Concerns Regarding the Proposed Rule to Restrict Drug Manufacturer Rebates in Medicare Part D and Medicaid MCOs

By Alex Brill

April 2019

MGA MATRIX GLOBAL ADVISORS

In February 2019, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued a proposed rule that would restrict drug manufacturer rebates to pharmacy benefit managers (PBMs) in Medicare Part D and Medicaid Managed Care Organizations (MCOs).[1] The proposed rule would instead permit negotiated point-of-sale discounts to beneficiaries. According to HHS Secretary Alex Azar, the proposed rule will "deliver savings directly to patients when they walk into the pharmacy."[2] But the impact would be far broader than that, stretching across the entire pharmaceutical supply chain, adversely affecting federal healthcare programs and taxpayers, and significantly redistributing costs across beneficiaries.

This paper's review of the proposed rule and its accompanying actuarial reports shows that the proposal to restrict rebates is poorly conceived and holds the potential for serious negative consequences to federal healthcare spending, beneficiaries' premiums, and competition in the supply chain. Some of these consequences are discussed in the proposed rule's own impact analysis and some are implicit.

This paper is organized as follows. Part 1 provides a brief background on manufacturer rebates and the safe harbor that has long existed to allow them in federal healthcare programs. Part 2 examines the premise of the proposed rule and details its conceptual flaws. Part 3 reviews the impact assessments accompanying the proposed rule and explains the negative consequences the proposed rule would have if it were finalized. Part 4 concludes.

Background

ANTI-KICKBACK STATUTE'S SAFE HARBOR FOR DRUG REBATES

Brand drug manufacturers regularly offer rebates on their products to payors such as PBMs. This gives manufacturers the ability to offer lower prices to large-volume buyers. The federal anti-kickback statute (42 USC § 1320a-7b(b)) codifies the government's longstanding prohibition of remuneration as inducement to provide goods or services that are financed by federal healthcare programs. The government has also long understood that price reductions in the form of rebates are not such inducements and has explicitly provided a safe harbor protection for these arrangements.

The statutory and regulatory history of the safe harbor exception to the anti-kickback statute for drug discounts dates back to 1987 legislation (the Medicare and Medicaid Patient and Program Protection Act) and regulations proposed in 1989 and finalized in 1991 (56 FR 35952).[3] As OIG notes in the February 2019 proposed rule, the 1991 safe harbor regulations "recognized that rebates can function like legitimate reductions in price."

The proposed rule expresses concern that drug rebates harm some beneficiaries, by inflating beneficiary cost-sharing, and increase costs for federal healthcare programs. OIG proposes removing the safe harbor protection for rebates in Medicare Part D and Medicaid MCOs and introducing a new safe harbor protection to facilitate point-of-sale discounts to beneficiaries instead.

[1] *84 FR 2340.*

[2] *Department of Health and Human Services, "Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients," news release, January 31, 2019.*

[3] *These rules were subsequently modified and updated in 1999 (64 FR 63518) and 2002 (67 FR 11928, 11934) and clarified in 2003 (68 FR 23731, 23735).*

ROLE OF REBATES IN PHARMACEUTICAL SUPPLY CHAIN

An example adopted from the proposed rule illustrates the payment and reimbursement structure for prescription drugs with rebates and the potential impact of prohibiting rebates. This example is only illustrative and does not represent actual costs or revenues.

Consider a prescription drug with a list price of $100. Assume that the drug manufacturer sells the drug to a wholesaler at a 2 percent discount, $98. The wholesaler then sells the drug to a pharmacy for $100. The PBM agrees that the pharmacy will be reimbursed $104 for the drug when their beneficiary fills a prescription. The patient is responsible for co-insurance equal to 25 percent of the pharmacy price, $26. The PBM will then pay the pharmacy the remainder of the bill, $78. The drug manufacturer pays a rebate of $30 to the PBM, which lowers the PBM's cost from $78 to $48.

Therefore, the net cost of the drug is $74. This can be derived by summing the net revenues across the supply chain: The drug manufacturer collects $68 ($98–$30). The wholesaler collects $2 ($100–$98). The pharmacy keeps $4 ($104–$100). The net revenues total $74 ($68+$2+$4).

