



April 8, 2019

Submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov>

The Honorable Alex M. Azar, II
Secretary of Health and Human Services
U. S. Department of Health and Human Services
Attention: OIG-0936- P
Room 5527, Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Re: “Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees” Proposed Rule (File Code: OIG-0936-P)

Dear Secretary Azar:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the “Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees” as published in the Federal Register on February 6, 2019 (hereafter referred to as the “Proposed Rule”). PCMA is the national association representing America’s pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and the health insurance marketplaces.

As the only entities in the supply chain whose mission is to lower costs, PBMs share and appreciate the urgency of addressing the rising cost of prescription drugs. We agree that there is a valid policy discussion to be had under Part D about the best use of PBM-negotiated savings – keeping premiums low for all beneficiaries or applying the savings at the point-of-sale. If it is structured properly, PBMs will be able to administer a system that strikes a new balance between premiums and out-of-pocket costs.

However, PCMA and its members are concerned about the disruption that will occur to the Part D benefit and the drug supply chain should PBMs be cut out or otherwise hampered from facilitating rebates under the new safe harbors. If Health and Human Services (HHS) and its Office of the Inspector General (OIG) are serious about a quick and seamless transition, PBMs must be empowered to actively participate under any restructured system. PBMs have the infrastructure, tools, and data to best operationalize the Proposed Rule, if certain changes are made and details provided.

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PCMA is extremely concerned about the implications should the Proposed Rule be finalized as proposed. First and foremost, we believe the Proposed Rule is unlikely to achieve the policy objective that we share with HHS and its OIG – lower drug prices – and instead may very well lead to an increase not only in beneficiary premiums but also to the chances of destabilization of the successful Part D program.

As we outline in our Executive Summary and in more detail in the attached comments, some of the key consequences that worry us include: the deleterious impact of the rule on beneficiary access, particularly given anticipated premium increases and disruptions in the current drug supply chain; the chilling effect the proposed safe harbor changes will have on current and future value-based arrangements; the lack of mechanisms to spur a reduction in list prices by drug manufacturers; and the significant adverse impact on overall federal spending, Part D plan operations, and Medicaid managed care arrangements.

We look forward to working with you to shape the Proposed Rule to best operationalize a revised system for the benefit of Medicare beneficiaries. For your convenience, we provide our comments in three parts: Part 1 is an Executive Summary; Part 2 sets forth our significant concerns with the rule as proposed; and Part 3 sets forth an alternative approach for the consideration by HHS, which would facilitate PBM management of a viable system.

We appreciate the opportunity to comment and urge HHS to adopt PCMA's recommendations as set forth in the attached.

If you have any questions, or if we can provide you with any further information, please do not hesitate to contact me at 202.756.5700.

Sincerely,

A handwritten signature in black ink, appearing to read "JC Scott", is written over a light blue horizontal line.

JC Scott
President and CEO

Attachment:

Comments Part 1 – Executive Summary
Comments Part 2 – Substantive Comments in Opposition to the Proposed Rule
Comments Part 3 – PCMA's Alternative to the Proposed Rule

cc:	John O'Brien, HHS	Jennifer Shapiro, HHS/CMS
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Part 1: Executive Summary

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the “Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees” as published in the Federal Register on February 6, 2019 (hereafter referred to as the “Proposed Rule”).

In general, PCMA is wholly aligned with the Administration goals of reducing drug prices and beneficiary out-of-pocket costs, by increasing competition and improving negotiation. We agree there is a valid policy discussion regarding the best use of PBM-negotiated savings in Part D, as one way to reduce beneficiary out-of-pocket costs. However, PCMA is extremely concerned about the implications should the Proposed Rule be finalized as proposed. Instead, we suggest an alternative approach that would utilize existing PBM mechanisms to implement a system of price concessions at point-of-sale.

As drafted, we believe the Proposed Rule is unlikely to achieve the policy objectives that we share with HHS. The Proposed Rule will not lead to lower drug prices and in fact will lead to a massive transfer of federal dollars to drug manufacturers, who alone have the ability to set and change drug prices. Despite manufacturers’ ongoing best efforts at increasing prices, states, PBMs, and Part D plan sponsors are making considerable progress in reducing drug spending.

PCMA’s comments highlight the harm and negative impact the Proposed Rule would have on the great successes enjoyed by the Part D program and its enrollees since its implementation in 2006. The Proposed Rule lacks any mechanism to spur a reduction in list prices by drug manufacturers or curb price increases. The Proposed Rule would negatively harm more beneficiaries than it would help due to the likely effects on premiums, the limited application of out-of-pocket savings, and the potential disruptions it could cause in the pharmaceutical supply chain. Moreover, the Proposed Rule’s revisions to existing safe harbors would have a chilling effect on current and future value-based arrangements. As evidenced in the actuarial analyses commissioned by HHS, the Proposed Rule would lead to billions in excess federal and state spending, mostly to the benefit of drug manufacturers. The potential benefits of the Proposed Rule can in no way outweigh these significant deficits.

We detail these concerns in Part 2 of our comments, which follow. However, to the extent HHS intends to proceed with a Final Rule, we offer in Part 3 of our comments an alternative that can be implemented more feasibly for 2020 (subject to the issuance of needed details), and would to varying degrees mitigate many of the concerns we raise throughout these comments.

PCMA's Concerns with the Proposed Rule (Part 2)

PCMA's comments in Part 2 regarding the Proposed Rule are set forth in nine sections. We describe each section below and include the page number where they can be found.

- **Section I: The Proposed Rule Would Undo Years of Success by PBMs in the Part D Program in Controlling Out-of-Control Drug Prices.** In Section I, we explain how the Proposed Rule would lead to an increase in net drug costs and put at risk the benefits generated by the Part D program since its inception. We recommend HHS consider approaches that would instead limit manufacturers' ability to raise their prices at will, preserve the role of PBMs in generating significant savings, and undertake any future rulemaking in concert with the subject matter experts at CMS and across the set of stakeholders who are already invested in the success of the program. (Page 9)
- **Section II: The Proposed Rule Upends Ongoing Efforts to Transform the Health Care System.** In this Section, we describe the harms the Proposed Rule would cause to existing and future value-based arrangements. PBMs play a fundamental role in extracting value from pharmaceuticals, while HHS calls into question that very role. We recommend that HHS consider rulemaking in the short-term to protect these important contracting innovations, or it will put at risk any future benefits and learnings. (Page 22)
- **Section III: The Proposed Rule's Effects on Transparency Would Place at Risk the Functioning of the Pharmaceutical Marketplace.** HHS's Proposed Rule oversimplifies the pharmaceutical marketplace and mischaracterizes the role of PBMs and the importance of proprietary and confidential negotiations. PCMA recommends that HHS not finalize this rule without acknowledging and mitigating the tacit collusion that manufacturers will engage in, once the results of negotiations are made public through pharmacy transactions. (Page 29)
- **Section IV: The Proposed Rule Will Harm Beneficiaries Due to Premium Increases and Confusion.** PCMA explains in this Section that the Proposed Rule would negatively affect far more beneficiaries than it would help, and to a greater extent than HHS has allotted. With an increase in premiums on the horizon due to the provisions of the Proposed Rule, beneficiary plan choices and enrollment decisions could lead to tremendous disruptions in enrollment and coverage. Confusion and dissatisfaction may overtake the program. We recommend that HHS withdraw the Proposed Rule until it can achieve its important aims – lower drug prices and lower out-of-pocket costs – without such clear negative consequences for the many enrollees who do not take high-cost medicines or are otherwise subject to coinsurance requirements. (Page 37)
- **Section V: HHS's Regulatory Impact Analysis is Inadequate and Incomplete.** In the section of the Proposed Rule that is meant to demonstrate that the Department has weighed its options and proposed the most justifiable policy possible, HHS instead fails to follow long-standing processes, calling into question why it is rushing through such a

fundamental change to the successful Part D program. The economic analysis provided by HHS does not adequately describe the effects of the Proposed Rule on other stakeholders, including state Medicaid programs, who we believe would see large reductions in Medicaid rebates without significant offsetting savings.

- The Proposed Rule's administrative cost estimates are underdeveloped and its benefits are unexplored. A more realistic estimate of the cost burden of the Proposed Rule argues against the HHS proposal altogether.
- The actuarial analyses accompanying the Proposed Rule's transfers are some of the strongest arguments against it. As a result of the Proposed Rule, federal spending on Part D would increase by \$196.1 billion. Of this \$196.1 billion, drug manufacturers would receive nearly seven times more money as a result of higher net prices (\$170.9 billion), than beneficiaries would receive in out-of-pocket spending reductions net of premium increases (\$25.2 billion).

We recommend that the rule be withdrawn until HHS can conduct a meaningful analysis of this rule and other options against its stated policy objectives of reducing list prices and beneficiary out-of-pocket costs. (Page 42)

- **Section VI: Significant Questions Remain Regarding Medicare Part D Implementation of the Proposed Rule.** In this Section, PCMA raises for HHS's benefit a detailed list of Part D bidding and operational implementation issues that this Proposed Rule generates. Many of these would need to be answered this spring, prior to the June 3, 2019 bid submission deadline. Others would need to be answered in the summer, well in advance of the Annual Enrollment Period for 2020 which opens October 15, 2019. Still others would need to be implemented by CMS for its own operations in the fall, in advance of plans being able to effectuate coverage on January 1, 2020. (Page 65)
- **Section VII: Medicaid Managed Care Should be Excluded from the Proposed Rule.** The Proposed Rule does not account for the current application of managed care in Medicaid and provides no measurable benefits to affected stakeholders (federal and state governments or enrollees). Enrollees in Medicaid managed care plans generally have low cost-sharing for all services, and cost-sharing for prescription drugs is required to be "nominal." In almost every case these are low-dollar, flat copays that would not be meaningfully reduced by rebates at the point-of-sale or up-front discounts provided to pharmacies. As a result, the Proposed Rule would impose administrative costs on states in reassessing pharmacy management models and redoing existing contracts and would yield no benefit whatsoever. PCMA recommends that Medicaid managed care plans and PBMs acting on their behalf be removed from any Final Rule. (Page 72)

- **Section VIII: The Proposed Rule Raises Serious Legal Concerns Regarding the APA, Non-interference, Antitrust, and Trade Secrets Act.** In this Section, PCMA raises a series of legal and procedural questions and concerns regarding the Proposed Rule. At the most basic level, the Proposed Rule does not solve the problem that HHS has identified: high drug prices in Medicare Part D and in Medicaid managed care. The Proposed Rule fails to consider a number of material consequences of its proposal, not limited to but including the effects of the Proposed Rule on future Part D and Medicaid Managed Care Organization (MCO) enrollment, its impact on MCO-negotiated supplemental rebates, and its impact on manufacturer behavior in light of current antitrust rules regarding upfront discount negotiations. In addition, we question whether a revised regulatory safe harbor can overcome the clear statutory safe harbor language protecting discounts, raise whether the Proposed Rule would violate statutory constraints regarding “negotiated price” and the Part D non-interference clause, and query whether HHS-OIG contemplated the interaction of this Proposed Rule with the Trade Secrets Act and existing antitrust law and regulation. (Page 80)
- **Section IX: Further Legal Concerns Including the Relationship to Existing Safe Harbors Need to be Addressed.** In this Section, PCMA finds that HHS-OIG fails to discuss the impact of its proposal on existing Safe Harbors and may inadvertently be encouraging the development of new, unintended discounts in the drug supply chain. PCMA recommends that any revisions to the safe harbor regulations appropriately account for all consequences and actors, to ensure that the behavior it seeks to limit or ban is not simply performed elsewhere in the supply chain. (Page 100)

PCMA’s Alternative to the Proposed Rule (Part 3)

To the extent HHS intends to proceed with finalizing revisions to the regulatory safe harbors, we offer in Part 3 of our comments an alternative that we believe is more viable for 2020 and would mitigate to varying degrees many of the issues we described above and discuss in detail in Part 2 of our comments. Specifically, our alternative is to require Part D plan sponsors to pass through nearly the full value of manufacturer price concessions to the price of a prescription drug at the point-of-sale. This could be accomplished through existing PBM and plan sponsor arrangements with pharmacies. Beneficiary cost-sharing would be calculated based on a new definition of negotiated price, but payments to pharmacies would not be at risk of delay based on an untested chargeback model. We believe that this alternative to the Proposed Rule would increase premiums by 40% less than what HHS has proposed, while passing through a majority of the cost-sharing savings, and reducing federal spending as compared to the Proposed Rule by 75%. The alternative more appropriately balances HHS’s stated goals, of addressing list prices, reducing beneficiary cost-sharing, and reducing federal spending. Part 3 also provides revised regulatory language to implement this option.

Our alternative would exclude Medicaid managed care plans from any Final Rule, since as we explain in our detailed comments in Part 2, Section VII, there is no public policy rationale for including these plans. (Page 104)

* * * * *

In summary, PCMA's detailed comments are intended to demonstrate to HHS that its Proposed Rule will fail to achieve the Department's stated objectives. PCMA's alternative provides HHS a path forward if it *must* change its treatment of price concessions for 2020. We caution HHS against making changes to the otherwise successful Part D system without a robust analysis of the costs, benefits, and transfers associated with its proposals and all reasonable alternatives. By contrast to the Proposed Rule, a robust and deliberative process, in conjunction with Congress and the various stakeholders that have made Part D a stirring success, would deliver to HHS meaningful and durable reforms on behalf of beneficiaries and taxpayers.

Part 2: Substantive Comments in Opposition to the Proposed Rule

Section I. The Proposed Rule Would Undo Years of Success by PBMs and the Part D Program in Controlling Out-of-Control Drug Prices

PCMA has significant policy objections to the Proposed Rule from a wide variety of perspectives. We have grouped the concerns into three main areas. First, the Proposed Rule will not achieve its goals of reducing drug prices, beneficiary spending, or federal spending. Second, the Proposed Rule is counter to the success to date of the Part D program as enacted by Congress and implemented by the private sector over the past 14 years. Third, the issuance of this Proposed Rule solely by OIG and without coordination with CMS is inappropriate given the far-reaching effects it would have on the entire health care system. A fourth major objection, the removal of protection for retrospective rebates not known at the time the product is dispensed in the absence of a safe harbor for value-based arrangements, does significant damage to the industry's efforts to improve the efficiency of the health care system related to prescription drugs. We discuss this argument in specific detail in Section II.¹

1. The Proposed Rule would lead to increases in net drug costs, beneficiary out-of-pocket spending, and federal spending

We agree with the Administration that list prices for newly approved and existing drugs are too high and that out-of-control list price increases continue to be a source of significant concern. To address the price of drugs, we have on several occasions offered a number of suggestions in response to a wide range of HHS issuances (e.g., Blueprint) to help spur much-needed competition in the pharmaceutical marketplace.² This Proposed Rule, if finalized, will have the opposite effect of its intention and undermine the ability of plan sponsors and PBMs to leverage that competition to achieve lower net costs.

Recent reports describing list price increases coupled with the moderation of net drug costs are direct evidence that the existing systems work. They do not demonstrate a problem in the market. Table 1 below presents a summary of these publications.

That net drug costs have moderated, due in large part to PBM negotiations, suggests that the monetary value of pharmaceuticals as determined by the market is not increasing.³ Ongoing

¹ All references to "Section" refer to this Part 2 of these comments.

² PCMA comments filed in response to the President's Blueprint on Drug Pricing, American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. July 16, 2018. Available at <https://www.pcmagnet.org/wp-content/uploads/2018/07/PCMA-comments-on-Blueprint-RFI-July-16-2018.pdf>.

³ For example, a 2016 analysis by IQVIA found that as a result of direct brand-to-brand competition leveraged by PBMs, the net cost of novel Hepatitis C medicines had been reduced to be on par with government-mandated prices

increases in list prices can only be addressed by the manufacturers themselves. This Proposed Rule will not lead or even incentivize manufacturers to reduce their list prices, and in fact, will lead to an increase in net costs for all consumers.

Table 1. Summary of Recent Studies of List and Net Drug Prices.

Report	Organization	Year	Years Studied	List Price/ Gross Spending Trend	Net Cost/ Net Spending Trend	Notes from Report
National Health Expenditures ⁴	CMS OACT	2019	2016		2.3%	All payers
			2017		0.4%	
			2018 (proj.)		3.3%	
The Global Use of Medicines in 2019 and Outlook to 2023 ⁵	IQVIA	2019	2016	5.8%	4.8%	All payers
			2017	1.2%	0.6%	
			2018	6%	1.5%	
Prescription Drug Spending ⁶	Altarum	2018	2016		0.5%	Retail drug spending
			2017		0.6%	
			2018		5.1%	
Quarterly Publications	SSR Health ⁷	2016-2018	2016	9.5%	-5.5%	Brand drug price trends averaged over 4 quarters
PBM Annual Drug Trend Reports	Prime Therapeutics ⁸	2016-2019	2016		2.5%	Commercial customer spending trend
			2017		-0.2%	
			2018		3.3%	
		2019	2016		-0.7%	Medicare spending trend
			2017		-0.8%	
			2018		4.7%	
	Express Scripts ⁹	2015-2018	2015		10.9%	Medicare spending trend
			2016		2.3%	
			2017		1.6%	
			2018		-0.3%	
	MedImpact ¹⁰	2017-2018	2017		1.6%	Commercial spending trend
			2018		1.5%	
			2017		1.8%	Medicare spending trend
			2018		2.9%	

in Europe. See IQVIA, "Comparison of Hepatitis C Treatment Costs Estimates of Net Prices and Usage in the U.S. and Other Major Markets," September 2016.

⁴ Available at <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.05499>.

⁵ Available at <https://www.iqvia.com/institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023>.

⁶ Available at https://altarum.org/sites/default/files/uploaded-publication-files/SHSS-Spending-Brief_January_2019.pdf. Adjusted for rebates using CMS estimates.

⁷ An archive of SSR Health's syndicated research report titles are available here: <http://www.ssrhealth.com/research-archive/>. Report access is subscription-based.

⁸ Available at <https://www.primetherapeutics.com/en/news/prime-insights/reports.html>.

⁹ Available at <http://lab.express-scripts.com/lab/drug-trend-report>.

¹⁰ Available at https://pbm.medimpact.com/press-releases/-/asset_publisher/zxpF3EXCvov/content/medimpact-achieves-record-low-trend.

Net costs will rise. Rather than reducing list prices for new drugs, and limiting list price increases for existing drugs, the Proposed Rule would increase prescription drug net costs.

- **There is no mechanism to spur any reduction in list prices by manufacturers.** Drug manufacturers alone set and change the list prices for their products. The Proposed Rule would change the manner of negotiations manufacturers engage in with Part D plan sponsors and PBMs, which would result in increased net costs to plans and the Part D program. OIG's current and proposed safe harbors have no effect on manufacturer list price behavior.
- **Manufacturers have no incentive to reduce list prices because of effects on sales outside of Medicare Part D and Medicaid managed care.** HHS suggests that a combination of list price reductions, up-front discounts, or rebates passed through in full could achieve the rule's intent of lowering beneficiary and federal government spending. However, the manufacturer-preferred avenue will likely be up-front discounts via chargebacks. Reducing list prices would affect sales outside of the Proposed Rule's affected federal health care programs, which would reduce manufacturer revenue. This poses a "free rider" problem for manufacturers, whereby they would be reducing prices to plans that were not preferring their product. By contrast, we have seen manufacturers issue newly labeled alternative products and authorized generics as ways to "reduce" list prices, but would note that in all cases we are aware of, these moves increase manufacturer revenue.¹¹ Further, discounts may be exempt from government price reporting requirements, and as we discuss in our comments related to transparency (see Section III), they reduce PBM negotiating power, in effect raising net prices.
- **The analyses in the Proposed Rule presume that manufacturers do not meaningfully change their list pricing strategies to match the rule's intended effects.** In its analyses for both Part D and Medicaid managed care, OACT assumes that manufacturers do not significantly reduce their list prices. They instead predict that eliminating rebates provides manufacturers an opportunity to provide fewer price concessions. While OACT assumes that manufacturers moderate future product list price growth, this is not the output of any modeling. Should list price increases not moderate, OACT's cost estimates would be significantly higher.
- **Manufacturer list pricing decisions are largely not directly related to rebates.** Proposing a change to Part D and Medicaid managed care rebates ignores that manufacturers set and change their list prices regardless of any price concessions they may offer. For example, it is well understood that list prices for brand name prescription drugs continue to increase even when a brand faces no direct competition by virtue of

¹¹ See for example our discussion in Section VII regarding the effects of these strategic choices on AMP and Medicaid rebates.

being truly innovative,¹² a brand faces limited direct competition because it has protected class status (for example),¹³ and generic competition has eroded a product's market.¹⁴

- **Increasing transparency on contract-specific price concessions has an anticompetitive effect for both manufacturers and health plans.** We describe in Section II of our comments the challenges this rule would create with regard to price concession transparency and beneficiary access. Generally, when a competitor's best offer is known, discounts offered by manufacturers will decrease. Plan sponsors and PBMs may also be hesitant to engage in negotiations that may yield adverse selection.

The proposed chargeback system creates opportunity for manufacturers to hold back current price concessions. The existing system of price concessions negotiated by PBMs on behalf of their plan clients is the most efficient market mechanism available. The tension between buyers and sellers results in an equilibrium that has kept spending growth moderate, per our cited evidence above. Should the price concession system be switched to one where wholesalers have a role in administering price concessions, the entity that is responsible for passing through discounts in that scenario would also be incentivized to sell products from their clients' (manufacturers) portfolios. The buyer (PBMs and plans) would no longer be fully informed about the use of their negotiated discounts and would have fewer guarantees that the plan's formulary or contract terms are upheld. For example, wholesalers administering chargebacks may be incentivized to bypass utilization management (UM) requirements and pass along the discount, even when the claim is not paid by the PBM or pending an appeal process, because they are paid by manufacturers for each unit sold. By contrast, PBMs administer UM according to the terms of formularies as duly developed by P&T Committees.¹⁵

More Part D beneficiaries will be harmed than helped by this Proposed Rule, and few if any Medicaid managed care enrollees would see any benefit. We discuss in Section V our specific concerns with the actuarial analyses underlying the proposal, believing them to be too conservative in terms of harms and costs. However, at face value, OACT's analysis concludes that 70% of non-low income beneficiaries would pay more in premiums than they would save in cost-sharing.¹⁶ Earlier analyses of related proposals concluded that a smaller fraction of beneficiaries would save in cost-sharing relative to premium increases if rebates were fully

¹² See for example Milliman, "Prescription Drug Rebates and Part D Drug Costs," July 2018, which found that manufacturers did not offer rebates for 64% of brand drugs; and OIG, "Increases in Reimbursement for Brand-Name Drugs in Part D, June 2018," which found that prices paid by Part D plans for a subset of drugs from 2011-2015 increased by 62% after accounting for rebates. Manufacturers continued to increase prices in excess of any rebates paid.

¹³ See Milliman, July 2018 and 83 Fed. Reg. 62159, in which CMS writes: "internal CMS analysis has also shown price trends for brand drugs are consistently higher for drugs in protected classes than such drugs in non-protected classes. On the whole, protected class drug prices have increased more than other, non-protected drug classes between 2012 and 2017."

¹⁴ See Milliman, July 2018.

¹⁵ Such a new system would also impose excessive administrative costs, which we discuss in Section V.

¹⁶ Low income beneficiaries – which are 30% of Part D enrollment on their own – are wholly unaffected from a cost-sharing perspective. (We discuss in Sections IV and V a series of concerns regarding LIS enrollees outside of cost-sharing, not accounted for by HHS or OACT.)

passed through at the POS.¹⁷ The Department should not undertake rulemaking that it knows will at best confuse, and at worst harm, the vast majority of seniors.

As we discuss in greater detail in Sections IV and V, the assessment of beneficiary premium and cost-sharing changes is inadequate, and likely underestimates the trade-offs between premium increases and cost-sharing savings. Simply put, except when a Medicare Part D beneficiary is in the deductible phase, the cost-sharing faced by beneficiaries on competitive drugs that offer rebates is unlikely to be improved by passing along the discount.¹⁸ To this point, a large fraction of Part D beneficiaries have no deductible whatsoever (37% of PDP and 45% of MA-PD enrollees). Further, premium increases of this magnitude (a projected increase of 19% for 2020 alone) will likely result in reduced PDP and MA-PD enrollment and significant levels of plan switching.¹⁹ Reduced enrollment of lower-risk beneficiaries will lead to premium increases above the predicted levels for 2021, further reducing enrollment in these programs. The Department would be better served to consider policy approaches to bringing in more of the Medicare population to the Part D program, further spreading risk across all enrollees. This could take the form of late enrollment penalty amnesties, improvements to the Medicare Plan Finder shopping experience, or changes to the subsidy levels.²⁰

Regarding Medicaid managed care, because so few plans impose coinsurance-based cost-sharing (which must by law remain “nominal” in nature), this rule creates confusion for states, plans, and enrollees with no ascertainable benefit in Medicaid programming.

Federal expenditures will increase without providing benefits in excess of costs. While we describe later our specific concerns about the various economic impact analyses underlying this rule, the OACT conclusion of significant increases in federal spending is likely correct, even though it certainly understates true federal program expenditures. While HHS believes the rule would lead to a change in the composition of prescription drugs dispensed (e.g., more generics and low cost drugs replacing high cost, high rebate drugs), this supposition demonstrates a lack of understanding of the complicated regulatory system underlying the Part D program, which ensures that taxpayer funds are protected against plan sponsor cost projection errors. In Medicaid, making this change to managed care operations will have limited effect since, if states switch back to fee-for-service administration, the underlying incentives for low-cost drug dispensing under Medicaid Drug Rebate Program remains unchanged.

PCMA Recommendation: PCMA’s principal objection to this Proposed Rule is that it would not address the Department’s stated goals, and in fact, would reinforce the ability

¹⁷ See PCMA comments in response to the CMS CY 2019 Part C and D Proposed Rule.

¹⁸ Dusetzina SB, Bach PB. Prescription Drugs—List Price, Net Price, and the Rebate Caught in the Middle. JAMA. Published online March 06, 2019. doi:10.1001/jama.2019.2445

¹⁹ See for example <https://www.psmbrokerage.com/blog/new-report-deft-researchs-2019-medicare-shopping-and-switching-study>. An increase in MA switching for 2019, to its highest level since 2015, of 14%, due to the addition of new supplemental benefits and minor premium price changes. In the face of large premium price changes, we would expect switching rates to greatly exceed 14%, and potentially harm continuity of care models.

²⁰ See Lisa Gill, “The Complex Web of Prescription Drug Prices, Part II: Untangling the Web and Paths Forward.” March 7, 2019. Available at https://www.aging.senate.gov/imo/media/doc/SCA_Gill_3_7_19%20x.pdf.

of manufacturers to set list prices at high levels and increase their list prices to the detriment of beneficiaries and taxpayers.

2. The Proposed Rule places at risk the benefits generated by the Part D program thus far, without addressing its known flaws

The Part D program is successful, and the current systems in place have effectively countered repeated manufacturer list price increases through negotiated price concessions.

The Part D program is tremendously successful. Since its implementation in 2006, the Part D program has become one of the most successful instances of health insurance expansion. A recent independent survey confirms these estimates: 83% of seniors enrolled in Part D plans are satisfied with the program, finding that plans cover the drugs they need, are easy to use, provide sufficient pharmacy access, and protect them against high out-of-pocket costs.²¹ Further, the program continues to operate well under its initial projected costs. By 2012, Part D was costing the federal government less than half of what CBO initially projected for that year. That was not a one-year “blip:” from 2006 to 2011, the program cost half as much as projected in total.²² The Medicare Trustees projected spending level for 2020 finally matches the amount projected by CBO for 2012: \$112 billion.²³

If there is a gap in Part D’s performance, it is enrollment. In 2004, CBO projected that as many as 87% of Medicare enrollees would elect coverage under Part D. However, the actual enrollment for non-low income beneficiaries has seemingly topped out at about 70%. It is estimated that about half of the remaining 30% are enrolled in creditable coverage offered by their former or current employers, while the other half are not enrolled in drug coverage at all.

Premiums have remained relatively flat for several years as well, suggesting that premiums are still too high to convince these eligible-but-not-enrolled individuals to enroll. See Chart 1. Rather than a proposal that increases premiums, the Department should instead consider policies that would convince those unenrolled in drug coverage to join Part D, such as policies that would reduce premiums or increase benefits.

Part D works by forcing plans to compete with each other for enrollees. Part D emerged as a private sector solution to providing prescription drug coverage in an affordable way to seniors and the disabled. Congress chose this approach because other solutions would have had a negative effect on employers currently providing prescription drug coverage. Instead, Part D plan sponsors used existing business relationships to negotiate with pharmacies and manufacturers to craft the most competitive products they could, given the parameters

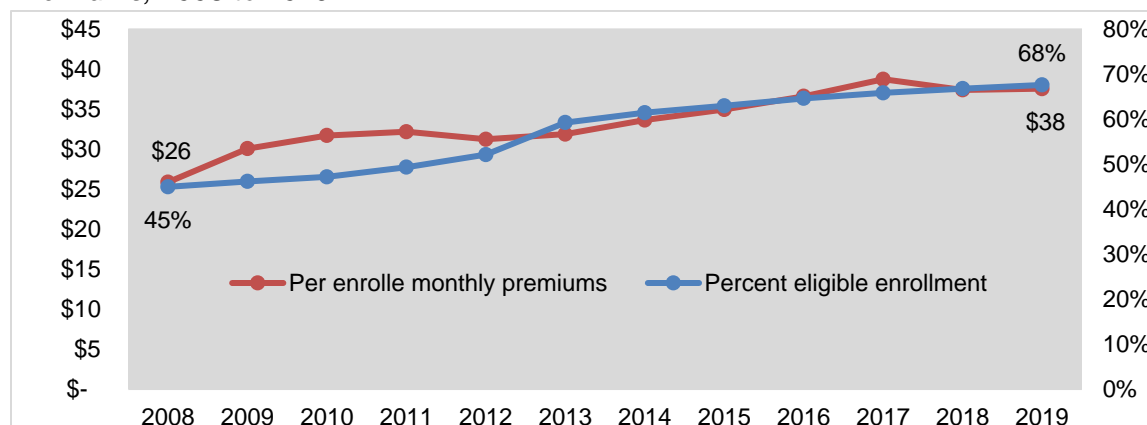
²¹ Northstar Research, available at <https://www.pcmagnet.org/wp-content/uploads/2019/03/NSO-PCMA-Senior-Part-D-Survey-Memo-March-6.pdf>.

²² Holtz-Eakin, Douglas and Robert Book. Competition and the Medicare Part D Program. Available at <https://www.americanactionforum.org/research/competition-and-the-medicare-part-d-program/>.

²³ Medicare Trustees Report, 2018. Table IV.B10.

established by the Congress and CMS. Within a few short years, these negotiations yielded a highly competitive marketplace where enrollees shopped for plans based on premiums.

