneration (DIR). The consequences specified in the models include utilization of brands and generics, plan spending, cost sharing, and spillovers to nonpharmacy medical spending, government budgets, and the pace of drug innovation.

The various regulatory consequences are connected in a logically consistent economic framework that allows for various market frictions and imperfections including market power, coordination costs, tax distortions, and incomplete innovation incentives. A rigorous economic interpretation is provided for what are sometimes called "rebate walls" or "rebate traps." The model's ingredients and operation are explained so that readers may adjust the model to consider alternative PBM regulations or invoke alternative assumptions.

As others have before, I find that rebate rules would substantially reduce volume discounting by drug manufacturers. More novel is that rebate rules can increase net brand prices by up to 52 percent and drug-plan premiums up to 31 percent. Rebate rules may reduce drug utilization (including generics) up to 8 percent for insulin and about 1 percent for drugs generally. Rebate rules reduce the pace of drug innovation even while redistributing from patients and plans to manufacturers because of the differential effects of rebate rules over the course of the drug life cycle. Through these mechanisms, rebate rules redistribute to incumbent drug manufacturers by imposing costs on patients, plans, and other third parties (such as taxpayers and future consumers) that are at least double the manufacturers' benefit.

Albeit on a smaller scale, pharmacy DIR regulations also increase net drug prices (both for brands and generics), increase drug-plan premiums, and reduce drug utilization. These are some of the regulatory costs of pharmacy DIR regulations imposed on patients, plans, and third parties that together are more than six times the benefit to pharmacies in the form of greater profits.

Section I of this paper begins with rebate rules. The impact of two rebate rules are estimated: the rule finalized in late 2020 by the Department of Health and Human Services (HHS) and the part of the proposed INSULIN Act that would prohibit manufacturer rebates paid to plans and PBMs on insulin products. Subsection I.D. specifically addresses the effect of rebates and their regulation on generics, which is the issue of "rebate walls" raised by the Federal Trade Commission (FTC) and others. The effects of regulating Pharmacy DIR are estimated in Section II, particularly for the proposed PBM Transparency Act (II.D) and the 2022 CMS rule (II.E).

Making it more difficult for PBMs to do business, as rebate rules and pharmacy DIR regulations do, will not encourage more companies to get into the PBM business. These regulations might discourage competition among PBMs to the extent that larger incumbent PBMs are better able to adapt to them, although the primary effect of these regulations would be to discourage competition among drug manufacturers and among pharmacies.

Section III analyzes possible effects of disclosure or transparency requirements on competition among manufacturers, pharmacies, PBMs. The FTC has noted in other healthcare contexts that requirements to disclose detailed information about price and cost, which the PBM Transparency Act would do in the prescription supply chain, can harm consumers by discouraging competition. The annual net costs of the potential anticompetitive effects of disclosure rules are likely in the tens of billions of dollars.

Any rigorous and realistic analysis of the consequences of PBM regulation must acknowledge what benefit management does and how its benefits compare to its costs. Section IV recaps the economic role of PBMs in pharmaceutical markets and in the regulatory impact models, with additional technical details provided in Appendices I-V.

Disclosure

I. Manufacturer Rebate Rules

Manufacturer rebates are defined, with reference to specific federal-government proposals, and interpreted as economic concepts. This section then provides an overview of the qualitative economic approach, followed by tables of quantitative estimates. The section concludes with a more detailed analysis of generics, rebate walls, and related metrics of market performance. Appendices provide a mathematical description of the model and its ingredients (Appendix I), details related to the effect of drug utilization on nonpharmacy medical claims (Appendix II), and further discussion of the consequences of regulation for the pace of drug innovation (Appendix III).

Many of the regulatory costs are presented as ratios to baseline rebates rather than absolute dollars. This presentation allows easy back-of-the envelope cost estimates for rebate rules that are not specifically examined in this paper, or to identical rebate rules that are implemented in a jurisdiction or time period that differs from the U.S. circa 2022 in terms of market size or rebate amounts. This paper is also accompanied by an excel spreadsheet, hosted at nber.org and http://PBMregsimulatorExcel.caseybmulligan.com, that allows readers to prepare more precise cost estimates for alternative rebate rules by editing therein the market and/or regulatory parameters.

I.A. Definitions

Manufacturer rebate rules require that manufacturer volume discounts be paid at the point of sale. Plans and PBMs cannot participate in manufacturer discounts, except perhaps when copays and

coinsurance have been reduced to zero.[1] In other words, rebate rules redistribute manufacturer discounts from one point in the supply chain to another. What follows is analysis of the various consequences of such redistribution.

Two specific rebate rules are the Part D rule and the Insulin Act. The Part D rule was proposed by the Department of Health and Human Services in 2019. The proposal attempted to eliminate manufacturer rebates retained by plans and PBMs (as any part of their Medicare Part D businesses) and replace them with manufacturer rebates paid at the point of sale. The Insulin Act applies to both Medicare and commercial markets, but is limited to contracts for insulin.[2]

I.B. Economic interpretation: distorted incentives

Manufacturer volume discounts are paid as rewards for utilization. As such, all else the same, discounts received by patients encourage patients to obtain prescriptions. Discounts received by plans and PBMs incentivize those companies to encourage adherence and proper utilization. In other words, by redistributing discounts across points in the supply chain, rebate rules increase utilization incentives for patients but reduce them for companies. Holding constant the overall discount, the redistribution therefore has opposite effects on utilization that would almost exactly offset to the extent that the baseline discounts had been distributed to maximize proper utilization. In the results that follow, this net utilization effect of discount redistribution is taken as zero.[3]

Rebates for plans and PBMs are important elements of benefit-management tools. They increase proper utilization because, among other things, the manufacturer and pharmacy counterparties agree only under the condition that utilization targets are reached or that the plan is designed to facilitate the achievement of sales targets. By constraining the use of benefit-management tools, rebate rules should be expected to reduce the value created by benefit management. Specifically, they would reduce utilization, the combined manufacturer discount received by patients and plans, and the productivity of benefit management resources. In terms of the market-level demand analysis, this corresponds to a leftward shift in the marginal management cost curve as shown in Figure 1. The more that the cost curve shifts, the more that utilization and rebate rates are reduced.

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[1] It is currently unclear whether the HHS Rebate rule (84 FR 2360) would permit plans and PBMs to retain discounts over and above cost sharing. The state of West Virginia implemented its own rebate rule allowing that "[a]ny rebate over and above the defined cost sharing would then be passed on to the health plan to reduce premiums" (Section 33-51-9 of the West Virginia Code). Rather than offering a legal opinion as to whether or not plans would be permitted to retain any such rebate under federal rebate rules, this paper considers a range of scenarios and shows how the model could be extended to additional scenarios that might be of interest to the reader.

[2] In addition to regulating manufacturer rebates, the Insulin Act also regulates cost sharing and list prices.

[3] As shown in Appendix IV, baseline regulation of out-of-pocket costs may leave the distribution below what maximizes utilization, so that any redistribution due to rebate rules would reduce utilization (plan-PBM disincentives exceed patient incentives). Furthermore, a "behavioral economics" model (not part of this paper) may predict that proper utilization is more responsive to company financial incentives than to patients' financial incentives because companies have various tools for nudging patients. These are two reasons why rebate rules might reduce utilization more than estimated in this paper.

Figure 1. Benefit-management costs are increased by constraining management tools
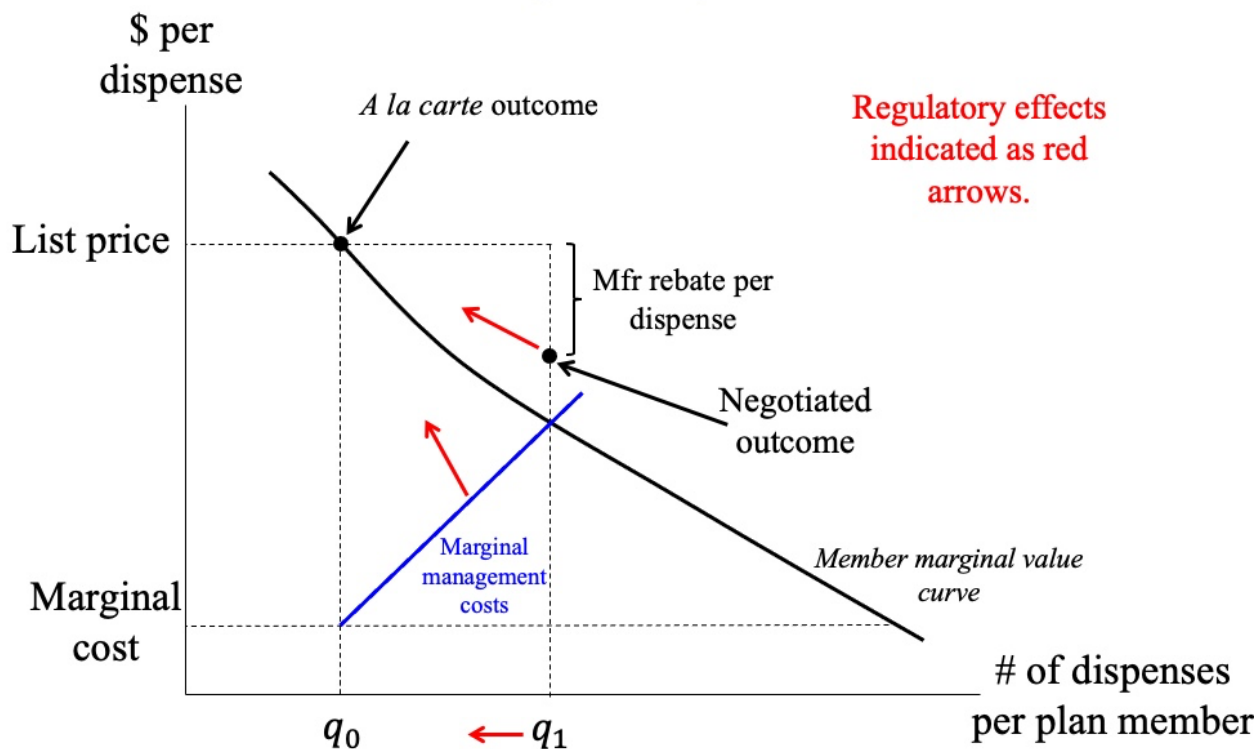
The blue curve is the sum of the marginal management costs with the other (and constant) marginal costs of manufacturing, delivery, etc.

Figure 1, whose algebraic representation is provided in Appendix I, is the core of the regulatory-impact model. It shows the brand-utilization effect of any given shift in the blue marginal management cost curve. The figure also shows the effect on the aggregate costs of benefit management, which may increase depending on how the vertical dimension of the marginal cost shift compares to the volume reduction. The brand-brand competition embedded in Figure 1 also permits estimation of the effect of regulation on net prices and manufacturer profits, which would increase in response to higher marginal-management costs as long as the equilibrium point is not shifted beyond the monopoly point on the demand curve.[4]

Additional outcomes can be assessed by combining Figure 1 with additional information. Adding information on competition between brands and generics permits assessment of the overall quantity effect, combining both brands and generics. Effects on nonpharmacy medical claims are derived from this quantity effect. Premiums paid for drug and other health insurance plans depend on net price, quantity, regulatory shifts of funds along the supply chain (e.g., rebates that must be paid at the point of sale), nonpharmacy medical claims, and the costs of benefit management. Because government

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[4] While each manufacturer offers rebates in the baseline in order to increase its own profits, its profits are reduced by the rebates offered by competing manufacturers. A rebate rule can increase aggregate manufacturer profits by suppressing this important means of competition among manufacturers.

subsizes premiums for drug and other health plans, the premium increases ripple into the wider economy as governments must increase taxes, increase debt, or reduce other government spending.

Mulligan (2022) shows how to derive effects of drug innovation by using different versions of Figure 1 to model the (negative) effect of benefit-management costs on the profits of monopoly brands and the (potentially positive) effect of the profits of manufacturers in markets with brand-brand competition. See also Appendix III.

I.C. Quantitative analysis

If the marginal cost curve shifted enough leftward, no benefit management would occur, which is the consequence examined by Mulligan (2022). Any specific regulatory impact analysis must assess how far regulation will push the market toward that extreme outcome. That is, the amount that regulation shifts Figure 1's management cost curve must be assessed. This paper shows results for three approaches to rebate rules, referred to as "management-productivity scenarios." Each scenario generates an alternative estimate of the various market outcomes (quantity, net price, plan premiums, etc.).

The first management-productivity scenario is described as the "OACT scenario" because the Office of the Actuary of the Centers for Medicare and Medicaid Services (OACT) concluded that a Medicare Part D rebate rule requiring that rebates be paid at the point of sale would only partially interfere with benefit management. Specifically, the rule would reduce discount rates by 15 percent as a consequence of shifting them from plans and PBMs to the point of sale and potentially to lower list prices.[5] That is, under the proposed rule, benefit management would result in plans and patients together receiving manufacturer discounts equal to 85 percent of what the rebates were in the baseline. In Figure 1's demand model, there is one and only one marginal-cost-curve shift corresponding to OACT's result, which is the shift assumed throughout the OACT scenario.

OACT did not specifically explain what would happen to drugs for which the hypothesized point-of-sale rebate exceeds what patients had been paying in terms of cost sharing. The OACT scenario assumes that plans and PBMs continue to receive that portion of the discounts that remains when cost sharing is set to zero. An alternative "Retain-Zero" scenario assumes that benefit management is only able to obtain discounts at rates equal to the baseline patient cost-sharing rates. Further discounts are, according to the Retain-Zero scenario, impossible because plans and PBMs are prohibited from retaining manufacturer discounts and will not implement negative cost sharing (that is, patients paid cash to take prescriptions out of the pharmacy). For example, if the baseline contracts had (i) discounts in the form of 30 percent rebates retained by plans and PBMs and (ii) baseline cost sharing were 10 percent of gross drug costs, then the Retain-Zero scenario assumes that a rebate rule cuts discounting by a factor of three (from 30 to 10). In Figure 1's demand model, there is one and only one marginal-cost-curve shift corresponding to Retain Zero, which is different in magnitude from the OACT-scenario's shift.

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[5] 85 FR 76725. OACT noted that manufacturers pay plan rebates to reward plans for hitting sales targets, whereas point-of-sale rebates would not provide plans that incentive. It also noted that manufacturers have less reason to offer point-of-sale rebates precisely because they do not incent plans.

A third scenario, also relevant for Section III's competition analysis, is OACTX2. The scenario doubles the discounting reduction assumed by the OACT scenario, but still allows plans and PBMs to retain manufacturer rebates as long as they reduce cost-sharing to zero. In Figure 1's demand model, there is one and only one marginal-cost-curve shift corresponding to OACTX2, which is somewhere in between the OACT shift and the Retain-Zero shift.

The net price received by the manufacturer is the difference between list price and manufacturer discounts. To the extent that regulations alter competition among manufacturers in a way that increases net prices (as OACT assumes), the net price impact might reflect higher list prices, reduced discounts from a given list price, or a substantially reduced discount from a reduced list price. All three scenarios for the HHS rebate rule take the list and net price effects as the outcome of the altered competitive equilibrium (Figure 1 and Appendix I).[6] In order to reflect the proposed Insulin Act's additional regulation of list prices, the OACT (OACTX2) scenario assumes that the 15 percent (30 percent) of baseline rebates is added one-for-one to net prices, respectively. List prices in the Insulin-Act scenarios are below the baseline list prices because the list price is taken as the sum of the corresponding net prices and the regulated discounts.

Another quantitative difference between the regulatory impact analysis of the HHS rebate rule and the proposed Insulin Act is the high baseline rebate rates for insulin, which are about 75 percent as compared to about 30 percent for Part D brand drugs generally. Equilibrium rebate rates approaching 100 percent are possible in the model of Figure 1, but only if the demand curve is sufficiently convex at the list price. In this case, even a small reduction in marginal management costs can substantially increase list prices and rebates while reducing net prices. Indeed, all three have occurred simultaneously in insulin markets.[7] Conversely, as regulation increases management costs, net prices would increase even while list prices and rebates might fall substantially. As shown in Appendix I, this paper employs demand systems that are linear in the neighborhood of the equilibrium quantity and marginal price, but allows for insulin demand curves that are convex at higher prices.