It is noteworthy that the $48 net payment from the PBM is considerably less than the pre-rebate amount ($78), and that the source of the $48 is the insurance premium paid by beneficiaries and, in the case of Medicare Part D, the federal government. If the PBM payment to the pharmacy increases, premiums paid by beneficiaries and the federal government should be expected to rise.

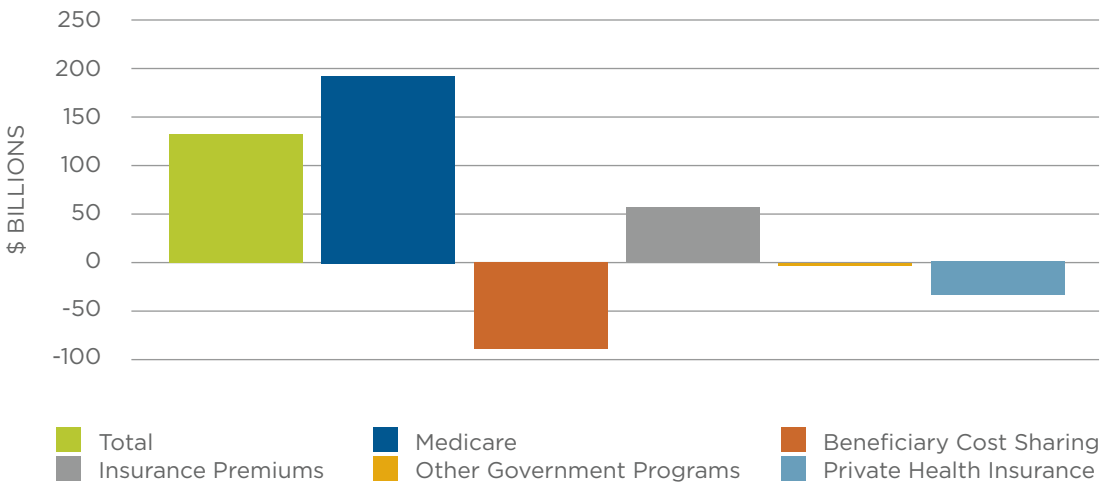
IMPACT OF THE PROPOSED RULE

OIG includes in the proposed rule a regulatory impact analysis and notes that the proposed rule is a significant regulatory action under Executive Order 12866, meaning that the economic impact of the rule is estimated to exceed $100 million annually. In a deviation from normal practice, HHS not only relied on its own actuarial analysis by the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary (OACT), but also contracted with two private-sector firms, Milliman Inc. and Wakely Consulting Group, to model the impact of the proposed rule. This section discusses only the OACT impact assessment. See Part 3 of this paper for a discussion of the Milliman analysis.

Despite the stated objective of the proposed rule being a reduction in federal healthcare spending, the government's own actuarial analysis estimates that it would increase spending in Medicare by nearly $200 billion over a decade.

According to OIG, a variety of groups would be directly affected by the proposed rule from an operations perspective, including more than 67,000 pharmacies, nearly 1,800 drug manufacturers, nearly 900 health insurance plans, approximately 60 PBMs, and 56 Medicaid agencies. More broadly, the proposed rule would have a significant effect on federal expenditures in the Part D program and a significant financial impact on beneficiaries through changes in Part D premiums and out-of-pocket prescription drug costs.

CHART 1. OACT ESTIMATED IMPACT OF PROPOSED RULE, 2020–2029



Specifically, the OACT analysis estimates that the proposed rule will have the following impacts from 2020 to 2029 (**see Chart 1**):

- Total drug spending — private and public combined — will increase by $137 billion.
- Federal government spending on Medicare Part D will increase by $196.1 billion, more than the total increase in drug spending, because the cost impact in the private health insurance market is negative.
- Medicare beneficiary costs will decrease by $25.2 billion (a projected $83.2 billion decline in beneficiary cost sharing is partially offset by a $58 billion increase in Part D premiums).
- The cost of Medicaid will increase by $2 billion, a burden borne primarily by the federal government.

