Testimony before the Senate Committee on Commerce, Science & Transportation

Hearing on "Bringing Transparency and Accountability to Pharmacy Benefit Managers"

Russell Senate Office Building 253
February 16, 2023

by

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Good morning Chairman Cantwell, Ranking Member Cruz and Members of the Committee. Thank you for this opportunity to comment on the economics of pharmacy benefit management.

Benefit management is fundamentally an economic activity. Because it is about contracting, coordination and trade, market-level economic analysis is required to fully understand its effects.

Including a 2018-19 leave of absence to serve as the Chief Economist of the White House Council of Economic Advisers (CEA), I have been a Professor of Economics at the University of Chicago for 20 years, and Associate and Assistant Professors before that. I have published extensively on regulatory economics including healthcare regulation.[1] I cowrote the textbook *Chicago Price Theory*, which is novel in terms of its emphasis on the role of what we call "buyers' clubs" in the economy. My research into the details of PBM operations began in 2018 when President Trump directed the CEA to estimate the economic and fiscal effects of rebate regulation.[2] Hearing from various industry participants and government experts, I built an artificial intelligence (AI) model of the regulatory effects. Six months later, the AI platform I created for answering regulatory and many other economic and statistical questions won a 2019 Wolfram Innovator Award.[3] Returning to the University of Chicago, I prepared research papers specifically relating the economics of buyers' clubs to employer-sponsored health insurance (Mulligan 2021a) and pharmacy benefit management (Mulligan 2022). Most recently I completed the development of an open-source quantitative model of the economic and fiscal effects of regulating pharmacy benefit management.[4]

My conclusions and opinions are based on my own research, teaching, and experience with economic regulation. They do not necessarily represent the views of the University of Chicago or of the prior administration.

The Economics of Benefit Management in the Context of Prescription-Drug Markets

The path from medical innovation to health

Prescription drugs have reduced mortality and morbidity from heart disease, cancer, infectious disease, and many other health conditions.[5] The U.S. market size is approaching $500 billion annually, with about two-thirds of adults using them and almost 300 million people participating

[1] These include Mulligan and Shleifer (2005), Mulligan (2015), and Mulligan (2021b).

[2] Chapter 10 of *You're Hired! Untold Successes and Failures of a Populist President* describes the genesis of the "rebate rule" (84 FR 2360) and its regulatory impact analysis.

[3] My *TheoryGuru* platform, which is written in the Wolfram Language, has been the basis for cooperation with computer scientists who specialize in the type of artificial intelligence known as "automated reasoning" or "quantifier elimination" (QE). See Mulligan, Bradford, et al. (2018a), Mulligan, Bradford, et al. (2018b), or Mulligan, Davenport and England (2018). Although the domain of QE is narrower than the more famous chatbot systems (such as ChatGPT), QE rigorously adheres to arithmetic and logical deduction and never contradicts itself.

[4] Mulligan (2023). In conducting these last two studies, I received financial support from the Pharmaceutical Care Management Association, understanding that it had no control over the ultimate findings or their distribution.

[5] Lichtenberg (2003, 2007, 2019).

in prescription-drug insurance plans. With the market so profoundly affected by public policy, it is essential to understand its structure, conduct and performance.

A fundamental fact is that even cost-effective new drugs are expensive to develop (Lichtenberg 2019), which drives a demand for third-party financing, both of which can distort drug utilization. Drugs may be underutilized because of high marginal costs to the patient, lack of patient knowledge, inadequate supply chain infrastructure, or the moral hazard involved with preventing conditions whose medical expenses are themselves covered by insurance.[6] Moral hazard may also result in drug misuse and health harms, as it did with opioid prescriptions (Council of Economic Advisers April 2019), or in fraud and improper payments. With the stakes so high, identifying business models that would permit better utilization and lower cost could have tremendous value.