Chart 1: Comparison of the Ratio of Eligible Part D Non-Low Income Enrollment to Monthly Premiums, 2008 to 2019.²⁴



The very intent of the Part D program was to allow for the private market to absorb millions of seniors into drug coverage, and use that leverage to negotiate better price concessions for drugs than seniors were paying at pharmacies. By instead requiring particular pricing structures or interfering with how negotiations must be conducted, the federal government would be intruding into the private market. Upon enactment, and in defending the law a few years later, members of Congress were clear about their intent. For example:

The competition in this bill achieves significant “bang for the buck” because it relies on drug plans to negotiate discounts. CBO says the private insurance model has a cost management factor of 25 percent—the effect of price discounts, rebates, utilization controls, and other tools that a PDP might use to control spending. By relying on the bargaining power of drug plans, this bill will drive down the costs of prescription drugs.²⁵

The Congressional record is full of similar quotes and entries, from 1999 when the first iteration of the eventual Part D program was proposed, to 2007 when repeal of non-interference was openly debated,²⁶ to today.

The rebate system existed prior to Part D. Statutory and regulatory safe harbors for prescription drug discounts and rebates were in place at the time of enactment and well understood by all actors as the program was being implemented. The OIG pharmaceutical manufacturer compliance guide, last revised in 2003, was a foundational document for

²⁴ Derived from Medicare Trustees Report, 2018, Tables IV.B9, IV.B10, and IV.C1.

²⁵ Senator William Frist, statement for the record to the U.S. Senate, November 24, 2003. Available at <https://www.congress.gov/congressional-record/2003/11/24/senate-section/article/S15670-2>.

²⁶ Senator Charles Grassley, statement for the record to Senate Finance Committee, January 9, 2007. Available at <https://www.finance.senate.gov/newsroom/ranking/senator-grassleys-floor-statement-on-the-history-of-the-medicare-part-d-non-interference-clause>.

manufacturers as they began to engage with possible Part D plan sponsors and PBMs. If the Department has significant concerns about the existing system then a more robust and deliberate approach is warranted, rather than a swift repeal of the foundational processes the entire system is based upon.

CMS has repeatedly declined to re-orient Part D's negotiated prices toward net prices. At the outset of the Part D program, it was not known to what extent Part D plans would pass along price concessions for specific drugs or use them to offset the cost of the benefit through premiums. In CMS's 2005 Part D Final Rule, the agency described a net-cost based benefit as its intention, in describing why it did not require sponsors to pass along a specific portion of discounts and rebates:

We believe that market competition will encourage Part D plans to pass through to enrollees a high percentage of the negotiated price concessions they obtain in the form of negotiated prices at the point of sale. ... Part D plans disclose to us aggregate negotiated price concessions that are passed through to enrollees and to us through lower subsidies, lower monthly premiums, and lower prices through pharmacies and other dispensers.²⁷

Both the passing through and use toward benefit costs were contemplated and expected, but neither approach was mandated.

A few years later, in its 2008 data sharing final rule, CMS specifically declared that price concessions not included in negotiated prices should not be shared publicly. In response to specific concerns raised by commenters about disclosing "competitively sensitive financial data regarding rebates, discounts or other negotiated price concessions," CMS wrote:

We share the commenters concerns about the need to protect the sensitive data under the Part D program. Because the Medicare drug benefit is based on a competitive business model, to release commercially or financially sensitive data to the public could negatively impact Part D sponsors' ability to negotiate for better prices, and ultimately affect the ability of sponsors to hold down prices for beneficiaries and taxpayers.²⁸

Apart from manufacturer rebates, in rulemaking for the 2015 plan year, CMS also declined finalize the inclusion of pharmacy price concessions in negotiated prices, due to the nature of such disclosures on competition among pharmacies.²⁹ A Request for Information (RFI) accompanying the 2019 Part D Proposed Rule sought comment on passing along manufacturer rebates at the point-of-sale.³⁰ While this RFI could have laid the groundwork for the current Proposed Rule, CMS did not propose any changes to the treatment of manufacturer rebates in

²⁷ 70 Fed. Reg. 4193, January 28, 2005, at 4244.

²⁸ 73 Fed. Reg. 30663, May 28, 2008, at 30668.

²⁹ 79 Fed. Reg. 29843, May 23, 2014.

³⁰ 82 Fed. Reg. 56336, November 28, 2017.

its 2020 Proposed Rule, but took a more limited step of seeking comments on whether applying only pharmacy DIR would have positive or negative effects.³¹

In each of these cases, CMS sought input on the costs and benefits and decided that the current model most appropriately balances premiums and cost-sharing. In fact, CMS each year praises the small increase in premiums, created by the current price concession regime.³² CMS's program favors low premiums. OIG in its limited enforcement role should not overrule the clearly stated preferences of another agency, or the market overall.

The Proposed Rule does not address the program's current most glaring concerns: the structure of the catastrophic benefit phase. A broad range of stakeholders have been calling for broader reforms of the Part D program for the last few years, mostly surrounding the catastrophic benefit phase, reinsurance, and addressing out-of-pocket spending for specialty drugs in this benefit phase.³³ As of 2014, aggregate federal reinsurance payments have exceeded direct subsidy payments to plans, despite the fact that fewer than 10 percent of Part D enrollees enter the catastrophic phase. The price of drugs (and the relatively low attachment point of the reinsurance phase) is driving increases in federal spending,³⁴ not manufacturer rebates negotiated by PBMs, as HHS seems to argue. However, this Proposed Rule and HHS overall, without statutory changes, cannot change levels of coverage within the catastrophic benefit. Despite the Proposed Rule many individuals with very high prescription drug costs will not see any savings.³⁵ Instead, under the Proposed Rule, beneficiaries taking very expensive drugs for which manufacturers do not offer rebates would be paying the same cost-sharing as today, plus higher premiums to access their Part D benefits.

PCMA Recommendation: PCMA opposes the Proposed Rule because changing the structure of the negotiations between plans and PBMs on one side, and manufacturers on the other, would upend the tremendous successes of the Part D program. Further, the rule is not aimed at the program's more pressing problems, which are driven by manufacturer pricing strategies.

³¹ 83 Fed. Reg. 62152, November 30, 2018.

³² See for example <https://www.cms.gov/newsroom/press-releases/medicare-part-d-premiums-continue-decline-2019>: "At a time when health insurance premiums are rising across-the-board, basic Part D premiums are expected to fall from \$33.59 this year to \$32.50 next year."

³³ See for example proposals from the American Action Forum (<https://www.americanactionforum.org/research/redesigning-medicare-part-d-realign-incentives-1/>), Medicare Payment Advisory Commission (original recommendations at <http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf>), and the Center for American Progress (<https://www.americanprogress.org/issues/healthcare/news/2019/01/29/465621/comprehensive-reform-lower-prescription-drug-prices/>), and descriptions of the rising costs of specialty drugs by Kaiser Family Foundation (<https://www.kff.org/report-section/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019-findings/>) and the Congressional Budget Office (<https://www.cbo.gov/publication/54964>).

³⁴ Antos, J and Capretta J. "Assessing The Effects Of A Rebate Rollback On Drug Prices And Spending." *Health Affairs Blog*. March 11, 2019. Available at <https://www.healthaffairs.org/doi/10.1377/hblog20190308.594251/full/>.

³⁵ Dusetzina SB, Bach PB. Prescription Drugs—List Price, Net Price, and the Rebate Caught in the Middle. *JAMA*. Published online March 06, 2019. doi:10.1001/jama.2019.244.

3. Such a fundamental change to the regulatory underpinning of the Part D and Medicaid managed care programs should have undergone a more deliberate process, in coordination with CMS

PCMA is concerned that this Proposed Rule was issued by OIG, without clear coordination with CMS's Medicare Part D and Medicaid managed care experts.

The OIG does not have subject matter expertise or direct jurisdiction over the Part D or Medicaid managed care programs. The OIG is delegated the authority by the Secretary to implement provisions of Title XI.³⁶ The Part D program and various Medicaid managed care programs are authorized under provisions of law wholly delegated to CMS. While CMS issues proposed rules on a regular basis regarding its Part D and Medicaid managed care programs,³⁷ OIG has not issued a proposed rule regarding the discount safe harbor since 2002, before the Part D program had even been enacted into law, let alone implemented.³⁸ While OIG has issued subregulatory documents related to this safe harbor since 2002, a regulatory process to update a regulation that has not been addressed for 17 years could have benefitted from stakeholder solicitations and public meetings, for example.

The Proposed Rule reads as if the subject matter experts at CMS were not engaged in developing this rule. There are numerous instances where basic input by CMS regulations is lacking. For example, HHS's cost estimates indicate a belief that Part D plan sponsors, wholesalers, and pharmacies can respond immediately to the proposed changes, and implement a new chargeback system without contemplating how such a system would be operationalized. In Section VI, we lay out many of the complex Part D regulatory and sub-regulatory matters that are implicated by the changes proposed by OIG, which are not discussed and thus could not be finalized under this process without further engagement and significant investment of time by CMS. On the Medicaid side, the Proposed Rule's effects on AMP and the Medicaid Drug Rebate Program are minimized, without acknowledging the complex and interconnected roles that government price reporting programs and mandatory rebates play on manufacturers and plan sponsors.

Major changes to the Part D and Medicaid managed care programs should involve CMS. We disagree with the Proposed Rule's changes to the regulatory safe harbors altogether. However, to the extent that a major regulatory change is being contemplated for the Part D and Medicaid managed care programs, it should occur jointly with the agency in charge of these programs. Layering this Proposed Rule on top of the existing and forthcoming new Part D rules for 2020 adds complexities not considered in the recent Medicare and Medicaid rules.

³⁶ See 81 Fed. Reg. 13807, March 15, 2016, which states that the Office of Counsel to the Inspector General "solicits and responds to proposals for new regulatory safe harbors to the Anti-Kickback Statute, modifications to existing safe harbors, and new fraud alerts."

³⁷ CMS has issued two Medicaid managed care proposed rules since 2011 and at least six proposed rules regarding Part D. This does not count the innumerable subregulatory documents, issued regularly to regulated entities.

³⁸ 67 Fed. Reg. 11928, March 18, 2002, according to the regulatory history recited at 84 Fed. Reg. 2345-6, February 6, 2019.

Instead, OIG should have partnered with CMS to discuss whether these proposed changes are sensible. This is the approach OIG and other agencies have taken in the past, including with respect to:

- **Medicare Shared Savings Program (MSSP), 2011-2013.** Several agencies cooperated to issue proposed and final rulemaking and necessary subregulatory issuances to stand up the Medicare Accountable Care Organization (ACO) program. The Federal Trade Commission (FTC), U.S. Department of Justice (DOJ), CMS, and OIG all weighed in related to AKS and self-referral provisions and waivers.³⁹ To the extent that an OIG enforcement authority was implicated in the newly-designed ACOs, OIG partnered with CMS to align positions and update regulatory standards through a public process including workshops and several Proposed and Final Rules.
- **CMS and the Office of National Coordinator for Health IT (ONC) proposed rule regarding interoperability (2019).** Just this year, CMS and ONC issued coordinated proposed rules seeking to update the standards related to electronic health record interoperability.⁴⁰ In conjunction with these proposed rules, both agencies have participated in public forums discussing their proposed rules, in order to explain benefits to consumers and engage affected stakeholders.⁴¹
- **Health reform regulations (2017-present).** This Administration has made an effort to reduce the regulatory burden of the ACA, and as a result, several agencies (EBSA, IRS, and CMS) have issued joint rulemaking affecting the individual and small group employer markets. See for example the 2018 rule on short-term limited duration plans.⁴²

The Proposed Rule does not take into account the programs under consideration by the Center for Medicare & Medicaid Innovation (CMMI). Manufacturers and plan sponsors have been working with CMMI staff for the last several years on demonstration programs including those related to value-based insurance design, value-based contracts, and reinsurance redesign. Specifically for value-based contracts, stakeholders have been working toward additional certainty on what authorities CMMI could consider waiving to accomplish program goals. However, because the Proposed Rule does not create specific safe harbor exceptions for ongoing work on these programs, it may have a chilling effect on manufacturer and plan sponsor participation in these discussions with CMMI.

These changes would have more far-reaching implications in the private sector than is explained or quantified in the Proposed Rule. HHS notes in the Proposed Rule that the safe harbors (and any revisions to them) would apply to federal health care programs. In this case, they would apply only to Medicare Part D and Medicaid managed care plans and PBMs acting

³⁹ See OIG <https://oig.hhs.gov/compliance/accountable-care-organizations/index.asp>

⁴⁰ See 84 Fed. Reg. 7424, March 4, 2019 and 84 Fed. Reg. 7610, March 4, 2019.

⁴¹ See for example <https://www.healthdataanswers.net/author/cms-onc-communication/>.

⁴² See 83 Fed. Reg. 38212, August 3, 2018.

on their behalf. However, HHS also notes that any rebate arrangement outside of federal health care programs that “explicitly or implicitly” ties commercial rebates to formulary placement across a plan sponsor’s products in these federal health care programs may not be protected by existing or revised safe harbors (at 84 Fed. Reg. 2347). This statement may have a chilling effect on the negotiations entered into by private health insurance plans purchased by employers or individuals.

Employers who offer health insurance typically employ PBMs to negotiate with manufacturers and create and administer their prescription drug benefits. In fact, this is true of pharmaceutical manufacturers as employers, as well.⁴³ The same kinds of rebates or discounts that can be negotiated in Part D are negotiated on behalf of employers. The difference is that when PBMs pass through the rebates they collect, employers have complete flexibility as to how the revenues are applied to the benefit. Some employers may choose to use the rebate dollars to offset overall premiums. Some may use them to offset cost-sharing for drugs specifically (e.g. point-of-sale rebates). This Proposed Rule interferes with an employer’s choice in how it uses rebates (or up-front discounts) negotiated by their contracted PBMs. Rather than dictating how contractual arrangements should be shaped, HHS should be learning from the private sector, and seeking its input on how to apply emerging best practices to government programs.⁴⁴

If finalized, one obvious consequence to this rule regarding the private health insurance market, which is not fully fleshed out in the economic analysis (see Section V), is that if manufacturers behave as OACT’s assumes and net costs rise, total health care spending outside of federal health care programs will also rise. With a rise in drug list prices, and to counter these increased costs, employers may change plan offerings specifically around prescription drugs, to the detriment of the 160 million covered lives. This would cause significant harm to an entire population that is not the subject of this rule at all.

The Proposed Rule would also have effects on the financial operations of numerous stakeholders in the private sector, which are not described or quantified by HHS. For example, pharmacies are at risk of major financial disruption. Under current practice, pharmacies are not at risk for higher or lower rebates, or rejected rebates, between PBMs and manufacturers. They purchase from wholesalers and are reimbursed based on list price models by PBMs or plan sponsors. As described by an investment analyst: “the rebate system keeps the supply side of the chain undisturbed while allowing for negotiated discounts on the PBM/payer side.”⁴⁵ Under a hypothesized chargeback model, there could be a significant lapse in time between the pharmacy dispensing of a drug (which was purchased at or near list price) and pharmacy

⁴³ Bob Herman, “Pharma companies hire drug pricing middlemen, too.” *Axios*. March 7, 2019. Accessible at <https://www.axios.com/pharmaceutical-companies-hire-pbms-too-7ed75232-8cf5-415d-a48f-0f587d10f18e.html>.

⁴⁴ See for example the range of options offered by Mercer, a benefits consultant: <https://www.mercer.us/our-thinking/healthcare/point-of-sale-drug-rebates.html>, and recent announcements by OptumRx to pass through rebates at the point-of-sale to clients, at <https://www.forbes.com/sites/brucejapsen/2019/03/12/unitedhealth-and-optumrx-to-pass-drug-maker-rebates-to-more-clients/>.

⁴⁵ The Marwood Group, Drug Pricing: Déjà Vu All Over Again; Pharmacies May Again be at the Center of the Discount Discussion, March 18, 2019.

receipt of the chargeback portion of the reimbursement for the dispensed drug. Under this scenario, the layering of a wholesaler chargeback could create a “mismatch in timing [that] could make it difficult for pharmacies to track, creating uncertainty and a sense that the system is not becoming any more transparent from their perspective.”⁴⁶ The complexity of such a system also raises important operational and Privacy Rule questions about wholesaler access to personally identifiable health information in order to process these transactions.⁴⁷

An additional issue, not contemplated by HHS in the Proposed Rule, is how such a chargeback system could be operationalized under current law and regulation. The current pharmacy transaction and claims processing system has evolved with the Part D program and in step with the rise of electronic prescribing platforms. PBM’s systems are interoperable with those of major health care systems and most pharmacies. Considerable development and careful consideration of parameters has gone into such a system, which allows for the confidential sharing of personally-identifiable health information, to facilitate claims processing. The costs of this are already built into the existing system. Any new system will require significant development costs, and HHS should expect that to be accompanied either by new fees in the marketplace to offset them, or retained up-front discounts, for example.

PCMA Recommendation: PCMA further opposes this Proposed Rule because HHS demonstrates a lack of understanding of the retail prescription drug and insurance markets. In proposing changes to the safe harbors that would be applicable to the Part D or Medicaid managed care programs, OIG should have engaged HHS’s subject matter experts (CMS) in a deliberative rulemaking process. This Proposed Rule will lead to significant unintended consequences on the private market, not well described or accounted for by HHS.

⁴⁶ *Ibid.*

⁴⁷ See for example Avalere Health, “Drug Rebate Proposal Fundamentally Changes Current System, Raises Critical Questions.” February 11, 2019. Available at <https://avalere.com/insights/drug-rebate-proposal-fundamentally-changes-current-system-raises-critical-questions>. See also the significant discussion on data sharing with MA-PDs and PDPs in the original Part D program Proposed Rule, 69 Fed. Reg. 46631, August 3, 2004. Specifically, Part D plans became HIPAA covered entities by virtue of providing drug coverage. Wholesalers may become business associates of pharmacies or Part D plans in order to process chargeback transactions, but standards for such a relationship and the minimum data sets needed to accomplish their tasks would need to be promulgated.

Section II. Value-Based Arrangements: The Proposed Rule Upends Ongoing Efforts to Transform the Health Care System

The Secretary has declared that “value-based transformation of our entire healthcare system is a top HHS priority.”⁴⁸ Great strides are indeed being made in this regard. As of the middle of 2018, there were at least 40 value-based contracts underway between commercial or public payers and drug manufacturers.⁴⁹ Commercially insured patients in health plans with value-based contracts for diabetes, high cholesterol and HIV medicines had copays that were, on average, 28 percent lower for those medicines compared to patients in other plans.⁵⁰ In the context of the CMMI Medicare Advantage Value Based Insurance Design (VBID) demonstration, many participating organizations chose prescription drug-based interventions, showing there is great appetite for value-based arrangements (VBAs) when all parties are adequately protected from risk.⁵¹

In the Proposed Rule, HHS notes: “The Department does not intend for this proposal to have any effect on existing protections for value-based arrangements between manufacturers and plan sponsors under Medicare Part D and Medicaid MCOs.” However, under this Proposed Rule, the implementation of any VBAs in Part D and Medicaid managed care will be nearly impossible, outside of narrowly-prescribed, government-backed initiatives such as those under CMMI. We urge HHS to consider the negative effects on value-based transformation that this Proposed Rule will have. Namely, without a regulatory definition for VBAs and safe harbor protection for these arrangements going forward, the returns for value-based transformation will remain underwhelming (and may, in fact, decline).

PCMA offers several recommendations in this section. First, we recommend that HHS define VBAs and protect them with a new safe harbor to encompass the meaningful and important work occurring in the marketplace outside of government initiatives. Second, HHS should recognize the role of PBMs and their activities in generating value from prescription drugs, including recognizing the role of retrospective price concessions (rebates) in delivering value to payers, generally and in terms of VBAs. Third, HHS should consider alternative approaches, which must be included in any Final Rule, and which would protect the gains that have been made on behalf of beneficiaries and taxpayers.

⁴⁸ 83 Fed. Reg. 22696, May 16, 2018.

⁴⁹ See PhRMA, “VALUE-BASED CONTRACTS: 2009 – Q2 2018,” June 2018. Available at http://phrma-docs.phrma.org/files/dmfile/PhRMA_ValueBasedContracts_Q2.pdf.

⁵⁰ See PhRMA, “Value-Based Contracts May Lower Patients’ Out-of-Pocket Costs by 28 Percent,” February 2018. Available at <https://www.phrma.org/press-release/value-based-contracts-may-lower-patients-out-of-pocket-costs-by-28-percent>

⁵¹ See first year evaluation report and summary slides here: <https://innovation.cms.gov/initiatives/VBID>.

1. HHS should provide a regulatory definition and a new safe harbor for value-based arrangements

This Administration has made clear its intent to encourage VBAs.⁵² Outside stakeholders, including PCMA, have provided numerous supportive public comments to encourage this movement.⁵³ However, the interested parties continue to wait, and now, by contrast, are addressing a Proposed Rule that would significantly curtail a tool (rebates) that has proven to be essential in promoting and recognizing value.

In the Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (the 2018 Blueprint), which is the acknowledged cornerstone of the Administration's efforts in this arena, HHS devoted substantial time to extolling the virtue of VBAs and proposing policies that would achieve greater uptake of these arrangements. For example, HHS sought feedback on various price reporting mechanisms that might be impeding VBAs, and specifically sought feedback on which regulations needed to be revised.

However, the 2018 Blueprint is the second time in recent memory that PCMA offered the same set of recommendations regarding approaches to encourage VBAs, without any movement on a regulatory change. OIG itself sought input on this question in August 2018.⁵⁴ We recognize that regulatory efforts take time, and that HHS may in the future create a safe harbor to protect VBAs. However, eliminating current discount safe harbor protection for rebates *prior* to establishing such safe harbor protection, risks stifling the growth of VBAs, directly counter to the Administration's goal to advance such efforts.

As HHS has previously recognized:

[V]alue-based pricing for pharmaceuticals involves linking payment for a medicine to patient outcomes, quality performance and cost-effectiveness rather than solely the volume of sales. The market today uses the term value-based to encompass a wide variety of different options designed to improve clinical results, quality of care provided, and reduce costs.⁵⁵

As part of an initiative to develop a definition of VBA, we further recommend that HHS define VBAs as involving only risk-bearing entities, where the contract's endpoints include both positive

⁵² See 83 Fed. Reg. 22,696, May 16, 2018. ("Value-based transformation of our entire healthcare system is a top HHS priority"). See also "Remarks on Value-Based Transformation to the Federation of American Hospitals," Alex Azar (March 5, 2018) ("Upon taking office at HHS, I identified using the value-based transformation of our entire healthcare system as one of the top four priorities for our department.")

⁵³ See for example: PhRMA, available at <http://phrma-docs.phrma.org/download.cfm?objectid=9583A320-8919-11E8-8DCF0050569A4B6C>. AHIP, available at <https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Letter-to-Secretary-Azar-and-Detailed-Comments-RE-FR-Doc.-201810435-HHS-Blueprint-to-Lower-Drug-Prices-and-Reduce-Out-of-Pocket-Costs-FIN.pdf>.

⁵⁴ 83 Fed. Reg. 43,607 (August 27, 2018).

⁵⁵ 81 Fed. Reg. 13,230 (March 11, 2016).

and negative outcomes, and where entities should face both upside and downside risk.⁵⁶ Alternatively, HHS could direct CMS to allow for VBAs in the Part D program by redefining categories of Direct and Indirect Remuneration (DIR) to include specifically only those kinds of rebates that cannot be known in advance. This approach has the downside of not being applicable to Medicaid managed care programs, but can potentially be operationalized without rulemaking. It could be considered as an interim option.

PCMA Recommendation: HHS should pursue regulatory changes that yield a common definition of VBAs and a new safe harbor to specifically protect VBA participants.

2. HHS should recognize the role of PBMs and their activities in generating value from prescription drugs

As PCMA has detailed in previous comments to the Department,⁵⁷ as well as in Section I, PBMs are major facilitators of value in the current drug supply chain. Through rebates paid under forward-looking contracting arrangements, PBMs continue to be at the forefront of innovation in promoting VBAs. Under the current discount safe harbor, protection for PBM-administered rebates means that plan sponsors and their contracted PBMs are capable of recognizing value, retrospectively, by paying rebates based on defined outcomes, or other endpoints. As proposed, the rule would significantly curtail PBM flexibility in administering rebates and, as such, restrict the use of and growth of VBAs. If finalized, the rule would appear to implicate most outcomes-based payment arrangements given that they are not (1) a flat fee paid to a PBM; nor (2) passed through at the point-of-sale. We argue against this proposal's absence of an exclusion for VBAs below.

With rebates, PBMs can adjudicate the value of a drug once sufficient data has been collected. At their most basic level, rebates are negotiation tools capable of recognizing and rewarding value provided in a transaction. Unlike pricing discounts, which are upfront, rebates are paid after a drug has been dispensed. Applying the price concession after the fact, rather than up-front, is critical. Regardless of the type of VBA under consideration, retrospective payments or price concessions (e.g., rebates) play a central role in the ability to vary payment based on the value provided. Contract performance can only be known for certain after a period's worth of transactions have taken place; whereas it can only be estimated – and much more conservatively, at that – if paid up-front.

There are additional opportunities for plans and their PBMs to go further in using rebates to enhance value. For example, a drug could be placed on a formulary for only the specific indications for which it is most effective. Indeed, CMS has taken a step in this direction for Part

⁵⁶ See PCMA's extensive comments on AKS safe harbors, RE: Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP (OIG-0803-N), filed October 23, 2018. These comments include specific statutory and regulatory language revisions that would incorporate these conditions.

⁵⁷ *Ibid.*

D for 2020 as set forth in its HPMS guidance issued on August 29, 2018.⁵⁸ Alternatively, a drug could be included on a formulary for all approved indications, but a manufacturer would be required to pay a higher rebate when the drug is used for an indication for which it is proven to be less effective or beneficial. Another option would be that the manufacturer of a less effective drug could be required to offer more price concessions in order to have it included on the formulary. Manufacturers of more effective drugs for the same indications may also be required to provide more favorable pricing and rebates in return for preferred formulary placement. Utilizing these strategies can help to deliver the most cost-effective pricing per drug, and per condition and greater price concessions for all drugs within a category.

Rebates are an expected and necessary component of VBAs. PCMA is not alone in recommending that the protection of rebates to promote VBAs is critical. Academicians,⁵⁹ drug manufacturers,⁶⁰ and health insurers generally understand that retrospective rebates are critical tools to promote value. For example, according to AHIP:

Limits on the use of rebates could inhibit efforts to encourage value-based arrangements, which typically require retroactive pricing adjustments based on the collection of data for and calculation of agreed-upon quality metrics. In addition to inhibiting value-based arrangements, preventing retroactive payments would severely limit a plan's ability to incentivize better pharmacy performance through payment-based quality improvement programs⁶¹

As noted throughout these comments, PBMs can be powerful partners to help HHS achieve its goal of value-based transformation. Unfortunately the net effect of the Proposed Rule is to largely eliminate retrospective rebates in the existing drug supply chain. This further uncertainty compounds the net effect of the Proposed Rule, which is to undermine and indeed move away from current value-based efforts.

PCMA Recommendation: HHS should not finalize a rule change that fails to acknowledge the role that rebate-like payments can have in VBAs.

⁵⁸ HPMS Memo, "Indication-Based Formulary Design Beginning in Contract Year (CY) 2020." August 29, 2018. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2018-Aug-29th.pdf>.

⁵⁹ See for example: "Overcoming the Legal and Regulatory Hurdles to Value-Based Payment Arrangements for Medical Products," Duke Margolis Center for Health Policy (December 2017), available at https://healthpolicy.duke.edu/sites/default/files/atoms/files/overcoming_legal_and_regulatory_hurdles_to_value-based_payment_arrangements_for_medical_products.pdf.

⁶⁰ See for example: PhRMA, available at <http://phrma-docs.phrma.org/download.cfm?objectid=9583A320-8919-11E8-8DCF0050569A4B6C>.

⁶¹ See AHIP's comments in response to the Blueprint here: <https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Letter-to-Secretary-Azar-and-Detailed-Comments-RE-FR-Doc.-201810435-HHS-Blueprint-to-Lower-Drug-Prices-and-Reduce-Out-of-Pocket-Costs-FIN.pdf>

3. The Proposed Rule could have a chilling effect on formulary negotiations

In the Proposed Rule, HHS appears to take a contradictory position. On the one hand, HHS states that it does not intend to impact existing VBAs but, at the same time, alludes to the fact that formulary-based rebates may currently be impermissible, in a footnote.⁶² (See Sections VIII and IX for PCMA's legal analysis of these claims.) We believe that any effort to encourage VBAs must recognize that formularies by definition are value-based. Formularies were one of the earliest forms of VB payment that continue to be used to the benefit of patients and plan sponsors today. The primary purpose of a formulary is to encourage patients and prescribers to choose safe, effective, and affordable medications. The use of drug formularies enables payers, prescribers, and PBMs to promote clinically sound, cost-effective medication therapy options and positive therapeutic outcomes. To create and manage formularies, payers and PBMs rely on independent panels of experts called Pharmacy and Therapeutics (P&T) Committees. These committees, largely made up of physicians, pharmacists, and other health care professionals, evaluate the latest and most authoritative clinical and medical literature and other evidence to select the most appropriate medications for individual disease states.

Formularies provide value to patients, prescribers, and pharmacies. Among other benefits, formularies ensure that the most effective and safest products are used after the medications have been evaluated systematically. Further, formularies enable plans to provide pharmaceutical therapy at lower cost by ensuring that ineffective, high-cost or high-risk drugs will generally not be prescribed.

A number of evidence-based and time-tested VBA and cost-saving elements are factored into formulary design, such as prior authorization, formulary tiers and step therapy, to encourage the most clinically appropriate and economically sound therapies. The effective use of formularies can minimize overall medical costs, improve patient access to more affordable care, and provide patients with an improved quality of life.

PCMA Recommendation: HHS should not finalize a rule change that calls into question the value or legal permissibility of formulary-based rebates, which have provided significant savings to enrollees, payers, and taxpayers without raising risks.

4. Without rebates available as a method of payment, fewer VBAs will be negotiated

As we have noted, the Proposed Rule comes at a time when HHS has identified “value-based transformation” as one of its top priorities. In the preamble, HHS writes that the rule is not intended to undermine existing value-based arrangements – yet by its plain language, would subject any VBAs that rely on rebates to anti-kickback statute scrutiny. Although HHS states that it does not “intend” the proposed safe harbor regulations to impact existing VBAs, by removing safe harbor protection for most rebate arrangements, and by failing to establish a new

⁶² 84 Fed. Reg. 2,340 (February 6, 2019).

safe harbor explicitly protecting VBAs, most arrangements that currently rely on rebates would need to be either significantly restructured or terminated.