In short, despite the stated objective of the proposed rule being a reduction in federal healthcare spending, the government's own actuarial analysis estimates that it would increase spending in Medicare by nearly $200 billion over a decade. The federal spending increase would be more than double the decline in out-of-pocket costs for beneficiaries. And, while beneficiaries might enjoy lower costs at the pharmacy, their premiums would rise.

OACT also estimates that the proposed rule will have a significant positive impact on the financials of drug manufacturers. First, costs for drug manufacturers will decline by $39.8 billion over the period, as fewer discounts by drug makers will be required in the Part D coverage gap. Moreover, OACT assumes that drug manufacturers will retain 15 percent of current rebates.

Conceptual Flaws in Proposed Rule

Primary conceptual flaws:

A. The proposed rule does not provide strong evidence supporting its foundational claim that rebates are tied to higher list prices.

B. The proposed rule is not appropriately targeted to meet its stated goals.

A. PROPOSED RULE DOES NOT SHOW CAUSALITY IN CLAIM THAT REBATES DRIVE UP DRUG SPENDING

In laying out the impetus for restricting rebates from drug manufacturers to PBMs, OIG discusses at considerable length the recent increase in drug

prices as well as the recent increase in Medicare drug spending. OIG then concludes in the "Need for Regulation" that "rebates to PBMs may be a factor in list prices rising faster than inflation. This phenomenon may also be causing PBMs to favor higher-cost drugs with higher rebates over drugs with lower costs." But OIG does not substantiate either claim. The "evidence" offered is at best anecdotal and at worst circular.

Below is a brief assessment of OIG citations supporting these claims. (See **Appendix A** of this paper for the sources cited by OIG.) In short, OIG's attempts to substantiate their claims would not be acceptable in a college term paper. Without question, they do not warrant blowing up the existing payment system, especially when the consequences are so difficult to predict, as the proposed rule readily acknowledges.

Review of OIG Evidence of Rebates Driving List Price Increases

Footnotes 3–9 in the proposed rule are all poor attempts to support OIG's claim that rebates drive up list prices.

- **OIG Footnote 3:** The ASPE Issue Brief cited finds that 30 percent of the increase in prescription drug spending from 2010 to 2014 is attributable to "either changes in the composition of drugs prescribed toward higher price products or price increases for drugs that together drove average price increases in excess of general inflation," but does not link drug prices to rebates in any way.
- **OIG Footnote 4:** The 2018 Medicare Trustees Report cited merely notes that estimated rebates differ from actual rebates. The *Wall Street Journal* article cited asserts only anecdotal evidence of a link between prices and rebates: "Drugmakers said they raise prices in conjunction with rebates they give to pharmacy benefit managers in order to be placed on formularies."
- **OIG Footnote 5:** The Drug Channel Institute post cited simply describes the phenomenon of a "gross-to-net rebate bubble."
- **OIG Footnote 6:** The Gilead Pharmaceuticals statement cited refers to rebates on Gilead's own products and simply asserts that "because these rebates are confidential and are not required to be passed through to patients, these discounts are effectively invisible and do not always translate into lower costs for patients."
- **OIG Footnote 7:** The comments to the Federal Trade Commission (FTC) cited were submitted by antitrust attorney David Balto in 2017. The closest Balto comes to showing evidence of a link between rebates and drug prices is an increase in Express Scripts' gross profit on an adjusted prescription. Otherwise, Balto only cites himself in his comment to the FTC. One of these citations is to an opinion piece he authored offering no evidence,[4] and the other refers to 2015 Congressional testimony he gave.[5] This testimony is also devoid of actual evidence.
- **OIG Footnote 8:** OIG merely defines price protection measures in this footnote.
- **OIG Footnote 9:** The Milliman analysis cited merely describes aspects of negotiations between drug manufacturers and Medicare Part D prescription drug plan sponsors.

[4] *David Balto, "How PBMs Make the Drug Price Problem Worse,"* The Hill*, August 31, 2016.*

[5] *David A. Balto, testimony before the House Judiciary Subcommittee on Regulatory Reform, Commercial and Antitrust Law hearing on "The State of Competition in the Pharmacy Benefits Manager and Pharmacy Marketplaces," November 17, 2015.*

Review of OIG Evidence of PBMs Pushing Higher-Priced Drugs

In support of its claim that "there may be a greater incentive for a PBM to encourage the use of drugs with higher list prices," OIG only offers two references:

- **OIG Footnote 15** supposedly supports this claim, but the Fierce Pharma article it cites only discusses one anecdote related to a unique drug/device combo product.
- **OIG Footnote 37** is intended to support the claim, but the *New York Times* article it cites reports on the rebate debate generally and offers no substantive support of OIG's assertion.