Tables 1a and 1b show the quantitative results with each scenario as its own pair of columns. Results vary within scenario depending which of two versions of the rebate rules are considered: the Part D rule or the Insulin Act. I assume that (i) a seller of insulin has somewhat different market power than the average branded drug in the Part D market, (ii) demand at the industry level is half as price sensitive for insulin than for the average drug, and (iii) the marginal costs of managing insulin benefits are potentially different than for the average drug in the Part D market. Based on expenditure data, I assume that baseline patient cost sharing is 10.1 percent (of gross spending) in Part D and 8.0 percent for insulin.[8]

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[6] Specifically, the equilibrium list price (what a plan would pay if it is unable to make a quantity commitment) is what maximizes a manufacturer's profits given that its competitors obtain quantity commitments in exchange for manufacturer discounts.

[7] For example, Van Nuys et al (2021) find that "Between 2014 and 2018, mean list prices of 32 insulin products increased by 40.1% … while mean net prices received by manufacturers decreased by 30.8%...."

[8] The 2020 National Health Accounts report that 13.3 percent of net drug spending is financed out of pocket. Assuming a 24 percent rebate rate for the entire market, 13.3 percent of net spend corresponds to 10.1 percent of gross spending, which is the same percentage I assume describes Part D. Cubanski and Neuman (2019) estimate that Part D enrollees paid $968 million out of pocket for insulin in 2016 when Part D gross insulin costs were $12.1 billion. I assume that the same out of pocket ratio of 0.08 applies to the insulin market as a whole.

Table 1a begins by showing market performance: prices and quantities (utilization). Under the OACT Scenario, the Part D rebate rule would reduce brand utilization by 5 percent and overall utilization about 0.4 percent due to some shifting to generics, as discussed further below. Even though insulin demand is less price sensitive than the average drug, the brand utilization and net price effects are somewhat greater for the Insulin Act (under any of the three scenarios) because the baseline rebates are greater for insulin than for the average Part D branded drug. The overall utilization effect of the Insulin Act is larger still because the insulin market is dominated by brands.[9]

Table 1a. Rebate Rules: Effects on Market Performance

Outcome	OACT Scenario		OACTX2 Scenario		Retain-Zero Scenario	
	Part D	Insulin Act	Part D	Insulin Act	Part D	Insulin Act
Quantity effect						
Brands	-5.0%	-6.5%	-9.4%	-11.6%	-18.5%	-15.8%
Entire market	-0.4%	-3.4%	-0.7%	-6.1%	-1.3%	-8.3%
Net price effect	11.6%	45.0%	23.2%	90.0%	51.6%	135.7%
Rebate rate (brands)						
Baseline	30.0%	75.0%	30.0%	75.0%	30.0%	75.0%
Regulated	25.5%	30.6%	21.0%	19.0%	10.1%	8.0%

Notes: Rebate rates include rebates at the point of sale. Each scenario is based on a different assumption about the extent that rebate rules reduce manufacturer rebates as a consequence of redistributing them across the supply chain.

Utilization falls more, and net prices increase more, in the OACTX2 and Retain-Zero scenarios because each of those scenarios assumes progressively more reduction in volume discounting. The Retain-Zero Scenario, which may be the most realistic scenario for analyzing an Insulin Act that would "ensure that insurance plans and pharmacy benefit managers can't collect rebates on insulin," shows particularly large effects. That scenario assumes that all volume discounting must be administered through reduced cost sharing, which in the baseline is far less than the average rebate amounts. This scenario gives plans and PBMs particularly little financial incentive to increase volume. Their strongest financial incentives would instead be to limit coverage and discourage utilization.[10]

Table 1b estimates various costs and benefits that follow from the fact that rebate rules affect market performance. The costs include monetary and resource costs as well as opportunity costs, which refer to the net value of goods of services not received as the result of regulation. The first row shows aggregate surplus, including the additional profits accruing to manufacturers, which (like Table 1a's quantity effects) are estimated directly from the model represented in Figure 1. The aggregate surplus falls in the OACT Scenario by an amount equal to 7.4 (3.5) percent of the baseline rebate amount for

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[9] I assume a 15 percent generic script share for insulin markets, as compared to 90 percent for drugs generally. 15 percent is the product of Humalog's share of Part D users (Cubanski, Neuman, et al. 2020) and the share of Part D Humalog claims that were for the authorized generic (Hayes 2022).

[10] Integrated plans would have an incentive, albeit less than in the baseline, to encourage utilization of drugs that help prevent nonpharmacy medical claims.

the HHS (Insulin Act) rules, respectively.[11] In other words, the costs of the rule to plans and patients exceeds the benefit to manufacturers, which is between 17.6 and 21.6 percent of the baseline rebates in the OACT scenario. Compared to the HHS rule, the net cost of the Insulin Act is a lesser percentage of the baseline rebate amount because the baseline rebates are so large in the insulin market.

Reduced prescription utilization by itself tends to reduce drug costs but increases nonpharmacy medical costs. Based on the findings of Kaestner et al, I estimate that rebate rules increase nonpharmaceutical health-plan costs by about 2% of the baseline rebate amount or about $2 billion annually for a rebate rule that covered all drug segments and payers. Because plans and patients recognize connections between drug adherence and nonpharmaceutical health expenses, some of this extra cost is already reflected in the reduced surplus (cited above) accruing to patients and parties to rebate transactions. However, part of the nondrug effect is not reflected in the pharmaceutical-market demand curve due to drug plans' imperfect incentives to control nondrug costs.[12] In order to avoid double-counting, only the second component of the nondrug medical costs is shown as a distinct category in Table 1b.

It might seem that the non-drug health savings that occur due to drug adherence are the result of the manufacturers and inventors rather than PBMs. Neither this paper nor Mulligan (2022) addresses the question of what would happen without drug inventors or manufacturers. This paper assesses how the market would be different with a regulation as compared to without it. Manufacturers, inventors, PBMs, patients, and others all behave differently with a regulation than without it. The results reported in this paper show the combined effect of these differences, which is the well-established concept of "the effect of regulation."

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[11] Recall from Table 1a that the baseline rebate rates are greater for insulin than Part D drugs generally. Therefore, the net cost of the rebate rule is a greater percentage of baseline gross drug spending for insulin than for Part D drugs generally.

[12] Especially because some drug plans, particularly in Medicare Part D, have no commercial connection to their members' other health coverage. Member churning between plans also affects plan incentives to the extent that the health benefits of drug adherence are experienced beyond the end of the drug-plan year. See Appendix II of this paper for more details and quantitative estimates.

Table 1b. Rebate Rules: Regulatory Costs

Monetary and opportunity costs expressed as a percentage of baseline rebate amounts

Outcome	OACT Scenario		OACTX2 Scenario		Retain-Zero Scenario	
	Part D	Insulin Act	Part D	Insulin Act	Part D	Insulin Act
Net costs in the supply chain	**7.4%**	**3.5%**	**14.7%**	**7.1%**	**31.7%**	**10.6%**
Manufacturer losses (- is profit)	-17.6%	-21.6%	-33.7%	-41.2%	-67.8%	-59.6%
Plan & patient lost value	25.0%	25.1%	48.4%	48.3%	99.5%	70.2%
External effects	**22.8%**	**25.3%**	**31.5%**	**39.2%**	**46.6%**	**49.2%**
3rd-party nondrug health costs	0.4%	0.9%	0.7%	1.5%	1.4%	2.1%
Tax distortions	19.6%	20.6%	25.4%	31.2%	35.8%	40.5%
Foregone drug innovation	2.8%	3.9%	5.4%	6.4%	9.5%	6.6%
Total net costs	**30.2%**	**28.8%**	**46.2%**	**46.2%**	**78.4%**	**59.9%**
$ billion per year	9		14		24	

Notes: Each scenario is based on a different assumption about the extent that rebate rules reduce manufacturer rebates as a consequence of redistributing them across the supply chain. Part D net loss in $ billion is calculated for a $31 billion baseline rebate.

Table 2. Rebate Rules affect Health Insurance Premiums

Impact on drug-plan premiums, expressed as percentages of baseline rebate amounts

Premium impact component	OACT Scenario		OACTX2 Scenario		Retain-Zero Scenario	
	Part D	Insulin Act	Part D	Insulin Act	Part D	Insulin Act
Net price impact: brands	27.0%	26.2%	54.2%	52.3%	120.5%	78.9%
Utilization impact: brands	-11.6%	-3.8%	-22.0%	-6.7%	-43.2%	-9.2%
Utilization impact: generics	0.9%	0.3%	1.7%	0.6%	3.4%	0.8%
Utilization-price interaction	-1.3%	-1.7%	-5.1%	-6.0%	-22.3%	-12.4%
Rebates shifted to POS	33.8%	18.6%	33.8%	18.6%	33.8%	18.6%
Added management costs	2.9%	1.9%	3.9%	1.9%	1.0%	1.0%
Added medical costs	0.8%	9.1%	1.5%	16.1%	3.0%	21.9%
Combined premium impact						
% of baseline rebate amount	52.6%	50.5%	68.1%	76.7%	96.1%	99.7%
% of baseline premium [a]	16.9%	16.3%	22.0%	24.7%	31.0%	32.1%

Note: [a] for the purposes of Insulin Act, this row refers to the part of the premium financing insulin claims.

The effects on manufacturer profits, plan and patient value, and third-party medical costs are about twice as large in the OACTX2 scenario as in the OACT scenario. They are about double again in the Retain-Zero scenario.[13] The costs progressively increase between these scenarios because the costs increase with the assumed degree that rebate rules interfere with benefit management practices, which plans purchase in order to obtain better utilization and lower costs. Even when expressed as a percentage of baseline rebates, the third-party medical costs are greater under the Insulin Act than under Part D because the former generates a larger quantity effect.

Because industry-level additions to plan marginal costs, or subtractions from plan marginal revenues, are passed on to consumers as higher premiums, rebate rules have several significant effects on health plan premiums. Table 2 summarizes the results. The first row reflects the higher drug acquisition cost as manufactures offer less volume discounts. This row reflects the net price change shown in Table 1a, except that Table 1a divides the change by the baseline net price whereas Table 2 divides by the baseline rebate amount. Partly offsetting the higher net prices is less brand utilization, as shown in the second row of Table 2.

Rebates reallocated to the point of sale also increase premiums because otherwise plans would use rebates to help finance benefits. I assume that the reallocation of rebates is limited to the amount of the baseline copayments and coinsurance, which is the same across scenarios.[14] The scenarios differ in whether and how much rebates are retained by plans, which can continue to reduce premiums as they do in the baseline.

Notice from the addenda row of Table 2 that I assume that plans use all of the cost sharing to absorb manufacturer discounts: cost sharing is zero under the regulations. Arguably zero cost sharing would particularly hinder benefit management because patients would have no skin in the game. Plans might therefore choose to forego some discounting in order to maintain some positive level of cost sharing, in which case the effects shown in Tables 1a, 1b, and 2 would be even greater.

Premiums also finance benefit-management costs and, for insurance plans that process claims from nonpharmacy providers, non-drug medical costs. Both costs are increased by rebate rules that hinder benefit management and reduce utilization. These additions to premiums are shown in Table 2's sixth and seventh rows. The seventh row exceeds the corresponding row in Table 1b because Table 2 counts the entire effect on nonpharmacy medical costs whereas Table 1b partitions that amount between plan/patient value and third-party value.

Overall, premiums increase by a dollar amount that is about 51-100 percent of the dollar amount of the baseline rebates; see the first "Combined premium impact" row. Expressed as a percentage change in drug-plan premiums from baseline to regulated, that is a 16-32 percent

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[13] The approximate linearity of results across scenarios allows readers to approximate results for additional scenarios that are between any two of OACT, OACTX2, Retain Zero (interpolation) or to extrapolate outside that range. The approximately linearity holds in Table 1a, the several rows of Table 1b, the drug innovation row of Table 1b, and the first four rows of Table 2.

[14] Baseline cost sharing per rebate dollar is less in insulin markets than prescriptions generally, which is why the rebate-shifting row of Table 2 shows less in the Insulin-Act columns.

increase.[15] For a population whose prescription utilization is supported by $31 billion in rebates in the baseline, the Part D rebate rule would add $16-31 billion to premiums of the health plans in which they participate, depending on the scenario.

The Department of Health and Human Services (84 FR 2360) and MEDPAC (2017, pp. Table 14-9) assert that rebate transactions are used by manufacturers, plans and PBMs to increase total government spending on Medicare Part D because rebates purportedly increase the share of patient costs that are out-of-pocket rather than premium. For the commercial market and much of the Part D market, this is incorrect because plans (or PBMs on their behalf) reallocate patient expense between premiums and copays by setting copayment rates, which is one of the reasons why manufacturers have a profit motive to negotiate about plan design (such as formulary placement). However, Medicare Part D regulates copayment rates, especially for Low Income Subsidy (LIS) participants and the subset of high-cost enrollees (those in the catastrophic phase of their drug benefit) whose plans receive government reinsurance subsidies equal to 80 percent of their drug spending at list price.[16] Reducing the list price and rebate one-for-one can reduce Medicare spending on reinsurance, but it also likely reduces refunds paid to Medicare by the plan under Part D reconciliation rules. Social Security's Office of the Chief Actuary (84 FR 2360) as well as the Congressional Budget Office (2019) concluded that the net of these two additional effects the rebate rule on Medicare Part D spending is dwarfed by the premium-increasing effect of the rebate rule.

Because health insurance premiums are heavily subsidized, the premium increase estimated in Table 2 requires the federal government to tax more, spend less, and/or borrow more, which has additional effects on the broader economy. This external cost of rebate rules is shown in the "tax distortion" row of Table 1b.[17]

By reducing the incentives of plans and PBMs to encourage adherence and proper drug utilization, rebate rules have two effects on the incentives of manufacturers to bring unique new drugs to market. The innovation incentive is reduced in the early patent phase after new drug launch, due to reduced brand sales. The incentive is increased in the late patent phase because plans and PBMs are unable to encourage as much competition between competing therapies. The former dominates the overall innovation incentive because of its size and its proximity in time to the introduction of the new drug.[18] I estimate that the social cost of this reduced

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[15] Note that the Insulin Act columns refer only to insulin transactions. Take, e.g., an integrated plan paying $1 million for insulin (not including patient cost sharing) in the baseline. According to Table 2's final column, the same plan would pay $1.34 million for insulin and additional non-drug medical costs as a result of the Insulin Act.

[16] The 2022 Inflation Reduction Act changes the Part D reinsurance subsidies but further regulates cost sharing, such as imposing a $2,000 annual cap per enrollee.

[17] OACT concluded that the HHS rebate rule would increase drug-plan premiums by 25 percent (84 FR 2358) and federal Part D spending by $19.6 billion per year. A key difference between their analysis and the OACT scenario in Table 2 is that I assume that rebates cannot be fully shifted to the point of sale because cost sharing cannot be negative. This by itself results in less premium increase (my Table 2 shows 17 percent for the OACT scenario) and less added federal spending. Another difference is that I track the net costs to various parties, including opportunity costs, whereas the published rebate rule quantifies only clerical costs that are miniscule by comparison.

[18] The latter dominates for the purposes of determining aggregate expenditure on branded drugs (see the first and third rows of Table 1a), because most of those drugs are beyond the early patent phase where benefit management is increasing profit through added utilization.

innovation is 3 to 9 percent of the baseline rebates, as shown in the Table 1b's "foregone drug innovation" row. More details of the estimates are provided in Appendix III.

Overall, the net loss of value ranges from 30 to 78% of the baseline rebates. In a market where those rebates were $31 billion per year, the Part D rebate rule would impose an annual net cost of $9 to $24 billion, depending on the scenario. As a net loss, this estimate already reflects the benefits to manufacturers (especially later in the patent life). The combined losses to patients, plans, and the wider economy is greater than the net loss shown at the bottom of Table 1b.