Why patients and plan sponsors seek a managed benefit

Drug insurance plan sponsors understand that it is wasteful – requiring premiums that are too high to attract members – to have third-party payment and leave the benefit unmanaged. Pharmacy benefit management services (PBM services) is the industry term for the management of patient utilization, processing of prescription drug claims, and negotiating plan savings from other actors in the healthcare supply chain. A PBM is a company that specializes in providing PBM services on behalf of plan sponsors. The services include plan design features such as allocating drugs to different copay tiers or requiring plan authorization prior to patient access, drug utilization reviews that help improve drug effectiveness and prevent adverse drug reactions, obtaining rebates and discounts from those providers whose sales are increased by the plan, and managing specialty drugs. PBM services thereby expand the economic pie in prescription markets.

PBM services also redistribute from manufacturers and pharmacies to consumers as negotiations and plan design fuel competition that lowers net retail and manufacturing prices. PBMs ultimately, if not intentionally, encourage drug innovation by increasing utilization early in a drug's patent life where sales are most important in terms of creating a financial return. By saving governments money and thereby limiting their need to increase distortionary taxes, PBM services also benefit the wider economy.

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

[6] Moral hazard refers to the distorted incentives that come with "spending other people's money" (Klick and Stratmann 2007). See also Burns' (2022, p. 603) description of the "implementation of outcome-based contracts requir[ing] significant investments in infrastructure (data collection and analytics capabilities)." The Food and Drug Administration (2020) cites the lack of financial incentives and quality management systems as two of the "root causes" of drug shortages.

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.[7]

Buyers' clubs induce sellers to limit their exercise of market power by presenting them with a more price-elastic demand curve (Jaffe, et al. 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 them all 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 and Topel 2014). Either way, lower prices and higher quantities are the proof that buyers' clubs are procompetitive.

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."[8]

Components of the value of management: utilization, drug innovation, and taxpayer savings

From the perspective of consumer demand, the first potential source of underutilization is the gap between list price and the marginal cost of producing, delivering, and administering the drug. This source is especially relevant for newer branded drugs that are still under patent and thereby available only from a single manufacturer, although other manufacturers may sell chemically different drugs that treat the same condition. It is also relevant for the purchase of retail pharmacy services. Economics has long noted that gaps between list price and marginal cost open opportunities for mutually advantageous trade between seller and buyers where the buyers receive a discount for purchasing more than they would at list price (Oi 1971, Telser 1994, Lakdawalla and Sood 2013). PBMs arrange such trades by (i) obtaining manufacturer rebates in exchange for placement in the plan's benefit structure that helps the manufacturer

[7] 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).

[8] 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…."

make additional sales to plan members and (ii) obtaining pharmacy 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.

To put it another way, benefit management improves drug utilization both as a condition of receiving manufacturer and pharmacy discounts and because of the reduced net prices.[9] Reduced net prices help plans reduce their premiums and enhance their benefits. Better utilization improves health, which itself reduces nondrug medical expenses (Lichtenberg 2007). Reduced premiums and medical expenses yield substantial government savings due to subsidies for health insurance premiums through Medicare and other government plans, the Affordable Care Act, and the exclusion of employer-plan premiums from income taxable by the personal income and payroll taxes.

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 and 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.

The size of the utilization and net price effects of benefit management are interrelated quantitative questions. They can be assessed, as I have in two recent studies, from the empirical magnitude of rebates on branded drugs. Alternatively, the magnitude of branded rebates can be assessed from the fact that the generic substitution occurring after patent expiration results in no discernible increase in overall utilization (Lakdawalla and Philipson 2012). Both approaches similarly show that benefit management substantially increases drug utilization as it reduces net prices. On this basis, I conclude that pharmacy benefit management is worth at least $145 billion annually beyond its resource cost (Mulligan 2022).

[9] The net manufacturer price refers to the difference between the manufacturer's list price and the discount or "rebate" paid by the manufacturer to PBM or plan sponsor. The net pharmacy price refers to the difference between the pharmacy's list price for retail services and the discount received by the PBM or plan sponsor from the pharmacy. As part of their task of reducing costs while encouraging proper utilization, PBMs also keep plans informed as to the availability of generics and encourage generic substitutes to be dispensed when they are appropriate and available. This is one reason why generic utilization rates are significantly greater in the U.S. than in Europe (Wouters, Kanavos and McKee 2017), where PBMs are much less common.