Two Health Policy Experts' Views Miscited by OIG

In **Footnote 14** of the proposed rule, OIG cites an article in support of a statement about PBM and manufacturer net revenue increasing with wholesale acquisition cost.[6] The article's authors, Professors Craig Garthwaite and Fiona Scott Morton, explicitly state in the article that "there is little systematic evidence of [perverse incentives'] impact on pharmaceutical prices." In their own analysis, Garthwaite and Scott Morton look at stock prices as an indicator of whether drug manufacturers' and PBMs' interests are aligned, and conclude that they appear to be so, according to this metric. Yet, the authors do not call for restricting rebates; they simply advocate for eliminating information asymmetries between parties.

Moreover, Garthwaite and Scott Morton have separately rejected the premise of the proposed rule. On March 12, 2019, Garthwaite wrote:

> There is no other part of the healthcare market that is currently more vilified than confidential rebates — a palpable anger that ultimately resulted in a Trump administration proposal to end this practice. But this vilification is vastly misplaced. Confidential rebates are necessary to secure large discounts because when a manufacturer knows all of its customers won't observe a big discount it gives to a particular client, it is more willing to give such a large discount in the first place.[7]

In Congressional testimony earlier that month, Scott Morton spoke against the proposed rule, saying, "A solution to tackle the problem of high out-of-pocket consumer costs that also promotes competition . . . is more desirable than one that reduces competition, such as the HHS rule. The HHS rule, by reducing competition between drugs, will lead to higher equilibrium prices."[8]

B. PROPOSED RULE DOES NOT APPROPRIATELY ADDRESS OIG'S OTHER STATED CONCERNS

In addition to claims about rebates leading to higher-priced drugs, OIG cites three impacts in its decision to propose restricting rebates. But this policy change is poorly designed to address these concerns.

Stated Concern #1: Rebates Harm Beneficiaries. OIG points out that Medicare and Medicaid MCO beneficiaries pay a higher share of their drug costs than they should because their out-of-pocket costs are not reduced by rebates. And, while beneficiaries'

[6] *Craig Garthwaite and Fiona Scott Morton, "Perverse Market Incentives Encourage High Prescription Drug Prices," ProMarket (blog of the Stigler Center at the University of Chicago Booth School of Business), November 1, 2017.*

[7] *Craig Garthwaite, "Making Markets Work for Pharmaceuticals," March 12, 2019.*

[8] *Fiona M. Scott Morton, testimony before the House Judiciary Subcommittee on Regulatory Reform, Commercial and Antitrust Law hearing on "Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets," March 7, 2019.*

premiums are lowered by rebates, premiums can be set too high if rebates are underestimated.

Stated Concern #2: Rebates Harm Federal Healthcare Programs. OIG's primary complaint regarding federal programs is that spending is high in these programs. A complaint directly tied to manufacturer rebates is that Medicaid is missing out on savings because the "best price" it could pay for drugs excludes manufacturer rebates.

Stated Concern #3: Rebates Lack Transparency. OIG worries that plan sponsors under Medicare Part D and Medicaid MCOs lack information about rebates.

On all three of these points, there are more direct ways to address legitimate concerns. In fact, a 2011 OIG report ("Concerns with Rebates in the Medicare Part D Program"), which the proposed rule cites, makes recommendations for relatively minor changes that would address some of these concerns:

- Ensure that sponsors more accurately include their expected rebates in their bids.
- Require sponsors to use methods CMS deems reasonable to allocate rebates across plans.
- Ensure that sponsors have sufficient audit rights and access to rebate information.
- Ensure that sponsors appropriately report the fees that PBMs collect from manufacturers.[9]

An evaluation of the effectiveness or appropriateness of the narrower proposals outlined in the 2011 OIG report are beyond the scope of this project, but they certainly appear on their face to be simpler and more targeted strategies with less apparent risk for broad-based disruptions to the supply chain. Alternatives aside, for each of the three concerns that OIG articulates, restricting rebates is certainly an outsized response to the issue.