VBAs work best when rebates are the incentive used to drive performance. Given the critical role that rebates play as a tool, in rewarding “value” in innovative contracting arrangements, PCMA believes that the rule would have a chilling effect on existing VBAs and would curtail formation of such arrangements in the future. Consider, by way of example, an arrangement in which a manufacturer agrees to provide a payer with a 20% discount off a drug’s list price, which is fully passed on to plan enrollees at the point-of-sale. Consider also that because the product’s real-world performance is uncertain, the manufacturer agrees to an additional 30% rebate if the drug does not achieve certain measures of outcomes, adherence. If the Proposed Rule is finalized as it is currently written, it appears that the second 30% rebate would not warrant protection under the discount safe harbor.

In line with the Administration’s ongoing effort to promote VBAs, arrangements such as the one discussed and other rebate-like models referenced above are now increasingly common. Yet, whether intentional or not, HHS now proposes to severely restrict such arrangements. Under the Proposed Rule, there are no mechanisms to operationalize a VBA without a retrospective reconciliation of some kind, that doesn’t put all of the financial risk on the payer.

The Proposed Rule would be problematic for current innovation in contracting for state Medicaid programs. We are also concerned about the Proposed Rule’s potential impact on Medicaid supplemental rebates. HHS seeks comment as to whether state supplemental rebates should continue to remain protected from scrutiny. This is a troublesome direction, given that the Administration has signaled specifically to states that supplemental rebates are a valid path forward for VBAs. This is particularly true given that supplemental rebates are not “required by law” in the same way the mandatory minimum rebates are required by section 1927(c) of the Social Security Act. For example, CMS has recently approved State Plan Amendments for value-based contracting models in Colorado, Michigan, and Oklahoma to allow these states to align supplemental rebates with clinical outcomes and value.⁶³ With these approvals, CMS has committed to giving states the flexibility they need to improve patient care and make healthcare more affordable and better aligned with value, by allowing these states to implement supplemental rebate agreements involving VBAs. The Proposed Rule, if finalized, calls into question whether these three approved arrangements can move forward without placing these arrangements at risk of violating the safe harbor.

In addition to the three states noted above, other states are seeking subscription-based contracts with manufacturers, whereby the manufacturer would guarantee a fixed purchase price for a contracted period of time from a large volume payer. Louisiana just announced this kind of agreement with a subsidiary of Gilead, for the treatment of Hepatitis C-infected Medicaid

⁶³ See Oklahoma (<https://www.cms.gov/newsroom/press-releases/cms-approves-state-proposal-advance-specific-medicaid-value-based-arrangements-drug-makers>), Michigan (<http://www.medicaidandthelaw.com/2018/11/15/cms-approves-michigans-state-plan-amendment/>), and Colorado (<https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/CO/CO-18-0044.pdf>).

enrollees.⁶⁴ Under the Louisiana model, for Medicaid-enrolled populations, the manufacturer would sell an unlimited quantity of the selected drug, and would operationalize the fixed purchase price by providing supplemental rebates over the contract period. For incarcerated populations, the manufacturer would operationalize the fixed purchase price through sub-ceiling discounts offered under the 340B Drug Discount program. On the Medicaid side, would the arrangement violate the new safe harbor if the rule is finalized, because a supplemental rebate payment may be made to Louisiana after the fact?

Moreover, while Part D price concessions are generally excluded from Medicaid Best Price determinations, any rebates negotiated by Medicaid managed care plans are not. Given the size of mandatory rebates under Medicaid, these plans are already at a significant disadvantage to create VBAs. (Manufacturers are unlikely to seek arrangements that impact Best Price or drive per-unit prices any lower.) This rule does not create a pathway for greater Medicaid managed care involvement in VBAs, which should be addressed going forward.

PCMA Recommendation: HHS should not finalize a rule change that disadvantages rebate-like incentives under VBAs. Further, any regulation to define and protect VBAs needs to account for the groundbreaking work conducted by state Medicaid agencies on behalf of their populations.

⁶⁴ See the announcement of Louisiana's contract with Asegua Therapeutics LLC (a subsidiary of Gilead Sciences, Inc.) here: <http://ldh.la.gov/index.cfm/newsroom/detail/5097>.

Section III. Transparency: The Proposed Rule's Effects on Transparency Would Place at Risk the Functioning of the Pharmaceutical Market

In the preamble to the Proposed Rule, HHS argues that the current rebate system is not transparent, and as such, impedes compliance and oversight efforts. In part, HHS notes that Part D and Medicaid managed care plans may have “limited information” about the percentage of rebates retained by PBMs; that the terms of rebate agreements with manufacturers may be unavailable to them; and, as such, that this “creates a potential program integrity vulnerability because compliance with program rules may be more difficult to verify.”⁶⁵ HHS seeks specific feedback on “possible negative or positive effects on pricing or competition that could result from an increase in transparency under the proposed point-of-sale discount safe harbor.” In issuing this Proposed Rule, HHS states its main objectives to be reducing the list price of drugs, reducing beneficiary out-of-pocket payments, and reducing federal spending.⁶⁶ HHS also argues that transparency is one of the two main benefits the rule would produce.⁶⁷ We discuss our detailed concerns over the HHS cost-benefit analysis’s methodology and results elsewhere (see Section V). In this Section, we describe why HHS’s focus on transparency as a goal will undercut its pursuit of lower list prices and reduced federal spending, and hamper the private sector actors that keep drug prices, costs, and spending in check to perform these roles.

At the outset, PCMA notes that it is generally supportive of efforts to bring transparency to consumers. Appropriate expansions of transparency may encourage consumers to shop for coverage that best fits their health needs and pocketbook, and once covered, use the most cost-effective, highest-value health care goods and services. Consumers should have real-time access to information on premiums, cost sharing, and benefits for their prescription drug coverage. However, mandating public disclosure of sensitive pricing information negotiated between PBMs and drug manufacturers or pharmacies would allow tacit collusion and lead to higher drug costs.

In the discussion below, we detail how the Proposed Rule may create more transparency than is appropriate for a functioning market. These unnecessary disclosures will harm the negotiations between PBMs and drug manufacturers. As a direct result, the Proposed Rule will have a negative effect on pharmaceutical pricing (net costs will rise) and introduce unnecessary interactions and complications in the market. Finally, we point out why this Proposed Rule’s intent on increasing transparency has no bearing on Medicaid managed care plans.

⁶⁵ These issues were initially raised by OIG in its report, “Concerns with Rebates in the Medicare Part D Program (2011)” (OEI-02-08-00050). CMS did not concur with most of OIG’s recommendations. The Bid Pricing Tool and DIR Reconciliation Reporting process have both matured in the 8 years since this report was published.

⁶⁶ See 84 Fed. Reg. 2343-2344, February 6, 2019.

⁶⁷ See 84 Fed. Reg. 2355, February 6, 2019.

1. The Proposed Rule oversimplifies the pharmaceutical marketplace, leading to misguided conclusions

In issuing this Proposed Rule, HHS does not demonstrate an understanding of the role of PBMs, the flexibility they provide in the marketplace, or the guardrails in place today to ensure that incentives are appropriately aligned.

PBM business models are about more than rebates. The Proposed Rule does not describe the breadth of services offered by PBMs or how PBMs operate. PBMs offer their contracted health plan clients many options for managing drug costs and coverage. For example, PBMs may process claims, negotiate discounts with manufacturers, negotiate prices with pharmacies, manage formularies, and operate mail-order and specialty pharmacies. Beyond transactional support, PBMs may also perform drug utilization reviews, operate disease management programs, or provide adherence and patient clinical support programs. PBM compensation for these services may range from fee-based payments based on volume, to contingency-based payments, whereby PBMs may be paid based on a percent of the savings they are able to negotiate, or a combination of these approaches, depending on the specific service provided.

Increasingly, health plans are seeking "transparent" PBM contracts. Many large employers now pull through at least some of the value of negotiated rebates to reduce the costs that enrollees paid at the pharmacy counter. Many are considering similar moves.⁶⁸ These arrangements help payers and enrollees become educated about the impact of their decisions, and make sure that their goals are aligned with those of their vendors. As has been publicly announced, PBMs are open to these arrangements, and are offering them today.⁶⁹ Additionally, PBMs offer the plans with which they contract the right to regularly audit contracts, to ensure compliance with the law and the contract terms. PBMs are selected by employers to manage drug benefits because the services they offer are worth the prices that employers pay for them. In fact, pharmaceutical manufacturers themselves hire PBMs to administer drug benefits for their own employees,⁷⁰ and almost none provide for rebates to be passed through at the point-of-sale.

Existing guardrails already protect Medicare and Medicaid beneficiaries and taxpayers. Inherent in the preamble discussion is a clear belief on behalf of the Secretary that PBMs, as contractors to Part D and managed Medicaid plan sponsors, are able to extract significant profit from the drug supply chain in a way that is either opaque or not otherwise accounted for in existing price reporting mechanisms. While others have also raised similar, unsubstantiated

⁶⁸ See for example, National Business Group on Health, Large Employer 2019 Health Care Strategy and Plan Design Survey.

⁶⁹ See Cigna's Express Scripts unit's statement here: <http://lab.express-scripts.com/lab/insights/industry-updates/lets-talk-about-rebates>, UnitedHealthgroup's OptumRx unit's statement here: <https://www.unitedhealthgroup.com/newsroom/2019/2019-03-12-prescription-drug-program-expands-to-benefit-consumers-point-of-sale.html>, and CVS Caremark's statement here: <https://cvshealth.com/newsroom/press-releases/cvs-health-introduces-new-approach-pricing-pharmacy-benefit-management>, as just a few examples.

⁷⁰ See Bob Herman, "Pharma companies hire drug pricing middlemen, too." Available at <https://www.axios.com/pharmaceutical-companies-hire-pbms-too-7ed75232-8cf5-415d-a48f-0f587d10f18e.html>.

concerns,⁷¹ independent analyses confirm that PBM models are in fact transparent and serve the interests of their plan and employer clients.⁷²

Congress and CMS have put multiple mechanisms in place to dutifully align the incentives for Part D plans and their PBMs to advocate for the lowest net costs. It is thus unreasonable for HHS to argue that prohibiting all remuneration between PBMs and manufacturers outside of a new safe harbor is necessary to curb such behaviors. Some of the many other programmatic features that limit Part D plan sponsor and PBM profits are included in Table 2 below.

Taken as a whole, the competitive structure and these many safeguards in Part D legislation, regulation, and guidance provide an airtight seal against profiteering in the Part D program and therefore obviate the need to micromanage the contracting relationships among plan sponsors, PBMs, and manufacturers. Not only that, but exposing the details of these arrangements, while having no obvious benefits and standing in direct violation of the Part D noninterference clause at SSA §1860D-11(i)(1), would cause harm elsewhere.

PCMA Recommendation: HHS should not require specific disclosures of contracts to outside parties or HHS.

2. The Proposed Rule fails to consider the negative impact of too much cost transparency on overall net drug costs

HHS intends for manufacturers to reduce their list prices and curb list price increases on existing drugs as a result of the Proposed Rule, because of the transparency it will bring to the market. However, both economic theory and real-world evidence points to manufacturers making use of heightened transparency to reset their pricing strategies, withhold price concessions from PBMs and plans, and more likely increase their list prices.

The creators of the Part D program wrestled with many of the same questions about the appropriate balance between transparency and the proprietary nature of contract negotiations. Those debates landed on today's Part D program, after significant contemplation of potential positive and negative consequences regarding further price concession disclosures. We find instructive the considerable thought given to the dangers of certain types of transparency by CMS, in its 2008 Part D Data Sharing Final Rule:

Comment: Several commenters expressed concern about access to cost and pricing data. Several commenters noted that pricing data contained on the Part D claim are not an accurate reflection of

⁷¹ See for example Dr. Gerard Anderson, Testimony to the Senate Finance Committee. January 2019. Available at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Dr.%20Gerard%20F.%20Anderson-Testimony%20re.%201-29%20FC%20Hearing.pdf>.

⁷² See Pew Charitable Trusts, *The Prescription Drug Landscape, Explored*: A look at retail pharmaceutical spending from 2012 to 2016. March 2019. Available at https://www.pewtrusts.org/-/media/assets/2019/03/the_prescription_drug_landscape-explored.pdf.

Table 2. Medicare Part D Plan and PBM-Related Financial Safeguards.

Safeguard	Description
<u>Risk Adjustment</u>	Plan profitability is affected by the direct subsidy, which is a risk-adjusted, capitated payment. Drug-level plan liability before risk adjustment may not be fully indicative of a plan's actual profit or loss for members taking a particular drug.
<u>Risk Corridors</u>	Plan sponsors participate in the risk corridor program, which is a risk-sharing arrangement with CMS where a portion of gains or losses are shared with CMS. Unexpected windfalls that exceed 5% from a filed bid target amount, including higher-than-anticipated rebates, must be shared with CMS.
<u>Medical Loss Ratio (MLR) Rebates</u>	Part D plan sponsors that do not meet the 85% MLR requirements must remit funds back to CMS. This limits the amount of administrative spending and profit that a plan can include in their bids. ⁷³
<u>Reconciliation</u>	Part D subsidies, such as federal reinsurance, are reconciled after the end of the plan year using actual expense and revenue items. There is no opportunity for plan sponsors to systematically underbid or overbid without the dollars making their way back to the Part D program, and constraining the plan's future projections.
<u>Prescription Drug Plan Margin Requirement</u>	CMS has a corporate margin requirement that limits the margin on Part D business as compared to another line of the company's business. CMS requires plan sponsors' projected Part D gain/loss margin to be within 1.5% of the sponsor's corresponding Medicare Advantage margin. If the Part D sponsor's corporate margin requirement instead is based on its non-Medicare business, CMS requires the projected aggregate Part D margin as a percentage of revenue to be within 1.5% of the Part D sponsor's corporate margin requirement.
<u>Actual vs. Expected Margin</u>	Plan sponsors report actual vs. expected margin for a three-year period in the supporting documentation included in the initial bid submission. CMS desk reviewers rely on this comparison to evaluate proposed plan sponsor margin during the bid review process
<u>Related Party Arrangements</u>	CMS requires all plan sponsors in a related-party arrangement to demonstrate that the margin of the related party is reflected in the bid margin. Thus, a Part D plan's PBM margin cannot be significantly greater than the Part D plan margin without affecting its ability to meet its margin requirement.
<u>Annual DIR Reporting and Reconciliation</u>	This report includes detailed DIR which requires the Part D sponsors to report on plan and PBM – retained rebates. The process is fully transparent to CMS and government oversight bodies.
<u>One-Third Financial Audits</u>	One third financial audits specifically test the entire Part D rebate continuum from the Part D Bid to the Part D Payment Reconciliation for a given contract year.
<u>Desk Review / Bid Audit</u>	CMS contracts with independent third parties to review and audit bid submissions to evaluate compliance with bid requirements and applicable actuarial standards of practice.
<u>Bid Approval</u>	The CMS Office of the Actuary will not approve a bid if the plan sponsor is consistently off with its projections. Likewise, HHS performs audits to ensure proper bid protocols are followed.

⁷³ The Medicare Trustees report that administrative expenses have ranged from 11.4 to 13.6% of total reconciled plan payments between 2008 and 2016. See Medicare Trustees Report, 2018, Table IV.B8, page 143.

the actual costs to plans. These commenters also requested clarification that the information we are proposing to collect and disclose relate only to Part D claims data, and not to competitively sensitive financial data regarding rebates, discounts or other negotiated price concessions. The commenters expressed a concern that release of competitively sensitive data could undermine the competitive bid process. They assert that plans will be able to adjust their bids on the basis of knowledge of each other's data, resulting in higher drug costs for all.

Response: We share the commenters' concerns about the need to protect the sensitive data under the Part D program. Because the Medicare drug benefit is based on a competitive business model, to release commercially or financially sensitive data to the public could negatively impact Part D sponsors' ability to negotiate for better prices, and ultimately affect the ability of sponsors to hold down prices for beneficiaries and taxpayers.⁷⁴

New disclosures of price concessions will lead to tacit collusion and lower discounts. We continue to agree with CMS's conclusion in the 2008 Final Rule. To further describe this theory, we quote the Congressional Budget Office (CBO)'s landmark 2007 paper, which laid out the advantages and disadvantages of price transparency in health care. In it, CBO writes:

The markets for some health care services are highly concentrated, and increasing transparency in such markets could lead to higher, rather than lower, prices. In markets where only a small number of firms operate, increased transparency would make it easier for those firms to observe the prices charged by their rivals, which could lead to reduced competition between them. In health care, reduced competition might result if more transparent pricing revealed the prices negotiated between insurers and providers, especially in concentrated markets.⁷⁵

Further, specific to highly-concentrated prescription drug markets (per CBO), "requiring the disclosure of discounts made to prescription drug plans in the Medicare program could set in place conditions for tacit collusion, as manufacturers would find it more difficult to set prices below their competitors' without detection."⁷⁶ In an earlier letter specific to the revelation of Part D rebates, CBO argues that disclosure "would create pressure to reduce those rebates, which would tend to increase costs for both the Medicare program and, on average, for enrollees."⁷⁷

The pharmaceutical market is highly concentrated both in terms of sellers (drug manufacturers) and buyers (PBMs). The concentration among buyers (who are in many cases obliged to purchase the drugs under the terms of the benefits they administer) further creates a scenario where transparency can be damaging, according to respected health economists.⁷⁸ Disclosures

⁷⁴ 73 Fed. Reg. 30668, May 28, 2008.

⁷⁵ CBO, "Increasing Transparency in the Pricing of Health Care Services and Pharmaceuticals," June 2008, page 4. Available at <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/06-05-pricetransparency.pdf>.

⁷⁶ *Ibid*, page 5.

⁷⁷ CBO, Letter to the Honorable Joe Barton and Jim McCrery, March 12, 2007. Available at <https://www.cbo.gov/system/files?file=2018-10/03-12-drug-rebates.pdf>.

⁷⁸ Alison Kodjack, "It Will Take More Than Transparency To Reduce Drug Prices, Economists Say." March 22, 2019. Available at <https://www.npr.org/sections/health-shots/2019/03/22/705469296/it-will-take-more-than-transparency-to-reduce-drug-prices-economists-say>.

are damaging to the overall health of the market because there are so few data points that a supplier needs to learn in order to have the upper hand.⁷⁹ More succinctly, the Federal Trade Commission has stated that:

[I]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors ...then tacit collusion among manufacturers is more feasible... Whenever competitors know the actual prices charged by other firms, tacit collusion—and thus higher prices—may be more likely.⁸⁰

In general, increased cost transparency reduces negotiation leverage, which would result in higher overall Part D program spending, through higher net costs. With enhanced price transparency at the point-of-sale, manufacturers will therefore be able to determine the exact contract terms offered by their competitors to each plan. This will result in tacit collusion and eliminate incentives for manufacturers to negotiate the lowest possible discounts, in order to protect market share. They will know exactly how much discount would have been required to “win” on contracts they have lost, or how much smaller a price concession they could have yielded on the contracts they won. In the Part D program this becomes particularly troubling, since as CBO notes, because Part D negotiated rebates are higher than those in the private market, rebates in Part D would compress in the direction of existing commercial rebates.⁸¹

And in fact, in its regulatory impact analysis, HHS assumes that manufacturers would retain some of the funds currently paid as rebates under the current confidential system, resulting in increases in net costs. While HHS may justify the rule by embracing a short-term reset of pricing structures to re-align the current incentives, CBO’s work instead cautions that such transparency will have lasting effects and changes the nature of negotiations altogether.

Concerns about the adverse impacts of unnecessary transparency is particularly true with regard to a wholesaler-administered system, where the pharmacy now becomes aware of the price concessions negotiated between manufacturers and PBMs. By introducing this knowledge to an entity without a clear and specific need to know, HHS has increased the probability of widespread disclosure. For example, pharmacy switch data is often sold by third party vendors, and they will surely offer an analysis of the amounts paid back to pharmacies as chargebacks as new data products for their clients. This uncovering of price concessions as widespread knowledge does not happen, by contrast, in any PBM-facilitated transaction.

The Proposed Rule might introduce more ambiguity. While HHS’s interests in promoting transparency are well-intentioned, such uncovering will have unintended consequences

⁷⁹ See Danson, PM. “Pharmacy Benefit Management: Are Reporting Requirements Pro or AntiCompetitive?” Available at [https://faculty.wharton.upenn.edu/wp-content/uploads/2015/10/Danzon-PBM-IJEB-2-25-15-formatted-4-1-15-\(002\).pdf](https://faculty.wharton.upenn.edu/wp-content/uploads/2015/10/Danzon-PBM-IJEB-2-25-15-formatted-4-1-15-(002).pdf).

⁸⁰ U.S. FTC, Letter to Assembly Member Greg Aghazarian, 2004. Available at https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf.

⁸¹ CBO, “Increasing Transparency in the Pricing of Health Care Services and Pharmaceuticals,” June 5, 2008. Available at <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/06-05-pricetransparency.pdf>.

throughout the Part D program and pharmaceutical market. First, manufacturer rebate contracts are among the most closely guarded information in the pharmaceutical industry and considered protected under the Uniform Trade Secrets Act. For example, many insurers that provide contract information to trusted consultants prefer to keep drug-specific rebate terms confidential, even if sharing would create cost efficiencies in consulting engagements. A change from this level of confidentiality could create market disruption, with any increases in net costs accruing to manufacturers as increased revenues.⁸²

Second, the proposed changes could potentially result in significant formulary and market disruption in terms of the Annual Enrollment Period. For example, if plan sponsors used transparent manufacturer cost rebate information to change formulary tier placement or coverage for high-utilization products, enrollees taking those products may either switch products or switch plans, based upon their net costs, which may lead to adverse risk selection. Beneficiaries with a specific condition today shop generally based upon premium and formulary position for their prescribed medicines. This generally spreads the risk associated with this condition across all plans.⁸³ In a world where beneficiary net costs are telegraphed as part of an enrollment process, these same beneficiaries may flock toward the one plan with the lowest up-front discounted price for their prescribed specialty drug. None of the risk stabilization programs can correct for a scenario where all multiple sclerosis patients, for example, are in just a few of the scores of available Part D plans.

There are even more unresolved questions regarding chargebacks. In addition to the ambiguity the Proposed Rule creates for private sector stakeholders, it also raises questions regarding the need and construction of a new transaction system. Under the Proposed Rule, to maintain protection under the new discount or rebate at point-of-sale safe harbors, price concessions would be required to go directly from the manufacturer (or indirectly through another party) to the dispensing pharmacy. This may require the creation of a new transaction system altogether, unless rebates are permitted or required to be transferred through the PBM.

Not described in the Proposed Rule is how HHS would ensure that the price concessions negotiated truly do lower the out-of-pocket cost of drugs for the patient and are not retained in part by these new entities, e.g., a pharmacy or a wholesaler administering a chargeback. Today, PBMs adjudicate all monetary aspects of a pharmacy's prescription transaction, telling the pharmacy how much cost-sharing to collect. Under the Proposed Rule, the onus may be placed on pharmacies, wholesalers, or an as-of-yet undetermined intermediary to perform that function. Thus, the designing of an entirely new claims adjudication system (perhaps largely by entities not even subject to the jurisdiction of CMS) seems that it would not accomplish the Administration's stated transparency goals, and would present the specter of significant uncertainty and the risk of many discontinuities in getting Part D enrollees their drugs.

⁸² See Section VIII for further arguments related to the effects of this Proposed Rule regarding the Trade Secrets Act.

⁸³ See Atlantic Information Systems (AIS), "With MA Switch Rates on the Rise, Plans Might Rethink 2020 Benefits." Available at <https://aishealth.com/category/abstract/>.

PCMA Recommendation: *The Proposed Rule will increase net costs for drugs by undercutting the ability of PBMs to hold fair negotiations on behalf of Part D plan sponsors. The Proposed Rule's uncovering of price concessions would also likely lead to market disruption and confusion for beneficiaries in terms of plan selection and pharmacy point-of-sale interactions.*

3. Requiring Transparency in Medicaid Managed Care Organizations (MCO)-negotiated rebates serves no public policy purpose

In a Medicaid MCO, the rebates negotiated by plans and manufacturers are typically reported to states but are not actionable data points or publicly disclosed, because the contracts states have with health plans are capitated. The approach has been that the MCO uses appropriate means to keep costs in line with actuarially sound capitated rates. How the plan achieves its financial goals is not the purview of the state.

From the beneficiary perspective, passing through rebates at the point-of-sale or providing for up-front discounts for the purposes of increasing price transparency will not provide a significant pricing signal. This is particularly true given that MCO enrollees generally pay fixed, nominal cost-sharing and premiums. HHS's proposal to increase transparency will not, on its own, result in shifts toward lower-cost drugs in Medicaid. In describing this dynamic at a recent public meeting, Medicaid and CHIP Payment and Access Commission (MACPAC) staff described the Proposed Rule as "not particularly relevant" and noting that capitation rates will increase unless states take countermeasures.⁸⁴ As noted in our discussion on excluding Medicaid managed care from the Proposed Rule altogether (see Section VII), the mandatory state rebates and supplemental rebates comprise the bulk of price concessions, and they won't be passed through or discounted up-front, or otherwise disclosed to beneficiaries. Thus, MCO price concessions, which are on the order of a few percentage points on average,⁸⁵ are unlikely to sway beneficiaries once disclosed.

As contemplated in the current proposal, transparency requirements result in the exposure of information through the sharing of negotiated rates, discounts, or service fees outside the PBM/client relationship. Such mandatory disclosure could establish an unintended, artificial "floor" for pricing reductions which could impinge on the ability of MCOs to compete in their markets, and thus increase costs.

PCMA Recommendation: *The Proposed Rule's efforts to increase transparency will serve no purpose in improving Medicaid managed care program operations. Medicaid managed care should be excluded from this rulemaking altogether.*

⁸⁴ MACPAC Public Meeting presentation materials, March 8, 2019. Available at <https://www.macpac.gov/wp-content/uploads/2019/03/Proposed-Rule-Affecting-Safe-Harbors-for-Prescription-Drug-Rebates.pdf>.

⁸⁵ See Milliman, 2019. "HHS's Proposed Modification of Pharmacy Rebate Safe Harbors: Implications for Medicaid." Available at <http://www.milliman.com/uploadedFiles/insight/2019/HHS-proposed-modification.pdf>.

Section IV. Impact on Beneficiary Access: The Proposed Rule Will Harm Beneficiaries Due to Premium Increases and Confusion

HHS seeks comments on the impact of the Proposed Rule on beneficiary access. We believe there is potential for significant adverse impact on beneficiary access to meaningful prescription drug coverage. Some of the impact is very obvious and other aspects are more subtle, but all of which may contribute not only to the destabilization of Part D but also and importantly, will reduce beneficiary satisfaction with the Part D benefit, which has remained remarkably high.

We have grouped the concerns into three main areas: access to plans and plan choice due to cost, access to drugs due to formulary placement, and beneficiary confusion and dissatisfaction. We address each of these below.

1. Beneficiary access to plans and plan choices will be reduced due to cost increases

Many facets of the proposed program could set up dynamics that are adverse to beneficiary access to affordable plans. This may be best illustrated by two hypothetical scenarios involving hepatitis C virus (HCV) drugs:

- **HCV scenario 1.** There would be a strong disincentive for any plan to have the lowest negotiated price for a drug in a competitive class like hepatitis C with several branded drugs. Likewise, there is a strong disincentive for any manufacturer to offer larger discounts than a competitor. This could actually increase costs for hepatitis C drugs.
- **HCV scenario 2.** Assume a plan offers the lowest negotiated price for a hepatitis C drug, and, through Medicare Plan Finder, enrollees easily find this information. The plan would expect to attract a disproportionate number of enrollees with hepatitis C. The plan's bid would result in significant premium increases, given the inability of the risk adjuster to adequately reflect this risk.

These HCV scenarios highlight the uncertainties that are likely to arise regarding steering, marketing, adverse selection, risk pool, and upward premium spirals, all of which could adversely impact access to plans based on costs. While CMS's risk adjustment program helps mitigate some of these selection effects, it was not designed for a situation where most beneficiaries in a market choose the plan with the lowest cost on a specific high-priced drug.

Another major cost-based access deficiency is that the increase in premiums could readily result in reduced or suboptimal enrollment. Specifically, healthier seniors already enrolled in a Part D plan, or those just aging into Medicare, may choose to take the risk of dropping out of Part D or not enrolling in Part D at all due to the premium increases. This in turn could spiral into sicker enrollees with higher drug costs staying in the plans, and causing premiums to further increase, exacerbating the non-enrollment numbers. (See Sections IV and V for our discussion on enrollment as it relates to increases in premiums.)

Today, about 56 percent of Part D enrollees elect coverage through stand-alone Part D plans, and about 43 percent through Medicare Advantage plans.⁸⁶ The Proposed Rule's premium increases would have several effects on enrollment choices. As a result of recent Medicare regulatory changes, plan sponsors are offering more MA-PD and Part D plans choices with enhanced benefits, to better tailor benefits to potential enrollees.⁸⁷ First, MA-PDs often have zero-dollar Part D premiums. Under the Proposed Rule, this may change, possibly making MA-PDs less favorable to enrollees. Stand-alone Part D plans, by contrast, cannot absorb premium increases across the entire benefit package, and are likely to see larger premium changes. Enrollees may find no suitable plan with premiums comparable to what they pay today.

In business, higher uncertainty means higher risk, which translates into higher costs. With the uncertainty created by the Proposed Rule, not only might plans increase premiums by more than projected by HHS, but smaller plans may also drop out of participation altogether due to inability to handle the increased risk of participating in Part D. This in turn would reduce beneficiary choice of plans, which to date has been robust and is specifically identified by beneficiaries as a driver of their overall satisfaction with the program.⁸⁸

These factors could all seriously harm beneficiary access to an affordable, predictable Part D plan and could result in many more seniors without any prescription drug coverage. We note that HHS was aware of many of these enrollment-related complications for beneficiaries, but did not address them in the Proposed Rule.⁸⁹ On pages 15 and 16 of the HHS-commissioned Milliman report, Milliman writes about four anticipated premium-related effects of the Proposed Rule on beneficiary enrollment. No part of this Proposed Rule seeks to mitigate any negative consequences on beneficiaries of such effects.

PCMA Recommendation: The Proposed Rule does not adequately consider the likely harms to beneficiaries caused by disruptions in enrollment and lapses in coverage.

2. Access to drugs due to formulary placement

In light of the likely loss of price concession revenue to be applied to improve the benefit, it is not unrealistic to anticipate that a foreseeable plan response to trying to keep the benefit affordable may be significantly narrowed formularies and greater use of utilization management (UM) tools. As recently noted in Drug Channels, Adam Fein speculates that "In a world without

⁸⁶ See CMS, Medicare Advantage/Part D Contract and Enrollment Summary Data, March 2019. Available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Contract-and-Enrollment-Summary-Report-Items/Contract-Summary-2019-03.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=descending>.

⁸⁷ See MedPAC March 2019 Report to Congress, Chapter 14. Available at http://medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf.