Regulatory Impact Analysis

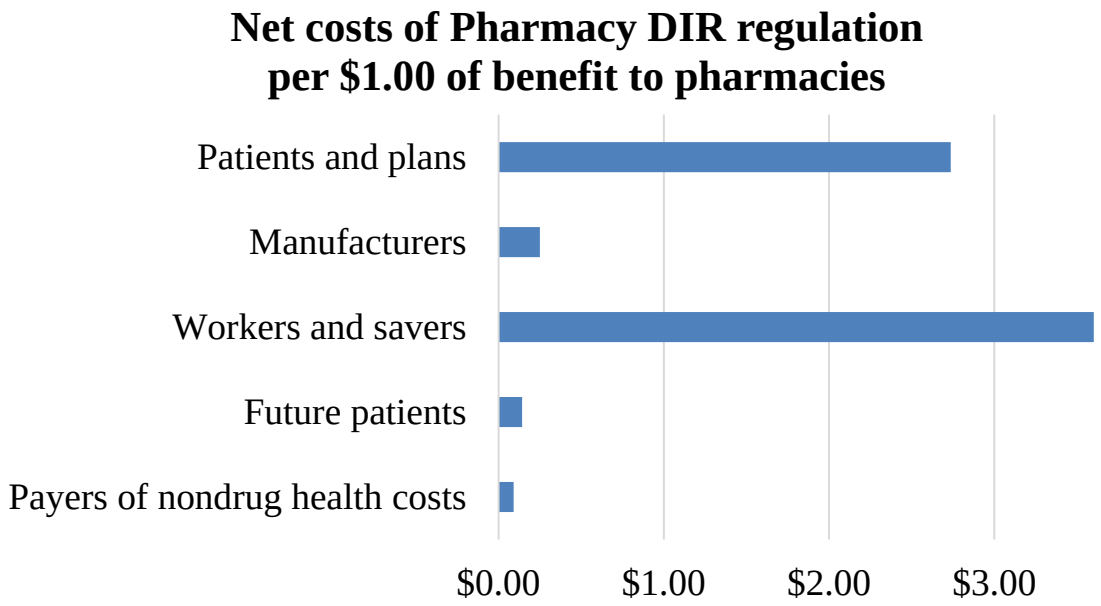
The risk-reward ratio: pharmacy DIR regulation

The PBM Transparency Act of 2023 and other PBM regulations put some of these economic gains at risk by constraining the use of benefit-management tools; discouraging investment in the capital assets that help manage utilization, claims, and other activities of drug plans; and creating barriers to further innovation and entry in the PBM business. In the likely case 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 – growing large PBMs at the expense of smaller ones – while they increase the resource costs of managing pharmacy benefits. Even if a new regulation eliminated only 10 percent of the value of benefit management – something like $14 billion annually – it would not pass a cost-benefit test unless it also resulted in a commensurate regulatory benefit.

The PBM Transparency Act of 2023 includes provisions related to pharmacy direct and indirect remuneration (DIR), spread pricing (PBMs charge plans a different drug price than they pay to manufacturers), and mandatory disclosure of the terms of contracts that PBMs negotiate with manufacturers or pharmacies.[10] Section 2 of the Act specifically would give 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." Because it remains to be seen how these terms would be interpreted and which of the two compliance options would be chosen by PBMs, I estimate the net (monetary and opportunity) cost of Section 2 for a couple of different scenarios.

One scenario is that a significant number of PBMs choose the pharmacy DIR restriction, which results in a reduction in the discounts provided by retail pharmacies. Pharmacies are potentially more profitable, but a far greater combined cost is imposed on patients, plans, manufacturers, and ultimately taxpayers. The chart below shows the net costs separately by type of market participant, expressed per dollar of pharmacy benefit.

[10] 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."



While potentially benefitting pharmacies by providing a degree of protection against competition, pharmacy DIR regulation in the 2023 PBM Transparency Act would increase the costs of benefit management. The resulting increased pharmacy fees, increased plan premiums, and reduced utilization impose net monetary and opportunity costs on patients, plans, manufacturers, workers and savers, future patients, and payers of nondrug health expenses.