Negative Impacts of Proposed Rule

Primary negative impacts:

A. The proposed rule would entail substantial costs to federal healthcare programs and beneficiaries.

B. The proposed rule is likely to have negative consequences on affected entities within the prescription drug supply chain, to the detriment of consumers.

A. PROPOSED RULE WOULD INCREASE FEDERAL AND BENEFICIARY SPENDING

According to OIG, "The goal of this policy is to lower out-of-pocket costs for consumers and reduce government drug spending in Federal health care programs." But, as discussed above, HHS's own actuaries estimate that the proposed rule will significantly increase federal spending on Medicare Part D and also increase Medicaid spending. While the federal share of Part D spending will increase significantly, premiums for all beneficiaries also will rise. Moreover, total spending on prescription drugs will increase as a result of the proposed rule. These outcomes are directly contrary to the stated goal.

Increase in Premiums

Under the current system, drug rebates are used to lower premium costs across all enrollees. The first-order impact of a change from rebates to discounts would be an increase in premiums, which would raise costs for both beneficiaries and the federal government. However, the decreased out-of-pocket costs are also shared between customers and the government, as fewer customers would reach the catastrophic phase in their coverage. On net, enrollees would pay less out of pocket under the new regime, as federal subsidies on premiums outstrip the government savings from lower catastrophic drug coverage. Therefore, the primary

[9] *Department of Health and Human Services Office of Inspector General,* Concerns with Rebates in the Medicare Part D Program, *March 2011.*

impact of the policy would be to redistribute from the government and from consumers who do not use rebated drugs to consumers who use rebated drugs.

To understand the distributive effects of the rule, consider the "no behavior changes" scenario that Milliman modeled in its supplementary actuarial analysis of the proposed rule. In this scenario, rebates paid by drug manufacturers to PBMs are eliminated and are assumed to be fully replaced with point-of-sale discounts to beneficiaries. Notably, this also means that list prices remain unchanged. In this scenario, the total cost of the Medicare program is unchanged, but the distribution of costs changes substantially over the 10-year budget window (2020–2029):

- Total member costs will decline by $14.5 billion, but this change masks a $26.4 billion increase in member premiums.
- Total government costs will increase by $34.8 billion.
- Drug manufacturer costs — their Part D liability through the coverage gap discount program — will decline by $20.6 billion.

This static scenario is illustrative of the redistributive effects of the proposed rule but excludes important behavioral responses in the marketplace that will lead to more profits for drug manufacturers and higher drug spending.

Increase in Drug Spending and Manufacturer Profits

In all scenarios considered by Milliman, the proposed rule is estimated to decrease drug manufacturers' costs. Estimates for this decrease range from $17.1 billion to $29.5 billion. Moreover, drug company revenues are predicted to rise. OACT reports that total drug spending will surge $137 billion, which can be expected to accrue to manufacturers given that they are clearly the entities in the supply chain earning economic profits.

In addition, OACT expects drug manufacturers to retain 15 percent of the rebate dollars for themselves; of the remaining 85 percent of rebate dollars, 75 percent will materialize as point-of-sale discounts to Medicare beneficiaries and 25 percent will materialize as lower list prices across the entire US prescription drug market. (See below for a discussion of the economic rationale for why manufacturers will retain a portion of the rebates previously given to PBMs.)

It is important to emphasize that, to the extent that the proposed rule's prohibition on rebates results in lower list prices, overall Medicare spending will increase. This is because a reduction in list price affects both Medicare Part D and private commercial plans; if current rebate dollars are repurposed to lower the list price of a drug, then a portion of that price discount accrues to private health plans and their members.

All but one of Milliman's non-static scenarios confirm large increases in federal spending on subsidies through Part D. The one scenario that yields projected savings for the government relies on the assumption that the prohibition on rebates will encourage PBMs to pursue other cost-containment strategies through formulary design and/or generic utilization. It is not apparent why prohibiting rebates will alter existing incentives to pursue these strategies. PBMs already face strong incentives to quickly achieve a high generic dispensing rate and craft the most cost-effective formularies.