I.D. Rebate Walls? Effects on generics and plan expenses

Essentially anything that increases the net price of brands tends to encourage generic substitution when available. Due to the anticompetitive effects noted above, rebate rules are examples of regulations that increase the net price of brands. Therefore, my estimates of the overall utilization effect of rebate rules (Table 1a's second row) are less than the corresponding effect on brand utilization (first row).

At first glance, generic substitution might seem able to reduce plan expenses enough for a policy increasing brand costs to nonetheless reduce overall plan expenses. This first guess is incorrect if plans were already minimizing the expense of covering the drug. Likely there are instances in which plans could reduce expenses by promoting generics, but plans and PBMs should be promoting such generics even without a rebate rule.[19] Indeed, plans and PBMs have already encouraged generics, for example by financially rewarding pharmacies for achieving generic targets. Generic scripts have reached 90 percent of the U.S. market, as compared to less than 60 percent in Europe, with much of the remaining 10 percent being branded drugs with no generic substitute available.

For similar reasons, generic substitution induced by increased brand prices likely reduces brand scripts more than it increases generic scripts.[20] The added plan expense will discourage individuals from having generous insurance coverage, and thereby discourage utilization of those categories that are cut out of coverage.

Furthermore, even if brand-price increases reduce brand scripts less than they increase generic scripts, the magnitude would be small because marginal cost (to plans and patients) of brands is also typically low when brands and generics are in competition. Rebates reflect manufacturer volume discounts, which means that the marginal price is less than the net price. Indeed, some economists have concluded that the marginal price paid by insurance plans is identical to the generic price, even in markets where generics do not compete (Lakdawalla & Sood, 2013). In my quantitative model, the marginal price of a brands exceeds generic prices (when they exist)

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[19] Formally, generics and brands can be understood as two distinct but substitutable inputs into treating a health condition. Shephard's Lemma says that the overall expense of treating the condition increasing in each of the (marginal) prices no matter how much substitution any one price increase might induce.

[20] Overall drug utilization must decrease in the brand price unless brands are a "inferior input" in treating a health condition, meaning that an increase in demand for the drug reduces brand utilization even while it increases generic utilization.

but the marginal brand price is closer to the generic price than it is to even the net brand price, let alone the brand list price.

In other words, the financial incentives for plans and PBMs to encourage utilization are significant even when patients are using brands, as long as the manufacturer rebate programs are generously rewarding plans and PBMs for achieving utilization targets. Empirical evidence supports this conclusion. Especially, studies find that the generic substitution that occurs after patent expiration results in no discernible increase in overall utilization (Lakdawalla & Philipson, 2012).

Even though volume discounts are typically procompetitive – their use in the market increase production while frustrating attempts by competitors to earn greater profits – some commentators have misconstrued the effects of volume discounts in pharmaceuticals by describing them as "rebate traps" or "rebate walls." As Arad et al (2021) describe, "payers are effectively incentivized by rebates, and the threat of losing them, to keep the more expensive drugs on their formularies." The Federal Trade Commission has heard from stakeholders concerns about rebate walls, issuing a "Report on Rebate Walls" in 2021 and a "Policy Statement on Rebates and Fees" in 2022.

Although the phrase "more expensive" needs more rigorous definition, the same incentives pejoratively described as "rebate walls" feature prominently in my model. I conclude that rebate rules would in fact reduce incentives to choose brands over generics, which may be no surprise to the rebate-wall commentators, but the reason is simply that rebate rules make increase both the net prices and marginal prices of brands. Nevertheless, the result of raising brand prices – which rebate rules would do – is inferior market performance in terms of utilization, consumer surplus, net prices, and even drug innovation. Consider Figure 1 again. Rebate rules shift the negotiated outcome up and to the left, moving the net price (the vertical dimension of the negotiated outcome) closer to the list price. The penalty for less brand utilization is a lower rebate rate. Algebraically,

$$net\ price * q = [1 - r(q)]Lq$$

(1)

where q is the brand quantity purchased by the plan, L is the list price, and $r(q)$ is the rebate rate as a function of utilization. We find the plan's marginal cost m of utilization by differentiating net drug spending (1) with respect to q:

$$m = \frac{d}{dq}\{[1 - r(q)]Lq\} = [1 - r(q)]L - r'(q)LQ < [1 - r(q)]L < L$$

(2)

Volume discounting not only means that the net price $[1-r(q)]L$ is less than the list price, but that the marginal cost m is less than the net price. Volume discounting makes branded drugs particularly cheap at the margin, even less than the brand net price. This is exactly what supports levels of utilization that are near (or, as in the Lakdawalla and Sood (2013) model, equal) to the competitive level and greater market surplus than would occur without volume discounts. By

every metric other than manufacturer profits, the low marginal brand prices described as "rebate walls" are an improvement over the higher marginal and average brand prices that would prevail under rebate rules.

I.E. Regulatory risk-reward: Quantifying the potential net benefits of changing competition among PBMs

Pharmacy benefit management is itself an industry whose performance is enhanced by competition. The subsection examines how this competition relates to regulatory impact analysis and how it may be affected by PBM regulation itself.

Little of the quantitative analysis of manufacturer rebate rules (Subsection I.C) and pharmacy-DIR regulation (Subsections II.D and II.E) requires specific assumptions about the degree of competition, or lack thereof, among pharmacy benefit managers. Plans and patients in the model are trading off the management costs, drug acquisition costs, and the patient benefits of proper drug utilization. To them, it hardly matters whether the management costs they pay reflect resource costs, PBM profits, or some combination thereof. Plans must decide whether the management costs justify what they save on drug acquisition and gain from better drug utilization. When new regulations add to those costs, plans and patients choose less management and thereby tolerate higher drug acquisition costs (lower rebates and higher net prices) and less drug utilization. This is exactly what happens in the model presented in this paper, e.g., Figure 1.[21]

Although many effects of regulation are independent of the degree to which PBMs compete, regulation itself could affect competition among PBMs, among manufacturers, and among pharmacies. Effects on competition among manufacturers are seen in Table 1a, where rebate regulation increases net brand prices while it reduces drug utilization and rebates. Analogous effects on competition among pharmacies are the subject of Section II of this paper. This section focuses on a third dimension of competition that may be affected by regulation: competition among PBMs.

To the extent the baseline includes imperfect competition among PBMs that restrains the quantity of benefit management, a regulation (or deregulation) that increased competition would *increase* rebates and pharmacy discounts. From the point of view of plans and patients, enhanced competition among PBMs reduces the costs of benefit management, leading them to consume more benefit management in order to further reduce drug acquisition costs, further reduce pharmacy-retailing expenses, and further improve drug utilization. Such procompetitive public policy would be the opposite of rebate rules and the opposite of restraints on pharmacy DIR (see Section II).

At first glance, it might appear that rebate rules encourage competition among PBMs because rebates are an important part of PBMs' revenue. This confuses punishment with competition.

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[21] The quantitative analysis in this paper treats the entire management cost as a resource cost, whereas some imperfectly competitive models would treat part of it as a transfer. If so, this paper's estimates of loss of surplus from PBM regulation is somewhat underestimated as shown in Appendix I.

Making it more difficult for PBMs to do business will not encourage more companies to get into the PBM business. Instead, to the extent that large incumbent PBMs are better able to adapt to the regulations than smaller new PBMs are, the regulations would have the unintended consequence of reducing competition while they increase the resource costs of managing pharmacy benefits.

Even if regulations succeeded at enhancing PBM competition without the costs estimated in Tables 1a, 1b, 2, and the tables that follow in Section II, the net regulatory gains through the competition channel are at best small because PBM net revenues are dwarfed by the value they deliver clients and the industry overall. The annual costs of PBMs are about $21 billion, of which about $7 billion is accounting profit (Sood, Shih, Van Nuys, & Goldman, 2017). Because much of the accounting profit of PBMs is a competitive return on the capital needed to manage benefits, any public policy that succeeded in enhancing competition among PBMs would at best be reducing annual profits by $1 or $2 billion in a $350 billion prescription market.[22] The dollar amount of the pro-competitive upside is even less for a regulation that applies only to particular industry segments such as Medicare or to particular drugs.

A greater risk is that regulation stifles competition among PBMs and significantly reduces the value of benefit management.[23] These risks can be quantified using the same linear demand systems already used to quantify regulatory effects on competition among manufacturers and pharmacies. Take the worst-case scenario of chilling competition among PBMs, which would be that PBM services are sold at monopoly prices. Measured as a share of the industry surplus from competitive benefit management, the deadweight loss from monopoly pricing of benefit management is between 1/4 and 5/12.[24] With baseline benefit management creating surplus of $92 billion per year in the industry plus another $53 billion of external effects (Mulligan, 2022), chilling PBM competition by itself would have a net cost of up to $36-60 billion. These indicate the magnitude of the net costs that would be incurred if an unintended consequence of PBM regulation were to reduce competition among PBMs.[25]

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[22] Also note that the allocative consequences of imperfect competition among PBMs may be especially small because PBM services may themselves be priced nonlinearly. Especially, instead of dealing directly with the largest PBMs, many insurance plans use smaller PBMs as an intermediary – essentially a buyers' club for the unique services provided by the largest PBMs. That is, small PBMs encourage competition among large PBMs without necessarily duplicating the services of the large PBMs in the same way that PBMs encourage competition among drug manufacturers without going into the manufacturing business themselves. See also Jaffe et al (2019, Chapter 13).

[23] See also Section III of this paper, which also examines effects of PBM disclosure on competition among manufacturers and among pharmacies.

[24] See Appendix I for details.

[25] Once we recognize that PBM regulations are often business-to-business price regulations, this high regulatory risk-reward ratio is an illustration of a general principle articulated in the Office of Management and Budget's (2003) Circular A-4 that imposing price regulations would, "in light of both economic theory and actual experience," require a "particularly demanding burden of proof."

II. Pharmacy DIR regulation

II.A. Background

Pharmacies are at the retail end of the prescription-drug supply chain. PBM services are also a procompetitive force in the retail pharmacy market, where PBMs obtain discounts and higher-quality retailing in exchange for favorable pharmacy placement in drug plan pharmacy networks, which is valuable to the pharmacy due to the traffic it directs to the retail stores.

The economics of the pharmacy part of PBM services is similar to the drug-manufacturer part illustrated in Figure 1. Without PBM services, plans would pay list price for retail services, which likely is at least somewhat above marginal cost due to (i) the significant market share of a small number of companies in that market and (ii) the fact that pharmacies may benefit from plan member patronage due to the nonpharmacy purchases they make at the retail stores. Pharmacy utilization would be greater, and pharmacy costs less, under a negotiated discount.

Due to their contact with patients, pharmacies can be valuable partners with plans and PBMs in managing the drug benefit. Pharmacy contracts therefore specify performance goals as well as negotiated discounts. The contracts financially incentivize pharmacies for dispensing less-expensive generics, achieving adherence goals, and otherwise aligning with the plan's objectives (Mattingly & Bai, 2021).

Pharmacies agree to discounts and performance goals in order to compete with other pharmacies hoping to receive the preferential position in the plan's benefit structure in the face of competitors also discounting retail services and offering to partner in managing the drug benefit. Conversely, if there were less competition among pharmacies, the pharmacies could charge more and/or refuse to be remunerated based on patient results.

II.B. Definitions

Specifically, as negotiated by PBMs on behalf of their client plans, pharmacies receive funds from the plans up front – at the point of sale – for dispensing prescriptions and conducting drug-adherence programs. After the point of sale, payment adjustments are made and pharmacies return some of the funds to the extent that performance metrics were not met during the year. These various post-sale fees and settlement payments from pharmacies to plans and PBMs are known in the Medicare Part D program as pharmacy direct and indirect remuneration, or "pharmacy DIR."[26]

In May of 2022, the Centers for Medicare and Medicaid Services (CMS) issued a final rule, to take effect January 1, 2024, requiring pharmacy DIR on Medicare Part D transactions to be reflected in the retail price that is the basis for determining patient cost sharing (87 FR 27704). Because, prior to the regulation, it appears that retail prices rarely reflect DIR, CMS projects that the rule will reduce cost sharing.

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[26] Fees and payment adjustments occurring after the point of sale among participants in the prescription supply chain are known as "direct and indirect remuneration" (DIR). The largest category of DIR consists of the negotiated manufacturer rebates paid to plans and PBMs. Pharmacy DIR is another example.

The PBM Transparency Act of 2023 is a bill introduced in the U.S. Senate that would apply to all segments of the prescription drug market. Its Section 2 gives PBMs two compliance options: one option requiring PBMs to publicly disclose their remuneration and prohibiting them from retaining any of the discounts paid by manufacturers and pharmacies and another option prohibiting (among other things) pharmacy DIR that is obtained "arbitrarily, unfairly, or deceptively."

II.C. Economic interpretation: distorted incentives

Pharmacy discounts are paid as rewards for utilizing that pharmacy. As such, all else the same, discounts received by patients encourage them to obtain prescriptions at the associated pharmacy. Discounts received by plans and PBMs incentivize those companies to encourage their members to obtain prescriptions at that pharmacy, which is also a financial partner in achieving the plans' drug management goals. In other words, by redistributing discounts across points in the supply chain, rebate rules increase pharmacy-utilization incentives for patients but reduce them for plans and PBMs. Holding constant the overall discount, the redistribution therefore has opposite effects on utilization that would almost exactly offset to the extent that the baseline discounts had been distributed to maximize proper utilization. In the results that follow, this net utilization effect of discount redistribution is assumed to be zero (a conservative assumption, as explained in Appendix IV).

Pharmacy DIR for plans and PBMs is an important element of benefit-management tools. By constraining the use of such tools, regulating pharmacy DIR would increase the cost to plans and PBMs of achieving their management goals, and thereby reduce the amount of benefit management they do. Specifically, DIR regulation would reduce drug utilization (both brand and generic), the combined pharmacy discount received by patients and plans, and the productivity of benefit management resources. The more constraining is the regulation, the more that utilization and pharmacy discount rates are reduced.

The quantitative analysis of both pharmacy-DIR regulations is represented in Figure 2 and Appendix V, which have the same economic and algebraic structure as Figure 1 and Appendix I except that the former refer to negotiations with retail pharmacies over discounting and execution of retail pharmacy services rather than negotiations with drug manufacturers. Pharmacy discounts retained by plans go toward reducing drug plan premiums and enhancing drug benefits. Drug utilization is affected because the marginal cost of pharmacy services is one of the components of the marginal cost of prescription drugs.[27]

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[27] In terms of Figure 1, the marginal cost curves shift up, reducing the quantities of both branded and generic prescriptions. As shown in Appendix V, the quantitative drug-utilization analysis is done using cost shares.