The net cost summed across the five categories is $6.82 for each dollar of pharmacy benefit.

Source: Table 3 of "Restrict the Middleman? Quantitative models of PBM regulations and their consequences." (Mulligan 2023)

Restrictions on pharmacy DIR reduce drug utilization directly because pharmacy DIR is an essential tool for incentivizing pharmacies, which are more proximate to patients than manufacturers or PBMs are, to help plans achieve adherence goals. The restrictions also reduce drug utilization indirectly by increasing the net price of retail pharmacy services, which are an essential part of the drug supply chain. Therefore, while DIR restrictions are expected to allow pharmacies to charge more for their retail services and spend less pursuing plans' management goals, these advantages accrue to fewer scripts due to the lower utilization. The redistribution from patient and plan to pharmacy has a side effect of lost opportunities from productive partnerships between pharmacy and plans.

As patients utilize less while net prices are higher (pharmacy charges apply to both brands and generics), pharmacy DIR regulation increases premiums for both drug plans and nondrug medical plans due to the additional medical costs that come with reduced drug adherence. Taxpayers – that is workers and savers who pay income and payroll taxes – are responsible for much of the added premium. They too miss valuable opportunities as they struggle to adapt to a greater tax burden, which is why the chart also shows a comparatively large burden on workers

and savers.[11] Overall, pharmacy DIR proves to be a particularly oblique way of adding to pharmacy profits as patients, plans, and others ultimately pay more than $6 for each $1 of pharmacy benefit. If all PBMs adhered to this compliance option in the PBM Transparency Act of 2023 (rather than Section 2's detailed disclosure and other requirements), pharmacies would gain one or two billion dollars annually at an annual cost of nine or ten billion to the rest of the market and wider economy. In this scenario, the Act would add between $8 billion and $11 billion to the federal deficit every year.

The risk-reward ratio: disclosure requirements

At last year's hearing, and elsewhere, it is alleged that (i) excess PBM profits increase drug costs and (ii) disclosure requirements would reduce drug costs by reducing excess PBM profits. Even if (i) were correct, (ii) does not necessarily follow because disclosure requirements could have unintended consequences that increase drug costs and perhaps even create excess PBM profits. A quantitative economic model such as that provided in Mulligan (2022, 2023) helps identify some of the unintended consequences and to assess their magnitude as compared to the intended benefits of the disclosures that would be mandated by the PBM Transparency Act of 2023.[12]

Mandatory disclosure may, among other things, hinder investment and innovation in benefit management.[13] One of the major intended (and procompetitive) results of a managed insurance benefit is to maintain different prices of products and services produced by monopolistic or oligopolistic manufacturers and pharmacies (Lakdawalla and Sood 2013). 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

[11] Of course, the fiscal effect of any one regulation is small on the scale of overall federal taxes collected. Nevertheless, because taxpayers are numerous, the value of the lost opportunities in labor and capital markets is not small on the scale of that one regulation's other costs and benefits. See also CEA (March 2019, Chapter 2).

[12] Section 2 specifically requires, as a compliance alternative to the aforementioned pharmacy DIR requirements, 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)."

[13] 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)."

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.

Unintended effects on investment and innovation may explain why, despite the presence of multiple PBMs as well as several other large companies in a position to enter the PBM business, voluntary full disclosure is, so far, hardly passing the market test.[14] If voluntary disclosure ultimately succeeds, then perhaps government mandates are not needed. Otherwise, plan-sponsor choices reveal that most of them assess the costs of publicly disclosed benefit management parameters to exceed the benefits.

The annual costs of PBMs are about $21 billion, of which about $7 billion is accounting profit (Sood, et al. 2017). Because much of the accounting profit of PBMs is a competitive return on the capital essential for managing benefits, any public policy that succeeded in reducing PBM profits through enhanced competition would at best be reducing annual profits by $1 or $2 billion in a $350 billion prescription market.[15]

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…."[16] The two anti-competitive concerns cited by the FTC are relevant to the PBM Transparency Act of 2023, 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 or that aggregate data is disclosed for which an individual seller contributes more than 25 percent to the

[14] Economics conceptually distinguishes disclosure from simple pricing, whereas some of the new PBM entrants have tied them together in practice. Lakadawalla and Sood (2013) and others find that complicated pricing provides substantial value in terms of high levels of utilization of unique drugs that are still under patent. Complicated pricing also helps to align incentives of various market participants (e.g., financially aligning pharmacies with a plan sponsor's adherence goals). Whether the complicated pricing remains propriety information is a different question that is the topic of Sections 2 and 4 of the PBM Transparency Act.