In the scenario most like the assumptions made by OACT, Milliman predicts that over the period 2020–2029:

- Total government costs will increase by $139.9 billion, of which $135.5 billion will be new Medicare costs.
- Total beneficiary costs will rise by $12.3 billion, as the projected increase in premiums ($44.9 billion) is larger than the projected decrease in out-of-pocket costs ($32.6 billion).
- Drug manufacturers will increase their bottom lines by a total of $17.1 billion.

In this scenario, Milliman assumes that manufacturers will retain 20 percent of drug rebates, whereas the OACT analysis assumes that manufacturers will keep 15 percent. There is strong economic logic to support the assumption that prohibiting drug rebates to PBMs and permitting point-of-sale discounts will not be a zero-sum rearrangement and instead will result in fewer overall price concessions by drug manufacturers.

Economic Rationale for Why Drug Manufacturers Will Not Pass On 100% of Rebates

There are at least two reasons why drug manufacturers are likely to retain a significant portion of PBM rebates if the proposed rule is finalized. Both reasons stem from point-of-sale rebates being transparent, while rebates to PBMs are confidential.

First, forcing drug manufacturers to switch to a transparent system of point-of-sale discounts will likely have an adverse effect on net prices in Part D because the discounts will "compress" across plans, as those receiving smaller rebates will see increases and those receiving larger rebates will see reductions. This increase in transparency can have an adverse effect on net prices. Drug manufacturers will likely be forced toward more similar rebate rules across customers — smaller discounts for larger customers and larger discounts for smaller customers. The net effect will likely be an overall reduction in discounts. Given that rebates are larger than average in Part D compared to the entire insurance market, the net effect will likely be negative. As the Congressional Budget Office (CBO) noted in 2007 when describing the effect on Medicare Part D of potential increased transparency of rebates:

> CBO's understanding is that PDPs [Medicare prescription drug plans] have secured rebates somewhat larger than the average rebates observed in commercial health plans. As a result, the revelation of rebates to PDPs would create pressure to reduce those rebates, which would tend to increase costs for both the Medicare program and, on average, for enrollees.[10]

Recent evidence suggests that the disparity between average rebates in Medicare Part D and in commercial plans has increased since CBO's comments. A Pew Charitable Trusts review of 2012–2016 drug spending reports that rebates for commercial plans increased 71 percent (relative to pharmacy benefit premiums) during this time, while manufacturer rebates paid in Medicare Part D have increased 212 percent (relative to total Part D spending).[11]

Drug rebates are used to lower premium costs across all enrollees. The first-order impact of a change from rebates to discounts would be an increase in premiums, which would raise costs for both beneficiaries and the federal government.

Second, moving from confidential rebates to PBMs to transparent rebates to beneficiaries would increase the probability of tacit collusion among drug manufacturers, thereby limiting competition and leading to higher average prices for prescription drugs. Tacit collusion refers to the dynamic whereby firms that should be competing can strategically set prices relative to one another. A necessary condition for tacit collusion is the ability of firms to observe their competitors' prices. If manufacturers provide rebates to PBMs that their competitors cannot observe, firms are more likely to compete to lower net prices on products. As CBO noted:

[10] *Congressional Budget Office (CBO), letter to Congressmen Joe Barton and Jim McCrery, March 12, 2007.*

[11] *Pew Charitable Trusts, "The Prescription Drug Landscape, Explored: A Look at Retail Pharmaceutical Spending from 2012 to 2016," March 8, 2019.*

> The current secrecy of rebate negotiations makes it difficult for manufacturers to monitor one another's behavior and thus impedes collusive activity: When rebates are confidential, manufacturers can pursue their self-interest in increasing their drug sales at the expense of their competitors by offering rebates without fear of retaliation.[12]

The FTC has also weighed in on drug price transparency and tacit collusion:

> Whenever PBMs have a credible threat to exclude pharmaceutical manufacturers from their formulary, manufacturers have a powerful incentive to bid aggressively. Willingness to bid aggressively, however, is affected by the degree of transparency with respect to the terms that pharmaceutical companies offer PBMs. Whenever competitors know the actual prices charged by other firms, tacit collusion — and thus higher prices — may be more likely.[13]

B. PROPOSED RULE WOULD IMPACT INDUSTRY MORE NEGATIVELY THAN ESTIMATED

In an obvious omission, OIG does not quantify the likelihood, which it acknowledges, that the proposed rule would lead to consolidation (vertical integration, specifically) among participants in the prescription drug supply chain. Such a development raises the possibility of reduced competition and higher drug costs.