Figure 2. Benefit-management costs are increased by constraining management tools
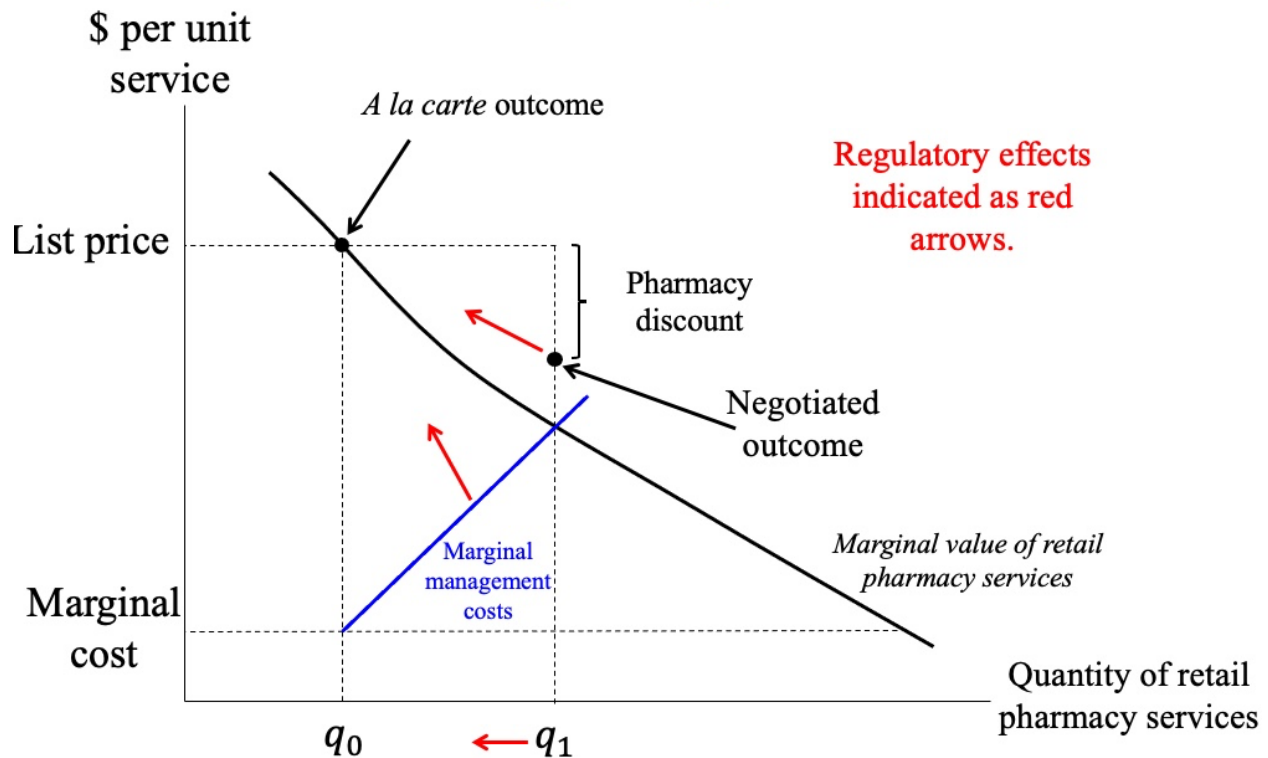
The blue curve is the sum of the marginal management costs with the other (and constant) marginal costs of pharmacy labor, etc.

Based on the 2019 and 2020 plan years, I estimate that pharmacy discounts are about 30 percent of the list price of pharmacy services.[28] The 30 percent discount rate indicates values for the slopes of industry- and firm-level demands for pharmacy services (see Appendix V), which are used to simulate market outcomes for regulations that reduce pharmacy discounts.

II.D. Quantitative analysis: The PBM Transparency Act

The PBM Transparency Act would impose two alternate compliance options, one of which explicitly prohibits pharmacy DIR if it is "arbitrarily, unfairly, or deceptively" obtained by PBMs. Presumably PBMs would choose the compliance option that is better for their business. Here I estimate the costs and benefits under the assumption that all PBMs choose the option that

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[28] Specifically, CMS reports that pharmacy DIR in the Part D segment is about $9 billion annually (87 FR 27834). With net pharmacy revenue of about $21 billion in the Part D segment (Sood et al (2017) estimate that net pharmacy revenue is 15 percent of net spending on prescriptions), the 30 percent discount rate is 9/(9+21). Lacking data on pharmacy DIR in the commercial segment, I assume that the 30 percent rate applies throughout the industry (albeit to a lesser dollar amount outside Part D).

limits pharmacy DIR. Section III.B estimates costs and benefits under the assumption that all PBMs choose the other compliance option.[29]

Both manufacturer rebates and pharmacy price concessions are volume discounts paid to plans and PBMs by providers in the pharmaceutical market. However, the dollar amount of discounts shifted from plans and PBMs to cost sharing in the Part D segment is less under the Act's DIR provision than under the HHS rebate rule both because Part D (and presumably also the commercial segment) has less pharmacy discounts than manufacturer rebates in the baseline ($9 billion annually compared to about $31 billion).[30] This suggests that the DIR provision would reduce the productivity of Part D benefit management resources less than the HHS rebate rule would.

The PBM Transparency Act does not clearly indicate what fraction of pharmacy DIR is arbitrary, unfair, or deceptive. I assume that passing all pharmacy DIR to the patient at the point of sale would (i) be a safe harbor for PBMs and (ii) be feasible in the event the baseline DIR is less than patient cost sharing: one could be fully substituted for the other without negative cost sharing. In this case, the Act's DIR provision is the pharmacy analog of the HHS rebate rule, except that the DIR provision would not be limited to the Part D segment and the "Retain-Zero" scenario is not relevant.

OACT concluded that a Medicare Part D rebate rule requiring that rebates be paid at the point of sale would interfere with benefit management enough to reduce discount rates by 15 percent as a consequence of shifting them from plans and PBMs to the point of sale.[31] I make the same assumption regarding paying pharmacy DIR at the point of sale. That is, under the Act's DIR provision, benefit management would result in plans and patients together receiving pharmacy discounts equal to 85 percent of what the pharmacy discounts were in the baseline. In Figure 2's demand model, there is one and only one marginal-cost-curve shift corresponding to OACT's result, which is the shift assumed throughout my "OACT scenario" for DIR regulation. I also consider an "OACTX2" scenario, which doubles the discounting reduction assumed by the OACT scenario.

Table 3 shows the results, assuming that the baseline pharmacy DIR is $16.2 billion per year, including the commercial and Medicaid segments.[32] Although the dollar amounts of discounts are less in pharmacy contracts than in manufacturer-rebate contracts, Table 3 (pharmacy DIR regulation) shows somewhat greater overall utilization effects than Table 1a (manufacturer rebate rules) because pharmacy contracts cover both brands and generics.[33] Premiums are

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[29] Therefore, the PBM Transparency Act costs and benefits should not be added between the two sections. Rather, they should be averaged according to the volume-weighted fraction of PBM contracts that adhere to the corresponding compliance option.

[30] If the baseline includes manufacturer rebate rules that have already driven cost sharing down to zero (recall Table 2's regulated cost-sharing row), then plans and PBMs retain all pharmacy DIR under either the PBM Transparency Act or the CMS rule.

[31] 85 FR 76725.

[32] The only pharmacy DIR data I have is for the Part D segment. To extrapolate to the entire industry, I assume that Part D has 50 percent more pharmacy DIR per dollar of net drug spend than the entire market does.

[33] In contrast, the utilization effects of rebate rules are partly (but not fully) mitigated as patients and plans shift to generics as brands become more expensive at the margin (Appendices I and IV).

primarily affected because under the regulation premiums are no longer financed with pharmacy DIR. The effect is greater in the OACT scenario than in the OACT2 scenario because the former assumes that PBMs are still negotiating comparatively large discounts from pharmacies.

Table 3. Consequences of the PBM Transparency Act's Pharmacy DIR Restrictions

The table shows the effects of the DIR restrictions on health plan premiums; net costs to patients, plans, manufacturers, and pharmacies; and external effects. Subcategories are shown in normal font.

	Scenario	
Outcome	OACT	OACTX2
	Regulated as % of baseline	
Rx quantity	-0.6%	-1.0%
Net price	0.2%	0.1%
	$ billions per year	
Increased premiums	**13.3**	**10.2**
Net costs in the supply chain	**1.9**	**3.4**
Patients & plans	2.6	4.7
Manufacturers	0.2	0.4
Pharmacy losses (- is profit)	-1.0	-1.7
External effects	**5.7**	**4.6**
3rd-party nondrug health costs	0.1	0.2
Tax distortions	5.5	4.2
Foregone drug innovation	0.1	0.2
Net cost = supply chain + external effects	**7.6**	**8.0**

Note: Quantities and prices refer to the entire prescription market (brands and generics). Table entry dollar amounts are rounded to the nearest $100 million.

Reduced prescription utilization by itself reduces drug costs but increases nonpharmacy medical costs. Those costs are a significant part of the $10-13 billion addition to health plan premiums.[34]

Table 3's middle panel shows the incidence of the pharmacy-DIR regulation, including both monetary costs and opportunity costs. It primarily redistributes from patients and plans to pharmacies. Manufacturers (especially the branded manufacturers selling at a markup) are also harmed, although by a lesser amount, due to the reduced utilization of their products.[35] Overall

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[34] The same methodology (Appendix II) is used for rebate rules and pharmacy DIR regulations. The estimated regulatory impact on nonpharmacy drug costs is proportional to the regulation's effect on utilization.

[35] Because of the manufacturer harm, the market may adjust to pharmacy DIR regulations that target PBMs by having manufacturers serve as middlemen between plans and pharmacies in order to incentive pharmacies to help achieve plan goals, albeit at greater management cost. Workarounds like this are reasons to emphasize the "OACT" scenario over the "OACTX2" scenario.

the regulation has a net cost to market participants – $2-3 billion annually – because (i) reduced utilization and (ii) benefit management is less productive and more costly.

Because plans and patients recognize connections between drug adherence and nonpharmaceutical health expenses, some of this extra cost is already reflected in the reduced surplus ("lost value in the supply chain") accruing to patients and parties to rebate transactions. However, part of the nondrug effect is not reflected in the pharmaceutical-market demand curve due to drug plans' imperfect incentives to control nondrug costs. To avoid double-counting, only the second component of the nondrug medical costs is shown as a distinct category in Table 3's bottom panel.

Because health insurance premiums are heavily subsidized (although to a lesser degree in the commercial market than in Medicare – see Appendix II), the premium increase estimated in Table 3 requires the federal government to tax more, spend less, and/or borrow more, which has additional effects on the broader economy. This external cost of rebate rules is shown in the "tax distortions" row of Table 3. Finally, with less utilization, incentives for drug innovation are somewhat less, which is an opportunity cost quantified in the "foregone drug innovation" row.

Overall, the net cost of the pharmacy DIR provision of the PBM Transparency Act would be about $8 billion, which includes a net benefit for pharmacies. In other words, the costs to patients, plans, manufacturers, and other market participants are at least six times the benefits to pharmacies.

II.E. Quantitative analysis: CMS rule

By requiring Medicare Part D pharmacy DIR to be reflected in the pharmacy price that is the basis for cost sharing, the CMS pharmacy DIR rule would also redistribute funds along the prescription supply chain. However, the effect is less than with the DIR provision of the PBM Transparency Act because (i) the CMS rule only applies to Medicare Part D and (ii) plans would be allowed to share DIR in the same proportion that they share other claims.

In Table 3, the OACT and OACTX2 scenarios have the shifting of pharmacy discounts reduce their total by 15 and 30 percent, respectively. As percentages, these automatically account for the fact (i) that a lesser dollar amount of pharmacy DIR falls under the CMS rule than under the PBM Transparency Act's DIR provision. To also account for fact (ii) the impact analysis of the CMS rule rescales the 15 and 30 percent by my estimate of the baseline share of gross drug costs that are paid out of pocket (0.10). For example, under the OACT scenario, a baseline pharmacy discount of 30 percent (more precisely, 29.8 percent) becomes a 25 percent discount (0.25 = (1−0.15)*0.298) under the PBM Transparency Act and a 29 percent discount (0.29 = (1−0.15*0.10)*0.298) under the CMS rule.[36] The CMS rule results are shown in Table 4 for the Part D segment.

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[36] The text shows discount rates to the nearest one percent, whereas the calculations producing the table preserve as many decimal places as Microsoft Excel allows.

Table 4. Consequences of the Part D Pharmacy DIR Rule

The table shows the effects of the rule on health plan premiums; net costs to patients, plans, manufacturers, and pharmacies; and external effects. Subcategories are shown in normal font.

Outcome	Scenario	
	OACT	OACTX2
	Regulated as % of baseline	
Rx quantity	-0.1%	-0.1%
Net price	0.0%	0.1%
	$ billions per year	
Increased premiums	**0.9**	**0.9**
Net costs in the supply chain	**0.1**	**0.2**
Patients & plans	0.2	0.3
Manufacturers	0.0	0.0
Pharmacy losses (- is profit)	-0.1	-0.1
External effects	**0.4**	**0.4**
3rd-party nondrug health costs	0.0	0.1
Tax distortions	0.3	0.3
Foregone drug innovation	0.0	0.0
Net cost = supply chain + external effects	**0.5**	**0.6**

Note: Quantities and prices refer to the entire Part D market (brands and generics). Table entry dollar amounts are rounded to the nearest $100 million.

As with the PBM Transparency Act, the CMS rule redistributes to pharmacies by raising premiums and imposing costs on plans, patients and manufacturers. Those costs are especially due to reduce utilization, greater plan expenses, and a premium burden to be financed by federal taxpayers.

Overall, the annual net cost ranges from $0.5 to $0.6 billion. In other words, the CMS rule for pharmacy DIR will increase pharmacy profits but at a cost to patients, plans, and third parties that is about seven times the pharmacy benefit. In the OACTX2 scenario, for example, pharmacies gain $120 million annually while others pay more than 6 times the pharmacy benefit ($760 million), for a net cost of $640 million.[37]

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[37] The Congressional Budget Office (2020) estimated larger effects in the same direction. Specifically, it concluded that "requiring pharmacy-negotiated price concessions, payment, and fees to be included in negotiated prices at the point of sale under Part D" would increase annual federal spending by about $3 billion, which would translated to $1.5 billion in tax distortions.

III.   Disclosure requirements and competition in the prescription supply chain

Section 2 of the PBM Transparency Act of 2023 gives PBMs two compliance options: one option requiring PBMs to publicly disclose their remuneration and prohibiting them from retaining any of the discounts paid by manufacturers and pharmacies and another option prohibiting (among other things) pharmacy DIR that is obtained "arbitrarily, unfairly, or deceptively." The purpose of this section is to assess the net cost of the disclosure option; the pharmacy DIR option is assessed in Subsection II.D of this paper.

The bill's Section 2 disclosure option specifically requires that the "pharmacy benefit manager, affiliate, subsidiary, or agent provides full and complete disclosure of—(A) the cost, price, and reimbursement of the prescription drug to each health plan, payer, and pharmacy with which the pharmacy benefit manager, affiliate, subsidiary, or agent has a contract or agreement to provide pharmacy benefit management services; (B) each fee, markup, and discount charged or imposed by the pharmacy benefit manager, affiliate, subsidiary, or agent to each health plan, payer, and pharmacy with which the pharmacy benefit manager, affiliate, subsidiary, or agent has a contract or agreement for pharmacy benefit management services; or (C) the aggregate amount of all remuneration the pharmacy benefit manager receives from a prescription drug manufacturer for a prescription drug, including any rebate, discount, administration fee, and any other payment or credit obtained or retained by the pharmacy benefit manager, or affiliate, subsidiary, or agent of the pharmacy benefit manager, pursuant to a contract or agreement for pharmacy benefit management services to a health plan, payer, or any Federal agency (upon the request of the agency)."

Disclosure requirements like this may stifle competition among manufacturers, among pharmacies, and among PBMs. On the first point, public disclosure of PBM contracts could facilitate collusion because the disclosure would allow competing manufacturers to know, in a more timely fashion, the amount of rebates that competing manufacturers were offering. In the context of disclosure of health care contract data, the Federal Trade Commission (2015) warned that "[w]hile [transparency] laws can be procompetitive, [they] may require public health plans to publicly disclose competitively sensitive information, including *information related to price and cost*. Such disclosure may chill competition by facilitating or increasing the likelihood of unlawful collusion, and may also undermine the effectiveness of selective contracting by health plans…."[38]   The two anti-competitive concerns cited by the FTC are relevant to the PBM Transparency Act, because the Act specifically targets "cost, price and reimbursement" for disclosure and because selective contracting is an essential tool for pharmacy benefit management. Moreover, both the Department of Justice and the FTC (1996) note that the anti-competitive effects are especially likely when data is disclosed for individual sellers (PBMs in this case) or that aggregate data is disclosed for which an individual seller contributes more than

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[38] Emphasis added. The Minnesota Department of Human Services (2015) also concluded that "classifying plan-provider contracts as public data would offer little benefit but could pose substantial risk of reducing competition in health care markets. Such disclosure may reduce the inventive for all providers to offer low prices and may facilitate collusion among providers. High levels of market concentration … would facilitate these outcomes."