[15] Some public policies that reduce profits also make consumers pay more because the policies create costs that are partly passed on to consumers. Making it more difficult for PBMs to do business may discourage companies from getting into the PBM business.

[16] 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 incentive for all providers to offer low prices and may facilitate collusion among providers. High levels of market concentration … would facilitate these outcomes."

aggregate. These are exactly the disclosure conditions set forth by Section 2 of the PBM Transparency Act.[17]

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.

I estimate that the annual net costs of reducing brand competition in this way would be more than $25 billion, which already nets out the extra profits for brand manufacturers. About $40 billion would be added to the deficit annually as the federal government spends more and sees its income tax base reduced as drug plan premiums increase.[18] A similar reduction in competition among pharmacies would have net costs of $8 billion per year. Reducing competition among PBMs, even if unintentional, could cost up to $48 billion per year. These are the risks of disclosure to be weighed against a potential reward of transferring one or two billion dollars annually from PBMs to other market participants.

Conclusions

Manufacturers and pharmacies sometimes refer to dedicated pharmacy benefit management companies (PBMs) as "middlemen" as if the PBMs were supply-chain toll collectors performing no legitimate economic function.[19] Insurance-plan sponsors – including state and federal governments in their roles as plan sponsors – do not agree. In pursuit of better value for their members, plans consistently retain PBMs to help design their benefit, negotiate prices, and process claims. In several instances plans have launched their own PBMs to service plan members. Leaving the drug benefit unmanaged would be expensive and wasteful, even if it did partially relieve manufacturers and pharmacies of competitive pressures.

To be clear, neither PBMs nor their client plan sponsors invent or manufacture drugs or dispense them to patients. Their important effects on utilization and costs operate through the marketplace, especially as they help coordinate the various supply chain actors to discover and realize mutually beneficial gains from trade. Predicting effects of PBM regulations requires expertise on the operations of markets, from inventor and manufacturer through to the final consumer. Among the testimony you are hearing today, mine is unique in reflecting market level

[17] 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.

[18] An analogy is the 2020 rebate rule (84 FR 2340), which the Congressional Budget Office (2019) and the Office of the Actuary of the Centers for Medicare and Medicaid Services (84 FR 2360) separately projected to add about $20 billion to the annual deficit, even though that rule would not apply to the commercial segment, whereas the Transparency Act would apply to all segments.

[19] Wilson (2021).

analysis, incorporating the various components of both supply and demand. None of the others is offering or relying upon an open-source quantitative market model of PBM regulation, which allows rigorous and transparent assessment of the tradeoffs and unintended consequences inherent in regulatory policy.

The PBM Transparency Act of 2023 is more of an economic regulation than a healthcare regulation. It would restrict pricing in business-to-business transactions and require disclosure of proprietary information. This by itself does not say whether the Act would have net benefits or net costs, but particularly the price controls are a warning that the unintended consequences may be numerous and profound.[20] I estimate that the pharmacy DIR restrictions in Section 2 would cost patients, plans, and others more than $6 for every $1 of benefit provided to pharmacies. I estimate that disclosure requirements could impose tens of billions of dollars in annual net costs by discouraging competition among manufacturers, among pharmacies, and among PBMs. Ten billion dollars, and perhaps much more, would be added to the annual federal deficit by the PBM Transparency Act of 2023.

[20] The federal government's executive branch acknowledges the high regulatory risk-reward ratio for price regulations in the Office of Management and Budget's (2003) Circular A-4. A-4 notes that imposing price regulations would, "in light of both economic theory and actual experience," require a "particularly demanding burden of proof."

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