The costs to industry that OIG does estimate are the regulatory compliance costs — approximately $76 million in the first year and $224 million over five years. OIG reports compliance-related costs at three stages: reviewing the rule when finalized, implementing and responding to the rule in the first year, and complying with the rule in every subsequent year. Simply reviewing the rule will cost affected entities an estimated $5.3 million, by OIG's calculation. First-year regulatory compliance will cost $53.5 million, and subsequent year costs will be $24.8 million, according to OIG. In addition, OIG estimates $5.45 million in costs for plan sponsors to update their 2020 bids if the rule is finalized, $1.28 million every year for PBMs to comply with new documentation and disclosure requirements, and $10.8 million per year for five years for IT system updates. (Notably, OIG assumes these IT system upgrades will not include any capital expenditures and bases its estimate only on an assumption that affected entities will need to dedicate five additional hours per year to IT system updates.)

These likely are significant underestimations of the true burden for affected entities for several reasons. First, OIG underestimates the amount of time it would take affected entities to review and respond to the rule. Second, OIG relies on unadjusted 2016 wage data for its calculations, which reduces the estimated cost by roughly 10 percent relative to current wage rates. And third, OIG assumes that small business community pharmacies would incur no regulatory compliance costs whatsoever, an omission that reduces OIG's first-year estimate by nearly $30 million.

Time Required to Review and Respond Is Underestimated. OIG assumes affected entities will review the rule in two hours, on average, split evenly between a lawyer and a manager. Given that the proposed rule is 123 pages (roughly 30,000 words) and given the expectation that the final rule will be at least as long, this seems like an implausibly short period of time and assumes no time for analysis, evaluation, or contemplation. OIG also seemingly assumes that only two people per entity will read the final rule, each apparently reading half the rule, a surprising assumption given that the rule would fundamentally alter the structure of payments

[12] *CBO, letter to Congressmen Joe Barton and Jim McCrery.*
[13] *Federal Trade Commission, letter to California State Assemblyman Greg Aghazarian, September 7, 2004.*

for prescription pharmaceuticals and have major consequences for the contractual arrangements and business operations of affected entities.

In addition, interpreting the rule, conferring with colleagues, analyzing the impact, and adjusting policies and contracts would all require substantial time, but OIG assumes that the average number of hours to respond to the new rule would be only 20 the first year and 10 in each subsequent year.

To understand the sensitivity of the OIG compliance cost estimates, assume that the required number of hours for pharmacies to review the new rule in the first year was 40 hours instead of 20 and that the number of hours required for manufacturers, PBMs, Part D plans, and Medicaid programs was 60 instead of 20. Under these more plausible assumptions, the total first-year compliance cost would more than double, from $53.5 million to $113.4 million.

Estimates Are Not Adjusted for Inflation. Because these estimates are in 2016 dollars, they are obviously deflated relative to current economic conditions. OIG's methodology for calculating these costs rests on an estimate of the average number of hours necessary to comply, the type of worker who will be directed to work on this task, and the average hourly wage of this specified worker category. Given that the median wage of workers with a college degree has increased approximately 10 percent since May 2016 (when the National Occupational Employment and Wage Estimates survey, the source OIG uses, was published), these estimates should be adjusted to reflect current costs. It is both unnecessary and misleading for OIG to more appropriately rely on unadjusted data for these calculations.

Applying a 10 percent wage adjustment to the above example, which included a more plausible assumption of the time required to review the new rule, yields a first-year compliance cost of $124.7 million, approximately 125 percent greater than OIG's estimate.