⁸⁸ In the most recent MedicareToday.org survey (2018), 85% of beneficiaries were satisfied overall. 83 percent reported it was important to them to have a variety of plans to compare and choose from. Available at <http://medicaretoday.org/wp-content/uploads/2016/07/8.21.18-Senior-Satisfaction-Survey-Fact-Sheet.pdf>.

⁸⁹ See Milliman, "Impact of Potential Changes to the Treatment of Manufacturer Rebates," January 2019. Available at <https://aspe.hhs.gov/system/files/pdf/260591/MillimanReportImpactPartDRebateReform.pdf>.

rebates, PBMs would hold winner-take-all auctions” meaning that “Formularies for some therapeutic categories could therefore become slimmer, offering fewer choices in those categories.”⁹⁰ Moreover, it could take several years before premiums and formularies stabilize, as the various stakeholders reset based on their experiences. Thus, plan formularies may be not only less robust, but also much less stable from year to year.

Ironically, another possible adverse impact on beneficiaries would occur if this new approach encourages increased utilization with no penalties for non-adherence or poor drug performance, which in turn could trigger the need for more expensive drugs. In other words, upfront discounts or POS rebates lower the price for sick individuals which then encourage increased utilization of higher cost drugs by offsetting patient OOP. There are many examples of patients who want to obtain a drug for which they have seen an advertisement, even though the drug is not appropriate for their condition.⁹¹

A more serious consequence that may emerge as a result of this Proposed Rule is a true lack of access altogether. If a new wholesaler-administered chargeback system is stood up, and fails to adequately compensate pharmacies in time, it is not inconceivable that pharmacies may refuse to participate in the Part D program or in Part D plan networks that rely on chargebacks rather than the existing PBM-facilitated transaction system.⁹²

Finally, as we noted in relation to enrollment-related consequences, HHS was also made aware of formulary-related beneficiary access consequences in Milliman’s report commissioned for the Proposed Rule.⁹³ On pages 16 and 17 of its report, Milliman wrote about possible formulary strategies, changes to the benefit design parameter thresholds, and actuarial equivalence testing that plans would have to undertake.

PCMA Recommendation: The Proposed Rule fails to account for the likely formulary and drug utilization changes, which could negatively harm beneficiaries.

3. Beneficiary confusion and dissatisfaction with Part D

We are concerned that there will be unmet expectations that beneficiaries will have based on media coverage around this rule. Currently, nearly 90 percent of the prescriptions dispensed to Medicare Part D enrollees are generic drugs.⁹⁴ There will be no out-of-pocket savings associated with these drugs, under this Proposed Rule. Instead, the way the Administration has

⁹⁰ See Adam Fein, “A World Without Rebates: Predictions for How the Channel Will Evolve and Why Drug Prices Will Go Down,” March 2019. Available at <https://www.drugchannels.net/2019/03/a-world-without-rebates-predictions-for.html>.

⁹¹ See, e.g., C. Lee Ventola, “Direct-to-Consumer Pharmaceutical Advertising Therapeutic or Toxic?” *Pharmacy & Therapeutics*, Oct. 2011.

⁹² See for example NCPA’s communication to its members, “NCPA’s Minimum Requirements on the Proposed Rule Regarding the Rebate Safe Harbor,” which points out a number of financial “must haves” before independent pharmacies can implement these provisions.

⁹³ See Milliman, 2019, cited above.

⁹⁴ See MedPAC, March 2019 Report to Congress, Chapter 14. Available at http://medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf.

described this Proposed Rule, compared to what will actually happen in practice, are very different. More specifically, since manufacturers do not provide rebates for the large majority of drugs (including generic drugs) do not have rebates, and many beneficiaries do not pay coinsurance for generic or preferred brand drugs, beneficiaries may feel misled by expectations that they will receive payment of rebates (or reduced cost-shares) at POS, compared to the certainty not only of higher premiums and possibly shrunken formularies but also that many of the drugs they take will have neither rebates nor lower cost-sharing.

Another likely roadblock to beneficiary access relates to resolution of the prescription at the POS. Specifically, the preamble indicates that “the reduction in price must be completely reflected in the price the pharmacy charges to the beneficiary at the point of sale.” We have significant concerns regarding the challenges created by yet-to-be-established chargeback methodology. A new system that transfers rebate payments from a pharmaceutical manufacturer to the network pharmacy may lead to at least a short-term delay in payments and, therefore, delay the POS transaction, leaving many beneficiaries without their prescription in hand at the POS. In this rule, HHS is perfectly content with completely reengineering a drug distribution program that has been in place for decades, in a very short time frame. Even assuming those implementing the new system had appropriate knowledge, skill, and data, it is inevitable that there will be glitches in such a large and complex undertaking.

We are also concerned that it will be very difficult to explain the benefit change to beneficiaries, and their representatives, including the difference between a rebate provided at POS as compared to an up-front discount, and why only some expensive drugs come with a rebate while many others do not. We assume the concept will be explained through documents geared to beneficiaries such as the ANOC, and EOC and EOB. For example, EOBs may need an extra box (regardless of whether the amount counts toward TrOOP) to show the discount or rebate amount. Likewise it is unclear how this new construct will be explained on Medicare Plan Finder which must be updated to display cost-sharing based on the POS price inclusive of rebates and discounts to allow beneficiaries to make an informed purchasing decision. And will formularies need to be tagged with drugs with discounts as compared to those without discounts? It is not hard to speculate that all of this new content could readily create significant beneficiary confusion on drug pricing.

The possibility of massive program-wide enrollment disruption, including mass plan changes for Low-Income Subsidy (LIS) enrollees, cannot be underestimated and LIS recipients’ interaction with the Part D enrollment rules will also be thrown into chaos. The Medicare population enrolled in LIS plans today is dominated by medically fragile members with chronic conditions. Currently, the lowest-income categories of LIS enrollees are automatically enrolled in plans within a narrow range of the benchmark premium in their region, and re-assigned as needed each year. These enrollees can then elect to remain in this plan in subsequent years and pay any additional premiums. The fact is that LIS enrollees are less likely to engage with the MPF

on an annual basis.⁹⁵ Therefore, absent definitive guidance or safeguards issued by CMS, there may be massive program-wide LIS plan enrollment disruption and drug access issues for these members. Further, LIS enrollees who do in fact use MPF may not be able to find an appropriate plan and could also disenroll altogether. See also discussion in Section V.

In light of the plan and formulary disruption noted above, and in addition to a significant increase in calls to the CMS help line and to plan service centers with questions on how this works, we would anticipate a significant increase in beneficiary exceptions and appeals requests, beneficiary complaints and grievances, beneficiary requests to switch or drop plans mid-year.

Finally, we would expect all of the above to have significant downward impact on beneficiary satisfaction with Part D, which as noted, has consistently been very favorable. As cited earlier, a 2018 enrollee survey echoes previous results showing that nearly 85 percent of seniors are satisfied with their Part D coverage and more than eight of every 10 are said their monthly premium is affordable.⁹⁶ These satisfaction results have been consistently high for over a decade,⁹⁷ but would be at risk under this rule.

PCMA Recommendation: We recommend that HHS not proceed with implementation of the Proposed Rule. HHS should instead undertake an assessment of the potential for significant adverse impact of the Proposed Rule on beneficiary access to meaningful prescription drug coverage, and consider alternatives that would not have such an adverse impact.

⁹⁵ In 2015, Kaiser Family Foundation noted that about 11% of non-LIS enrollees switched plans each year, compared to only 4% of LIS enrollees who were not auto-reassigned. CMS will have to issue guidance regarding auto-reassignment to minimize disruption to these enrollees. See <http://files.kff.org/attachment/report-to-switch-or-be-switched-examining-changes-in-drug-plan-enrollment-among-medicare-part-d-low-income-subsidy-enrollees>.

⁹⁶ Medicare Today, "Senior Satisfaction Survey," August 2018. <http://medicaretoday.org/wp-content/uploads/2016/07/8.21.18-Senior-Satisfaction-Survey-Fact-Sheet.pdf>

⁹⁷ See previous Medicare Today Part D Satisfaction Surveys at www.medicaretoday.org.

Section V. Regulatory Impact Analysis: HHS's Analysis is Inadequate and Incomplete

HHS performed a Regulatory Impact Analysis to support this Proposed Rule, and seeks comments on its methods, data sources, and results. Separately it calculates costs associated with changing business practices related to the removal of the existing safe harbor and replacement with two new safe harbors, the benefits associated with transparency and net cost-based out-of-pocket spending, and transfers related to how these changes would flow through the health care system, financially.

In general, we find that HHS's estimates for costs, benefits, and transfers are underdeveloped especially in light of the economic significance of this rulemaking. Further, there are key areas where estimates were not apparently considered at all, demonstrating continued lack of understanding of the complex businesses that operate the Part D and Medicaid managed care programs. We first discuss a general concern regarding HHS's regulatory impact analysis process, and then address further concerns in the order the topics are listed in the Proposed Rule: need for regulation, then costs, then benefits, and finally transfers. A summary of our major points is below:

- HHS has not followed accepted regulatory development practices nor has it performed a meaningful regulatory impact analysis, which should include the thoughtful development of cost and benefit estimates, for its proposal and for reasonable alternatives, as well as a proposal as to how to offset the rule's substantial costs.
- Adopting more reasonable estimates for affected entities, the costs of implementing this regulation (\$2.9 to \$4.2 billion in the first year) far outweigh the limited benefits and transfers to beneficiaries that would result from this rule change.
- HHS should instruct OACT to update its analysis of transfers to account for actual enrollment in plans as chosen by Part D enrollees, rather than the standard benefit design.
- As designed, the Proposed Rule would create a massive transfer of dollars from the federal government to manufacturers and possibly new and unnecessary actors in the supply chain.

1. This Proposed Rule does not respect the role of regulatory impact analyses and ignores long-standing rulemaking requirements

The regulatory impact analysis process is intended to ensure that any proposed rules issued by an agency serve a legitimate public policy purpose and can be commented on thoughtfully by the public. This Proposed Rule, however, fails to meet the minimum standards established for

rulemaking, including specifically lacking information on what the proposed regulatory trade-offs for this rule would be.

The rule does not pass the minimum standards based on existing law and standards. Per the preamble to the Proposed Rule, “Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits.”⁹⁸ Guidance provided to all agencies by the White House Office of Management and Budget (OMB), Circular A-4, states succinctly:

A good regulatory analysis should include the following three basic elements: (1) a statement of the need for the proposed action, (2) an examination of alternative approaches, and (3) an evaluation of the benefits and costs—quantitative and qualitative—of the proposed action and the main alternatives identified by the analysis.⁹⁹

However, as is broadly evident throughout the regulatory impact analysis section of this rulemaking, the Department does not adequately justify the need for regulation, does not meaningfully describe and assess the impacts of any alternatives, nor does it demonstrate a careful weighing of the effects of the Proposed Rule on the affected stakeholders. As we detail below, cost estimates are woefully underdeveloped, transfers do not account for likely behavioral changes, and various stakeholders and their costs and transfer activity are omitted altogether. Conclusively, HHS’s analysis fails to meet the standards set forth in the Executive Orders applicable to all agencies.

The rule does not propose or indicate any cost mitigation, contrary to current requirements. President Trump’s Executive Order 13771 requires that the costs of significant rules be offset by eliminating existing costs from at least two prior final rules.¹⁰⁰ First, the estimate provided in the EO 13771 paragraph – \$56.2 million – is not even the accurate recitation of its own estimates (first year costs of \$285 million, subsequent year costs of \$260 million for years two through five, and ongoing costs thereafter).¹⁰¹ It is of primary importance that the true estimated costs be reflected in this rulemaking, at each location they are discussed, so that the public is best able to understand the rule and assess its implications. Second, this rule is subject to the requirements of EO 13771 as a major rule, because it imposes significant costs on non-Federal entities, which need to be offset through the withdrawal of other regulations. Therefore, the Department is required under EO 13771 to inform the public which regulatory costs they seek to remove to meet the President’s requirements. At this juncture, all the rule indicates is costs in excess of benefits, without any indication how the Department will offset them, in clear violation of this Executive Order. The public must be given an opportunity to weigh the benefits of what would be removed in order to achieve this rule change, as well as the costs of new regulation.

⁹⁸ See 84 Fed. Reg. 2350, February 6, 2019.

⁹⁹ See <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>.

¹⁰⁰ Executive Order 13771, 82 Fed. Reg. 9399, February 3, 2017.

¹⁰¹ See 84 Fed. Reg. 2362, February 6, 2019.

PCMA Recommendation: HHS should withdraw the rule or delay finalizing any regulatory change until it can satisfy regulatory impact analysis requirements as established by OMB.

2. Compelling evidence demonstrates PBMs are the market's most efficient response to increasing drug list prices

In the “Need for Regulation” section, HHS justifies this rulemaking by writing that “manufacturers paying rebates to PBMs may be a factor in list prices rising faster than inflation” and that “[t]his phenomenon may also be causing PBMs to favor higher-cost drugs with higher rebates over drugs with lower costs, and discouraging the adoption of lower-cost brand drugs and biosimilars.”¹⁰² HHS cites an IQVIA study demonstrating a growing difference between gross drug spending and net drug spending, and the 2018 Medicare Trustees Report showing a growth in manufacturer rebates under the Part D program. These two citations – and many others – in fact prove the opposite. Drug list prices are set and changed only by pharmaceutical manufacturers. States, PBMs, and Part D plan sponsors are making considerable progress in reducing drug spending despite manufacturers’ best efforts at increasing list prices.

Moderation in the growth of Part D net costs demonstrates the success of PBMs and the current Part D model. The recent spate of publications in response to this Administration’s efforts at getting manufacturers to reduce list prices have concluded that net costs are the more meaningful measure of efficiency in the prescription drug system, and are showing signs of a well-functioning market. Further, comparing net program expenditures to rebates also shows that the current system generates economic efficiencies.

- **Net spending trends indicate that price concessions identify the true value of pharmaceutical products.** Inclusive of the IQVIA study cited by HHS in the Proposed Rule, a series of other well-regarded organizations – including OIG itself – have found continued and persistent growth in list prices, which is largely responsible for growing drug spending.¹⁰³ These same studies also find a growing divide between list prices and gross drug spending on one hand, and net drug spending on the other. It would be difficult to explain this in any way other than concluding that in the face of direct competition, pharmaceutical manufacturers’ list price increases are blunted by the negotiations of PBMs and plan sponsors. Independent analyses of PBM’s publicized results have largely confirmed the success of these models.¹⁰⁴ As was stated by Dr.

¹⁰² 84 Fed. Reg. 2351, February 6, 2019.

¹⁰³ See for example HHS OIG, “High-Price Drugs Are Increasing Federal Payments for Medicare Part D Catastrophic Coverage,” OEI-02-16-00270 and Credit-Suisse, “Exploring future US pricing pressure,” April 18, 2017, available at <https://bit.ly/2BpJ3JE>.

¹⁰⁴ Adam Fein, “Who Best Managed the Drug Spending Slowdown in 2017: CVS Health, Express Scripts, MedImpact, or Prime Therapeutics?” *DrugChannels.net* blog. Available at <https://www.drugchannels.net/2018/05/who-best-managed-drug-spending-slowdown.html>.

Fiona Scott Morton at the February 26, 2019 Senate Finance Hearing regarding drug prices:

In pharmaceutical and device markets, final consumers are generally both uninformed and insured, so on their own they cannot respond to a price discount by moving their purchases, nor are they able to ask for one as individuals. The institutional innovation that creates competition in pharmaceuticals is the PBM... The PBM is informed about available substitute treatments, is sensitive to price, and controls a large group of final consumers. ... In a market with competitive alternatives the PBM has the ability to negotiate for lower prices in exchange for market share. ... The PBM's role of seeking out discounts from manufacturers is critical because it is one of the few *agents in our commercial pharmaceutical marketplace that creates price competition...*” (emphasis in original)¹⁰⁵

Indeed, in recent years several studies and analyses have concluded similarly, that moderation in the growth of net costs is the result of PBMs and other actors extracting price concessions from manufacturers as a result of competition. Specifically, Credit-Suisse writes:

We find a strong correlation between the level of rebates reported and the uniqueness of a company's portfolio. Companies with more unique products typically report lower levels of rebates and we believe should be able to maintain higher long-term pricing, access to patients and, ultimately, profitability.¹⁰⁶

As a result of net cost moderation due to PBM negotiations, total net prescription drug spending has been nearly flat over the previous two years. See Table 1 in Section 1 for a list of recently published evidence demonstrating net costs and net spending are moderating, while list prices and gross spending is still increasing. As highlighted by Dr. Scott Morton and others, PBMs are driving this lower net spending trend.¹⁰⁷

- **Individual manufacturers have conceded that price concessions keep list price increases from generating additional revenue.** Rather than price concessions leading to list price increases, rebates are forcing manufacturers to rethink the value of their products. Manufacturers including Eli Lilly, Merck, and Johnson & Johnson have reported aggregate list and net cost trends.¹⁰⁸ In each case, net cost growth is significantly lower than list price growth, and in some cases is negative, meaning that

¹⁰⁵ Testimony of Dr. Fiona Scott Morton, February 26, 2019, available at <http://docs.house.gov/meetings/JU/JU05/20190307/109024/HHRG-116-JU05-Wstate-MortonF-20190307.pdf>.

¹⁰⁶ Credit-Suisse, “Exploring future US pricing pressure,” April 18, 2017, available at <https://bit.ly/2BpJ3JE>.

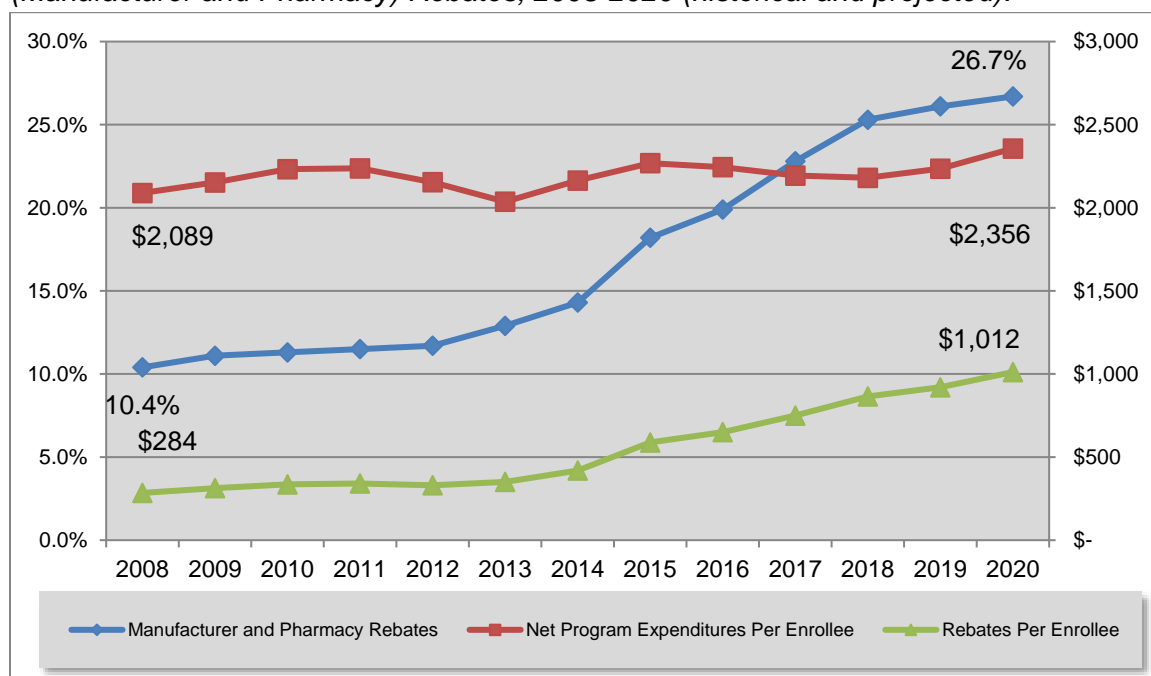
¹⁰⁷ The single largest category of price concessions are Medicaid rebates (\$35 billion in 2017, see MACPAC MACStats 2018). They have similarly increased over time in step with PBM rebates, due to an increase in price inflation penalty-related rebates, but are not “negotiated,” *per se*, meaning that the most meaningful negotiations are being led by PBMs in Part D and the commercial market.

¹⁰⁸ Cathy Kelly, “Signs Of Change? Lilly, Merck, Janssen Report Slowing List Price Growth In 2018,” March 25, 2019. *The Pink Sheet*.

payers are finding these company's products less valuable over time compared to direct competitors. As HHS indicated in 2018, since 2017, list price increases have become less of a strategic approach to revenue generation.¹⁰⁹

- The Proposed Rule mischaracterizes the Trustee's Report's implications.** A more accurate reading of the Medicare Trustees Report language regarding rebates and trends in the Part D program is that the leverage PBMs and plan sponsors are exerting on manufacturers is yielding continued moderate program expenditure growth. Chart 2 below presents the same Trustees Report data on rebates in Part D since 2008, compared to total net program expenditures per enrollee.¹¹⁰ As rebates have risen, program expenditures have remained relatively constant. Per-enrollee expenditures increased by \$267 over the 13 year period (\$2,089 to \$2,356), while per-enrollee rebates increased by \$728 per enrollee (\$284 to \$1,012).¹¹¹ In stark contrast, in Medicare Part B, where PBMs play a small role if any on a drug-by-drug basis, spending has risen almost 10% per year, with at least half of the growth being attributed to price.¹¹²

Chart 2. Comparison of Part D Net Program Expenditures per Enrollee and Total (Manufacturer and Pharmacy) Rebates, 2008-2020 (historical and projected).



¹⁰⁹ Assistant Secretary for Planning and Evaluation, "Data Point: Prescription Pharmaceutical Price Changes since the Release of the President's Drug Pricing Blueprint," August 21, 2018. Available at <https://aspe.hhs.gov/system/files/pdf/259611/DPrxpricechanges100dayspostblueprint.pdf>.

¹¹⁰ CMS estimates that roughly \$4 billion of the \$30 billion in total rebates received by Part D plans are pharmacy rebates. The remainder (\$26 billion or 87%) is rebates from drug manufacturers. See 83 Fed. Reg. 62191.

¹¹¹ Calculations also account for plan administration expenses and profits as provided in the 2018 Trustees Report, Table IV.B8.

¹¹² Medicare Payment Advisory Commission (MedPAC), public meeting March 7, 2019, presentation available at <http://www.medpac.gov/docs/default-source/default-document-library/part-b-drugs-march-19-public.pdf>.

The Proposed Rule would not improve the market uptake situation for biosimilars. HHS further hypothesizes that manufacturer rebates have led PBMs to prefer high cost drugs over low cost drugs, specifically citing biosimilars. However, this supposition is erroneous. Rather, biosimilars have not yet succeeded in the US because of innovator biologic manufacturer behaviors. The constraining factor in terms of biosimilar market adoption in the US is the lengthy and costly patent litigation process that innovator manufacturers are foisting upon biosimilar manufacturers. In the US, only seven of 18 biosimilars approved for marketing in the US are available, due to ongoing or resolved patent litigation.¹¹³ Even then, only four of the currently-approved biosimilars can be covered under Part D, though that is not their typical benefit category.¹¹⁴ Several of these 18 will never be sold in the US due to case resolutions or because manufacturers will withdraw their applications and move on to other investments. In contrast to the US, there are dozens more approved biosimilars in the EU,¹¹⁵ which face far fewer patent-related delays upon approval. As noted above regarding price competition and lower spending, a single biosimilar for a reference product may not suffice. Until such time that there are several biosimilars for the same reference product, PBMs and Part D plan sponsors will continue to monitor the market and ensure that the lowest net cost product is preferred. This may in some cases be the innovator, but if the innovator is negotiating only against one competitor, then PBMs and plan sponsors are generally not yet able to benefit from true price competition.

In summary, HHS in this rulemaking has failed to meet the requirements imposed upon agencies for significant rulemaking, and provides no rational basis for issuing this rule regardless. The evidence instead supports our position that price competition is the only check against runaway brand drug list prices, as negotiated by PBMs.

PCMA Recommendation: HHS should withdraw this Proposed Rule because its rationale is not supported by the available evidence.

3. Costs: HHS does not accurately estimate the excessive administrative burden that these new requirements would impose on the private sector and Medicare beneficiaries

In the Costs section of the Proposed Rule's regulatory impact analysis, HHS calculates significantly fewer costs than the various industry stakeholders would actually face. This is due in part to HHS's failure to address how each of the stakeholders interacts with one another. As

¹¹³ See for example <https://www.patentdocs.org/2018/06/status-of-us-biosimilar-approvals-and-pending-applications.html> and <https://insidehealthpolicy.com/inside-drug-pricing-short-takes/fda-approves-pfizer-breast-cancer-drug-biosimilar-no-18>

¹¹⁴ See list available at <https://www.biosimilarsip.com/2019/02/05/fdas-biosimilar-approvals-accelerate-in-2018-how-the-u-s-compares-to-europe-on-biosimilar-approvals-and-products-in-the-pipeline/>. A third trastuzumab biosimilar has since been approved. Pegfilgrastim and filgrastim are supportive care drugs for dialysis and cancer patients. They are typically Part B drugs, but can be dispensed at outpatient pharmacies to beneficiaries with appropriate training.

¹¹⁵ See for example <https://www.biosimilarsip.com/2018/05/02/how-the-u-s-compares-to-europe-on-biosimilar-approvals-and-products-in-the-pipeline/>, finding 39 approved biosimilars in Europe as of May 1, 2018.

is expected as part of the regulatory impact analysis process,¹¹⁶ more accurate regulatory impact analysis at the outset would have argued strongly against imposing these changes altogether. By failing to accurately characterize the onerous burdens that this rule would create, HHS is able to dismiss realistic concerns that otherwise should have been highlighted in the regulatory development stage. Below we discuss each of the Proposed Rule's cost estimate assumptions and methodologies.

Affected entities: HHS lists a number of private sector affected entities,¹¹⁷ but did not include all who would be affected by this Proposed Rule. Below we list additional private entities not listed by HHS, or those which HHS did not adequately count or describe.¹¹⁸

- **Distributors, wholesalers, and others in the supply chain.** The rule envisions a system whereby up-front discounts largely administered by wholesalers could replace PBM-administered rebates. (84 Fed. Reg. 2361) While we disagree altogether that wholesalers are a necessary part of implementing many of these changes, should they be involved on a voluntary basis, it would surely require significant administrative costs to implement. However, HHS does not estimate any costs for this stakeholder, or the various types of distributors that may play this role.¹¹⁹ While we disagree that wholesalers are necessary for implementing rebate-related reforms, for the sake of completeness, they should have been included in the list of affected entities, given HHS's description of the envisioned system. We identify about ten large wholesalers and request that an updated economic analysis account for their costs.¹²⁰
- **Pharmacy chains and PSOs.** In the rule, HHS includes among its list of stakeholders about 68,000 pharmacies. As HHS notes, each PBM and plan sponsor will have to update its network and payment contracts with pharmacies to account for the new chargeback system and other changes. However, these contracts are likely negotiated at the chain level, or with pharmacy service administrative organizations (PSO) for independent pharmacies. We estimate there are approximately 45 retail pharmacy chains¹²¹ and 20 PSOs.¹²² We note also that not all independent pharmacies use PSOs, but we are unable to estimate any such number.¹²³

¹¹⁶ See OMB Circular A-4, <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>, discussed previously.

¹¹⁷ We note that federal and state government costs are not included in these estimates. We raise this to point out that if finalized, states will expend considerable time and resources renegotiating contracts for their Medicaid managed care programs, and assessing the trade-offs between managed care and state supplemental rebate approaches to pharmacy management.

¹¹⁸ In the Proposed Rule, HHS cites PBMI in its estimate of 60 PBMs. A more recent 2019 analysis by PBMI identifies 66 PBMs. We consider this difference to be *de minimis* and carry forward 66 PBMs in our estimates later in this Section.

¹¹⁹ For example, in the long term care or specialty pharmacy context, there may not be such an entity in the supply chain.

¹²⁰ See <https://www.mdm.com/2017-top-pharmaceuticals-distributors>, in which Adam Fein lists the top three and a handful of others.

¹²¹ See for example https://en.wikipedia.org/wiki/Pharmacies_in_the_United_States, for the top 25. We estimate that another 20 regional chains exist.

- **Medicaid managed care plans.** HHS does not estimate the number of health plans that participate in Medicaid managed care. Based on a 2018 published analysis of the Medicaid managed care market overall,¹²⁴ we estimate that about 150 health plans identified by HHS are under contract to provide comprehensive Medicaid managed care coverage including pharmacy benefits in at least one state. We note that according to the cited report, 88% of Medicaid managed care plans operate only within a single state and may qualify as small businesses, especially vulnerable to the excessive administrative costs this rule would generate.

Costs associated with reviewing the rule. HHS allocates two hours to each affected business to read and understand the rule, estimating a total of \$5.3 million in costs in doing so. However, businesses will take seriously a Proposed Rule issued by OIG, due to the criminal nature of any violations of the Anti-Kickback Statute. HHS should have allocated significantly more time to this activity. Over the sixty-six day period during which affected businesses are preparing their comments and discussing internal strategies, businesses may reasonably devote at least one full-time equivalent employee (FTE) on average per company, and maybe as many as five, through the close of the public comment period. Table 3 at the end of this subsection presents what we believe is a more realistic cost estimate by entity type for reviewing the rule.¹²⁵

Changing business practices to implement the rule. HHS estimates a total of \$53.5 million in costs so that businesses and Medicaid agencies would make the necessary changes to their business practices to comply with the rule. HHS estimates affected businesses need 20 hours to make all of these changes. Rather, affected entities may assign five to eight FTEs, assuming a July 1 final rule through the end of the calendar year, for making changes for plan year 2020. We note that larger companies may assign more staff. This task is more onerous than the previous task (reviewing the Proposed Rule), because the force of a Final Rule would be void portions or all of each existing contract a PBM has with drug manufacturers. This is an activity not contemplated in any of the cost categories described by HHS. Each of these agreements would be subject to renegotiation, as would contracts between PBMs and pharmacies/PSAOs, PBMs and Part D and Medicaid managed care plan sponsors, and in the event of a chargeback-based system administered by wholesalers, a new set of contracts between PBMs and wholesalers, and between wholesalers and pharmacies/PSAOs and wholesalers and manufacturers. Based on input from our members, Table 3 presents our best estimates for the costs of changes in business practices related to this rule for plan year 2020.¹²⁶

Updating Part D bids for 2020 based upon the Final Rule. HHS estimates that Part D parent organizations and plan sponsors will bear \$5.45 million in costs updating their bids with new

¹²² See for example <https://www.gao.gov/products/GAO-13-176> and <https://www.drugchannels.net/2016/03/surprise-psao-consolidation-hd-smith.html>, which points to recent consolidation in the PSAO market.

¹²³ The 2013 GAO report cited above indicates that nearly all independent pharmacies are contracted to PSAO but does not state this definitively.