25 percent to the aggregate. These are exactly the disclosure conditions set forth by Section 2 of the PBM Transparency Act.[39]

Consider, for example, three branded therapies competing. Absent disclosures, one pays a 20 percent rebate, a second pays 30 percent, and a third pays 40 percent. The second and third understand that they are rebating more than another competitor but are unaware that the gap from the more expensive competitor is a full 10 percentage points. As full disclosure reveals the gaps, the second reduces its rebate to 21 percent while the third reduces to 22 percent. In other words, full disclosure reduces the average rebate from 30 percent to 21 percent.

The consequences of reducing manufacturer rebate rates from 30 to 21 percent are already shown in Tables 1a, 1b, and 2 as the OACTX2 scenario, although only for the Part D segment. Table 5's manufacturer-competition column shows the results for the entire market, including commercial and Medicaid. Although manufacturers would profit from reduced rebate rates, the cost to plans and patients exceeds the manufacturer benefit by $12.3 billion per year, as shown in the first cell of Table 5. The external costs of reduced manufacturer competition are another $14.6 billion.[40]

Table 5. Competition and the Net Costs of Disclosure Requirements

Net costs in $ billions per year, entire market

The table shows the net costs of three types of reduced competition that may be the result of disclosure requirements.

Type of Regulatory Net Cost	Regulatory impact on competition among:		
	Manufacturers	Pharmacies	PBMs
In the supply chain	12.3	3.4	up to 31
External	14.6	4.6	up to 18
Total net costs	26.9	8.0	up to 48
Addendum: Rebate or Discount Rates			
Baseline	30%	30%	NA
With disclosure	21%	21%	NA

Sources: Table 1b scaled to industry rebates, Table 4, Section III. The external costs in this table exclude any tax distortion from rebates or discounts shifted to the point of sale, which are part of Table 4.

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[39] These conditions may also be set forth by Section 4 of the PBM Transparency Act, depending on if and how the disclosed data is presented to the public or to competitors.

[40] Among the external costs shown in the rebate-rule Tables 1b and 2 are tax distortions associated with government financing of increase drug-plan premiums. One consequence of rebate rules not shared with disclosure requirements is the shifting of discounts to the point of sale and the associated premium increase. That part of net cost is therefore excluded from the external-cost row of Table 5. Still, the annual fiscal cost of the reduced manufacturer competition shown in Table 5 would be almost $20 billion.

The disclosure requirements may reduce pharmacy discounts for the same reason: competing pharmacies would know sooner and more precisely the discounts being offered by competitors. If the requirements reduce average pharmacy discounts from 30 percent of the list price of pharmacy services to 21 percent, the consequences are essentially those shown in Table 3 for the OACTX2 scenario. Although pharmacies would profit from reduced pharmacy discounts, the cost to plans and patients exceeds the pharmacy benefit by $3.4 billion per year, as shown in the middle column of Table 5. The external costs of reduced manufacturer competition are another $4.6 billion.

Disclosure rules may affect PBM competition in three ways. One is they put smaller PBMs at a competitive disadvantage because they are not integrated with pharmacies and plans and thereby have fewer ways to adjust PBM remuneration without affecting performance along the supply chain. A second potential anti-competitive result is analogous to the tacit collusion already highlighted among manufacturers and among pharmacies: disclosure would provide PBMs with more timely information about what their competitors' clients pay and the services they receive.

A third potential harm to competition is hindering investment and innovation in benefit management.[41] One of the major intended (and procompetitive) results of a managed insurance benefit is to maintain different prices of products produced by monopolistic or oligopolistic healthcare providers.[42] Because the systems for doing so are intellectual property that is rarely protected by patent or copyright, disclosure of proprietary information about those systems would remove much of the financial incentive to invest in advancing them because competitors could use the disclosed information to more rapidly imitate. Unlike other areas of healthcare where the product is a chemical, procedure, or device, much of the product of benefit management is the pricing and other contract provisions.

These risks can be quantified using the same linear demand systems already used to quantify regulatory effects on competition among manufacturers and pharmacies. Take the worst-case scenario of chilling competition among PBMs, which would be that PBM services are sold at monopoly prices. Measured as a share of the industry surplus from competitive benefit management, the deadweight loss from monopoly pricing of benefit management is between 1/4 and 5/12.[43] With baseline benefit management creating surplus of $92 billion per year in the industry plus another $53 billion of external effects (Mulligan, 2022), chilling PBM competition by itself would have a net cost of up to $36-60 billion, the midpoint of which is shown in Table 5.

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[41] Burns (2022, Chapter 10) provides a history of PBM innovations. Burns points out (p. 603) that, among other investments, "implementation of outcome-based contracts requires significant investments in infrastructure (data collection and analytics capabilities)."

[42] Lakdawalla and Sood (2013). In terms of Figure 1, the intended result is to push both the net price and marginal price below the list price.

[43] See Appendix I for details.

IV.   Paying Less for Prescriptions: the Value of Group Drug Purchasing

Although benefit management is usually omitted from economic models of the pharmaceutical industry, essentially every prescription-drug plan sponsor dedicates significant resources to that activity. They either hire or vertically integrate with a dedicated PBM firm to manage benefits and negotiate discounts with manufacturers and pharmacies. Any rigorous and realistic analysis of the consequences of PBM regulation must acknowledge what benefit management does and how its benefits compare to its costs (see also Burns 2022).

PBMs are a procompetitive force in healthcare markets, where drug manufacturers and retail pharmacies frequently have market power. Some of the manufacturer market power derives from pharmaceutical patents. In the retail pharmacy market (excluding mail pharmacies), the top three retailers have 60 percent of the market.

Perhaps public policy changes could increase competition among drug manufacturers and among retail pharmacies. But until that happens, competition can still be enhanced by group purchasing and negotiated discounts. PBMs do exactly that, in some of the same ways that Costco, Sam's Club, and other buyers' clubs obtain manufacturer discounts on behalf of their members.[44] Limiting or even eliminating benefit management tools likely reduces the ability of PBMs to obtain discounts and manage drug benefits.

To further appreciate that group purchasing is more than a zero-sum game (benefits the purchasers more than it reduces seller profits), it helps to recall how sellers exercise market power: by restricting the quantity that they sell. A seller would like to raise its price – charge more – but cannot do so without restricting quantity.   The Organization of Petroleum Exporting Countries (OPEC) is perhaps the most famous sellers' cartel. OPEC exercises its market power by limiting the oil production of each of its members. Healthcare providers do that too, often with the assistance of industry regulation (U.S. Department of Health and Human Services, 2018). Exercising market power delivers more profits when the sellers face a demand curve that is less price sensitive, so that small reductions in quantity can sustain large price increases.

Buyers' clubs induce sellers to limit their exercise of market power by presenting them with a more price-elastic demand curve (Jaffe, Minton, Mulligan, & Murphy, 2019). The members of Costco may not have a particularly price-elastic demand for particular brands of, say, skateboards. Skateboard manufacturers know this and hike their prices when dealing with consumers individually. But Costco limits the number of manufacturers who can sell to their members to one or two manufacturers pricing the lowest. In effect, each manufacturer bidding to be in Costco faces a very price-elastic demand from the club because a small increase in price will cost her all of her sales through Costco. With a low price of skateboards in the store, Costco members buy more skateboards than they would if there were no buyers' clubs in that market. Quantity discounts obtained by buyers' clubs serve much the same purpose (Murphy, Snyder, & Topel, 2014). Either way, lower prices and higher quantities are the proof that buyers' clubs are procompetitive.

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[44] Costco is a buyers' club for a range of consumer products, including prescription drugs. Specifically, Costco owns the PBM Costco Health Solutions and is a partial owner of another PBM (Navitus).

In much the same way that Costco excludes skateboard manufacturers and restaurants exclude soda vendors, PBMs can exclude manufacturers, or place a manufacturer's products less favorably in the plan, to incentivize the favored manufacturers to deliver drugs to plan members at a lower price. As Patricia M. Danzon put it, "[t]he basic principle is that PBMs can drive discounts on drug prices and pharmacy fees by restricting patients' choice of drugs or pharmacies, thereby increasing volume for preferred suppliers that accept the discounted prices. Thus, more restrictive drug formularies or pharmacy networks generally obtain larger discounts."[45]

Just as Costco membership has little relation to skateboard-brand preference, or restaurant choice little relation with soda-brand preference, working for a business (employers are the most common sponsor of prescription-drug plans) has at most a weak relation with the demand for prescription drugs. The diversity of the group is what allows the group purchasing to deliver so much value. If all patrons of a restaurant strongly preferred Coca-Cola, Coca-Cola would have little reason to offer the restaurant a discount for an exclusive position on its menu knowing that customer demand alone would sustain that position.[46]

At first glance, the direction of the quantity effect of negotiations with manufacturers by restaurants, Costco, or PBMs might appear ambiguous because the ultimate customer may have less choice albeit at a lower price. It is important to recognize that no single PBM is the only one contracting for a drug. While the plans served by the PBM might consider reducing utilization in exchange for a lower price, individual plan members are (with a physician's prescription) capable of making drug purchases at list price outside the plan. A PBM loses bargaining power when its formulary restrictions excessively burden a segment of its members because the manufacturer expects it may reach those members outside their plans. In other words, the existence of other PBMs as well as individuals capable of purchasing on their own incentivizes PBMs to use management tools that create value rather than redistributing it.

Four important types of evidence indicate that PBM services increase prescription-drug utilization rather than reducing it. One is a study of drug-patent expirations by Lakdawalla and Sood (2013) showing how the quantities sold under patent are further below the post-patent quantities when the potential drug consumers are less likely to have prescription-drug coverage and thereby less likely to be served by a PBM.[47] A related finding is that patent expiration does little to increase sales aggregated between the brand and its new generic competitors (Lakdawalla & Philipson, 2012), which in terms of my Figure 1 further suggests that q_1 is well above q_0 and further supports my conclusion that PBM services significantly increase utilization even when generics are not available.

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[45] Danzon (2015, p. 246). See also FTC's (2014) conclusion that the "ability of health plans to construct networks that include some, but not all, providers (so-called 'selective contracting') has long been seen as an important to enhance competition and lower costs…."

[46] In the context of health insurance, a diverse group also helps reduce the costs of "adverse risk selection," which in extreme circumstances can leave a large fraction of the population uninsured (Hackmann, Kolstad and Kowalski 2015, Bundorf, Levin and Mahoney 2012).

[47] In other words, the high utilization rates prior to patent expiration belie assertions that rebate negotiations are anticompetitive, because anticompetitive practices by definition reduce utilization. Discussion of utilization rates is conspicuously absent from, e.g., the Department of Health and Human Services claim that "rebates … prevent[] competition to lower drug prices…" (84 FR 2343).

A second comparison is with the uninsured. Of course, the uninsured population is different from the insured, but studies of changes in drug coverage for a given population find that insurance coverage by itself increases drug utilization (Lichtenberg, 2007; Kaestner, Schiman, & Alexander, 2019), which in terms of Figure 1 suggests that $q_0 < q_1$. Third, several studies show that mail-order pharmacies, an important service provided by PBMs, by themselves increase medication adherence. The fourth comparison is the rebates received from manufacturers facing more therapeutic competition from those facing less.

V.　　Appendix I: Algebraic Representation of the Rebate-Regulation Model

The economic model has four goods: two branded drugs in quantities q and Q, generic drugs G, and all other goods z. The market demand system is represented by the preferences $u(q,Q,G) + z$, where u is a jointly concave function that is symmetric in q and Q. I assume that u is a quadratic form, which makes the marginal rate of substitution between any of q, Q, G and all other goods that is linear in the three drug quantities. This ultimately results in a linear demand system, as shown further below.

V.A. The Demand System

The market for a monopoly drug is analyzed by setting $Q = G = 0$ and determining the equilibrium q. The oligopoly market for a drug without generic competition is modeled by setting $G = 0$. Most of the analysis uses the oligopoly version ($G = 0$), except when assessing the effect of shifts of brand utilization on generic utilization.

The symmetric quadratic form u is:

$$u(q,Q,G)$$
$$= \frac{1}{\eta} \frac{(q + Q + a_1 G)(\eta - 1)\varepsilon + \left[(\eta - \varepsilon)(q\,Q + a_2 q\,G + a_2 Q\,G) - \varepsilon \frac{q^2 + Q^2 + G^2}{2}\right] \frac{\eta + \varepsilon}{\eta - 2\varepsilon}}{1 + \varepsilon} \quad (3)$$

where a_1, a_2, η, and ε are constant demand parameters satisfying:

$$\varepsilon < \eta < 0 \wedge \varepsilon < -1 \wedge 0 < a_1 \leq \frac{2a_2(\eta^2 - \varepsilon^2) + \eta(\varepsilon + 1)(2\varepsilon - \eta)}{(\eta - 1)\varepsilon(2\varepsilon - \eta)} \wedge 0 < a_2 \leq 1 \quad (4)$$

The remaining preference parameters in (4) are set to normalize the quantities so that the oligopoly marginal rates of substitution would be one when $q = Q = 1$. At marginal values of $\varepsilon/(\varepsilon+1)$, each oligopolist's demand curve has own price elasticity $\varepsilon < -1$ and cross-price elasticity $\eta - \varepsilon > 0$. The restrictions on a_1 and a_2 imposed in (4) require that generic demand would be zero if both brands price at marginal cost. These two demand parameters are irrelevant in the oligopoly version.

V.B. Costs and Pricing

The marginal cost of producing, distributing, and retailing the drug as part of an unmanaged plan is normalized to one. If generics are part of the market, they are assumed to set price equal to one. The brand manufacturers each chooses its prices (sic) taking as given the prices of the competing brands and generics.

Each brand manufacturer has the option of selling at a single "list" price or, in cooperation with each client plan, engage in nonlinear pricing and share the surplus from the nonlinear pricing

with the plan. In the latter case, quantities are determined by marginal prices (the unique solution to the linear system that equates marginal rates of substitution to the corresponding marginal price), which are denoted m and M for each brand.

Nonlinear pricing must be accompanied by managed distribution or else resale, fraud, stockpiling and other behaviors would undermine the pricing scheme as consumers attempt to make both marginal and inframarginal purchases at the lowest price. In addition to its net payments to the manufacturer, each plan therefore faces a management cost $c\left(\frac{L+l-M-m}{2}\right)^2 \geq 0$ that is proportional to the square of the average gap between marginal price and list price. L and l denote the list prices, each of which is chosen by the manufacturer to maximize profits in the contingency that the plan does not cooperate but is cooperating with the competing brand to implement its two-part pricing scheme. The scalar c is a cost parameter that is affected by regulation, illustrated by the red arrows in Figure 1.

The management cost $c\left(\frac{L+l-M-m}{2}\right)^2$ is the area shown in Figure 1 between the blue marginal management cost curve and the horizontal line at marginal cost of one. The symmetric equilibrium quantities, marginal prices, and industry surplus are where the marginal management cost crosses the industry demand curve.

V.C. Regulatory impact as an equilibrium comparative static

Regulatory impact is modeled as an equilibrium comparative static with respect to the management cost parameter c. Because c is common to the symmetric oligopolists in the same market, regulatory impact on price, quantity, and industry surplus $u(q,q,0) - 2q - c(L-m)^2$ can be examined at the industry level, such as using Figure 1 and interpreting the demand curve as the brand-aggregate demand. Algebraically, the equilibrium oligopoly quantities and marginal prices are:[48]

$$q = Q = \frac{\frac{\varepsilon}{\varepsilon+\eta}c - 2\frac{\varepsilon+1}{\varepsilon+\eta}\eta\frac{\varepsilon}{\varepsilon+\eta}}{c - 2\frac{\varepsilon+1}{\varepsilon+\eta}\eta\frac{\varepsilon}{\varepsilon+\eta}} \in \left(\frac{\varepsilon}{\varepsilon+\eta}, 1\right) \tag{5}$$

$$m = M = \frac{\varepsilon}{\varepsilon+1}\frac{c - 2\left(\frac{\varepsilon+1}{\varepsilon+\eta}\right)^2\eta}{c - 2\frac{\varepsilon+1}{\varepsilon+\eta}\eta\frac{\varepsilon}{\varepsilon+\eta}} \in \left(1, \frac{\varepsilon}{\varepsilon+1}\right) \tag{6}$$

To the extent that benefit-management regulation increases the cost parameter c, rather than decreasing it, (5) and (6) predict that regulation moves the market up the demand curve in the

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[48] These expressions reflect the fact that an oligopolist's equilibrium list price depends on its competitor's marginal price, which itself demands on list price and the management-cost parameter c. See equation (7) of this paper and equations (9) and (10) of Mulligan (2022) for the derivation.

direction of lower quantities and higher marginal prices. As shown below, that is also the direction of higher net prices and lower rebate rates.