More Than 20,000 Small Business Community Pharmacies Are Excluded. OIG also assumes that the compliance cost for 21,909 small business community pharmacies is zero, and that a compliance burden will only accrue to 19,500 pharmacy and drug store firms. (See **Appendix B** for a reconstruction of the calculations underlying the OIG cost estimates.)

Conclusion

According to OIG, "This proposed rule seeks to eliminate rebates so that manufacturers will have an incentive to lower list prices and PBMs will have more incentive to negotiate greater discounts from manufacturers. The goal of this policy is to lower out-of-pocket costs for consumers and reduce government spending in Federal health care programs."

As this analysis shows, the proposed rule is not expected to achieve these goals. Total federal government spending would increase, and it would increase far more than any expected reduction in total beneficiary costs. Moreover, net drug costs and, relatedly, drug company revenues would rise significantly.

In essence, the proposed rule would raise net drug prices in Medicare Part D under the guise of reducing list prices, shift drug costs from the commercial market to the Medicare Part D market, and raise costs on all Medicare beneficiaries through higher premiums in order to lower out-of-pocket costs for those with expensive prescription drugs.

More concerning is the uncertainty regarding the effects of the proposed rule in numerous critical regards. It would be premature for policymakers to proceed without better understanding the proposed rule's impact on federal healthcare programs and beneficiaries, its far-reaching effects in the drug supply chain, and its indirect effects on the commercial market.

APPENDIX A: OIG CITATIONS DISCUSSED IN ANALYSIS

Footnote 3: Observations on Trends in Prescription Drug Spending. U.S. Department of Health and Human Services. Assistant Secretary for Planning and Evaluation. March 8, 2016.

Footnote 4: 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds 143 (2018). Jared S. Hopkins, Drugmakers Raise Prices on Hundreds of Medicines, Wall St. J. (Jan. 1, 2019).

Footnote 5: New Data Show the Gross-to-Net Rebate Bubble Growing Even Bigger. Drug Channels Institute. June 14, 2017.

Footnote 6: A perspective from our CEO: Gilead Subsidiary to Launch Authorized Generics to Treat HCV. Gilead Pharmaceuticals.

Footnote 7: Letter from David A. Balto on Behalf of Consumer Action to Federal Trade Commission (Dec. 6, 2017).

Footnote 9: Pharmacy manufacturer rebate negotiation strategies: A common ground for a common purpose. Milliman. November 17, 2015.

Footnote 15: Shire, Pfizer antitrust lawsuits could rewrite the rules for formulary contracts: report. Arlene Weintraub. Fierce Pharma. October 10, 2017.

Footnote 37: "Meet the Rebate, the New Villain of High Drug Prices. New York Times. July 27, 2018.

APPENDIX B: ESTIMATED COST FOR AFFECTED ENTITIES REVIEWING PROPOSED RULE

The cost for an affected entity to review the rule can be calculated as:

(hours) * (weighted average wage rate) * (adj for overhead and benefits) * (number of affected entities)

According to OIG, the regulatory compliance costs are as follows:

First review of final rule
2 * (0.5*52.58 + 0.5*67.25) * 2 * (19,500 + 1,775 + 880 + 60 + 56) = $5.3 million

First-year response to new rule
20 * (0.5*52.58 + 0.5*67.25) * 2 * (19,500 + 1,775 + 880 + 60 + 56) = $53.3 million

Response in subsequent years
10 * (0.8*52.58 + 0.2*67.25) * 2 * (19,500 + 1,775 + 880 + 60 + 56) = $24.7 million

ABOUT THE AUTHOR

Alex Brill is the CEO of Matrix Global Advisors, an economic policy consulting firm. He is also a resident fellow at the American Enterprise Institute and in 2010 served as an advisor to the Simpson-Bowles Commission. Previously, he was chief economist and policy director to the House Ways and Means Committee. Prior to his time on the Hill, he served on the staff of the President's Council of Economic Advisers.

This paper was sponsored by the Pharmaceutical Care Management Association. The author is solely responsible for the content. Any views expressed here represent only the views of the author.

MATRIX GLOBAL ADVISORS

1350 Connecticut Avenue, NW Suite 610 Washington, DC 20036 | 202-558-7159 | info@GetMGA.com www.GetMGA.com