¹²⁴ PriceWaterhouseCoopers, "The Complicated State of Medicaid in the United States: Stability Amidst Considerable Future Uncertainty," 2017.

¹²⁵ We use the same even split among lawyers and managers, wage rates, and overhead assumptions as HHS.

¹²⁶ We use the same 20/80 split among lawyers and managers, wage rates, and overhead assumptions as HHS.

information, for the 2020 plan year. First, we detail in Section VIII why HHS cannot expect Part D plan sponsors to re-bid their entire business based upon the publication of new requirements subsequent to the annual 2020 Part C and D Advanced Notice and Call Letter, on April 1.¹²⁷ Second, the estimate is far too low. The most recent PRA submission by CMS for the annual bid pricing tool (2020 plan year) estimates that the total burden for the submission of bids is approximately \$22,477,500 for all plan sponsors for each contract year.¹²⁸ We expect that the entire process would need to be repeated – at the same \$22,477,500 in costs – should plans have to update their bids following an initial submission by June 3, 2019, in response to the provisions of a final rule issued after April 1. As we describe above, nearly every facet of the Part D program is interrupted by this rule change, and each component part of the BPT would require a re-assessment. (See Table 3.)

New disclosure requirement for PBMs. HHS proposes that PBMs and pharmaceutical manufacturers have written agreements specifying their contractual arrangements and interactions with plans, that PBMs disclose such agreements with plans, and that PBMs may be required to disclose this information to the Secretary upon request. They estimate the cost of these disclosures to be \$1.28 million each year. Elsewhere in these comments (see Section IX), we argue that the requirement is unnecessary given the contractual relationships that exist between plans and PBMs. Regardless, should PBMs be required to make such disclosures, HHS's cost estimates are likely adequate.

IT and claims processing system updates. HHS estimates that PBMs, pharmacies, and plans will need to update their information technology (IT) and claims processing systems to account for up-front discounts instead of rebates, at a cost of \$10.8 million for each of the first five years, requiring just five hours per affected business. These estimates are wholly inadequate.

- First, all of the investment must be made up front, and could not be spread over a five-year period. There may be ongoing upgrades over time, but HHS envisions that all Part D plans will be able to provide reduced out-of-pocket spending for beneficiaries as of January 1, 2020. This means that the PDE and Medicare Plan Finder (MPF) submissions by plan sponsors, and other CMS systems that require plan sponsor, pharmacy, and manufacturer coordination must be ready to go well in advance of January 1. (The Annual Enrollment Period for 2020 begins October 15, 2019.)
- Second, these IT upgrades are missing at least two key parties: wholesalers and manufacturers. If any final rule requires or permits the creation of a secondary claims processing system to facilitate chargebacks, pharmacies would receive partial payment from the plan or PBM and beneficiary, and recoup the up-front discount from the

¹²⁷ CMS, Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 1, 2019. Available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf>.

¹²⁸ See <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10142.html?DLPage=1&DLEntries=10&DLFilter=bpt&DLSort=1&DLSortDir=descending>, December 14, 2018.

manufacturer via the wholesaler. The manufacturer needs to know to which pharmacy the wholesaler is providing the discount, to ensure contract compliance on its end. In today's supply chain, the manufacturer and wholesaler are not privy to the final adjudicated Part D claim. Generally, it's not clear this envisioned system is even viable, but if it were, its costs are missing from HHS's estimates altogether.

- Third, HHS does not discuss engaging with the existing industry processes determine standards for implementing systematic changes, such as with the National Council on Prescription Drug Plans (NCPDP). Namely, NCPDP is currently working through standards related to the reporting of rebates passed through at the point-of-sale. We understand that it is not scheduled to conclude this work until sometime in 2020. Therefore, the minimum transaction standards required for a new system that adequately provides the supposed benefits of this rule will not be ready by January 1, 2020.
- Fourth, elsewhere in HHS, great strides are being made to improve interoperability. Through this Proposed Rule, HHS would introduce new transactions without having engaged the Office of the National Coordinator for Health IT (ONC) or the appropriate offices elsewhere within CMS. Recent rules issued by ONC and CMS do not contemplate such drastic changes to prescription drug transactions.¹²⁹
- Fifth, HHS does not account for the importance of systems testing in this timeline or cost estimate. Around the Medicare program, significant IT changes take on the order of years, not months, to implement.¹³⁰ Cost estimates need to account for the tremendous outlay of resources required to compress a normal development timeline into a few short months.

Accounting for the additional stakeholders noted above and considerably expanded time required to make these changes, we estimate this would require at least three to five network and computer system FTEs per affected business from an assumed July 1 final rule through the end of 2019. Table 3 includes our estimate for these costs.¹³¹

Costs based upon changes for beneficiaries. The last stakeholder addressed by HHS is Medicare Part D enrollees. HHS estimates total costs using implied wages to be \$209 million each year, assuming that 20% of enrollees will learn about and change their plan selection due to this rule. However, if the rule is finalized, many plans will look considerably different in 2020 compared to 2019. Current enrollees may find that premiums are increasing significantly, and after some shopping might also find that cost-sharing for their drugs may be lower on another plan. We assume that a larger proportion of non-low income enrollees (including those in MA-

¹²⁹ 84 Fed. Reg. 7424, March 4, 2019 and 84 Fed. Reg. 7610, March 4, 2019.

¹³⁰ For example, in 83 Fed. Reg. 16440 (April 16, 2018), CMS finalized requirements for the provider preclusion list to be implemented for 2019. Industry stakeholders continue to work through implementation issues with CMS including the ongoing submission and publication of FAQs.

¹³¹ We otherwise use the same implied wage rates and overhead assumptions as HHS.

PD plans and those new to Medicare Part D) will shop for new plans for 2020.¹³² While the Cost Accounting process does not include costs imposed on the government, we would note that the Medicare.gov and 1-800-Medicare operations teams should expect a significantly higher volume of inquiries during open enrollment, at unquantified costs to taxpayers.

Relatedly, low-income subsidy (LIS) recipients' interaction with the Part D re-enrollment *de minimis* rules will also be thrown in chaos. The Medicare population enrolled in LIS plans today is dominated by medically fragile members with chronic conditions. Currently, the lowest-income categories of LIS enrollees are automatically enrolled in plans within a narrow range of the benchmark premium in their region, and re-assigned as needed each year. These enrollees can then elect to remain in this plan in subsequent years and pay any additional premiums. LIS enrollees are less likely to engage with the Medicare Plan Finder (MPF) on an annual basis.¹³³ Absent definitive guidance or safeguards issued by CMS, there may be massive program-wide LIS plan enrollment disruption and drug access issues for these members. LIS enrollees who do in fact use MPF may not be able to find a suitable plan.

In total, we assume that about 80 percent of Part D enrollees across non-LIS and LIS will assess their plan choices, and calculate total first year costs of \$836 million. (See Table 3.) Not addressed in the Costs aspect, but discussed in Transfers below, is that some of these enrollees may choose to leave Part D altogether.

Summary of first year costs. In summary, OIG projected first year costs of \$285 million, which is a significant regulatory burden to impose on stakeholders for a Proposed Rule without a well-formed rationale. However, using what we believe are more realistic assumptions of the amount of time each stakeholder will spend assessing and responding to the rule and changing their business practices, we estimate these costs to be at least \$2.92 billion, for the first year alone. (See Table 3.) At that level of annual costs, this rule is the second most expensive rule issued by this Administration.¹³⁴

This \$2.9 billion is an added cost on the order of 2 percent of the entire Part D and Medicaid program's net expenditures for 2020.¹³⁵ It includes \$2.1 billion to be spent by the private sector to comply with this rule, rather than being spent on investments in pharmaceutical research and

¹³² See Deft Research, "Medicare Shopping and Switching Study," March 2019. Summary available at <https://www.psmbrokerage.com/blog/new-report-deft-researchs-2019-medicare-shopping-and-switching-study>. This report finds that 14% of MA-PD enrollees switched plans for 2019, when there was not a significant change in premiums.

¹³³ In 2015, Kaiser Family Foundation noted that about 11% of non-LIS enrollees switched plans each year, compared to only 4% of LIS enrollees who were not auto-reassigned. CMS will have to issue guidance regarding auto-reassignment to minimize disruption to these enrollees. See <http://files.kff.org/attachment/report-to-switch-or-be-switched-examining-changes-in-drug-plan-enrollment-among-medicare-part-d-low-income-subsidy-enrollees>.

¹³⁴ See American Action Forum, www.RegRodeo.com. The SEC Securities Transaction Settlement Cycle final rule, issued in 2017 with \$4.2 billion in one-year (and total) costs, and the SEC 2017 final rule - Requirements for Systemically Important U.S. Bank Holding Companies – had one-year and total costs of \$2.0 billion.

¹³⁵ The Medicare Trustees Report estimates Part D net expenditures to be \$112 billion for 2020. HHS estimates at 84 Fed. Reg. 2343 that net Medicaid drug spending was about \$29 billion in 2016. There are no projections for 2020 Medicaid net drug spending available. \$2.9 billion divided by \$142 billion is 2.0%.

development by manufacturers, or health care information technology by PBMs, plans, and pharmacies, for example. Costs borne by Part D plan sponsors, Medicaid managed care plans, and PBMs may be ultimately paid by beneficiaries and taxpayers through the administrative costs included in Part D bids and Medicaid managed care capitated rates, further increasing premiums and federal and state payments.¹³⁶ Nearly \$1.6 billion of these costs are borne by manufacturers, as they renegotiate contracts with PBMs and health plans and wholesalers. These increases in operating costs will be passed along to consumers and taxpayers in the form of higher drug prices.

PCMA Recommendation: HHS should update its estimates of the cost of this regulation and re-assess whether the significant costs imposed on the private sector by it are justified.

4. Benefits: The rule does not clearly articulate or document the supposed benefits of replacing rebates with up-front discounts

HHS describes qualitatively only two possible benefits that would result from this Proposed Rule: transparency to improve consumer choice, and improved compliance to prescribed therapies. Overall, this section of the rule is underdeveloped, and given the excessive costs associated with the rule overall, is underwhelming. In failing to develop this section, the Department seems to indicate that the benefits of the rule are not important to understand. This fails the standards set forth by Congress for rulemaking and puts a tremendous burden on the reviewing public to complete the research itself to judge whether the rule appropriately balances costs and benefits.

Transparency. We establish in Section III that HHS's view of transparency is not supported by the economic literature or long-standing government views on the effect on net costs, should all parties be aware of each other's best offers. The benefit described in this section of the rule, however, is focused on consumers who would have improved information upon which they can choose prescription drugs or plans. While HHS anticipates that this information will help beneficiaries make more efficient enrollment and therapeutic decisions, this statement is not supported by any cited evidence. We counter that other proposed rules from the Department would have a more profound effect on consumer decision-making. Real time benefit tools, for instance, as proposed by CMS would allow beneficiaries and prescribers to see at the point of prescribing what their cost-sharing would be for a range of therapeutic choices.¹³⁷

¹³⁶ The interplay of MLR requirements and CMS bid review will require additional guidance to implement. In 2020, administrative costs are expected to account for 11.1% of gross Part D program expenditures. See Medicare Trustees Report, 2018, Table IV. B8.

¹³⁷ 83 Fed. Reg. 62152, November 30, 2018. PCMA filed comments regarding real-time benefit tools, supporting their implementation but noting that plan year 2020 was likely too aggressive of a timeframe for doing so, due to the complexity of the proposed requirement.

Table 3. Summary of Costs for Calendar Year 2019 for Plan Year 2020 Operations.

Business Type	Affected Entities	Reviewing the Rule	Updating Part D Bids	PBM Disclosures	Changing Business Practices	IT Systems	Enrollment Options	Total
	Timing:	February-April	May-July	July-December	July-December	July-December	October-December	
PBMs	66 ¹³⁸	\$3,036,972	\$0	\$1,480,000	\$38,691,037	\$16,990,491	\$0	\$59,998,500
Part D plan sponsors	218	\$10,031,209	\$22,477,500	\$0	\$127,797,669	\$56,120,106	\$0	\$216,396,484
Medicaid agencies	56	\$2,576,824	\$0	\$0	\$32,828,759	\$14,416,174	\$0	\$49,821,757
Medicaid managed care plan sponsors	150	\$6,902,208	\$0	\$0	\$87,934,176	\$38,614,752	\$0	\$133,451,136
Drug manufacturers	1,775	\$81,676,128	\$0	\$0	\$1,040,554,416	\$456,941,232	\$0	\$1,579,171,776
Pharmacy chains or PSAO	65	\$2,990,957	\$0	\$0	\$38,104,810	\$16,733,059	\$0	\$57,828,826
Wholesalers	10	\$460,147	\$0	\$0	\$5,862,278	\$2,574,317	\$0	\$8,896,742
Medicare Part D enrollees	44.5 million	\$0	\$0	\$0	\$0	\$0	\$0	\$836,000,000
Total		\$107,674,445	\$22,477,500	\$1,480,000	\$1,371,773,146	\$602,390,131	\$836,000,000	\$2,941,565,222

¹³⁸ As noted earlier, PBMI now reports there are 66 PBMs as of 2019.

Adherence and outcomes. The second benefit offered by the Department is that with reduced out-of-pocket spending on some prescription drugs for some people, compliance with prescribed therapies would increase, and health outcomes would improve. HHS also acknowledges that spending on drugs may increase in this scenario, which may not be offset by reduced medical spending. However, HHS does not explore this topic despite its importance and despite significant academic investigations into these claims.¹³⁹ PCMA supports policies that improve compliance with prescribed therapies, including programs run by our PBM members and pharmacist counseling programs. We wish that HHS had better quantified these potential benefits (and costs) in this rulemaking, since understanding how many beneficiaries might benefit and to what extent would help the public assess the actual effects of this rule.

PCMA Recommendation: HHS should not move forward with a rule with such inadequately quantified benefits. There is a robust literature on both the transparency and adherence topics that deserves to be described and explored, in the context of this Proposed Rule or a similar initiative.

5. Transfers: HHS's analysis demonstrates that the Proposed Rule is a windfall for manufacturers, harming beneficiaries and taxpayers

In the context of a regulatory impact analysis, transfers differ from costs and benefits in that they describe a change in the allocation of existing resources, while costs describe new resources to be deployed and benefits describe changes in outcomes. In this rulemaking, HHS characterizes transfers through its citation of the CMS Office of the Actuary's (OACT) August 31, 2018 report, Milliman Consulting's January 31, 2019 report, and Wakely Consulting Group's August 8, 2018 report. The Milliman and Wakely reports provide additional context around the rule's possible effects, but should not be considered as on par with an analysis provided by OACT, which functions as the Department's official score-keeper.

One specific issue surrounding the OACT report is that it assumed behavior changes only by manufacturers, which OACT assumes would retain a portion of the existing rebates and in return reduce their list prices somewhat and slow the rate of list price growth on their products. No other behavioral changes are assumed. The manufacturer behavioral assumptions may be well supported by literature regarding price transparency, but other behavioral changes by beneficiaries are documented in the literature. Specifically, we would expect a portion of beneficiaries to disenroll or not join Part D plans if premiums rise as much as predicted. We also would expect additional utilization of drugs with rebates as a result of induced demand. Both of these behavioral responses would have the effect of further increasing premiums. By not considering these behavioral changes, and many other likely responses, OACT's results do not fully characterize the likely effects of the Proposed Rule. In the sections below, we detail specific questions or recommendations to bolster OACT's analysis, for a fuller understanding of the effects of this Proposed Rule.

¹³⁹ See as one example Eaddy et al., 2012, "How Patient Cost-Sharing Trends Affect Adherence and Outcomes: A Literature Review." *Pharmacy & Therapeutics*; Vol 37(1).

The range of estimates associated with Medicare Part D demonstrates an apparent interest in helping drug manufacturers. Notwithstanding the negative impact on beneficiaries, OIG is open about the financial harm this rule would bring to beneficiaries and taxpayers. We make the suggestions below to improve the current analysis, or demonstrate areas where OACT and the other actuaries' assumptions are problematic.

- Beneficiary premiums and their effect on enrollment.** While OACT estimates that Medicare Part D plan premiums may increase by as much as 25%, its analyses do not account for the effect on enrollment such an increase may have. The recent literature on Part D premium-related plan switches or drop-outs is not robust. However, it was well-documented that a sizable portion of those electing not to enroll in Part D plans had relatively better health and higher incomes, meaning they were better able to absorb unanticipated drug spending.¹⁴⁰ A 2019 study found that each \$100 increase in MA-PD premiums yielded a 34% increase in the rate of MA-PD plan switching. The background rate of MA-PD plan switching is 3-5% among individuals without complex care needs, and 5-15% for those with such needs.¹⁴¹ This Proposed Rule could create scenarios where all plan premiums increase substantially. Based on uncertainty and plan pricing, some plans may choose not to participate in PDP or MA-PD markets in 2020. Combining these, PDP and MA-PD enrollees may not find a suitable plan to switch to, and may disenroll from Part D coverage, or leave their MA-PD for fee-for-service Medicare (with or without a Part D plan). In the face of likely substantial premium increases, plan switching and disenrollment should be more fully accounted for in OACT's analysis. We note again that HHS was in possession of an analysis that highlighted many of these as likely consequences, and failed to address them in the Proposed Rule's regulatory impact analysis.¹⁴²
- Beneficiary spending.** OACT's analysis concludes that premiums will increase and beneficiary cost-sharing payments will decrease, but the people seeing decreases are outnumbered by those with premium increases. OACT's analysis, however, does not account for actual enrolled plan benefit packages, instead assuming a full deductible and 25% coinsurance on all non-low income beneficiaries in the initial coverage limit and coverage gap.¹⁴³ Accounting for benefit designs of plans actually chosen by enrollees would significantly reduce the transfers from manufacturers to beneficiaries. We provide detail on deductibles, copays, and the coverage gap below.

Deductibles: Beneficiaries pay 100% of the Part D negotiated price during the deductible phase of their Part D benefit. OACT's analysis results in all non-low income beneficiaries dispensed drugs with rebates receiving transfers from the Proposed Rule change. MedPAC, however, found that for 2018, 54% of PDP enrollees have no deductible or a

¹⁴⁰ See for example Neuman, P et al. 2007. "Medicare Prescription Drug Benefit Progress Report: Findings From A 2006 National Survey Of Seniors." *Health Affairs*. DOI 10.1377/hlthaff.26.5.w630

¹⁴¹ Meyers DJ, Belanger E, Joyce N, McHugh J, Rahman M, Mor V. Analysis of Drivers of Disenrollment and Plan Switching Among Medicare Advantage Beneficiaries. *JAMA Intern Med*. Published online February 25, 2019. doi:10.1001/jamainternmed.2018.7639.

¹⁴² See Milliman, 2019.

¹⁴³ On page 5 of the OACT report, it states its methodology as follows: "The impacts for Part D were calculated using the distribution of beneficiaries by gross drug spending for 2016 and the defined standard benefit design."

lower than standard deductible.¹⁴⁴ Among MA-PDs, only 3% of enrollees face the standard deductible.¹⁴⁵ **With the vast majority of enrollees choosing plans with less than the standard or no deductible at all, an analysis that assumes all pay the full amount will overstate the savings associated with reduced point-of-sale out-of-pocket payments.**

Coverage Gap: Under the Part D standard benefit, beneficiaries pay 25% coinsurance after reaching a total drug cost threshold, and until they reach the True Out-Of-Pocket cost (TrOOP) threshold. However, more than a third of MA-PD PBPs offer additional coverage in the Coverage Gap.¹⁴⁶ This can take the form of copays for generics or other preferred drugs rather than coinsurance. Beneficiaries electing these plan designs are also not aided to the extent that OACT has estimated.

Copays: According to the Kaiser Family Foundation, eight of the top 10 Part D plans by enrollment (accounting for 77% of non-low income enrollees) require copays for preferred drugs, rather than coinsurance. Under current regulations, plans must ensure that the balance of copays and coinsurance are actuarially equivalent. If finalized, under the new rules, plans may have to reduce copays marginally to meet these same requirements, but one analysis finds that most preferred drugs are likely still priced high enough after rebates not to require any significant reductions in copays.¹⁴⁷ All told, a beneficiary paying a copay today may see no reduction in out-of-pocket costs if the negotiated price is reduced per the terms of this Proposed Rule.¹⁴⁸ This is highlighted by Milliman's report commissioned by HHS for the Proposed Rule, but not cited or otherwise described.¹⁴⁹

Formulary changes: As we noted previously, in response to the Proposed Rule, Part D plans may adjust formulary cost-sharing tiers, which could have unknown effects on 2020 drug utilization. Formularies themselves may be narrowed in order to extract similar levels of price concessions from manufacturers.¹⁵⁰ Plans balance access and cost when constructing formularies today, but strategies may have to shift in order to remain competitive.

Recommended updates to the analysis: In conclusion, OACT's estimates of beneficiary cost-sharing savings are overstated, based on the plans that enrollees actually choose. Enrollees generally elect plans without deductibles and with copays rather than coinsurance. Preferred drugs are often placed on copay tiers because their

¹⁴⁴ MedPAC March 2019 Report to Congress, page 397.

¹⁴⁵ *Ibid.*

¹⁴⁶ PCMA analysis of the 2019 CMS MA Landscape file, available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/index.html>.

¹⁴⁷ See Wakely Consulting Group, "Where, Oh Where, Should My Pharmacy Rebates Go?," March 2019. Available at <https://www.wakely.com/blog/medicare-part-d-2020-where-oh-where-should-my-pharmacy-rebates-go>.

¹⁴⁸ A preferred drug copay tier may move from \$25 to \$20, to meet actuarial equivalence, for example. However, to the extent a drug's list price is reduced by rebates below the imposed copay, the pharmacy is required to sell it to the beneficiary at the actual cost of the drug. See Part D Prescription Drug Benefit manual, Chapter 6.

¹⁴⁹ See Milliman, 2019.

¹⁵⁰ See for example "A World Without Rebates: Predictions for How the Channel Will Evolve and Why Drug Prices Will Go Down," DrugChannels.net blog, available at <https://www.drugchannels.net/2019/03/a-world-without-rebates-predictions-for.html>.

manufacturers offer larger rebates than their competitors. Simply put, there is much less savings available to beneficiaries for those rebates being passed along at the point-of-sale or turned into up-front discounts than the analysis implies. Under a revised analysis accounting for plan benefit package enrollment, OACT would find fewer beneficiaries with out-of-pocket savings, while the premium impacts likely would remain the same or worse (due to enrollment changes). In this majority of cases where cost-sharing would not be reduced, the Proposed Rule offers no financial benefit to any party.

- **Federal spending.** OACT estimates that federal spending will increase by \$196 billion over ten years, driven mainly by the payment of increased premium subsidies to Part D plans. Some of these transfers are related to a change in the volume of prescriptions dispensed in the coverage gap rather than the reinsurance phase, assuming reduced negotiated prices. This is countered somewhat by OACT's estimates on changes to the benefit design parameter thresholds, as presented in the Proposed Rule. The general result is that reinsurance payments are reduced as spending is shifted toward earlier benefit phases. Given the points above about how many fewer beneficiaries will see reduced out-of-pocket spending than is estimated by OACT, and significant questions on whether benefit design parameters would be changed at all (see our comments and regulatory implementation questions in Section VI), we are unsure whether these results hold. We suggest that as OACT revises its estimates to account for public comments, it should ensure it has sufficient and documented guidance from CMS for its assumptions.
- **Manufacturers are the net recipients of most of the \$170.9 billion in excess federal spending identified by OACT.**¹⁵¹ OACT's estimate accounts for reduced liabilities for manufacturers in the Coverage Gap Discount Program (CGDP) as a result of both beneficiaries entering the coverage gap less frequently or later in the year, and because the discount would be based upon a lower Part D negotiated price. In addition to savings up to \$39.8 billion from changes to the CGDP, manufacturers are also the net recipients of most of the additional \$131.1 billion in federal spending, not allocated to beneficiaries. However, we believe this \$170.9 billion in transfers is still an underestimate. As we note later in this section, transfers from states to manufacturers regarding reduced Medicaid Drug Rebate Program (MDRP) liability, from manufacturers to 340B covered entities due to the effects on that program's ceiling price, and related to other stakeholders including the uninsured, are only referenced briefly. We request that OACT carefully consider the full range of effects on manufacturers and provide an estimate accounting for these effects. **By our estimates, transfers to manufacturers incorporating all of these effects could reach \$200 billion over ten years.**
- **Transfers related to a new wholesaler chargeback system are missing altogether.** HHS describes, but does not propose, a new system for processing up-front discounts in Part D and Medicaid managed care that replace retrospective rebates. However, such a fundamental change in the pharmacy transaction process would require significant

¹⁵¹ Pew Charitable Trusts. Letter to Senate Aging Committee. March 6, 2019. Available at <https://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2019/03/06/pew-submits-letter-on-drug-price-proposal-to-senate-panel-on-aging>.

administrative cost (as described above) and would generate transfers not contemplated within this rule. We re-iterate our position that wholesaler involvement is not required for the rule's provisions to be implemented. This supposition by HHS introduces a new and unnecessary "middleman" whose interests are aligned with manufacturers. However, if HHS is to proceed, we request for the purposes of public comment that HHS and OACT fully flesh out this model and calculate transfers to and from wholesalers, manufacturers, pharmacies, and PSOs. Under such an analysis, we expect that pharmacy revenue would decrease. Reduced PBM payments to pharmacies net of price concessions plus the chargebacks received from wholesalers would be less than payments currently received from PBMs. Wholesalers would probably see increased revenues, keeping a portion of the discounts as service fees. Manufacturers might see reduced gross revenues (if list prices are reduced) but increased net revenues regardless (as OACT describes) based on a less than one-to-one replacement of rebates with discounts, as described in Section III.

The Proposed Rule's estimates for Medicaid need further exploration. HHS describes the transfers expected in Medicaid in the opening section of the Regulatory Impact Analysis section. Only the CMS OACT report quantifies effects on Medicaid. Because so much more is written about the Medicare effects, it appears that Medicaid was not given the level of attention it deserved. These estimates should instead be included in the Transfers section and the accounting statement that follows it. We raise several specific concerns with HHS's interpretation of transfers in the Medicaid program as a result of this rule.¹⁵²

- **It is not clear if all effects on MDRP calculations are included.** Based upon changes to the calculation of AMP, OACT calculates that these prices will decline by 3.2%, reducing payments made by manufacturers to states by 4.25%.¹⁵³ These reduced rebates are mostly offset by reduced payments from states or managed care plans to pharmacies for these drugs. Below we list specific areas in which the effect on MDRP calculations can be better described. In general, and as is acknowledged by HHS in the Proposed Rule and OACT in its analysis, many of these questions will require specific CMS guidance to manufacturers in terms of their government price reporting obligations.

Incorporation of the statutory price increase penalty rebate seems incomplete: In addition to a minimum mandatory rebate in Medicaid of 23.1% of AMP, manufacturers also pay an additional rebate to account for price increases that exceed the rate of inflation. Lacking specific guidance otherwise from CMS, if list prices are reduced by manufacturers under this Proposed Rule (or authorized generics are introduced), then AMP will decline proportionately. Under MDRP's price increase penalty rebate component, a number of drugs will fall out of the price increase penalty component of the rebate, or at least see these penalties reduced, as new AMPs compare more

¹⁵² For a fuller analysis of the Medicaid effects, see Milliman, Inc., "HHS's Proposed Modification Pharmacy Rebate Safe Harbors: Implications for Medicaid." March 22, 2019. Available at <http://www.milliman.com/uploadedFiles/insight/2019/HHS-proposed-modification.pdf>.

¹⁵³ OACT estimates about \$1.7 billion in reduced rebate payments in 2020. We project about \$40 billion in Medicaid rebate payments for 2020, based upon MACPAC's rebate receipts figures and OACT's NHE Medicaid net prescription drug spending. \$1.7 billion divided by \$40 billion is 4.25%.

favorably to base date AMPs. In its report, OACT acknowledges that it accounts for the price increase penalty. However, we expected to see a larger effect in rebate revenue reductions to states, given the estimated number of drugs that are paying price increase penalty rebates. MACPAC estimated that by the fourth quarter of 2015, 18.5% of drugs had reached the inflationary cap.¹⁵⁴ For further triangulation, Medicaid rebates accounted for 54% of gross drug spending, far in excess of the 23.1% minimum rebate for brands and 13.1% for generics. This indicates that drugs with rebates reflecting either Best Price (BP) or the price increase penalty rebate are dominating the Medicaid pharmaceutical market. Earlier estimates by OIG found that as early as 2012, 54% of total brand drug rebates were associated with the price increase penalty rebate rather than statutory minimum or BP.¹⁵⁵ We ask that OACT reconsider its inputs for this portion of the analysis to better account for the transfer to manufacturers this would generate.

Best Price could be triggered much less frequently: If as a result of this Proposed Rule, AMPs are generally reduced, then the comparison of the minimum mandatory rebate to the Best Price offered by a manufacturer may yield a reduction in the number of drugs subject to Best Price-based rebates. This will decrease total rebates paid to states (and shared with the federal government). Unless CMS issues specific guidance otherwise, the current definition of AMP explicitly excludes PBM discounts and rebates but, by its own terms, *includes* discounts and/or rebates facilitated by wholesalers or retail pharmacies. In addition, the regulatory definition of BP currently excludes PBM rebates and discounts, excludes manufacturer-provided copay assistance, but includes any wholesaler-facilitated discounts. In net, manufacturers are unlikely to negotiate as steep discounts if the rule is finalized, in order to avoid resetting BP.

Ambiguity in the calculation of AMP: The Proposed Rule does not provide clarity as to how new up-front discounts in Part D that are reflected in the prices paid by pharmacies would be treated for purposes of AMP.¹⁵⁶ Lacking specific guidance otherwise from CMS, manufacturers may make reasonable assumptions to include them as discounts provided to pharmacies, reducing their products' AMPs. Should these price concessions be included in AMP, then rebate revenues will fall even further (as will reimbursement rates). OACT should provide an analysis under both scenarios for discounts counting toward AMP until CMS provides such clarity, demonstrating the transfer effect that each interpretation would have.

Manufacturer actions complicate the rebate calculations: Recent manufacturer actions in which they claim to have lowered their list prices add complexity to the calculation of the effects of this Proposed Rule. We are unaware of any case where a brand drug

¹⁵⁴ See MACPAC, Potential Recommendations on Drug Coverage Grace Period and Rebate Cap, March 7, 2019. Available at <https://www.macpac.gov/wp-content/uploads/2019/03/Potential-Recommendations-on-Coverage-Grace-Period-and-Rebate-Cap.pdf>.

¹⁵⁵ See OIG, "Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin." OEI-03-13-00650, April 2015. Available at <https://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf>.