Equilibrium list prices are:

$$l = L = \frac{\dfrac{\varepsilon}{\varepsilon+1}c - \dfrac{2\varepsilon^2 + \varepsilon - \eta}{(\varepsilon+\eta)^2}\eta}{c - 2\dfrac{\varepsilon+1}{\varepsilon+\eta}\eta\dfrac{\varepsilon}{\varepsilon+\eta}} \in \left(\frac{1}{1+\varepsilon}\frac{2\varepsilon^2 + \varepsilon - \eta}{2\varepsilon}, \frac{\varepsilon}{1+\varepsilon}\right) \tag{7}$$

From (5) - (7), industry surplus is calculated as $u(q, q, 0) - 2q - c(L - m)^2$, which is decreasing in the cost parameter c. This surplus is greater than it would be if the oligopolists were only setting a single price. The equilibrium value of that single price would be $\varepsilon/(1+\varepsilon)$.

The equilibrium rebate rate and net price depend on how the surplus from two-part pricing is split between manufacturer and client plans. Denoting $\beta \in [0,1]$ the share of surplus going to clients, the equilibrium rebate rate is:

$$r = \frac{1+\varepsilon}{4\varepsilon}(\varepsilon+\eta)\eta\frac{(\varepsilon+\eta)[\beta 4\varepsilon + (1-\beta)3\eta]c - 2\varepsilon(\varepsilon+1)(\beta+1)\eta}{(\varepsilon+\eta)^3\varepsilon c^2 - (\varepsilon+1)\eta(\varepsilon+\eta)(4\varepsilon^2 + \varepsilon - \eta + 2\varepsilon\eta)c + 2(\varepsilon+1)\eta\varepsilon} \tag{8}$$

The equilibrium rebate rate increases with the share parameter β and decreases with the cost parameter c. Both of these parameters shift the net price $(1-r)L$ in the opposite direction as the rebate rate.

Notice that the entire management cost is treated as a resource cost to be excluded from industry surplus. Formally, this cost increases with the parameter c while the increase is partially offset as plans and patients opt for less benefit management.

$$\frac{d[c(L-m)^2]}{dc} = (L-m)^2 + 2c(L-m)\frac{d[L-m]}{dc} \tag{9}$$

One symptom of less benefit management is a smaller gap between list price and marginal price. The first term is positive (a resource cost) and second term negative (a resource savings). To the extent that the second term reflects less profit rather than a resource savings, that part of the second term should be excluded from surplus calculations. The increase in the costs of resources used in benefit management shown in Table 2, as well as the reduction in industry surplus shown in Table 1b, would be understated. However, the magnitude of understatement would be small if most of the costs (to plans and patients) of benefit management reflect resource costs rather than a transfer.

V.D. Model calibration: drugs generally

For drugs generally, I set the demand parameters at $\varepsilon = -1.2$ and $\eta = -0.5$ in order to fit estimates of oligopoly (list-price) markups and estimates of industry-level price elasticities of demand.[49] Equilibrium equations (5), (6), and (7) therefore specialize as, rounded to three decimal places, (10) - (12):

$$q = Q = \frac{0.706c + 0.083}{c + 0.083} \tag{10}$$

$$m = M = \frac{6c + 0.083}{c + 0.083} \tag{11}$$

$$l = L = \frac{6c + 0.377}{c + 0.083} \tag{12}$$

The model is calibrated to match an observed baseline rebate rate, which I assume to be 30 percent for branded drugs generally. Because the management-cost parameter c is not measured, any value of the sharing parameter $\beta \in \left(\frac{229}{425}, 1\right]$ is consistent with a 30 percent rebate rate. I calibrate β at the midpoint of this interval, which is $\frac{327}{425}$. The corresponding cost parameter is about $c = 0.0181$. Regulatory impact by comparing this baseline with the equilibrium associated with a different value of the cost parameter c (holding constant β, ε, η) namely the one that achieves each scenario's target rebate rate: 25.5 percent (OACT, $c = 0.0426$), 21 percent (OACTX2, $c = 0.0774$), or 10.1 percent (Retain Zero, $c = 0.288$). For example, the −5.0 percent brand-quantity impact show in Table 1a's first entry is a comparison of the first part of equation (10) evaluated at the aforementioned values $c = 0.0181$ and $c = 0.0426$.

V.E. Model calibration: insulin markets

Manufacturer list prices for insulin have increased dramatically, accompanied by even greater increases in rebate rates. This pattern can be explained in a benefit management model such as Figure 1 by having a demand curve that is convex at and above the price (7) even though it is linear below that price. Indeed, as the baseline benefit cost parameter c approaches zero, any list price above (7) and any rebate rate up to (but not including) 100 percent is consistent with the oligopoly equilibrium as formally defined by Mulligan (2022).

Recall that, to the extent that the management-cost parameter c exceeds 0, higher list prices increase management costs by increasing the differential between list price and the marginal price achieved by benefit management. Plans, and PBMs on their behalf, thereby have an incentive to penalize manufacturers with high list prices but this incentive declines as innovation

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[49] See Mulligan (2022) for references to that literature.

in benefit management reduces management costs. That is, benefit management innovation (c falling) over time may simultaneously explain falling marginal and net prices for insulin even while list prices increase. Because PBM regulation increases management costs (c increases) it has the opposite effect on marginal and net prices, even though it may reduce list prices in markets with sufficiently convex demand curves.

My quantitative modeling therefore assumes that an insulin manufacturer's demand curve coincides with its iso-profit curve for prices above (7). To simplify that analysis, and to be conservative about the net cost of regulations that increase c, I assume that (i) the sharing parameter β is one, (ii) the baseline has $c = 0$ and (iii) regulations increase c only as much as required to meet the regulation's rebate targets.[50] As a result, equilibrium quantities and marginal prices are on the linear part of the demand curve, described by equations (5) and (6), both in the baseline and under regulation. The regulated list prices are also described by (7). Because any baseline rebate rate is consistent with equilibrium as long as it comes with a list price resulting in the same manufacturer profits as in fully linear model, I assume that the baseline insulin rebate is 75 percent as a representation of insulin markets as of the year 2022.

I assume that insulin is half as price elastic at the industry level ($\eta = -0.25$) than drugs generally. To capture less cross-price elasticity among insulin products (e.g., biologics may substitute less readily than small molecules do), I set the insulin brand own-price elasticity closer to -1: $\varepsilon = -1.1$. Equilibrium equations (5)-(7) therefore specialize as, rounded to three decimal places, (13)-(15):

$$q = Q = \frac{0.815c + 0.030}{c + 0.030} \tag{13}$$

$$m = M = \frac{11c + 0.030}{c + 0.030} \tag{14}$$

$$l = L \geq \frac{11c + 0.215}{c + 0.030} \tag{15}$$

where (15) holds with equality under regulation.

In its analysis of the Part D rebate rule, OACT concluded that 15 percent of the baseline rebate would go toward an increased net price. When the baseline rebate rate is 75 percent of gross drug cost, as I assume for insulin, that means a 45 percent increase in net price.[51] For the OACTX2 scenario, the net price increase is 90 percent. Beginning from the baseline management cost parameter of $c = 0$, the regulatory increases in c that result in those net price changes are 0.016 and 0.050, respectively. It follows from (13) that brand utilization falls 6.5 percent and 11.6 percent, respectively, in the two scenarios.

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[50] Note that the baseline management cost parameter for drug markets generally ($c = 0.0181$) is already close to zero.
[51] $0.45 = 0.15*0.75/(1-0.75)$, with the denominator converting between gross price to net price.

The Retain-Zero scenario assumes that the management cost parameter is increased by 0.172, because that reduces manufacture discounts to the baseline amount of insulin cost sharing.

All three scenarios predict reductions in insulin list prices, even though the net and marginal prices increase (recall Table 1a). The regulatory impact on list prices is −48 percent, −41 percent, and −36 percent according to the OACT, OACTX2 and Retain-Zero scenarios, respectively.

V.F. Simulating generic quantities

Rebate rules increase the marginal brand prices. In the model (3) with the $G = 0$ constraint relaxed and the parameter restrictions $\varepsilon < \eta < 0 < a_2 \leq 1$, brand prices increase generic consumption G, reduce brand consumption $q = Q$, and reduce total consumption measured either as $u(q,Q,G)$ or $q + Q + G$.[52] In other words, brands are not an inferior input in the treatment of health conditions. Despite the fact $dm = dM > 0$ shifts consumption from high marginal price drugs (brands with $m = M > 1$) to low marginal price drugs (generics with marginal price of one), the shift is not associated with an increase in the total. This contradicts some of the more extreme characterizations of "rebate walls."

Furthermore, the ratio of the total consumption change to the brand consumption change must be in the interval $[\eta/\varepsilon,1)$. My regulatory impact analysis assumes the midpoint of that interval. For example, the −5.0 percent brand quantity effect, which by itself is a −0.50 percent change in aggregate utilization (brands are 10 percent of total scripts) translate to −0.35 percent for the entire market because −0.35 is −0.50 times first column the average of η/ε and 1.

V.G. Simulating drug-plan premiums

Drug-plan premiums finance brand drug acquisition, generic drug acquisition, and management costs to the extent that these are not covered by patient cost sharing. Brand drug acquisition cost are the net price of times quantity. The former is increased by rebate rules while the latter is decreased (see Table 1a), with the former dominating. Each of these contributions to premiums is shown in the first two rows of Table 2, expressed as a ratio to baseline rebate amounts by multiplying the corresponding entry in Table 1a by $(1/r−1)$, where r is the baseline rebate rate. For example, a 5.0 percent reduction in brand utilization by itself reduces plan spending on brands by 5.0 percent. Because baseline net brand spending differs from the brand rebate amounts by a factor of 2.33 (1/0.3−1), an 11.6 (=5.0*2.33) percent reduction is shown in the second row of Table 2.

Added use of generics by itself increases plan spending (Table 2's third row), but less due to the lower net price of generics. The fourth row accounts for the interaction between quantity and net price. For example, a 5.0 percent quantity reduction followed by a net price increase of 11.6 percent, or vice versa, increases expenditure by less than 11.6−5.0 percent.

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[52] This result does not require the specific values $\eta = −0.5$ and $\varepsilon = −1.2$ or $−1.1$, just the inequality constraints $\varepsilon < \eta < 0 < a_2 \leq 1$.

Because drug acquisition costs are financed with premiums and cost sharing, the reduced cost sharing resulting from moving rebates shifting to the point of sale must involve a premium increase in order to finance the same net expenditure. The fifth row of Table 2 shows the amount of the increase. The additional management costs in the sixth row show the effect of rebate rules on the management cost $c(L - m)^2$. The added medical costs shown in the seventh row of Table 2 and the fifth row of Table 1b are discussed in the Appendix II that follows.

Summing the first seven rows of Table 2 shows the combined premium change resulting from rebate rules. The part of those added premiums that are government financed require additional taxes, additional government borrowing, reduced government spending, or some combination thereof that affects the wider economy. This "deadweight cost of tax distortions" is quantified in the fifth row of Table 1b by multiplying Table 2's corresponding combined premium change by the share of premiums subsidized – I assume 74.5 percent for Medicare Part D and 83 percent for plans (including Medicaid) providing insulin products – and by the marginal excess tax burden (0.5). The marginal excess tax burden" is widely used in academic policy analysis and is recommended by the White House Office of Management and Budget (1992; 2003) for regulatory impact analysis.[53] Table 1b uses a METB of 0.5 in order to reflect the various taxes, markups and implicit taxes in the economy where the tax liabilities accrue (Council of Economic Advisers, March 2019).[54]

The foregone drug innovation row of Table 1b is discussed in the Appendix III that follows.

V.H. Simulating a PBM monopoly

In order to assess the magnitude of anti-competitive effects of regulation in the market for pharmacy benefit management, I use the model (3) to characterize a hypothetical market with a monopoly PBM. Specifically, the monopoly PBM faces the management cost $c\left(\frac{L+l-M-m}{2}\right)^2$ (inclusive of the cost of capital needed to manage benefits) but passes on the cost $(1 + \tau)c\left(\frac{L+l-M-m}{2}\right)^2$ to its client plans, yielding it an economic profit of $\tau c\left(\frac{L+l-M-m}{2}\right)^2$. From equations (6) and (7), the equilibrium gap between list price and marginal price is therefore:

$$L - M = l - m = \frac{\eta}{\varepsilon + \eta}\frac{1}{(1 + \tau)c - 2\frac{\varepsilon + 1}{\varepsilon + \eta}\eta\frac{\varepsilon}{\varepsilon + \eta}} \tag{16}$$

The value of τ maximizing the equilibrium economic profit is

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[53] See Dahlby (2008). OMB (2019) recommends that more federal regulatory impact analyses use the METB.
[54] CEA (March 2019) uses a METB of 0.5. OMB (1992) recommends a METB of 0.25, but this does not include state and local taxes, implicit taxes (which have increased since A-94 was published), or markups in the economy.

$$\tau = 1 - \frac{2\,\varepsilon + 1}{c\,\varepsilon + \eta}\frac{\varepsilon}{\varepsilon + \eta}\eta \qquad (17)$$

The proportional loss of industry surplus from having τ maximizing economic profit rather than $\tau = 0$ must be in the interval (1/4,5/12).[55] If the equilibrium economic profits were fully dissipated as resource use, the loss interval would be (3/8,1/2).

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[55] Defined as $u(q, q, 0) - 2q - c(L - M)^2$, industry surplus excludes external effects, which also increase with the degree of competition among PBMs.

VI. Appendix II: Algebraic Analysis of Spillovers from Drug Utilization to Nonpharmacy Medical Spending

Part, although not all, of the value of proper drug utilization to patients, plans, and the industry is that it helps prevent more expensive medical treatments. That value is reflected in Figure A1 as the gap h between total marginal value to patients and plans (dashed curve) and the other sources of Rx value (black curve).

Figure A1. Nondrug health savings from medication adherence
Connecting empirical literature to prospective quantity changes
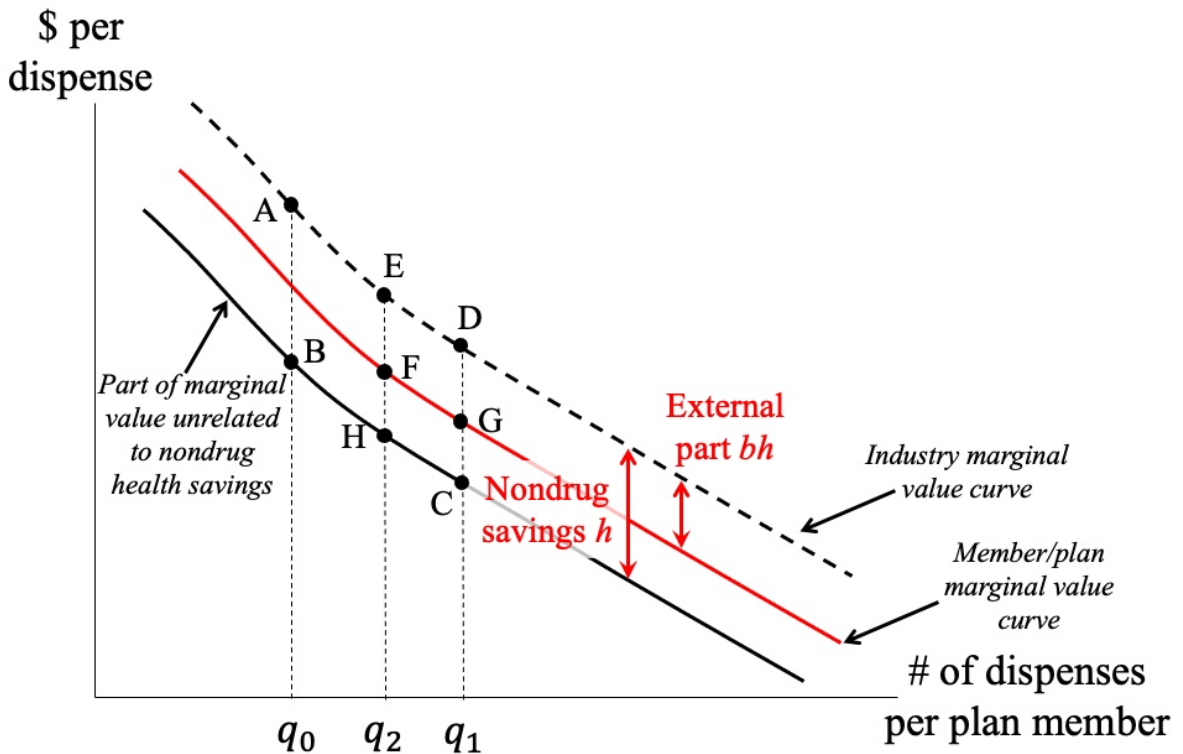
The figure illustrates consequences of quantity changes due to changes along the supply chain.

Some of the savings on nonpharmacy medical treatments, as well as the Rx costs achieving those savings, do not accrue to the patients and their plan making the decisions on drug utilization. The patient may have separate coverage for nonpharmacy medical claims (that is, her drug plan is not "integrated"), or may have transitioned to another health plan by the time that the nonpharmacy medical savings are realized. The government may also finance a significant share of the nonpharmacy medical claims. Therefore, Figure A1 also shows the marginal value to all participants (dashed curve).

Kaestner and Kahn (2012) examined the creation of Medicare Part D (the federal drug coverage program for the elderly), which increased elderly prescription utilization by about 35 percent. This finding is represented in Figure A1 by placing q_1 (drug utilization among the elderly with

Medicare Part D but without the PBM regulations examined in this paper) 35 percent above q_0 (drug utilization among the elderly before Medicare Part D). Looking at the same Medicare episode, Kaestner, Schiman and Alexander (2019) estimate that the added Rx utilization reduced inpatient hospital spending by about 6 percent over a three-year interval.[56] Extrapolating to also include home health care, office visits, outpatient, and emergency room, I find 9.7 percent of inpatient hospital spending.[57] Because Kaestner et al do not attempt to allocate the savings between patients, plan, and third parties, the dollar equivalent of the 9.7 percent nonpharmacy savings is represented by the entire area of Figure A1's shape ABCD, which is approximately $(q_1-q_0)h$. Algebraically, the nonpharmacy savings h is, expressed as a ratio to the net Rx price:[58]

$$\frac{h}{net\ Rx\ price} = \frac{H\delta}{1 - \frac{q_0}{q_1}} = 0.71 \tag{18}$$

where δ denotes the nonpharmacy savings (resulting from changing utilization from q_0 to q_1), expressed as a ratio to baseline inpatient hospital spending. H denotes the ratio of inpatient hospital spending to net Rx spending. The second equality in (18) uses the values for δ (0.097), and q_1/q_0 (1.35) calibrated as above. I calibrate H as 1.9.[59]

Figure A1 shows how to apply these findings to any regulation that shifts changes the equilibrium quantity from q_1 to q_2 due to changes in incentives and performance along the prescription supply chain. Using the result (18), the area DEFG, expressed as a share of baseline Rx expenditure is (19):[60]

$$\frac{DEFG}{Rx\ spend} = \frac{(q_1 - q_2)bh}{Rx\ spend} = 0.71b\left(1 - \frac{q_2}{q_1}\right) \tag{19}$$

In other words, equation (19) is my estimate of the cost to third parties (in the form of additional nonpharmacy medical costs) of reducing Rx utilization from q_1 to q_2.[61] Equation (19) essentially (i) rescales the Kaestner, Schiman and Alexander (2019) estimate to fit the change from q_1 to q_2 rather than the 35 percent increase in their study and (ii) isolates the part of those costs falling on third parties. The area DEFG can alternatively be expressed as a share of the baseline rebate amount by rescaling equation (19) by the ratio of net Rx spending to the dollar amount of rebates paid in the corresponding segment.

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[56] 6 percent is the midpoint of their 2-10 percent range.
[57] My extrapolation is based on Lichtenberg's (2007) findings about the distribution of medical savings from Rx utilization between the various nonpharmacy categories. Namely, the other categories add another 61 percent of savings to the inpatient hospital savings.
[58] The first equation in (19) is found by solving $(q_1 - q_0)h = \delta\ (inpatient\ spending)$ for h and then substituting the definitions of H and net Rx price (Rx spend per unit q_1).
[59] $1.9 = 0.52*1270.148/348.411$, where 0.52 is the share of hospital revenue that is inpatient (Gerhardt and Arora 2020) and the other two values are 2020 National health expenditure on hospital care and retail prescription drugs, respectively from Centers for Medicare and Medicaid Services (2021, Table 19).
[60] Here the area of DEFG is calculated as the area of a parallelogram with vertices at those four points.
[61] If $q_1 < q_2$, then equation (19) would be negative with magnitude representing a savings rather than a cost.

The values of b and q_2/q_1 vary depending on the Rx segment being regulated. The quantity change q_2/q_1 comes from Figure 1 and related analysis, as shown in the main text. I approximate the externality factor b from information about copay and subsidy rates for both drug and nonpharmacy medical claims for the relevant segment. The share of upfront Rx costs paid by patient and plan is $c_{Rx} + (1-c_{Rx})(1-t_{Rx})$, where c_{Rx} is the share of Rx costs paid out of pocket (rather than financed through premiums) and t_{Rx} is the share of premiums that are government subsidized. The share of future nonpharmacy medical spending that is financed by the drug plan of the average patient making the nonpharmacy medical claims, or by the patient herself, is $c_H + \beta(1-c_H)(1-t_H)$, where c_H and t_H are the corresponding parameters for health insurance plans with nonpharmacy benefits. β denotes the fraction of drug plan members whose future nonpharmacy health costs are covered by the same plan, which I take as the product of the fraction of members in integrated plans times the retention rate of the members. The time frame retention is taken to be 1.5 years because of my reliance on data that measures effects on inpatient health expenditures over a 3-year time interval. Equation (20) shows the model of b based on these benefit parameters:

$$b = 1 - \frac{c_H + \beta(1 - c_H)(1 - t_H)}{1 - (1 - c_{Rx})t_{Rx}} \tag{20}$$

For example, copayment rates were 100 percent, then b would be 0. Another way for b to be zero would be 100 percent retention and integration rates as well as equal benefit parameters for drug and nonpharmacy plans.

Rows (a) through (f) of Table A1 show estimates of the components of the third-party share b of nonpharmacy savings. Row (g) is the resulting estimate of b, which varies by segment because the benefit parameters potentially vary by segment. The final row uses the estimates of b to estimate the factor (equation (19)) for converting a regulation's quantity effect into additional nonpharmacy claims financed by third parties. All of the estimates are economically significant, but are greater for the Medicare segment due to the lower propensity of drug plans to be integrated with nonpharmacy medical benefits.[62]

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[62] For the purposes of Table A1, a member is part of an integrated plan if there is a commercial relationship between the sponsors of the drug and nonpharmacy plans. For example, even if an employer contract with separate pharmacy and nonpharmacy insurers, the pharmacy plan has a financial incentive to consider its effect on nonpharmacy claims because it makes the drug plan more attractive to the employer than a plan that ignore those claims.

Table A1. Benefit parameters and retention rates by segment

Parameter	Medicare	Commercial	Entire market
(a) Copay share of net spend: Rx	0.133	0.133	0.133
(b) Copay share: Nonpharm.	0.102	0.102	0.102
(c) Premium subsidy rate: Rx	0.745	0.488	0.830
(d) Premium subsidy rate: Nonpharm.	0.745	0.488	0.757
(e) Plan retention rate (1.5 yearly)	0.873	0.873	0.873
(f) Share of Rx plans that are integrated, enrollment weighted	0.532	0.910	0.816
(g) Third-party share of nonpharm. savings $= 1-[(b)+(e)*(f)(1-(b))(1-(d))]/[1-(1-(a))(c)]$	0.413	0.191	0.085
(h) factor for converting quantity impacts $= 0.71*(g)$	0.292	0.135	0.060

These results are used to construct the medical cost row in each of Table 1b and Table 2. Table 2 shows estimates of the entire area DEHC while Table 1b shows just the part DEFG accruing to third parties. Table 1b multiplies the row (h) of Table A1 by the "entire market" quantity change from Table 1a. For example, the 2.1 percent entry in the last column of Table 1b is the product of the corresponding quantity effect from Table 1a (−0.083) times the final entry in Table A1's row (h), rescaled by the ratio 4.2 of industry net spend (including generics) to rebates. The corresponding entry in Table 2 (21.9 percent) is the entire addition to medical premiums – not just the part born by third parties – and therefore differs from Table 1b by the factor of 0.085 shown in row (g) of Table A1 and the share (1−0.102) of medical spending financed through health insurance premiums.

VII. Appendix III: Benefit management regulation and the pace of drug innovation

Because drug sales revenue is an essential motivation for private-sector drug development and PBMs work to obtain reduced drug prices, drug development and PBM services would appear to be in conflict. However, additional utilization, and not just rebates, is also an outcome of plan-manufacturer negotiations. The relative importance of these two outcomes varies across drugs according to their age and characteristics. Manufacturers of unique new drugs – the drugs that add the most value – benefit from plan-manufacturer negotiations because of the additional utilization that occurs while paying a comparatively low rebate rate. In contrast, plans (or PBMs on their behalf) extract greater rebates from the manufacturers of older or "me too" drugs.

Unique new drugs are a small fraction of all drugs, as evidenced by the fact that 90 percent of drugs dispensed are generics. Even among spending on branded drugs, only a fraction is on single-source drugs, which means that the patent has not yet expired. Even among those, many faced significant competition from manufacturers of alternative drugs treating the same condition (Lakdawalla & Li, 2021). In this way PBM services reduce aggregate manufacturer revenue while increasing the revenue for the small fraction of drugs that are unique and new.

As a simple approximation to this reality, I assume that each drug goes through three phases of competition over its lifecycle. It faces the least competition when its patent is new.[63] During this early-patent phase, manufacturers enjoy enhanced utilization from PBM services and pay comparatively less rebate due to less competition from therapeutic substitutes. The second phase has additional competition as new substitute drugs have entered the market and older substitutes begin to have generic versions. PBMs have more leverage during this phase. In the third phase, the patent is expired and generics have entered. The first two phases are assumed to last four years and 7.5 years, respectively. Potential innovators assess revenue trajectories using a six percent real annual discount rate.[64] The annualized present value of revenue is:

$$
\begin{aligned}
APV = 0.06 \Bigg[& Rev_{monopoly} \int_0^4 e^{-0.06t} dt + Rev_{oligopoly} \int_4^{11.5} e^{-0.06t} dt \\
& + Rev_{competition} \int_{11.5}^{\infty} e^{-0.06t} dt \Bigg] \\
\approx\ & 0.21\, Rev_{monopoly} + 0.29\, Rev_{oligopoly} + 0.50\, Rev_{competition}
\end{aligned}
\tag{21}
$$

The same management cost curve and the same market demand curve operate in each phase, but market performance varies due to the differences in competition. As discussed in connection with Figure 1, regulatory policy affects market outcomes such as manufacturer revenue and APV by shifting the management cost curve.[65]

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[63] For further analysis and literature references, see Mulligan (2022).

[64] The innovation modeling focuses on manufacturer revenue rather than profit in order to utilize result from the empirical literature, which also focuses on revenue.

[65] Based on the analysis of generic entry in Mulligan (2021), here I assume that the manufacturer's revenue post patent is 13 percent of what it is during the oligopoly phase. That is, $Rev_{competition} = 0.13 Rev_{oligopoly}$.

For each present value dollar of revenue that is redistributed from manufacturers to consumers, Mulligan (2022) estimates a \$0.41 social opportunity cost from less drug innovation.[66] Therefore the social opportunity cost, in the form of reduced drug innovation, of shifting the management cost curve is 0.41 times the impact of the cost shift on APV. These are the values shown in Table 1b, expressed as a share of the baseline rebate amount.

The equilibrium under monopoly is represented in Figure 1 except that the inverse demand curve facing the monopolist is $\partial u(q,0,0)/\partial q$ (recall equation (3)). As a function of the management cost parameter c, the equilibrium quantity, marginal price, and list price are:

$$q = \frac{2\varepsilon - \eta}{2\varepsilon} \frac{c - 4\frac{\varepsilon + 1}{\varepsilon + \eta}(2\varepsilon - \eta)\frac{\eta}{\varepsilon}}{c - 2\frac{\varepsilon + 1}{\varepsilon + \eta}(2\varepsilon - \eta)\frac{\eta}{\varepsilon}} \in \left(\frac{2\varepsilon - \eta}{2\varepsilon}, \frac{2\varepsilon - \eta}{\varepsilon}\right) \tag{22}$$

$$m = \frac{1}{2\eta} \frac{1}{\varepsilon + 1} \frac{(\eta - \varepsilon + 2\eta\varepsilon)c - 4\frac{\varepsilon + 1}{\varepsilon + \eta}(\varepsilon + 1)(2\varepsilon - \eta)\eta\frac{\eta}{\varepsilon}}{c - 2\frac{\varepsilon + 1}{\varepsilon + \eta}(2\varepsilon - \eta)\frac{\eta}{\varepsilon}} \in (1, L) \tag{23}$$

$$L = \frac{1}{2\eta} \frac{\eta - \varepsilon + 2\varepsilon\eta}{\varepsilon + 1} > 1 \tag{24}$$

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[66] This estimate recognizes the savings from fewer resources used in the innovative process as an offset against the opportunity cost to consumers of having fewer drugs or accessing those drugs later in time.

VIII. Appendix IV: The utilization of pharmaceuticals and the division of labor in their distribution

The purpose of this appendix is to provide both theory and evidence on the interconnected roles of patient and plan resources in achieving proper utilization of prescription drugs. It shows why policies that reduce copays nonetheless reduce proper drug utilization when those policies reduce the financial incentives for plans and PBMs to achieve utilization goals.[67] Whereas the market equilibrium model shown in Figure 1 and Appendix II infers from the effect of regulation on manufacturer rebates that regulation increases the costs of benefit management, this appendix shows more specifically how regulation increases those costs and their effects on the division of labor between patients and plans. The model is an application of the "industry model" of Jaffe et al (2019, p. Chapter 11) and is closely related to the Diamond and Mirrlees' (1971) analysis of production efficiency.

VIII.A. Equilibrium division of labor

Let $Q = F(K,L)$ denote the quantity of properly-utilized prescription drugs. K and L are factors of production with rental rates r and w, respectively. K is supplied by plans. L is supplied by patients. The two factors can be substitutes, complements, or neither. F is assumed to exhibit constant returns in the two inputs.

Although often omitted from economic models of the pharmaceutical industry, plan inputs are an essential part of benefit management. Striving to make those inputs productive, essentially every drug plan hires (or vertically integrates with), at significant expense, a dedicated PBM firm to manage the benefit. Any rigorous analysis of the consequences of PBM regulation must acknowledge what benefit management does and what it costs.