¹⁵⁶ Specifically, if finalized, CMS will need to reconcile the language in §1927(k)(b)(i)(IV) and (ii) regarding whether the discount, despite being negotiated by an entity whose transactions are excluded under (IV), is "received by, paid by, or passed through to, retail community pharmacies," possibly through its own rulemaking. Note however that we presume these price concessions would remain exempt from Best Price under §1927(c)(i)(VI).

manufacturer simply reduced the product's list price in response to the rule. Instead, we have seen manufacturers issued a second unique brand NDC using a different NDC labeler code. For purposes of Medicaid rebates, lacking specific CMS guidance otherwise, the new NDC likely qualifies for a new AMP and base date AMP. While we do not have foresight into the manufacturer's strategy for this decision, the Department should consider the effects of having multiple AMPs for the same product, and the effect this may have on state finances and pharmacy reimbursement and operations. In at least two other cases, the manufacturer issued an "authorized generic" of its high-cost, high-rebate product. One of these products is insulin, which accounted for over \$17 billion in gross Medicaid and Part D spending in 2017. The other is a direct-acting antiviral to treat Hepatitis C, the class for which Medicaid and Part D spent nearly \$10 billion in 2017, accounting for nearly 10% of gross drug spending in these programs.¹⁵⁷ As we noted earlier in regards to the price increase penalty component of the MDRP rebate, the manufacturer may benefit from these products by paying lower rebates. In the case of an authorized generic, the manufacturer's AMP is calculated as the volume-weighted average of sales of the brand and authorized generic. This will result in the reduction of each of these products' AMPs, and based on comparison to base date AMPs at least for the insulin product, a significant reduction in the inflation-based penalty the manufacturer currently pays. While lower-priced products can produce benefits for consumers and purchasers, HHS should consider how its complex price reporting system may be incentivizing manufacturers to issue copies of their drugs at lower list prices, rather than simply reducing the list prices for their existing products. We request that OACT, in any updated analysis, account for these manufacturer behaviors as well.

Secondary effects of changes in Medicaid managed care negotiations: The changes proposed under Medicaid managed care also may translate into changes in a drug's AMP or Best Price. Currently, the rebates negotiated by PBMs under Medicaid managed care contracts are excluded from AMP (as are all PBM rebates per §1927(c)), but are included in Best Price (only Part D rebates are excluded, among this rule's target contracts). As we point out above, lacking specific guidance otherwise from CMS, the up-front discount that replaces rebates may not qualify for protection from AMP. Thus, the transition of high AMP, low BP units to low AMP, low BP units will lead to a reduced AMP and the possibility that BP is no longer triggered. The reduced AMP on its own will reduce rebate revenues and reimbursements; the recovery from a BP-based rebate only further reduces rebate liability for manufacturers, creating possibly greater transfers from states to drug companies.

- **States are likely to change course in their management of prescription drug costs vis-à-vis supplemental rebates and Medicaid managed care.** Later in these comments (see Section VII), we describe how undoing the negotiating leverage for Medicaid managed care will lead states to reconsider how they are contracting for managed care and prescription drug benefits. Any such changes would require states to

¹⁵⁷ PCMA analysis of the CMS Medicaid and Part D Drug Dashboards, last revised March 15, 2019. For insulins we summed total spending for any molecule name that included "insulin," except for supplies. For direct-acting antivirals to treat Hepatitis C, we summed spending for Harvoni, Epclusa, Daklinza, Olysio, Viekira XR, Viekira Pak, and Sovaldi.

undertake significant analyses to understand their options. OACT assumes in its report that half of the managed care rebates negotiated today will disappear, as transfers back to manufacturers with the other half being translated to state supplemental rebates. However, we believe a more robust analysis should contemplate a number of managed care contracts being renegotiated, or having prescription drug benefits “carved out,” at higher net expense to the federal government. If the prescription drug benefit is a part of the capitated payment received by MCOs, then the federal government shares in the savings MCOs negotiate on drugs, because the entirety of the MCO-negotiated rebate is used within the managed care program. If a state instead opts for a state supplemental rebate regime, then the dollars paid by manufacturers are not necessarily used to offset health care costs, and federal savings are reduced.

The Proposed Rule’s estimates for Part A and Part B are underdeveloped. The Proposed Rule does not describe how its effects would affect other federal health care programs, such as Medicare Part A and B drug spending. OACT, in its analysis accompanying the Proposed Rule, describes small effects on the Average Sales Prices (ASP) paid for drugs covered under Parts B and D, depending on how they are prescribed and administered. Lacking specific guidance otherwise from CMS, we would expect that manufacturers would maximize reporting to limit the effect of these changes in price concessions on their ASPs. However, in addition to effects on the government price calculations, there are farther-ranging pharmaceutical market effects. OACT’s analysis, when updated, should reflect two likely manufacturer behavioral responses in the future mix of facility-administered versus Part D drugs.

First, while the anticipated effects on ASP may in fact be minimal, as reported, OACT should account for a lack of CMS guidance on the treatment of up-front discounts offered to pharmacies. As we described above regarding statutory Medicaid rebates and AMP, depending on CMS guidance, the effects may be significantly larger.

Second, drugs used in hospital outpatient and physician office settings, while rarely Part D covered drugs, may compete with Part D drugs. For instance, in the rheumatoid arthritis and inflammatory conditions market, there are about 20 brand name drugs approved to treat a range of similar conditions. About half are physician-administered and half are self-administered injections or oral formulations. Should manufacturer pricing leverage for Part D drugs shift as a result of this rule, the effects on the Part B market are not addressed. One could imagine manufacturers shifting R&D to push drugs to outpatient pharmacy settings or engaging in strategies to shift Part B-covered prescriptions to an enrollee’s Part D benefit.

The transfers associated with private insurance and state employee coverage should be appropriately categorized and included in this section. OACT estimates that private health insurance spending will decrease by \$11.8 billion, and state employee spending will decrease by \$4.3 billion, over the next ten years. OACT’s findings are based mainly upon reduced list prices and lower trend. OACT’s analysis expressly does not contemplate that rebates would be replaced by discounts to commercial plans,¹⁵⁸ but in several places in the Proposed Rule, it is

¹⁵⁸ By implication. In the OACT report, Table 4b allocates price concessions for Part D to “discounts” and for non-Part D to “rebates.”

clear that HHS would both prefer this outcome, and believes its enforcement authority could spur such an outcome.¹⁵⁹ The OACT analysis should have been structured in such a way as to estimate this outcome. We presume that such an analysis would lead instead to a net transfer of dollars from employers and states to drug manufacturers, as we see in the Part D analysis, rather than the results which are presented in the OACT report and the Proposed Rule.

Effects on other stakeholders are not adequately described or quantified. OACT's report includes a single line in its Table 2 indicating a total of \$6.3 billion in savings over ten years for all other stakeholders including the uninsured.

- **Pharmaceutical supply chain.** Neither the Proposed Rule nor the accompanying OACT report discuss the effects on wholesalers or other distributors, pharmacies, PSOs, or others in the drug supply chain. Pew, in its letter to the Senate Aging Committee, notes that among all the transfers that would flow back to manufacturers, it is likely that a portion would end up with its intermediaries including distributors.¹⁶⁰ HHS and OACT should more fully consider the recipients of transfers stemming from this Proposed Rule to include all supply chain stakeholders.
- **Federal purchasers.** The preamble to the Proposed Rule adds somewhat more context than OACT, noting that Federal Supply Schedule (FSS) or Federal Ceiling Price (FCP) purchasers such as the Veterans Healthcare Administration, Department of Defense, and others may see reduced acquisition costs. FCP, used by the VA as the basis for its negotiations with drug manufacturers, is based upon the non-federal sales portion of AMP. As AMPs broadly decline, manufacturers may be less interested in providing additional discounts to the VA. Based on the sizes of these programs, these transfers to federal purchasers or back to manufacturers may be consequential and should be more fully fleshed out.
- **340B.** Effects on the 340B program and the transfers it would generate from manufacturers to hospitals and other covered entities are not accounted for in the preamble of the rule or the OACT analysis. The 340B program is estimated to account for more than \$30 billion in gross drug sales and growing,¹⁶¹ about half the size of the Medicaid program, and relying upon much of the same pricing infrastructure. In the broadest terms, a reduced AMP would reduce 340B ceiling prices, benefiting covered entities. However, as we note in the MDRP section above, the interaction of the price increase penalty and BP require a drug-by-drug analysis to fully quantify these effects.
- **The uninsured.** OACT includes the uninsured in its catch-all row in Table 2 of its report. In the most straightforward way, any reduction in list price will immediately benefit all cash pay customers for prescription drugs. However, despite OACT's assumption regarding slight list price decreases or a slowing of list price increases by manufacturers,

¹⁵⁹ E.g. 84 Fed. Reg. 2347, describing how rebates to private payers may violate the AKS if this rule is finalized.

¹⁶⁰ Pew Charitable Trusts. Letter to Senate Aging Committee. March 6, 2019. Available at <https://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2019/03/06/pew-submits-letter-on-drug-price-proposal-to-senate-panel-on-aging>.

¹⁶¹ See <https://www.drugchannels.net/2018/05/exclusive-340b-program-reached-193.html>.

there is nothing in the Proposed Rule that would require such an action, and thus there is no positive effect for the uninsured outside of that analytic assumption. Given HHS's expressed concern about out-of-pocket costs, transfers from manufacturers to this population would seemingly be of interest. We reiterate, however, that there is no mechanism by which manufacturers will be forced to reduce their list prices, and the uninsured are not guaranteed any benefit from the rule whatsoever. We ask that HHS emphasize that in any Final Rule that the uninsured do not benefit from the Proposed Rule's provisions.

- **Other unaddressed populations and programs.** A growing number of consumers are using discount programs such as GoodRx to find the best pharmacy prices for their prescribed medicines. This kind of transparency can greatly benefit consumers. However, this Proposed Rule does not consider such third party programs. By contrast, many brand drug manufacturers offer copay coupons and refer patients prescribed their products to copay assistance foundations. These organizations provide significant levels of funding for enrollees both inside and outside of federal health care programs.¹⁶² Based on the use of manufacturer patient support programs within Part D,¹⁶³ and to the extent that the rule's effects could spill over to the private market, OACT should consider that the donations and payments made by manufacturers under these programs may be reduced, resulting in further net transfers from patients to manufacturers.

PCMA Recommendation: The economic impact analysis does not fully characterize the effects of the rule, leaving the public with incomplete information to assess the rule's negative effects. HHS should withdraw these proposed regulatory changes because they do not sufficiently address beneficiary out-of-pocket concerns, and result in a transfer of billions of dollars from the federal government, state governments, and Medicare beneficiaries to drug manufacturers.

¹⁶² See for example Austin Frerick, "The Cloak of Social Responsibility: Pharmaceutical Corporate Charity." November 2016. *Tax Notes*: 153(9). Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2874391. And also Jennifer Chen, "Copay Assistance Programs." Available at <https://comm.ncsl.org/productfiles/119423533/DrugPricing-ChenPowerPoint.pdf>. Frerick estimates that \$7 billion was donated to these charitable foundations. Chen estimates that at least \$5 billion in copay coupons were provided for specialty drugs in in 2017.

¹⁶³ While generally manufacturer coupons are disallowed in federal health care programs, payments made by manufacturer-supported patient assistance programs do not count toward TrOOP. However, payments made by independent non-profit organizations do count toward the enrollees' TrOOP obligations. See CMS, Medicare Part D Prescription Drug Benefit Manual, Ch. 14, Appendix E.

Section VI. Significant Questions Remain Regarding Medicare Part D Implementation of the Proposed Rule

We are puzzled as to how the OIG can issue a rule that would completely upend the drug pricing construct in Medicare Part D without any reference or consideration regarding the role of CMS in managing, regulating and overseeing Part D. This is of particular concern because of the large number of Part D regulatory requirements and guidance, including bidding and reporting mechanisms that need to be changed, clarified, or developed, in order to make the new pricing construct viable if the Proposed Rule is finalized. Moreover, some of the issues may have different answers depending on whether the rebate is passed through at POS or is reflected as a discount.

Beyond totally undermining the Part D benefit construct, the Proposed Rule would also completely undo the current drug supply chain with an untested approach that can be expected to result in major costs and burdens to all entities in the supply chain as well as barriers to beneficiary access to drug coverage. Frankly, we just do not see how the chargeback system envisioned is viable under Part D at a time when CMS has no regulatory structure or oversight mechanism applicable to chargebacks. For example, to the extent wholesalers would seek to facilitate such transactions, wholesalers – unlike Part D plans and their PBMs – are not entitled to access enrollee-level data related to costs for Part D and thus would not be able to access the LIS status of the enrollee. We have raised these concerns in other sections of this letter.

Importantly, these CMS programmatic issues must be addressed and resolved prior to the effective date of any safe harbor changes in order to provide the Part D program some level of certainty as to how the program will operate. The potential for major disruption of the program in general, and for beneficiaries in particular, in the absence of duly promulgated regulatory standards with sufficient time for implementation cannot be ignored.

In Table 4 on the next several pages entitled “Medicare Part D Details Needed for Implementation of Proposed Rebate Rule,” we list the key Medicare Part D regulatory requirements (many of which have related subregulatory guidance) that would need to be addressed to make implementation feasible. We further note that this largely needs to be accomplished by duly issued proposed notice and comment rulemaking emanating from CMS, as the delegated entity within HHS to regulate Part D.

Table 4. Medicare Part D Details Needed for Implementation of Proposed Rebate Rule.

Category	Rulemaking or guidance needed	Citation	Is there a different approach if...	
			Rebates are passed through at POS	Discounts replace rebates
Benefit design	Does the price concession count toward a patient's TrOOP?	42 CFR §. 423.104		
Benefit design	Does the price concession count toward total drug cost?	42 CFR §. 423.104		
Benefit design	Does the price concession count toward negotiated price for purposes of the Coverage Gap Discount Program?	42 CFR §. 423.104		
Benefit design	If price concessions are negotiated at the plan sponsor level, across all plan benefit packages and benefit phases and populations, how would CMS require them to be apportioned to enrollee cost-sharing?	42 CFR §. 423.104		
Benefit design	Can a manufacturer offer different price concessions for the same drug to the same plan sponsor depending on the plan benefit package?	42 CFR §. 423.104		
Benefit design	If a price concession is granted in one benefit phase, must it apply to all benefit phases?	42 CFR §. 423.104		
Benefit design	In the Coverage Gap, what happens to plan payments and enrollee cost-sharing if the price concession exceeds 30%?	42 CFR §. 423.104; 42 CFR § 423.2320		
Benefit design	If price concessions aren't applied uniformly across benefit phases, how will CMS handle straddle claims?	42 CFR § 423.104; 42 CFR § 423.329		
Benefit design	How will pricing be handled for drugs that can be covered under Part B or Part D and are adjudicated using CMS systems (e.g. immunosuppressants for prevention of transplant rejection) or "white bagged"? When covered as Part B, what if Part D cost-sharing would be lower due to price concessions? Could a beneficiary appeal?	42 CFR § 423.104; 42 CFR § 423.566		
Benefit design	How does the price concession reduce cost-sharing if the enrollee has a copay for preferred brand drugs?	42 CFR § 423.104		

Category	Rulemaking or guidance needed	Citation	Is there a different approach if...	
			Rebates are passed through at POS	Discounts replace rebates
Benefit design	What cost-sharing should a plan assess for drugs where the total price concessions bring the net cost of a drug to or below \$0.00? For example, if the rebate passed through at the point of sale is larger than beneficiary coinsurance, because of the manufacturer discount that is also provided in the Coverage Gap?	42 CFR § 423.104		
Benefit design	Many vaccines are covered by Part D plans. Does the change in safe harbors apply to vaccines? Many plans include them on \$0 tiers (especially the USPSTF endorsed preventive services vaccines). How could a price concession be “passed through” when the cost-sharing is already \$0?	42 CFR § 423.104		
Benefit design	Since risk adjustments are used to calculate the bid amounts, will CMS recalibrate the RxHCC model to reflect the new applicable costs associated with high-rebate versus low-rebate classes?	42 CFR § 423.265		
Benefit design/LIS	What if LIS enrollee is in the copay phase of benefit?	42 CFR § 423.782		
Benefit design/LIS	What if tier is \$0 for an LIS enrollee? (e.g. a biosimilar on the preferred drug tier)	42 CFR § 423.782		
Benefit design/LIS	What if LIS enrollee is in the \$0 cost-sharing benefit phase?	42 CFR § 423.782		
Benefit design/LIS	Will the de minimis premium policy for LIS be increased for 2020? This may be critical to avoid massive plan disruption for LIS enrollees.	42 CFR § 423.782		
Beneficiary design – different types of pharmacies	The rule discusses pharmacies only in general terms but the application of the rule to various kinds of pharmacies is complicated – LTC, mail order, specialty will have different applications and expectations.	42 CFR § 423.120 42 CFR § 423.124		
Beneficiary rights	How would CMS expect plans to apply tiering exceptions policies? Would the percentage price concession applied to the lower-tier drug be applied to the higher-tier drug's price?	42 CFR § 423.578		

Category	Rulemaking or guidance needed	Citation	Is there a different approach if...	
			Rebates are passed through at POS	Discounts replace rebates
Beneficiary rights	How would CMS expect plans to apply formulary exceptions when approving a no price concession drug?	42 CFR § 423.578		
Beneficiary rights	What are beneficiary appeal rights, if any, regarding the amount of rebate they receive?	42 CFR § 423.566		
Beneficiary rights	How will CMS handle transition fills given the likelihood of significant formulary changes and enrollment changes for the first year this is in effect?	42 CFR § 423.120(b)(3)		
Bid process	If price concessions are negotiated at the plan sponsor level, rather than the plan benefit package level, how would CMS require them to be allocated in the bid?	42 CFR § 423.265		
Bid process	What is the timing for updating the Bid Pricing Tool to accommodate these changes to price concessions?	42 CFR § 423.265		
Bid process	How would CMS handle OOPC tool and Total Beneficiary Cost revisions?	42 CFR § 423.265		
Bid process	How will changes in Part D bid amounts be incorporated into MA-PD submissions?	42 CFR § 423.265 42 CFR § 422.254		
Bid process	Would CMS require other plan types (e.g. EGWPs) to follow its lead on the above topics?	42 CFR § 423.265		
Data reporting	Will there be changes to the PDE record? How will claims be reported where a rebate was provided?	Medicare Part D Reporting Requirements		
Data reporting	What is the effect on PDE data reporting procedures? Would the price concession be reported on the estimated rebate field?	Medicare Part D Reporting Requirements		
Data reporting	Since only plan sponsors have all the data to submit PDEs (and PDEs are the basis for the Coverage Gap Discount Program), how will PDEs be reported when wholesalers are involved?	Medicare Part D Reporting Requirements		

Category	Rulemaking or guidance needed	Citation	Is there a different approach if...	
			Rebates are passed through at POS	Discounts replace rebates
Data reporting	How are claims to be reported where a rebate was provided but the script was later determined not to be eligible for a rebate (e.g., due to 340B, denial, patient recoupment, duplicate claims)?	Medicare Part D Reporting Requirements		
Data reporting	How will these price concessions be reflected in DIR reports and how will CMS revise DIR reporting procedures to account for these price concessions? And, how will the reporting requirements be revised to account for the new requirements for PBM service fees?	42 CFR § 423.352; 42 CFR § 423.360		
Data reporting	Would existing NCPDP reporting mechanisms be able to accommodate these changes?	NCPDP Reporting Standards		
Data reporting	Would CMS need to create a manufacturer agreement since confidential data is being collected and reported?	42 CFR § 423.322		
Definitions	Will CMS adopt the same definitions as OIG? What is the definition of a rebated or discounted drug? How will the definition of 100% rebate at POS accommodate those drugs that are rebatable but are then subject to retroactive denial due to a range of reasons (e.g., due to 340B, patient recoupment, duplicative claims)? What is the definition of negotiated price for rebated drugs or discounted drugs? What is the definition of a chargeback?	42 CFR § 423.100; 42 CFR § 423.308		
Enrollee communications	What price is to be reported on Medicare Plan Finder (MPF)? How often will prices be required to be updated?	TBD		
Enrollee communications	What price is reported on the Explanation of Benefits (EOB)?	42 CFR § 423.128		
Enrollee communications	What price is to be reported on the forthcoming Real Time Benefit Tool (RTBT)?	TBD		
Enrollee communications	What changes will be required by CMS in terms of the language in the Evidence of Coverage (EOC) and model marketing materials?	42 CFR § 423.128		
Enrollee communications	Will enrollees be told the price concession amount at POS? What if a plan uses both rebates passed through at POS and discounts?	42 CFR § 423.128; 42 CFR § 423.132		

Category	Rulemaking or guidance needed	Citation	Is there a different approach if...	
			Rebates are passed through at POS	Discounts replace rebates
Enrollee communications	Would the plan Advanced Notice of Changes (ANOC) have to be revised for 2020 (and annually thereafter) to reflect changes in the rebate status?	42 CFR § 423.128		
Formulary structure	Will the CMS formulary review process change? If a plan has both rebated drugs and discounted drugs (in lieu of rebates) is that to be reflected in the formulary?	42 CFR § 423.272		
Formulary structure	Can rebated drugs be placed on their own tier? Will additional tiers be allowed to accommodate the new arrangements?	42 CFR § 423.104; 42 CFR § 423.272		
Formulary structure	If a manufacturer's price concession takes the form of alternative NDCs for existing products, how will CMS adopt formulary flexibility to allow for this?	TBD		
Formulary structure	If instead of rebates or discounts, a manufacturer provides the same drug but gives it a new NDC, or offers it as an authorized generic, or an authorized biosimilar, or some other alternative category, how is such option treated under the formulary? E.g., can a plan meet the two drugs per category/class by offering a rebated drug with POS pass-through and the same drug with a different NDC?	TBD		
Other Part D requirements – MLR	How will the significant new costs (e.g., to update systems, update contracts, staff call centers) be included for purposes of administrative costs for purposes of MLR compliance? In order to meet the targets, plans will have to collect significantly higher premiums and make larger than expected claims payments, driving up enrollee and taxpayer costs if there isn't an exception for these new costs.	42 CFR § 423.2420		
Other Part D requirements – MTM	How would the price concession or reduction be accounted for in the cost component of MTM? Might previously-qualified enrollees no longer qualify as they no longer meet the cost-threshold?	42 CFR § 423.153		

Category	Rulemaking or guidance needed	Citation	Is there a different approach if...	
			Rebates are passed through at POS	Discounts replace rebates
Other Part D requirements – prompt pay	Will payments to pharmacies still be subject to prompt pay? How will that work with regard to chargeback payments where CMS has no regulatory authority over wholesalers?	42 CFR § 423.520		
Other Part D requirements – star ratings	For appeals and exceptions, will CMS handle beneficiary complaints in such a way that plan quality ratings are not affected? (E.g., enrollee thinks rebate should be higher, but it isn't)	42 CFR § 423.186		
Other Part D requirements – transition fill	How will the price concessions or reductions be applied to transition fills?	42 CFR § 423.120		
Reconciliation	Use of projected price concessions on market share – what if not achieved?	42 CFR § 423.343		
Reconciliation	How will the price concessions be reported for purposes of reconciliation?	42 CFR § 423.343		
Reconciliation	Will CMS create a process to reconcile over- or under-payments of price concessions to enrollees?	42 CFR § 423.343		
Risk score model	When and how will CMS recalibrate the RxHCC model to reflect these changes? If there is meaningful selection bias (e.g., all Hep C beneficiaries enroll in the same plan), how will the model compensate for that?	42 CFR § 423.265		
Administrative burden	What of the above needs to go through PRA processes, notice-and-comment rulemaking versus guidance, or other formal mechanisms?	TBD		
Attestation	Plan sponsors are required to certify the accuracy, completeness and truthfulness of all data. Without complete, detailed and workable guidance on every facet of this undertaking, plan sponsors will not be able to make these certifications. CMS must provide an alternative good faith compliance approach as the standard one is not viable for the foreseeable future.	42 CFR § 423.265		

Section VII. Medicaid Managed Care Should be Excluded from This Proposed Rule

HHS proposes to include Medicaid managed care plans as being subject to the repeal of the existing prescription drug discount and rebate safe harbor and the application of two new safe harbors, for up-front discounts or rebates passed through at the point-of-sale and for fixed fee arrangements between PBMs and manufacturers and plan sponsors.

As we have already stated, we disagree with HHS's statements regarding the risks that rebates in their current form pose to beneficiaries and federal health care programs. Accepting that, Medicaid managed care does not pose nearly the same risks that HHS hypothesizes for Medicare Part D plans. In fact, per the Medicaid and CHIP Payment and Access Commission (MACPAC), this rule is "not particularly relevant" to Medicaid managed care operations.¹⁶⁴ Should a final rule move forward under the current proposed structure, MCOs and their contracted PBMs should be excluded from the change to the regulations at 42 C.F.R. 1001.952(h) and (cc).

Below we establish that HHS does not account for the unintended consequences of its proposed changes on state financial and operational, managed care plan, and enrollee disruptions, and that the supposed benefits of the rule (which we dispute) would not accrue to Medicaid stakeholders regardless. We discuss our concerns with the costs, benefits, and transfer calculations as they relate to Medicaid in Section V.

1. The Proposed Rule does not account for the current application of managed care in Medicaid and activities under way to promote program improvements

The Medicaid program is jointly operated by the states and the federal government, as a partnership both in terms of operations and financing. The federal government has delegated to the states, under a series of complicated rules and often in conjunction with waivers, several options including the ability to contract with managed care plans to administer these benefits to eligible populations. The Proposed Rule does not acknowledge the roles that managed care programs fill across state Medicaid programs, and how the variety of models that currently exist cannot be treated in such a uniform way. Below we detail how the Proposed Rule would limit the effectiveness of managed care programs and create confusion across states, these plans, and their enrollees.

Medicaid managed care was established to provide states help in controlling health care costs. Medicaid managed care programs are established predicated on the ability of MCOs and their subcontractors such as PBMs to apply tools that focus on driving overall program savings,

¹⁶⁴ MACPAC Public Meeting, March 8, 2019, staff presentation available at <https://www.macpac.gov/publication/proposed-rule-affecting-safe-harbors-for-prescription-drug-rebates/> and transcript, available at <https://www.macpac.gov/wp-content/uploads/2018/03/March-2019-Meeting-Transcript.pdf>.

ensuring beneficiary access and promoting clinical quality.¹⁶⁵ The Proposed Rule does not appropriately account for the characteristics of Medicaid managed care programs that differentiate them from Medicare Part D. Applying this rule to MCOs will not deliver the expected results of lower beneficiary out-of-pocket expense, lower drug list prices, or reduced program costs for Medicaid, at either the federal or state level. As such, it is recommended that the administration exclude Medicaid from implementing the Proposed Rule as currently drafted.

Per MACPAC, states elect managed care models for Medicaid because “compared with fee for service, managed care can allow for greater accountability for outcomes and can better support systematic efforts to measure, report, and monitor performance, access, and quality.”¹⁶⁶ Approximately 73 percent of Medicaid covered lives were enrolled in some form of managed care, in 48 of the 50 states plus DC.¹⁶⁷ About 68 percent of lives in managed care programs are enrolled in comprehensive managed care plans, which cover acute, primary, and specialty medical care services, and often include prescription drugs.¹⁶⁸ Since the enactment of the ACA’s the provision allowing states to collect mandatory rebates for MCO-dispensed drugs, most states now include pharmacy benefits in their managed care contracts.

At the time it was implementing these Medicaid Drug Rebate Program (MDRP) provisions in the ACA, CMS issued guidance to states and plans informing them that it was not making any changes to how MCOs manage formularies, as an endorsement of the managed care formulary or pharmacy management model in Medicaid. Medicaid MCOs have proven successful in effectively managing pharmacy benefits. In one study, managed care plans that integrating drug benefits lowered the cost of branded drugs by 18% and generic drugs by 15% compared to state Medicaid FFS programs.¹⁶⁹ In the year following the enactment of the ACA, a study looking at the 14 remaining “carve out” states found that they could save 17% in the first year alone (2012) and nearly 21% on pharmacy costs over the ten year study window.¹⁷⁰ Thus, any rule change that renders managed care formularies less than effective may increase program costs. By 2016, the average statutory MDRP rebate for drugs dispensed by MCOs exceeded that for drug dispensed under FFS, intimating that MCOs were driving utilization toward lower net cost products through their formularies.¹⁷¹

¹⁶⁵ For a discussion on the potential positive effect of the new managed care quality rating system, see Anthem, “The Impact of Medicaid Quality Rating Systems on Consumer, Health Plan and Provider Behavior,” October 2016. Available at

https://www.antheminc.com/cs/groups/wellpoint/documents/wlp_assets/d19n/mjc4/~edisp/pw_q278743.pdf.

¹⁶⁶ Medicaid and CHIP Payment and Access Commission (MACPAC), available at

<https://www.macpac.gov/subtopic/managed-care/>.

¹⁶⁷ PriceWaterhouseCoopers, “The Complicated State of Medicaid in the United States: Stability amidst considerable future uncertainty,” 2017. Available at https://www.medicaidplans.org/docs/2017_State_of_Medicaid.pdf.

¹⁶⁸ MACPAC, MACStats 2018, Exhibit 29, available at <https://www.macpac.gov/wp-content/uploads/2018/05/EXHIBIT-29.-Percentage-of-Medicaid-Enrollees-in-Managed-Care-by-State-July-1-2016.pdf>.

¹⁶⁹ The Menges Group, “Comparison of Medicaid Pharmacy Costs and Usage in Carve-In Versus Carve-Out States,” 2015. Available at <https://www.ahip.org/wp-content/uploads/2015/11/Medicaid-Pharmacy-Carve-In-Final-Paper-The-Menges-Group-April-2015.pdf>.

¹⁷⁰ The Lewin Group, “Projected Impacts of Adopting a Pharmacy Carve-In Approach Within Medicaid Capitation Programs,” 2011. Available at

http://www.lewin.com/content/dam/Lewin/Resources/Site_Sections/Publications/MHPAPaperPharmacyCarve-In.pdf.

¹⁷¹ Analysis of FY 2016 CMS-64. Available at <https://data.medicaid.gov/Uncategorized/FY-2016-Financial-Management-Data-National-Totals/27my-s6bh>. Specifically, statutory rebates collected for MCO utilization account

Federal authority and waivers have established many categories of managed Medicaid. In the Proposed Rule, HHS seeks comments as to whether only MCOs as defined under § 1903(m) of the Social Security Act should be included in the revisions to the regulatory safe harbors, or if a broader definition is needed. However, in its guidance, CMS (rather than OIG) does not describe the authorities Medicaid MCOs operate under as being limited to these types of arrangements, and lists at least a dozen specific federal authorities under which managed care plans can fall.¹⁷²

A common pathway for comprehensive managed care coverage is §1115 waivers for Medicaid expansion, for example. As proposed, the rule would not clearly include §1115 waiver-approved managed care plans, since under these programs states may specifically waive aspects of § 1903(m). Limiting the application of this rule to Medicaid MCOs as defined under §1903(m) may lead to states and plans re-organizing their contracts under other authorities, at added administrative cost. Further, limiting the plans covered under this rule could lead to confusion and complexity for manufacturers and pharmacies trying to comply with administering the revised price concessions processes. While applications of changes in managed care programs need to be applied uniformly, we detail below why such uniform changes would be problematic within states and across managed care programs. All of managed care must be treated the same way, and excluded altogether from any final rule, if published.

State program designs differ significantly. Each state operates its Medicaid program according to its own needs and under its own laws and regulations. A state's decision to offer or require managed care enrollment is based upon its own unique circumstances. Changes made by HHS regarding Medicaid managed care would take significantly more time to work out across the states. Conforming changes may need to be enacted by state legislatures (which may not be in session when a final rule is issued), or require state regulatory action, which may require a public comment period as well. From an operational standpoint, imposing sudden changes on states also poses obstacles to the collection of the data required for it to submit for manufacturer rebates in order to satisfy CMS reporting obligations.

Just as managed care programs vary across and within states, the role of PBMs in administering these programs is also not uniform. Some PBMs may be contracted to an MCO to provide the full suite of services, from creating and managing a formulary including negotiating with manufacturers, to operationalizing claims processing at the point-of-sale. Other PBMs may be under contract with a state (or several states) to administer state supplemental rebate agreements. There is no one way in which PBMs interact with Medicaid MCOs and state programs, and this sweeping change set forth in the Proposed Rule does not recognize these various roles outside of transactions with manufacturers.

for 51% of gross drug costs paid under MCOs. Rebates for FFS utilization 41% of gross drug costs. This difference likely reflects composition differences since the statutory rebate levels are identical.

¹⁷² CMS, 2016 Medicaid Managed Care Enrollment Report, available at <https://www.medicaid.gov/medicaid/managed-care/downloads/enrollment/2016-medicaid-managed-care-enrollment-report.pdf>, page 6.

The effective dates of the Proposed Rule are particularly problematic from a Medicaid managed care perspective. A significant concern regarding implementing this Proposed Rule in Medicaid managed care effective January 1, 2020 is that many states' contracts with managed care plans are not renewed annually, but are instead in place for one or more years. States often work on a July 1 to June 30 fiscal year, so a change effective January 1 is troublesome and could require mid-year rate adjustments, to ensure that capitated payments to managed care plans are actuarially sound.

States and managed care plans will need significant guidance in order to implement these proposed changes. Most of the plans that participate in Medicaid managed care are small and community-based.¹⁷³ Large disruptions could reduce their abilities to participate altogether. As acknowledged by HHS in the Proposed Rule, these agreements would need to be renegotiated. Providing states only a few months to issue new requests for applications or procurements outside of their normal contracting cycles may be infeasible. As with Medicare Part D, there is a robust list of unanswered questions that this Proposed Rule generates, with regard to how states and their contracted managed care partners and PBMs could operationalize these changes. (See Section VI for the list for Part D bidding and operations questions). Some of the questions include areas such as bidding assumptions, benefit design, ability to change the formulary, beneficiary appeal rights, enrollee communications, and MLR.

Recent and ongoing CMS rulemaking is currently transforming the Medicaid managed care program. States and their Medicaid MCOs are undergoing significant operational updates based upon three recent CMS rules. It's hard to understand how HHS can assert that rebates are creating a problem in Medicaid managed care, given all of the concurrent changes that CMS, states, and managed care plans are currently incorporating. For example, the US Government Accountability Office (GAO) highlighted in two reports (July 2018¹⁷⁴ and November 2018¹⁷⁵) that many of the provisions in CMS's 2016 Medicaid Managed Care Final Rule have yet to be fully implemented by CMS, and thus state implementation and managed care plan operations still do not reflect the regulatory standards.

Further, had CMS believed that rebates for prescription drugs negotiated by MCOs were problematic, it would have proposed changes in its recent significant rulemaking cycles. However, none of these significant rules speak to the concerns HHS is raising in the Proposed Rule. CMS's 2016 Covered Outpatient Drug Final Rule implemented provisions related to the extension of statutory rebates for drugs paid for by Medicaid MCOs.¹⁷⁶ CMS's 2016 Medicaid managed care Final Rule implemented several provisions related to prescription drug benefits, including codifying long-standing formulary coverage rules, and issuing data reporting standards

¹⁷³ See PriceWaterhouseCoopers, 2017. 88% of Medicaid managed care plans operate within a single state, and 42% of plans have 50,000 enrollees or fewer.

¹⁷⁴ US Government Accountability Office (GAO), "Medicaid Managed Care Improvements Needed to Better Oversee Payment Risks," GAO-18-528. June 2018. Available at <https://www.gao.gov/assets/700/693418.pdf>.

¹⁷⁵ US GAO, "Medicaid Managed Care: Additional CMS Actions Needed to Help Ensure Data Reliability," GAO-19-10. October 2018. Available at <https://www.gao.gov/assets/700/695069.pdf>.

¹⁷⁶ Medicaid Program; Covered Outpatient Drugs; Final Rule. 81 Fed. Reg. 5170. February 1, 2016.

so that states may collect appropriate statutory rebates.¹⁷⁷ The 2018 Medicaid managed care Proposed Rule is silent on any changes to the prescription drug benefit altogether.¹⁷⁸ This last rule is not expected to be published in final form until the end of 2019, with an effective date likely well into 2020, making any parallel implementation of this HHS Proposed Rule and CMS's upcoming program rule particularly burdensome.¹⁷⁹

Finally, the recently released 2020 President's Budget Request adds further confusion to the Administration's stances on Medicaid overall, including managed care and prescription drugs.¹⁸⁰ In it, HHS requests the authority to administer a five-state demonstration to test a closed formulary under which states negotiate prices directly with manufacturers, rather than participating in Best Price reporting or the Medicaid Drug Rebate Program. The HHS budget request also would transform Medicaid into a block-granted per capita payment to states, which would increase the likelihood of states contracting with fully capitated managed care plans for all statutory and optional benefits. Two other provisions in the budget seek to streamline Medicaid managed care: making permanent some five-year waiver programs, and increasing flexibilities for states under other waivers. This suite of HHS proposed legislative changes would appear to reinforce that HHS believes that the use of managed care, PBMs, and PBM-like tools are an effective strategy for containing pharmaceutical and overall costs. This contrasts confusedly with this Proposed Rule.

PCMA Recommendation: HHS should exclude Medicaid managed care organizations and PBMs acting on their behalf from any change to the regulatory safe harbors.

2. Should these changes be applied to Medicaid managed care plans, there are no measurable benefits to affected stakeholders

Beneficiary cost-sharing will not be meaningfully reduced. The Department writes that one of its goals is to reduce beneficiary out-of-pocket spending by way of ensuring that the value of price concessions is passed along to beneficiaries. However, this concept does not fit well with either the limited cost-sharing required of beneficiaries in the Medicaid program, or with the scope of rebates under discussion.

Regarding Medicaid cost-sharing, CMS limits what states can impose with strict maximum out-of-pocket maximums on prescription drugs. Under current regulations, cost-sharing must be "nominal" and may not exceed \$4 for preferred drugs and \$8 for non-preferred drug (adjusted

¹⁷⁷ 81 Fed. Reg. 27498, May 6, 2016. See also this summary of the covered outpatient drug provisions from CMS: <https://www.medicaid.gov/medicaid/managed-care/downloads/mco-cod-presentation.pdf>.

¹⁷⁸ Proposed Rule: Medicaid Program; Medicaid and Children's Health Insurance Plan (CHIP) Managed Care. 83 Fed. Reg. 57264, November 14, 2018.

¹⁷⁹ Remarks by Calder Lynch, Senior Counselor to CMS Administrator Seema Verma, in remarks made to the World Congress on Medicaid Managed Care, February 27, 2019.

¹⁸⁰ HHS FY 2020 Budget Request, March 18, 2019, available at <https://www.hhs.gov/sites/default/files/fy-2020-budget-in-brief.pdf>.

annually for inflation), in all but a few circumstances.¹⁸¹ As we understand the likely interpretation of the Proposed Rule, copays would not be materially affected by discounts and rebates passed through to the point-of-sale. Enrollees paying copays thus would not receive any cost reduction benefit.

If states instead impose coinsurance-based cost-sharing, and this rule is in effect and rebates are passed through at the point-of-sale, the amounts paid by enrollees at the pharmacy counter would not be appreciably reduced. MCO-negotiated rebates are estimated to be about 4.5 percent of the initial pharmacy prices on average.¹⁸² These rebates are negotiated on a smaller subset of drugs than broader commercial rebates are. Any pass-through of managed care rebates at the point-of-sale would benefit a small number of enrollees by a marginal amount. (See Table 5 for an illustrative example below.) The administrative costs for implementing these changes (which we detail in Section V) could far outweigh any beneficiary-level savings.¹⁸³

*Table 5. Illustrative Example of MCO Rebates' Effects on Medicaid Beneficiary Cost-Sharing.*¹⁸⁴

	Current Rules	Proposed Rule
Drug List Price	\$150	\$150
MCO-Negotiated Rebate	4.5% (\$6.75)	4.5% (\$6.75)
Pharmacy Counter Price	\$150	\$143.25 (\$150 minus \$6.75 rebate)
Beneficiary Cost-Sharing	\$7.50 (5% of \$150)	\$7.16 (5% of \$143.25)

Due to the limited role of rebates in Medicaid managed care, eliminating rebates in these programs is unlikely to affect manufacturer pricing behavior. A second aspirational goal of the Department in issuing this Proposed Rule is to reduce the list prices charged by manufacturers for their products. In the Medicaid program, rebates come in three forms:

- 1) Statutory rebates: Manufacturers, as part of a national agreement with HHS under which all of its drugs would be covered by Medicaid programs, pay a minimum statutory rebate to states under the MDRP. Using a complicated formula that incorporates penalties for price increases in excess of underlying inflation, and the best discount offered to other purchases (Best Price), MDRP rebates accounted for \$30.1 billion in fiscal year 2016.¹⁸⁵ These rebates exceed those in any other category of price concessions.¹⁸⁶

¹⁸¹ 42 C.F.R. 447.53.

¹⁸² Milliman, Inc., "HHS's Proposed Modification Pharmacy Rebate Safe Harbors: Implications for Medicaid." March 22, 2019. Available at <http://www.milliman.com/uploadedFiles/insight/2019/HHS-proposed-modification.pdf>

¹⁸³ According to the Kaiser Family Foundation, only one state currently imposes coinsurance on prescription drugs. Kentucky requires 5% coinsurance for non-preferred drugs for Medicaid expansion-enrolled adults. See <https://www.kff.org/health-reform/state-indicator/premium-and-cost-sharing-requirements-for-selected-services-for-medicaid-expansion-adults/> for other state prescription benefit design choices.

¹⁸⁴ Assumes no change in list price for simplifying purposes.

¹⁸⁵ PCMA analysis of FY 2016 CMS-64 national level data file. Original file available at <https://data.medicaid.gov/Uncategorized/FY-2016-Financial-Management-Data-National-Totals/27my-s6bh>.

¹⁸⁶ Altarum Institute, "The Impact of Prescription Drug Rebates on Health Plans and Consumers," 2018. Available at https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf.

- 2) State supplemental rebates: States can further negotiate supplemental rebates if they create Preferred Drug Lists (PDLs). Not all states do, but in total, these rebates accounted for \$1.1 billion in FY 2016, or 3 percent of total Medicaid rebates.
- 3) Medicaid managed care-negotiated rebates: Managed care organizations can create narrower formularies than states typically operate under PDL rules. Rebates in this class are estimated to be about equal to state supplemental rebate amounts, overall in the single digit percentages.¹⁸⁷

Payments from manufacturers to states for statutory rebates under MDRP and state supplemental agreements far outweigh the additional rebates plans are able to extract from manufacturers for formulary placement. Both MDRP rebates and state supplemental rebates are excluded from Best Price consideration, while rebates negotiated by MCOs are not. Manufacturers are thus unlikely to change list prices or limit price increases, since changes are not being made to the largest portion of price concessions they offer in the market. In addition, nothing in this Proposed Rule obligates manufacturers to maintain current levels of rebates in the transition to an up-front discount or point-of-sale rebate model. We discuss the effects of this rule on MDRP rebates amounts in greater detail in Section V.¹⁸⁸

The ongoing use of state supplemental rebates is unclear. HHS remarks that state supplemental rebate agreements are protected under the revised safe harbor language, but seeks comment regarding this supposition. HHS should clarify that organizations operating under contract with a state or states are also protected by the revised safe harbor (if finalized).¹⁸⁹ Some states opt to outsource the construction of their PDLs to multi-state purchasing organizations. It is not clear whether these arrangements would be protected by the existing safe harbors for statutory rebates they negotiate on a state or states' behalf, because the organizations are not "states." Further, CMS has approved three states to negotiate value-based contracts with manufacturers through the use of supplemental rebate agreements.¹⁹⁰ Other states are proposing and implementing "subscription models" through a supplemental rebate mechanism as well.¹⁹¹ We discuss our concerns related to the Proposed Rule's chilling effects on value-based arrangements in Section II above, and note here the specifically negative effect the Proposed Rule may have on innovative Medicaid approaches.

Other benefits from this rule are unlikely. HHS hypothesizes, but does not quantify, benefits related to adherence and persistence with prescribed therapies and the possibility of improved

¹⁸⁷ See Lewin, 2011 and Milliman, "HHS's Proposed Modification Pharmacy Rebate Safe Harbors: Implications for Medicaid," 2019.

¹⁸⁸ See Milliman, "HHS's Proposed Modification Pharmacy Rebate Safe Harbors: Implications for Medicaid," 2019 for a thorough overview of the complicated nature of projecting the effects of this Proposed Rule on MDRP estimates.

¹⁸⁹ See 84 Fed. Reg. 2348.

¹⁹⁰ See Oklahoma (<https://www.cms.gov/newsroom/press-releases/cms-approves-state-proposal-advance-specific-medicare-value-based-arrangements-drug-makers>), Michigan at <http://www.medicaidandthelaw.com/2018/11/15/cms-approves-michigans-state-plan-amendment/>, and Colorado at <https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/CO/CO-18-0044.pdf>.

¹⁹¹ See Louisiana's contract for Hepatitis C medicines here: <http://ldh.la.gov/index.cfm/newsroom/detail/5097>.

health outcomes. We support any opportunity to minimize barriers to Medicaid beneficiary access to medication and to promote adherence to appropriate medication therapy protocols; however, given other challenges (access to transportation, housing instability, food insecurity, *et al.*) and the generally low fixed-price out-of-pocket payments, it is unclear that the application of small discounts will have as significant effect on beneficiary adherence as predicted in the preamble of this Proposed Rule.

States and the federal government will likely see increased costs as a result of these proposals. The third goal proffered by HHS for issuing this rule is to reduce federal expenditures on prescription drugs. We discuss our concerns and suggestions for improving the costs, benefits, and transfers that would result from this rule in Section V. There, we conclude that states may change their behaviors related to managed care contracting and the prescription drug benefit. Removal of MCO rebates will lead to higher capitated rates, since rates must be actuarially sound and certified.¹⁹² By the nature of financing relationship CMS has with states, any rule change that increases capitated payments will result in larger payments from CMS to states. As a result of the rule, states may carve out the prescription drug benefit or include managed care lives in their existing supplemental rebate negotiations.¹⁹³ Both of these outcomes would introduce administrative changes on contracted plans and enrollees. Outside of rebate receipts, information systems would need to be updated, with significant effort to ensure adequate performance, at significant administrative costs. Data collection standards for the MDRP have long received attention for needing additional oversight.¹⁹⁴ Under this Proposed Rule, there could be further delays in data reporting from MCOs to states, and states to CMS, to ensure that manufacturers are appropriately paying statutory rebates.

PCMA Recommendation: If the rule is finalized yet still includes Medicaid managed care, HHS will need to allow for significant lead time so that CMS can issue guidance to states, and states to managed care partners, before any changes can be implemented.

¹⁹² See OACT, 2018 and MACPAC, 2019.

¹⁹³ See MACPAC, 2019; See also testimony to the state's House Finance Committee on March 20, 2019, Ohio Department of Medicaid's Director stated that Ohio would move toward a single statewide PDL model for managed care plans, to ensure the state retains existing savings, should this Proposed Rule go into effect. See http://search-prod.lis.state.oh.us/cm_pub_api/api/unwrap/chamber/133rd_ga/ready_for_publication/committee_docs/cmte_h_finance_1/submissions/cmte_h_finance_1_2019-03-20-0900_253/corcoran.pdf, page 11, and recorded testimony.

¹⁹⁴ See for example:

- OIG, 2017, "Potential Misclassifications Reported by Drug Manufacturers May Have Led to \$1 Billion in Lost Medicaid Rebates," OEI-03-17-00100. Available at <https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf>.
- OIG, 2014, "Medicaid Drug Rebate Dispute Resolution Could Be Improved," OEI-05-11-00580. Available at <https://oig.hhs.gov/oei/reports/oei-05-11-00580.pdf>.
- OIG, 2011, "States' Collection of Medicaid Rebates for Physician-Administered Drugs," OEI-03-09-00410. Available at <https://oig.hhs.gov/oei/reports/oei-03-09-00410.pdf>.

Section VIII. The Proposed Rule Raises Serious Legal Concerns Regarding the APA, Non-interference, Antitrust, and Trade Secrets Act

As discussed at length throughout these comments, PCMA believes that the Proposed Rule, if finalized, will fail to achieve the stated policy objectives of HHS-OIG and the Secretary in lowering drug costs in the Medicare Part D and Medicaid managed care programs. Notwithstanding these very real policy concerns, significant legal barriers also stand in the way of HHS-OIG achieving its stated goal of removing protection under the discount safe harbor for rebates involving prescription pharmaceutical products.

First, if adopted as proposed, the Proposed Rule would raise significant concerns under the Administrative Procedure Act (APA) given the very clear statutory exception for “discount[s] or other reduction in price[s].”¹⁹⁵ Likewise, in the preamble to the Proposed Rule, HHS-OIG raises the specter that “[r]ebates paid by drug manufacturers to or through PBMs to buy formulary position are not reductions in price.”¹⁹⁶ Such an interpretation appears to fly in the face of the plain language of the Anti-Kickback Statute (AKS), the legislative history underlying the statute, and past-agency practice.

The rule raises additional concerns under the APA, as well. The Proposed Rule is arguably arbitrary and capricious given the clear failure of HHS-OIG to consider material information during the rulemaking process, as well as a number of erroneous assumptions on costs and burden estimates contained in the proposal. Moreover, we discuss the problematic implications of the Proposed Rule for the statutory definition of “negotiated price” in the Part D statute which requires that negotiated prices “shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations.”¹⁹⁷

The rebate policy contemplated in the Proposed Rule also arguably violates the Part D non-interference clause.¹⁹⁸ While the Proposed Rule, in creating a new point-of-sale price reduction model does not completely eliminate the ability of Part D plans to use rebates (or chargebacks), it places significant constraints on this practice, including the ability of manufacturers to pay retrospective rebates.

Below we discuss these, and other legal impediments to adoption, including: procedural/timing issues with implementation for FY 2020, barriers raised by the Trade Secrets Act, and the need for HHS-OIG to take into account all substantive comments prior to publication of a Final Rule.

¹⁹⁵ 42 U.S.C. § 1320a-7b(b)(3)(A).

¹⁹⁶ 84 Fed. Reg. at 2340 (February 6, 2019).

¹⁹⁷ 42 U.S.C. § 1395w-102(d)(1)(B) (Emphasis added).

¹⁹⁸ 42 U.S.C. § 1395w-111(i).

1. OIG lacks the legal authority to subject rebates to AKS because they are subject to a clear statutory exception in § 1128B for “discount[s] or other reduction in price[s]” and thus acted ultra vires

The federal Anti-Kickback Statute (AKS), §1128B(b) of the Social Security Act, 42 U.S.C. 1320a-7b(b), makes it a civil and criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. “Remuneration” is defined to include a “kickback, bribe, or rebate.”¹⁹⁹ Penalties under the statute apply to both parties in a “kickback” transaction, and include fines, prison terms of up to five years, civil monetary penalties, and/or exclusion from participation in federal healthcare programs.

Because, under the clear terms of a rebate arrangement, a manufacturer is offering “remuneration” to a Part D plan or Medicaid MCO in order to induce the purchase of its products – payment for which is ultimately reimbursable by a federal healthcare program – the AKS is plainly implicated. Indeed, HHS-OIG has stated in guidance that “[a]ny rebates or other payments by drug manufacturers to PBMs that are based on, or otherwise related to, the PBM’s customers’ purchases **potentially** implicate the anti-kickback statute.”²⁰⁰ However, the AKS has both statutory and regulatory exceptions that appear to protect these rebate agreements in certain circumstances.

The AKS Statutory Exception for Discounts or Other Reductions in Price Protects Rebate Arrangements. Under current law, the AKS contains eight statutory exceptions. Of the eight, the exception most applicable to rebate agreements as currently administered in the drug supply chain is the discount exception, which provides that the AKS does not apply to “a discount or other reduction in price obtained by a provider of services or other entity under [Medicare] or a State health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity.”²⁰¹ Although the exception does not explicitly refer to rebates, its language is broad and appears to encompass *any* reduction in price obtained by any entity so long as it is properly documented—including rebates administered by PBMs.

The exception’s legislative history supports this reading. Following passage of the Social Security Amendments of 1972 (which included the original anti-kickback legislation),²⁰² in 1977 Congress added the exception as part of its first amendments to the AKS.²⁰³ According to the House Report language, the exception:

¹⁹⁹ 42 U.S.C. § 1320a-7b(b)(1).

²⁰⁰ OIG, Compliance Program Guidance for Pharmaceutical Manufacturers, April 2003, available at <https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf> (emphasis in original).

²⁰¹ 42 U.S.C. § 1320a-7b(b)(3)(A).

²⁰² See Social Security Amendments of 1972, Pub. L. 92-603, 86 Stat. 1329 (1972).

²⁰³ See Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. 95-142, 91 Stat. 1175 (1977).

[W]ould specifically exclude the practice of **discounting or other reductions in price** from the range of financial transactions to be considered illegal under Medicare and Medicaid, but only if such discounts are properly disclosed and reflected in the costs for which reimbursement could be claimed... In fact, the committee would encourage providers to seek discounts as a good business practice which results in savings to Medicare and Medicaid program costs.²⁰⁴

As noted above, the wording of the statutory exception for discounts to the AKS is broad – protecting from scrutiny any “discount or other reduction in price,” so long as it is properly disclosed and appropriately reflected in the costs claimed or charged made by the provider.²⁰⁵ This interpretation is supported by both the legislative history of the AKS,²⁰⁶ as well as by the OIG itself, which has previously taken the position that the safe harbor regulations merely replicate, and do not expand, the scope of activities prohibited by the statute.²⁰⁷ If it is OIG’s longstanding position that the safe harbor regulations “do not expand the scope of activities that the [AKS] prohibits” – and given that current rebate arrangements are protected by the plain language of the regulatory safe harbors – then the OIG lacks the regulatory authority to exclude rebates from the discount safe harbor.

Under the Administrative Procedure Act, a Reviewing Court is Likely to Find HHS-OIG’s Proposal to Exclude Rebates from the Discount Safe Harbor is Substantively Invalid. The Administrative Procedure Act is instructive here. In particular, there is a strong argument that the underlying language of the AKS (exempting from scrutiny any “discount or other reduction in price,”) unambiguously indicates that Congress did not intend that rebates, of any form (so long as they meet the base requirements of the statutory exception) be subjected to AKS scrutiny. Indeed, the legislative history of the AKS makes clear a desire for “providers to seek discounts as a good business practice which results in savings to Medicare and Medicaid program costs.”²⁰⁸ As such, a reviewing court is likely to find such policy changes as substantively invalid because they would be promulgated *ultra vires* and/or would be “arbitrary, capricious, or manifestly contrary to the statute.”²⁰⁹

Any attempt by HHS-OIG to amend the existing discount safe harbor to exclude certain rebate arrangements would be entitled to *Chevron* deference.²¹⁰ Under *Chevron*, a court reviewing an agency’s construction of a statute which it administers must examine two questions. The first is whether “Congress has directly spoken to the precise question at issue” (“*Chevron* Step One”).²¹¹ If the statute is unambiguous, then that is the end of the inquiry and the text of the

²⁰⁴ H.R. Report No. 95-393(II), at 53, reprinted in 1977 U.S.C.C.A.N. 3039, 3056 (emphasis added).

²⁰⁵ 42 U.S.C. § 1320a-7b(b)(3)(A).

²⁰⁶ H.R. Report No. 95-393(II), at 53, reprinted in 1977 U.S.C.C.A.N. 3039, 3056 (emphasis added) (“The committee included this provision to ensure that the practice of discounting in the normal course of business transactions would not be deemed illegal.”)

²⁰⁷ Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions; Final Rule,” 56 Fed Reg. 35952, 35954 (July 29, 1991).

²⁰⁸ H.R. Report No. 95-393(II), at 53.

²⁰⁹ See *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 844 (1984).

²¹⁰ See *Nat’l Mining Ass’n*, 758 F.3d at 251 (“Legislative rules generally receive Chevron deference....”).

²¹¹ *Chevron U.S.A., Inc.*, 467 U.S. at 842.

statute must be followed.²¹² If, however, “the court determines Congress has not directly addressed the precise question at issue...the question for the court is whether the agency’s [interpretation] is based on a permissible construction of the statute” (“*Chevron* Step Two”).

Here, a reviewing court is likely to find that OIG’s “shrinking” of the discount safe harbor would fail *Chevron* Step One as being promulgated beyond the agency’s delegated authority, given the broad wording of the statutory exception for discounts, and therefore not be entitled to deference. In particular, as worded, the proposed rule would exclude from protection under the discount safe harbor at § 1001.952(h) *any* “reduction in price or other remuneration from a manufacturer,” unless it is a rebate required by law.

If, as HHS has stated in the past, the regulatory discount safe harbor merely replicates the statutory exception for discounts,²¹³ it is entirely unclear under what authority OIG intends to use to subject existing rebate arrangements to AKS scrutiny to the extent they are consistent with the statutory exception. Recall, of course, that the statutory exception is broad, allowing a Part D plan latitude in its treatment of rebates, including the ability to retain rebates so long as this is “properly disclosed and appropriately reflected,” as is currently required under existing DIR reporting requirements.

Of course, HHS has also proposed a new safe harbor in paragraph (cc) to protect certain point-of-sale reductions, including rebates that are dispensed through one or more chargebacks, but this does not mitigate its obligation to respect the careful statutory scheme created by Congress in enacting the AKS; nor does it preserve the use of rebates as currently administered. In particular, the broad language of the statutory exception for discounts is careful to avoid requiring that the full value of a discount or rebate be reflected in the price charged to a beneficiary, instead requiring only that the rebate value be (1) disclosed; and (2) reflected in the cost claimed or charges made by the provider.

As the D.C. Circuit observed in *Arent v. Shalala*,²¹⁴

Chevron is principally concerned with whether an agency has authority to act under a statute. Thus, a reviewing court’s inquiry under Chevron is rooted in statutory analysis and is focused on discerning the boundaries of Congress’ delegation of authority to the agency; and as long as the agency stays within that delegation, it is free to make policy choices in interpreting the statute, and such interpretations are entitled to deference...In such a case, the question for the reviewing court is whether the agency’s construction of the statute is faithful to its plain meaning, or, if the statute has no plain meaning, whether the agency’s interpretation “is based on a permissible construction of the statute. (Internal citations and quotations omitted; alterations made).

²¹² *Id.*

²¹³ *See* 54 Fed. Reg. 35,954 (July 21, 1991) (“The statute itself describes the scope of illegal activities. The legality of a particular business arrangement must be determined by comparing the particular facts to the proscriptions of the statute.”)

²¹⁴ 70 F.3d 610, 615 (D.C. Cir. 1995).

Under this interpretation, HHS-OIG does not have the statutory authority to subject manufacturer rebates, if properly structured, to AKS scrutiny. Congress has spoken to the precise issue of discounts *or any other reduction in price* (which clearly includes a rebate, including one not fully passed through at the point-of-sale) and their relationship to the AKS. If Congress intended rebates to be subject to AKS scrutiny, it would have surely foreclosed that possibility by more narrowly defining discounts to only include “up-front discounts.” However, Congress clearly did not do this.

The Secretary’s ability to exceed the scope of his or her statutory has recently been tested – and curtailed. In *Am. Hosp. Ass’n v. Azar*, 895 F.3d 822, the D.C. Circuit recently clarified the scope of the Secretary’s authority to set drug reimbursement rates in the 340B program. While concerning a different matter, the D.C. Circuit’s decision stands very clearly for the proposition that the Secretary is constrained by the authority granted to him or her by Congress. Citing *Amgen v. Smith*, 357 F.3d 103, 117 (D.C. Cir. 2004), the Court in *AHA v. Azar* explained that “if the Secretary makes ‘basic and fundamental changes in the scheme ... the Secretary would, in that event, exceed his statutory authority.’”²¹⁵ Given the very clear wording of the AKS, the Secretary simply does not have the authority to change the treatment of rebates beyond the bounds of which Congress has already set.

Even assuming *arguendo* that HHS’ suggested policies could advance to Chevron Step Two, a reviewing court would likely find them to be arbitrary, capricious, or manifestly contrary to the statute. The appropriate inquiry under *Chevron* Step Two is whether the exclusion of rebates from the definition of discounts is a “reasonable” interpretation of the statute.²¹⁶ The agency may be hard pressed to argue that a rebate is not somehow included in the broad statutory exception for discounts, and does not qualify as a “reduction in price.”

HHS-OIG Incorrectly Asserts that a Rebate Conditioned on Formulary Placement is Not Protected by the Discount Safe Harbor. Perhaps most perplexing and concerning, in a footnote in the preamble to the Proposed Rule, HHS-OIG makes the unfounded and novel argument that “rebates paid by drug manufacturers to or through PBMs to buy formulary position are not reductions in price.”²¹⁷ According to the agency, because rebates negotiated in exchange for formulary position “may not have the effect of reducing the price of an item or service to a buyer,” “such a payment would not qualify as a ‘discount or other reduction in price’” under the AKS statutory exception for discounts. Elsewhere in the preamble, HHS-OIG provides:

In the Secretary’s view, moreover, the statutory exemption for discounts (42 U.S.C. 1320a–7b(b)(3)(A)) does not apply to most rebates paid by drug manufacturers to part D plans or to

²¹⁵ *Am. Hosp. Ass’n v. Azar*, 895 F.3d 822, 828 (D.C. Cir. 2018).

²¹⁶ See generally *Chevron U.S.A. Inc.*, 467 at 844; *Texas v. United States*, 497 F.3d 491, 506 (5th Cir. 2007) (“[C]hevron step two compels a judicial evaluation of congressional intent.”)

²¹⁷ 84 Fed. Reg. at 2340 (February 6, 2019).