Assume for the moment that patient and plan inputs are chosen to minimize cost. Such an allocation is described with the following cost and derived-demand functions $f()$, $K()$, and $L()$, each expressed per unit quantity Q:

$$Qm + Qf(r,w) \equiv Qm + \min_{K,L} rK + wL \quad s.t. \ F(K,L) \geq Q$$

$$\{QK(r,w), QL(r,w)\} \equiv \operatorname*{argmin}_{K,L} rK + wL \quad s.t. \ F(K,L) \geq Q \tag{25}$$

where m denotes PBM's acquisition cost for manufactured drugs. Note that $f(r,w)$ is both an average and marginal cost. It is increasing in both rental rates. As derived demand functions, $K()$ and $L()$ are decreasing in own price and increasing in the other factor price.[68]

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[67] Except when a distinction is necessary, I refer to "plans and PBMs" as "plans" because the PBMs are agents of the plans (and sometimes are vertically integrated with them).

[68] The two factors can still be complements if the effect of one factor price on the other factor demand through equilibrium quantity outweighs the substitution effect at a given quantity.

The marginal cost of Q is $m + f(r,w)$. Absent coordination costs, this marginal cost would drive decision making regarding the quantity of prescriptions and the resources to be used obtaining, distributing, and properly utilizing them. However, patients' role in decisions is sometimes assumed to be outsized relative to their financial stake.[69] Taxes and regulations can also distort decisions. I therefore represent the equilibrium quantity as:

$$Q = D(m + f(r + t, w) - s) \qquad (26)$$

where $D()$ is a downward-sloping demand curve. As a market-level demand curve, it not only reflects utilization decisions by patients and plans conditional on coverage, but also the breadth of coverage and the fraction of the population that has any drug coverage. The parameter $s \geq 0$ represents distortions creating a gap between the joint marginal cost $m + f()$ and the marginal cost reflected in decisions. The parameter $t \geq 0$ represents distortions that discourage the use of plan inputs. Note that, with one exception cited below, no restrictions are placed on the magnitudes of the slopes of $D()$ or the derived demand functions, other than the usual Hicksian restrictions (homogeneity, etc.).

Take $dr > 0$, for example, which means that it is more expensive for plans to supply their factors. They do less of it. Plans may be less likely to cover easier-to-administer versions of a drug, allocate fewer resources to patient-reminder programs, or invest less in mail-order pharmacies, to name a few adjustments. Patients may compensate to some degree by supplying more of their factor, but still marginal cost increases with r (Shephard's Lemma). $dt > 0$ has a similar effect: plans behave as if it is more expensive to supply their factors, and therefore supply less.

VIII.B. Regulatory impact

An important application of the model (26) of the division of labor in the pharmaceutical supply chain is the effect of patent expirations on aggregate utilization of the erstwhile-patented drug. As generics enter, plans' acquisition costs fall ($dm < 0$). Patient copays do too. But manufacturer and plan efforts to expand sales may be less profitable at the generic prices, which in my notation is $dt > 0$. Empirically, this latter effect Kdt on the marginal cost driving behavior appears to be close enough in magnitude to dm that it is difficult to detect any market-wide increase in utilization when patents expire (Lakdawalla & Philipson, 2012).

Another application is to drug shortages. The Food and Drug Administration (2020) cites the lack of supplier financial incentives as "Root Cause 1" for drug shortages. Generic drugs are at a high risk of shortage, the FDA says, precisely because those are the products where companies in the drug supply chain have the least financial incentives.[70] Drug shortages are acute cases

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[69] The discrepancy between the patient's financial stake and influence on purchasing outcomes is often called "moral hazard." For example, Gaynor, Haas-Wilson, and Vogt (2000) assume that the quantity of prescriptions is chosen entirely by the patient on the basis of the amount of cost-sharing, without regard for the plan's acquisition cost (or for plan resources, which are absent from their model).

[70] Generic drugs manufacturers, for example, almost never pay rebates to plans or PBMs outside of the Medicaid program (Lieberman and Ginsburg 2018).

starkly illustrating how patient cost sharing is not the only financial incentive driving proper drug utilization.

Various regulations such as rebate rules and pharmacy-DIR rules restrict the payments that plans and PBMs can receive from manufactures and pharmacies. Instead, those payments must go to patients "at the pharmacy counter." Such rules can be modeled as $dt > 0$ and $ds > 0$. The dt condition represents the removal of funds – the manufacturer rebates and pharmacy discounts – that were received by plans and tied to utilization. The ds condition represents the increase in funds received by patients in proportion to the amount Q they purchase. That is, $ds > 0$ represents lower patient cost sharing.

In order to focus on redistribution between patients and plans rather than injecting or withdrawing funds from the system, I assume that t and s are linked through a budget constraint:

$$Qs = Kt \tag{27}$$

In other words, funds that make prescriptions cheaper for the patient ($s > 0$) come at the expense of plans ($t > 0$).[71] I assume that an increase in s must be associated with an increase in t, which must be true near $s = t = 0$ and more broadly restricts the derivatives of $K()$ to rule out the possibility that these "taxes" are on the wrong side of the Laffer curve.

For the moment, I hold constant acquisition cost m in order to focus on factor usage. In this case, the regulatory impact on quantity and marginal cost is described by

$$
\begin{aligned}
dQ = D'(MC)dMC &= D'(MC)\left[\frac{\partial f}{\partial r}dt - ds\right] \\
&= D'(MC)\left[K(r+t,w)dt - K(r+t,w)dt - t\frac{\partial K}{\partial r}dt\right]
\end{aligned} \tag{28}
$$

where $MC \equiv m + c(r+t,w) - s$ denotes the distorted marginal cost driving decisions. The final equality of (28) is derived by making two substitutions. The first substitution is $\partial f/\partial r = K(r,w)$, which is Shephard's Lemma applied to the definition (25) of derived demand. The second comes from the restriction on ds coming from the budget constraint (27). Collecting terms,

$$dQ = -D'(MC)t\frac{\partial K}{\partial r}dt \leq 0 \tag{29}$$

where the inequality is strict when $s > 0$. In words, redistributing resources from plans to patients does not increase utilization and must decrease it if some redistribution exists in the

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[71] Subsidies received from outside the industry are not analyzed in this appendix, but presumably would have the more obvious effect of increasing drug utilization as Kaestner and Kahn (2012) found.

baseline.[72] The redistribution increases the marginal cost of benefit management, which is the same conclusion reached in Figure 1 and Appendix I, albeit by different methods.

The regulatory-induced shift in marginal cost represented by the RHS of equation (29) can also be demonstrated graphically, as in Figure A2. The quantity K of plan inputs is measured on the horizontal axis while the quantity L of patient inputs is measured vertically. The unit isoquant is shown because the results for any other level of Q can be found by scaling K and L proportionally. Average costs, which are also marginal costs due to constant returns of F, can be measured (in units of patient inputs) as vertical intercepts of iso-cost lines. In the model (26), the quantity increases if and only if marginal cost declines, which in Figure A2 means that an intercept moves closer to the origin.

Figure A2. Distorting factor allocation in Rx delivery
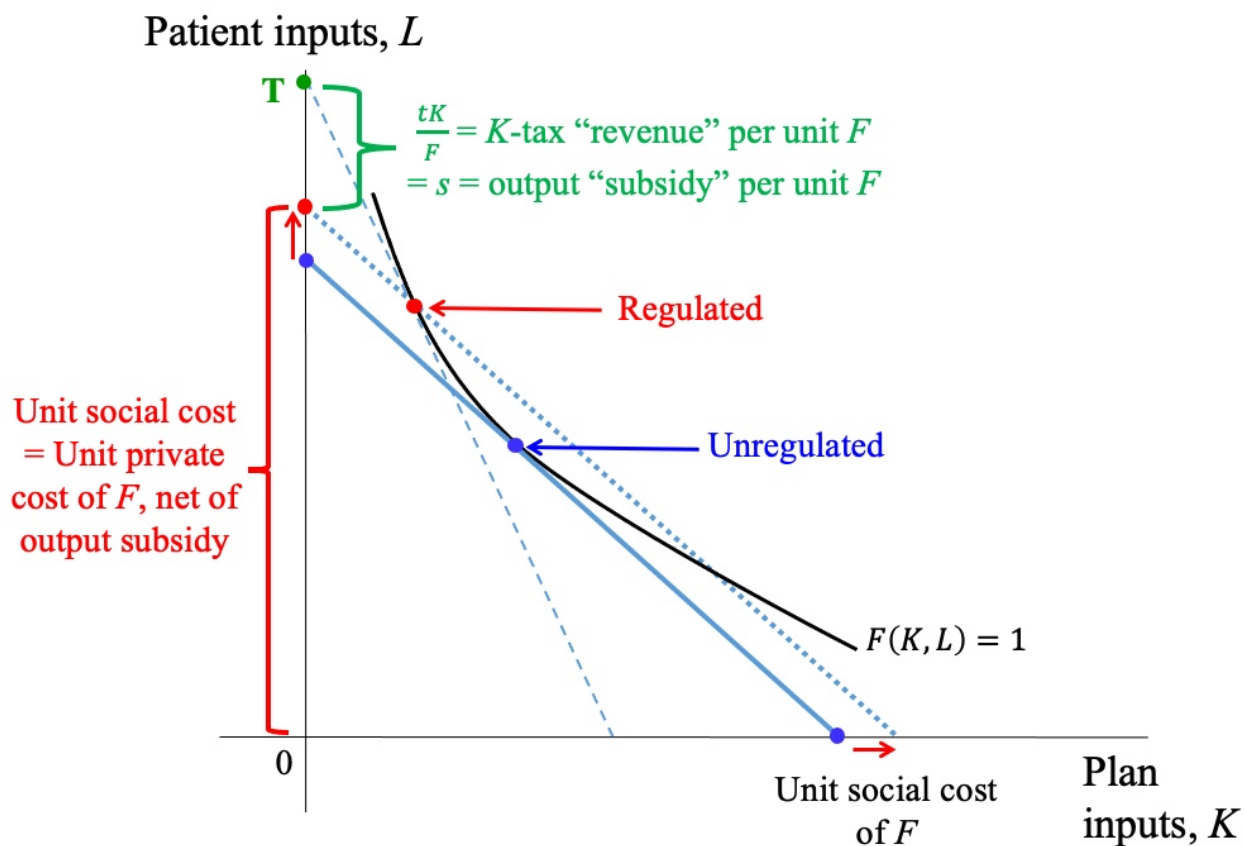
The figure shows a regulation distorting factor usage in the direction of fewer plan inputs and relatively more patient inputs.[73] If this distortion had been created by a tax on plan inputs whose

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[72] This result is closely related to the conclusion of Nobel laureates Peter Diamond and James Mirrlees (1971) that public policy should avoid distorting the mix of industry inputs (K and L in this case) even if the policy goal is to change the amount of output in the industry (Q in this case).

[73] Note that the absolute level of patient inputs could fall too if the scale effect of reduced quantity (not shown in Figure 1) is enough to offset the substitution of L for K at a given level of Q.

revenue was removed from the system (especially, not given to patients), then the joint average and marginal cost would increase all the way to the point T in the figure. Note that the increase $f(r+t,w) - f(r,w)$ in marginal cost has two components: (i) the average tax revenue per unit tK/F and (ii) the reduced productivity of production inputs due to their distorted composition. The second component is sometimes known as "excess burden" because it is a cost beyond the "revenue" paid.

If the revenue tK is kept within the system, as required by equation (27), then the increase in marginal cost has only the second component. With the rebate rule, revenue is shifted from plans to patients in proportion to how much quantity they received. Algebraically, that is the budget constraint (27). Geometrically that means that net marginal cost is below the point T in Figure 1 although above what marginal cost would be without any factor distortion.

The inequality (29) is strict if $s > 0$. In words, even ignoring effects of rebate rules on acquisition costs, further copay regulation would reduce utilization.[74]

In summary, both patients and plans have roles to play in determining utilization. Patients have a comparative advantage in some tasks, while plans have a comparative advantage in others. Copay regulations require patients to take on tasks where they are at a comparative disadvantage. The result is greater average and marginal costs, including the costs of patient time and effort, and thereby less utilization.

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[74] To be conservative as to the costs of PBM regulation, the main text of this paper assumes that the utilization effect highlighted in this Appendix is zero. Instead, restrictions of benefit management tools reduce utilization due to the increased acquisition costs that occur when benefit management resources become less productive.

IX. Appendix V: Algebraic Representation of the Pharmacy-Discount-Regulation Model

Pharmacy DIR regulation is analyzed with the same algebraic structure (5)-(8) that is used for rebate rules, but with ε and η referring to firm- and industry-level elasticities of demand for retail pharmacy services. β and $1-\beta$ refer to the division of the surplus from plans' contracts with pharmacies rather than their contracts with manufacturers.

The industry-level elasticity of retail pharmacy services might be closer to zero than the industry-level elasticity for a typical prescription drug because pharmacies are just a part of the overall prescription-drug supply chain. On the other hand, the former elasticity might be more elastic due to the option for mail pharmacies (often run by PBMs) and that pharmacies dispense multiple drugs. The firm-level elasticities can also be different between the two markets because of the different roles of patents, geographic location, and other factors that differentiate sellers.

In principle, the local firm-level elasticity of demand for retail pharmacy services could be inferred from the percentage by which pharmacies markup up their retail services over their marginal costs. However, this inference would be complicated because the value of retail sales incidental to prescription dispensing may significantly subtract from marginal cost.[75] Instead, I use my estimate of the discount rate (30 percent) and the model's prediction (8) to partially identify the model's parameters. Namely, with $r = 0.3$, the demand parameters must be in the set:

$$\varepsilon < -1 \wedge -\frac{2 + \sqrt{4 - 3\eta}}{3} \leq \varepsilon < \eta < 0 \wedge 4\frac{\eta - \varepsilon - 2\varepsilon^2}{\eta + \varepsilon}\frac{3}{10} - 1 \leq \beta \leq 1 \tag{30}$$

To be conservative as to how much the list prices for pharmacy retail services are marked up over their full marginal cost, while remaining in the set (30), the DIR-regulation estimates in this paper use the point estimate $\varepsilon = -1.5$. I set $\eta = -1.125$, which is at the midpoint of the interval $[-1.5, -0.75)$ conditionally required by (30). The sharing parameter β is also set at the midpoint of its (narrow) partially-identified set.

As in Appendix I, the baseline and regulated outcomes are simulating by selecting the unique value of the cost parameter c that is consistent with the baseline and regulated discount rates, respectively. From (6), the equilibrium marginal price m of pharmacy services is:

$$m = M = \frac{3c + \frac{12}{49}}{c + \frac{12}{49}} \tag{31}$$

Any regulatory impact dm is translated into a proportional impact on the marginal price of prescription drugs (both branded and generic) by scaling dm by the ratio of 0.15 to the baseline

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[75] The fact that the pharmacist desk is often at the back of retail drug stores may indicate that retailers expect that prescription buyers may make other purchases while in the store.

net price of retail pharmacy services times 0.62.[76] The elasticity of prescription utilization with respect to the marginal price of prescriptions is assumed to be –0.5.

Pharmacy contracting generates a total "industry surplus" to plans and their contract partners (PBMs, pharmacies, and manufacturers) that is the sum of $u(q, q, 0) - 2q - c(L - m)^2$ and the (assumed constant) markup that brand manufacturers get on the quantity of drugs they manufacture.[77] As noted in Appendices II, external effects related to nonpharmacy medical expenses are estimated based on each regulation's effect on drug utilization. Reduced drug utilization is assumed to reduce brand-manufacturer revenues proportionally, with each dollar imposing a $0.41 social opportunity cost in the form of a reduced pace of drug innovation (Appendix III). Health plan premiums, and thereby government funding and the associated marginal excess burden, depend on drug utilization, management costs, and pharmacy expenses to the extent that they are plan liabilities.

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[76] Sood et al (2017) find that net pharmacy revenue is 15 percent of overall prescription spending. Fein (2022) reports that the prescription revenue share of retail pharmacies (as distinct from mail-order pharmacies) is 62 percent.

[77] The functional form for u is (3), with the parameters calibrated as noted in this appendix. Here q, L, and m refer to the market for retail pharmacy services (Figure 2) rather than the market for manufactured prescription drugs (Figure 1).

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