Medicaid managed care plans. To the extent those rebates are paid to or through PBMs to buy formulary position, such payments would not be protected by the discount statutory exemption.²¹⁸

Not only is this position very clearly in conflict with the plain language of the statutory exception for discounts, it also reflects a fundamental misunderstanding of Federal price reporting rules, formulary negotiations, and the agency's own past statements. Simply put, these statements appear to be rooted more in a desire to provide legal cover for an otherwise *ultra vires* policy, than based in any true understanding of the current drug supply chain.

First, we reject the portrayal of rebates used to negotiate formulary position as something other than a reduction in price. As detailed elsewhere in these comments, PBMs on behalf of their Part D plan and Medicaid MCO clients generate significant savings for consumers through formulary negotiations, by way of both lower negotiated drug costs, and lower premiums. At the root of HHS-OIG's position appears to be a false belief that there is some "runaway profit" opportunity for plans and their contracted PBMs. Yet, as detailed elsewhere in these comments (see Section III) and in previous PCMA comments, Congress and CMS have put multiple mechanisms in place to prevent abuse in Part D and in Medicaid, and thus it is unreasonable for HHS-OIG to argue that rebates negotiated in response to formulary negotiations are somehow not "reductions in price."

"Buying formulary position," as HHS-OIG nefariously frames it, is a vast simplification of the complicated formulary development process undergone by plans, PBMs, and their respective P&T committees. PBMs work tirelessly in evaluating the efficacy of various products, designing formularies that provide value to enrollees, and negotiating with manufacturers in order to reach the lowest net cost for a particular drug product. Where a particular drug will appear on a formulary is a product of both the drug itself (i.e. the value it provides), the price concessions offered, the tier on which it is placed, and any applicable utilization management protocols. As a result of these successful negotiations, costs in the Part D program remain at historic lows. Indeed, CMS in the 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund ("Medicare Trustees Report"), *credited rebates* with lowering costs in the Part D program. CMS said, "[t]his upward revision to projected rebates is a major reason for decreases in overall Part D costs compared to 2017."²¹⁹

HHS-OIG's position that rebates conditioned on formulary placement run afoul of the statutory exception for discounts is also not supported by the plain language of the statutory language itself. First, there is nothing in the discount exception or the discount safe harbor that bars conditioning discounts on favorable treatment of the seller's product. Indeed, since inception of discount safe harbor protection for rebates, PBM rebates have been conditioned on formulary placement. By its plain language, the statutory exception for discounts at §1128B(b)(3) protects

²¹⁸ 84 Fed. Reg. at 2343, February 6, 2019.

²¹⁹ 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds (June 5, 2018) at 143.

“reduction[s] in price obtained by a provider of services or other entity under title XVIII or a State health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider.”

Finally, at no point previously has HHS-OIG challenged this practice. Rather, in the OIG’s 2003 Compliance Guidance for Pharmaceutical Manufacturers, the OIG called into question only “lump sum payments” for formulary placement, stating that, “Lump sum payments for inclusion in a formulary or for exclusive or restricted formulary status are problematic and should be carefully scrutinized.”²²⁰

To now call into question the legality of rebates negotiated in exchange for formulary placement raises serious questions about OIG’s past statements and well as its current understanding of the scope of the relevant statutory exceptions and safe harbors. It also begs the question as to why HHS now believes it must amend the discount safe harbor to prevent such transactions, to the extent it already believes they are impermissible. In the final rule, we ask that HHS-OIG correct the record in its understanding of rebates negotiated in exchange for formulary placement in order to preserve this critical feature of the Medicaid and Medicaid programs.

PCMA Recommendation: HHS-OIG should consider and address the extent of its legal authority to subject rebates to AKS scrutiny given the clear statutory exception for discounts. In the Final Rule, PCMA asks that HHS-OIG clarify that rebates conditioned on formulary placement are protected under the discount safe harbor.

2. HHS-OIG’s proposal is arbitrary and capricious because the agency has failed to consider material information in developing the rule, and has failed to seriously consider the costs and burdens associated with its proposal

As explained in Section I, HHS-OIG in developing this Proposed Rule has failed to consider a number of significant factors that merit careful consideration prior to even proposing such a policy. At the most basic level, HHS-OIG has identified a problem – high drug prices in Medicare Part D and in Medicaid managed care—and proposed a solution that, even by the agency’s own actuarial estimates, will not solve the problem. Moreover, HHS-OIG has failed to consider a number of material consequences of its proposal, not limited to but including the effects of the Proposed Rule on future Part D and Medicaid MCO enrollment, its impact on MCO-negotiated supplemental rebates, and its impact on manufacturer behavior in light of current antitrust rules regarding upfront discount negotiations. Such oversight on behalf of the agency raises serious questions about the care and time taken to truly evaluate its policy proposal.

As the Courts have concluded previously:

²²⁰ OIG, Compliance Program Guidance for Pharmaceutical Manufacturers, April 2003. Available at <https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf>.

Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.²²¹

The arbitrary and capricious standard “require[s] the reviewing court to engage in a substantial inquiry.”²²²

Importantly, as part of proposed rulemaking, an agency must “provide an accurate picture of the reasoning that has led the agency to the proposed rule.”²²³ The courts reject any claim that deference to the agency requires the abdication of judicial duty to ensure the agency exercised a reasoned decision.²²⁴ Reasoned decision-making requires an agency to “examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’”²²⁵ It requires an affirmative showing “that the agency genuinely consider[ed] the salient problems presented in the record.”²²⁶ As such, “ipse dixit conclusion[s]...epitomizes arbitrary and capricious decision making.”²²⁷ Furthermore, an agency’s mere assertion that a factor was taken into consideration cannot serve as a substitute for actually considering it.²²⁸

It is clear – not simply in reading the preamble to the Proposed Rule, but also in reading through the three actuarial analyses prepared by and for the agency – that significant impacts, consequences, and results were overlooked and/or discarded in developing the Proposed Rule. Just by way of example, HHS-OIG has prepared burden estimates that are so far-fetched that they verge on the preposterous. For example, HHS-OIG estimates that the rule will “lead PBMs, pharmacies, and health insurance providers to update their IT systems for processing claims and payments,” and estimates that these entities will require an average of “five hours per year over the first five years” following publication of the rule.²²⁹ Put another way, HHS-OIG expects that a PBM, on average, will spend five hours developing an entirely new claims processing system to account for the new “chargeback” flow envisioned by the rule. Moreover, it provides

²²¹ See *Motor Vehicle Mfrs Ass’n of the United States, Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

²²² *Citizens to Preserve Overton Park*, 401 U.S. 402, 415 (1971).

²²³ *Connecticut Light & Power Co. v. Nuclear Regulatory Com.*, 673 F.2d 525, 530 (D.C. Cir. 1982). See also *Owner-Operator Indep. Drivers Ass’n v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 199 (D.C. Cir. 2007) (agency must allow its decision-making to be “exposed to refutation” as part of rulemaking) (citing *Association of Data Processing Service Organizations* 745 F.2d at 684); *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 (“[T]he notice required by the APA, or information subsequently supplied to the public, must disclose in detail the thinking that has animated the form of a proposed rule”).

²²⁴ See *American Mining Cong. v. EPA*, 907 F.2d 1179, 1187 (D.C. Cir. 1990).

²²⁵ *State Farm*, 463 U.S. at 43 (1983); see also *Bowman Trans., Inc. v. Arkansas-Best Freight Syst., Inc.*, 419 U.S. 281, 288 n.4 (1974) (“[A] party is entitled...to be apprised of the factual material on which the agency relies for decision so that he may rebut it.”).

²²⁶ See *Cross-Sound Ferry Servs. v. Interstate Commerce Com.*, 738 F.2d 481, 487 (D.C. Cir. 1984).

²²⁷ See *Illinois Pub. Telecomm. Ass’n v. FCC*, 117 F.3d 555, 564 (D.C. Cir. 1997).

²²⁸ See *Treasury Employees Union, v. Horner*, 854 F.2d 490, 499 (D.C. Cir. 1986).

²²⁹ 84 Fed. Reg. at 2,355 (February 6, 2019).

no estimate on the time to be spent by wholesalers who would, as discussed elsewhere in these comments, be starting from scratch. These – and other – estimates are so far divorced from the reality of what is and will occur that it truly begs the question of whether any thought was put into these figures.²³⁰

Given these and other major gaps in material considerations, HHS-OIG cannot in good faith finalize the rule as proposed. Major oversights of key impacts and costs have occurred such that any effort to finalize the rule would trigger against the “arbitrary and capricious standard.”

PCMA Recommendation: PCMA believes that, until HHS considers the full scope of impact of the Proposed Rule and solicits public comments on these impacts, the Proposed Rule cannot be finalized. As noted above, the APA requires that the public be fully apprised of all material changes under a regulatory proposal.

3. The statutory definition of “Negotiated Price” prohibits the rule, as proposed

The Part D statute clearly requires that negotiated prices “shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations.”²³¹ Yet, as proposed, HHS-OIG’s changes to the discount safe harbor appear to conflict directly with this definition. In particular, the underlying language in the Part D statute (“take into account”) unambiguously indicates Congress did not intend that Part D sponsors be required to pass on manufacturer rebates to the consumer at the point-of-sale. Yet, under HHS-OIG’s proposed rule, Part D plan sponsors, to the extent they negotiate rebates or discounts, would be required to do precisely this. They would pass *the full value* of any discounts or rebates through to the price charged at the point-of-sale. Despite the fact that HHS has previously recognized the agency’s ability to require all or a portion of rebates or price concessions to be passed through at the point-of-sale is “limited,”²³² under the guise of the AKS, HHS-OIG now proposes to take this precise policy position.

As noted above, because the policies in the Proposed Rule would constitute legislative rules, they would be entitled to *Chevron* deference. And here, a reviewing court is likely to find that HHS-OIG’s finalization of a policy that requires rebates be passed through at the point-of-sale would fail *Chevron* Step One as being promulgated beyond the agency’s delegated authority, given the narrow definition of “negotiated prices,” and therefore not be entitled to deference.

In this instance, HHS-OIG does not have the statutory authority to require that manufacturer rebates and pharmacy price concessions be reflected in the price charged at the point-of-sale in Part D. Congress has spoken to the issue of negotiated price concessions in the Medicare Part

²³⁰ Another far-fetched figure is the estimated 20 hours HHS-OIG expects Part D plans will spend reviewing their policies and figuring out how to respond in the first year. *See* 84 Fed. Reg. at 2,354. This figure pales in comparison to the number of hours that most of our members have already spent reviewing the rule, even before its publication in final form.

²³¹ 42 U.S.C. § 1395w-102(d)(1)(B)).

²³² 82 Fed. Reg. 56,421 (November 28, 2017).

D program. More specifically, Congress has stated that negotiated prices “shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations....”²³³ If Congress intended to dictate that negotiated price concessions must be passed through to beneficiaries at the POS, it would have surely foreclosed the possibility that Part D sponsors could report negotiated price concessions used to reduce costs under the plan in other ways. As HHS has previously noted, “had the Congress intended that all negotiated price concessions be passed through to beneficiaries, they would have used a phrase other than “take into account” in the definition of term ‘negotiated prices.’”²³⁴ However, Congress clearly did not do this.²³⁵

Therefore, it is entirely unclear under what statutory authority HHS-OIG would justify its interference with Part D sponsors’ management of plan costs. Perhaps HHS believes that – in light of the need to reconcile conflicting policies (on the one hand, respecting the carefully developed statutory scheme in Part D, and on the other, achieving its policy objective of limiting rebates) – it has full discretion to reconcile these conflicts in a light most favorable to its current policy objectives. Yet, such a position is not supported by law.

First, as detailed above, the statutory exception for discounts very clearly permits “reductions in price”, so long as they are appropriately reflected in costs/charges. Thus, there is nothing in the underlying statute that compels HHS-OIG to pursue a policy that requires the full value of a rebate to be reflected in the price charged at the point-of-sale. On the other hand, there is a very clear statutory mandate in the definition of “negotiated price” that compels a result in which Part D plans are granted discretion in determining the amount of a rebate that is reflected at the point-of-sale.

The Supreme Court’s analysis in *Chevron* actually speaks to this precise issue now before HHS:

The principle of deference to administrative interpretations has been consistently followed by the United States Supreme Court whenever decision as to the meaning or reach of a statute has involved reconciling conflicting policies, and a full understanding of the force of the statutory policy in the given situation has depended upon more than ordinary knowledge respecting the matters subjected to agency regulations. If this choice represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute, courts should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned.²³⁶

Were HHS to be balancing two clear and conflicting statutory policies, a reviewing Court would likely grant the agency discretion in reconciling the two. But that is not the issue at present.

²³³ 42 U.S.C. § 1395w-102(d)(1)(B).

²³⁴ 70 Fed. Reg. at 4194, 4244 (Jan. 28, 2005).

²³⁵ See id. at § 1395w-102(d)(2).

²³⁶ *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 844 (citing *United States v. Shimer*, 367 U.S. 374, 382, 383 (1961)).

Instead, Congress has clearly spoken to the issue of “negotiated price,” while left, at best, ambiguous the scope of the statutory exception for discounts.

In reconciling the two, HHS is obligated to act where Congress clearly spoke. As previously noted, a clear and fair interpretation of the statutory exception for discounts is that rebates as currently administered (in which some, but not all, of the rebates are passed through at the point-of-sale) are protected. So, too, a plain reading of the definition of “negotiated price” necessitates an interpretation that HHS *cannot* require that all rebates be reflected in the price at the point-of-sale. HHS-OIG is thus obligated to adopt the policy that best reconciles with Congress’ clear statutory grant.

PCMA Recommendation: In the Proposed Rule, HHS fails to address or reconcile the statutory definition of “Negotiated Price” with its proposed policy changes. Given the clear authority granted to Part D sponsors from Congress to reflect some, but not all, rebates at POS, the Final Rule should conform to this clear requirement.

4. The rebate policy contemplated in the Proposed Rule violates the Part D non-interference clause

Under the Part D statute, the Secretary is explicitly prohibited from “interfer[ing] with the negotiations between drug manufacturers and pharmacies and Part D plan sponsors.”²³⁷ Preventing such interference was very clearly the intent of Congress when it created the Part D program, as evidenced by multiple Conference report statements. This provision has long been understood as prohibiting the Secretary from interfering in payment negotiations between both Part D plan sponsors and pharmacies, and Part D plan sponsors and manufacturers.²³⁸ Indeed, HHS has long taken an appropriate view of the non-interference clause’s applicability to negotiations between Part D plan sponsors and pharmacies and manufacturers, reflecting the understanding that the Part D program’s success is built upon free market competition. In the 2005 final Part D rule, for example, HHS interpreted the non-interference clause as prohibiting the Secretary from “interfer[ing] with negotiations between drug manufacturers and pharmacies and PDP sponsors, and requir[ing] a particular formulary or a price structure for the reimbursement of covered Part D drugs.”²³⁹ This free market approach (and CMS’s past

²³⁷ 42 U.S.C. § 1395w-111(i)(1).

²³⁸ See House Conference Report No. 108-391 at 461 (Nov. 21, 2003), reprinted in 2003 U.S.S.C.A.N. 1808, 1840 (“In order to promote competition, the Secretary is prohibited from interfering with the negotiations between drug manufacturers and pharmacies and Part D plans.”) See also id. at 748-9 (Nov. 21, 2003), reprinted in 2003 U.S.S.C.A.N. 1808, 2105 (“[t]hese negotiations would be carried out by private plans, eager to capture market share through lower premiums, and manufacturers, willing to negotiate discounts for volume assurance. Such private sector entities are far better suited to achieve maximum discounts and lower premiums for plan participants than a disinterested Administrator.”)

²³⁹ 70 Fed. Reg. 4,194, 4,396 (January 28, 2005). See also 69 Fed. Reg. 46,632, 46,681 (August 3, 2004) (where CMS stated that the MMA “envision[s] that most price negotiation including discounts, rebates, or other direct or indirect subsidies or remunerations would take place between PDP sponsors or MA organizations (or their subcontractors) and pharmacies and pharmaceutical manufacturers” and that “price negotiation would be conducted

willingness to abide by the statute and not to intercede in between negotiations) is generally credited for the overwhelming success of the program.²⁴⁰

In the Proposed Rule, by eliminating protection for rebates as currently administered in the discount safe harbor, and establishing a new safe harbor in which the full value of any rebates must be reflected in the price charged at the point-of-sale, Part D plan sponsors and their PBMs will lose significant bargaining power in the negotiation of manufacturer rebates. In particular, Part D plans currently utilize rebates as negotiating tools – to lower drug costs, develop formularies that respond to consumer needs, reduce pharmacy costs, and improve the beneficiary experience at the pharmacy counter.

In a 2014 final rule in which the Secretary *declined* to reinterpret the non-interference clause, the agency reiterated its position that “the intent of 1860D–11(i) is to ensure that we do not create any policies or become a participant in any discussions that could be expected to interfere with negotiations leading to the selection of drug products to be covered under Part D formularies.”²⁴¹ Yet, five years later, the Secretary (albeit through a different mechanism) is now proposing to step directly in between manufacturers and Part D plans and dictate the very details of the pricing arrangements between the parties. This clear interference will have the very obvious result of impacting drug formulary placement.

Under a final rule, to the extent the new safe harbors would mandate that rebates be passed through at the point-of-sale, as opposed to being reflected in part as director or indirect remuneration (DIR), the policy *would clearly constitute interference* in Part D plan sponsor negotiations. Such allocation of rebates is appropriately the subject of business negotiations between Part D sponsors and manufacturers. The Secretary’s previous statements have correctly recognized that mandating particular pricing features—as opposed to a requirement about how payments must be reported—would constitute interference in pharmacy-Part D sponsor negotiations.²⁴² Under the statute, the Secretary may not interfere in those negotiations.

PCMA Recommendation: The Proposed Rule would clearly violate the non-interference clause of the Part D statute.

by the private drug benefit managers and plans that are already familiar with negotiating prices of prescription drugs on a local, regional or national basis.”)

²⁴⁰ “In beginning with the words ‘In order to promote competition under this part and in carrying out this part. . .’ we believe that the Congress intended that the activities addressed in the rest of the provision should take place through private market competition.” 79 Fed. Reg. 29,874 (May 23, 2014).

²⁴¹ 79 Fed. Reg. 29,844, 29,874 (May 23, 2014).

²⁴² See 79 Fed. Reg. at 29,873 (“In practice we have generally invoked the spirit of this provision in declining to intervene in negotiations or disputes involving payment-related contractual terms between participants in the drug distribution channel.”)

5. The Proposed Rule would also impermissibly institute a price structure

The Part D statute also states that the Secretary may not require “a particular formulary or institute a price structure for the reimbursement of covered part D drugs.”²⁴³ Yet, by proposing a policy that would, if adopted, create a structure around manufacturer rebates – with all rebates required to be included at POS – the Secretary would also clearly be violating the prohibition against instituting a price structure for the reimbursement of covered Part D drugs.

As with its interpretation of the non-interference clause, with respect to the prohibition against instituting a price structure, the Secretary has previously carefully balanced the competing goals of pharmacy access and Part D plan flexibility, ensuring neither of these requirements is read out of the statute. While neither Congress nor the agency has ever formally adopted a definition of “price structure,” the meaning of the clause is clear: CMS is prohibited from not only specifying a “standard” (e.g., what is paid or how payments are calculated), but also imposing any “structure” (e.g., any rules around the elements of that pricing). This meaning is evident both from the plain language of the statute (i.e., the term “structure” is commonly defined as an arrangement or organization of elements or parts²⁴⁴), as well as other language in the Part D statute. For example, the significance of the clause is evident when one compares it to how Congress phrased the limitation on CMS activity involving formularies. In particular, §1860D-11(i)(2) prohibits CMS from requiring a “particular” formulary. The statute does not use the same modifier “particular” in front of the price structure language.

Thus, HHS-OIG’s Proposed Rule very clearly implicates, and would, if adopted, violate, the prohibition on establishment of a price structure. In particular, should HHS-OIG finalize a policy in which the full value of a rebate must be reflected in the price charged at the pharmacy counter, manufacturers are apt to move toward lower, standardized rebates in order to avoid running afoul of applicable antitrust laws, contributing to any “free rider” effect, and driven in part by the disclosure of previously undisclosed rebate amounts.

PCMA Recommendation: Adopting this Proposed Rule would clearly violate the prohibition against the institution of a price structure.

6. The Proposed Rule could disclose confidential information in violation of the Trade Secrets Act

In the Proposed Rule, HHS-OIG notes: “We seek comments on possible negative or positive effects on pricing or competition that could result from an increase in transparency under the proposed point-of-sale discount safe harbor.”²⁴⁵ As discussed in detail in Section III above, the

²⁴³ 42 U.S.C. § 1395w-111(i)(2).

²⁴⁴ Merriam-Webster Dictionary (online); available at <http://www.merriam-webster.com/dictionary/structure>.

²⁴⁵ 84 Fed. Reg. at 2,344 (February 6, 2019).

agency rightly raises the specter that, through the rule, the negative implications of transparency could be revealed.

Under the Part D statute, Part D plans are required to provide the Secretary with information about prescription drug price concessions and rebates.²⁴⁶ This provision applies the confidentiality protections that apply in the Medicaid prescription drug rebate program (at 42 U.S.C. § 1396r-8(b)(3)(D)) to all such information submitted to the Secretary. Specifically, these protections preclude disclosure of information submitted to the Secretary “in a form which discloses the identity of a specific manufacturer or wholesaler [or] prices charged for drugs by such manufacturer or wholesaler,”²⁴⁷ subject to five exceptions. Only one exception allows the Secretary to make a public disclosure:

to disclose (through a website accessible to the public) the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug in accordance with 42 U.S.C. § 1396r-8(f).²⁴⁸

The SSA’s designation as “confidential” information from which “prices charged for drugs” can be derived makes disclosure of such information a crime unless specifically authorized by statute. In particular, the Trade Secrets Act at 18 U.S.C. § 1905 prohibits “disclosure of confidential information” by any “officer or employee of the United States or of any department or agency thereof.”

The arrangements contemplated Proposed Rule would be contrary to the confidentiality provisions in the Part D program, and thus violate the Trade Secrets Act, because they would require public disclosure of “confidential” information. In the preamble, HHS-OIG explicitly identifies as one of its goals the disclosure and transparency of rebate amounts negotiated between Part D plans, PBMs and manufacturers.²⁴⁹ Yet, under the plain language 42 U.S.C. § 1396r-8(b)(3)(D), information reported by a Part D sponsor to CMS which allows a member of the public to derive “prices charged for drugs” to a Part D sponsor is confidential.

It is beyond doubt that any such proposal that requires even a specific portion of manufacturer rebates to be passed through at POS will expose confidential information, in direct violation of the Trade Secrets Act.

PCMA Recommendation: Given the clear confidentiality protections applied to rebate amounts, HHS may only finalize a policy that protects these prices from impermissible disclosure.

²⁴⁶ 42 U.S.C. § 1395w-102(d)(2).

²⁴⁷ 42 U.S.C. § 1396r-8(b)(3)(D).

²⁴⁸ 42 U.S.C. § 1396r-8(b)(3)(D)(v).

²⁴⁹ 84 Fed. Reg. at 2,344 (February 6, 2019).

7. The Proposed Rule fails to consider that current antitrust law will prevent and disincentive manufacturers from offering differential discounts and/or discounts as deep as current rebates

As noted elsewhere in these comments, HHS has promulgated a Proposed Rule without taking into account a number of significant factors that will ultimately determine whether or not the agency's policy objective is successful. Chief among these factors that has not been considered is the very real impact of antitrust law on future manufacturer discounting behavior. As HHS considers comments on the Proposed Rule, it must take into account the very clear legal reality that if the Proposed Rule is finalized as proposed, manufacturers *will not* negotiate discounts as large as the do under the existing-rebate based system.

Senior HHS officials have already publicly acknowledged this troubling reality. In a 2016 Forbes article, recent FDA Commissioner Scott Gottlieb explained, the current practice of retrospective rebating is a direct result of litigation in the 1990s in which pharmacies sued manufacturers, wholesalers and plans alleging price discrimination under the Robinson-Patman Act:

But the entire scheme isn't a concoction of business efficiency. It's the outcome of a two-decade old legal dispute that forced drug makers to try and conceal just how much they discounted off the medicines that they were selling to health plans. Addressing the precedent set by that court ruling, and the intricate system it created, could provide policy makers with a simple way to improve the transparency, competitiveness and affordability of how drugs are priced and sold.

This warning should be heeded. Absent careful consideration of the antitrust constraints placed on manufacturers in a world in which rebates can no longer be based on market share (and ultimately, some action by Congress to repeal the Robinson-Patman Act), manufacturers will be forced to move to a system of lower and unvaried discounts offered to all competing purchasers.

As discussed elsewhere,²⁵⁰ the widespread practice of retrospective rebating emerged largely out of a mid-1990s legal settlement as a way for manufacturers to negotiate differential discounts with purchasers, without violating applicable antitrust laws. Prior to this period, it was common for manufacturers and wholesalers to offer upfront discounts to purchasers. In particular, and as alleged in the 1994 lawsuit brought by the pharmacy plaintiffs, it was common practice at the time for drug manufacturers and their wholesale partners to refuse to offer

²⁵⁰ See Health Care Financing Admin., Study of Pharmaceutical Benefit Management Industry, at 24 (June 2001) ("By 1994, the PBM business began to mature, and manufacturers were generally not recognizing the anticipated value from their contracting practices, despite the dramatic increases in total rebate payments. At the same time, pricing litigation placed manufacturers under scrutiny and caused them to become more discerning about conditions under which rebates would be paid. As a result, manufacturers made a fundamental change in their approach to contracting with PBMs. In general, rebate pricing criteria were changed so that PBMs would have to deliver increases in market share before all or most of the rebate would be paid.") See also "Antitrust Implications of HHS' Proposed Rule to Limit Manufacturer Rebates," (March 2019) available at <https://www.jdsupra.com/legalnews/antitrust-implications-of-hhs-proposed-99668>.

pharmacies the same discounts on drug purchasers that were offered to health plans and managed care organizations.²⁵¹

In a 1994 lawsuit (designated “In re Brand Name Prescription Drug Antitrust Litigation”), a group of plaintiff pharmacies alleged that this refusal to offer the same discounts extended to health plans constituted price discrimination under the Robinson-Patman Act. The Robinson-Patman Act, for its part, protects competitors by prohibiting the specific practice of price discrimination, requiring that each purchaser be given an “equal opportunity” by the seller to receive the benefit of higher or lower prices.²⁵² Under the theory advanced by the pharmacies, manufacturers were in violation of the Robinson-Patman Act by failing to extend the same discounts provided to health plans and managed care organizations, to them.

As a result of the litigation, manufacturers entered into a settlement agreement with the plaintiff pharmacies agreeing to a set of principles based off of the requirements under the Robinson-Patman Act. In approving the settlement agreement, the Court articulated “two commitments which it felt to be appropriate on the part of the settling defendants: (1) That a manufacturer shall not refuse to discount its goods based solely on the status of the buying entity; and (2) To the extent that retail pharmacies and retail buying groups can demonstrate an ability to affect market share in the same or similar manner in which managed care entities are able, retailers will be entitled to the same types of discounts given to managed care entities for this reason.”²⁵³

Out of this settlement agreement – and the very real risk under the Robinson-Patman Act – emerged the current practice of retrospective rebating. In particular, this practice of retrospective rebating was designed to ensure that even pharmacies could access beneficial discounts previously not offered to them, if they are able to affect market share. In order to settle the litigation, manufacturers agreed that, “retail pharmacies and buying groups that are able to demonstrate an ability to affect market share will be entitled to discounts based on that ability, to the same extent that managed care organizations would get such discounts.”²⁵⁴

Now, under the Proposed Rule, HHS is considering a policy in which the practice of market-share based rebating would largely be eliminated from the Medicare and Medicaid programs. This is because, of course, manufacturers are capable of truly reflecting market share movement only through rebates. Despite spending countless hours considering the impacts of the Proposed Rule (including more than five separate commissioned actuarial analyses), HHS fails to consider the very real legal and practical reality of an upfront discounting system through the lens of liability under the Robinson-Patman Act. Unless it is the agency’s intention that

²⁵¹ See generally In re Brand Name Prescription Drugs Antitrust Litig., No. 94-C-897, 1996 Dist. WL 167350, at *10 (N.D. Ill. Apr. 4, 1996), opinion modified on reconsideration, No. 94 C 897, 1996 WL 351178 (N.D. Ill. June 24, 1996), and rev’d, 123 F.3d 599 (7th Cir. 1997).

²⁵² See 15 U.S.C. § 13(a).

²⁵³ In re: Brand Name Prescription Drugs Antitrust Litigation, No. 94-C-897, 1996 U.S. Dist. LEXIS 8817 at *10 (N.D. Ill. June 21, 1996).

²⁵⁴ Testimony of Sarah F. Jaggar, Director of Health Services Quality and Public Health before the House of Representatives Subcommittee on Oversight and Investigations Committee on Commerce (Sept. 19, 1996) (Emphasis added).

manufacturers move to lower and unvaried discounts (and based on the economic analyses, we do not believe this to be the case), HHS has wholly failed to consider manufacturer pricing behavior in light of current and still-applicable antitrust law.

As the agency considers whether to move forward with its proposal, it cannot ignore what is the likely future behavior of manufacturers in a system relying on upfront discounts. Simply put, discounts will go down (and net prices will rise) unless Congress steps in to repeal the Robinson-Patman Act, or as discussed elsewhere in these comments, HHS adopts an alternative approach.

PCMA Recommendation: Unless and until Congress amends or repeals the Robinson-Patman Act, any proposal that relies on upfront discounts will have the effect of reducing the overall level of discounts offered in the drug supply chain. HHS has failed to consider this key impact in its Proposed Rule and, as such, should reconsider its legal authority to finalize such a policy.

8. Given HHS-OIG's obligation to give consideration to all public comments, a January 2020 Effective Date is not feasible

In the Proposed Rule, HHS-OIG proposes to amend the existing discount safe harbor effective January 1, 2020. The agency solicits comment on “whether the proposed effective date gives affected entities a sufficient transition period to restructure any arrangements that could implicate the anti-kickback statute and no longer would be protected by a safe harbor.”

As discussed below, PCMA believes that a January 1, 2020 effective date is not realistic, given all the operational questions and items requiring further guidance that we have raised. Nevertheless, we remain concerned that HHS intends to move forward with this proposed effective date, particularly in light of recent statements by Senior Administration officials.²⁵⁵ This apparent disregard for timing issues is concerning for two major reasons: (1) various procedural and timing challenges around the 2020 plan year make a January 1, 2020 effective date inherently problematic; and (2) HHS appears to have “made up its mind” without taking into account comments, as required by the Administrative Procedure Act.

- **The Part D Bid Submission Timeline Makes a 1/1/2020 Effective Date Infeasible.** First, from a purely practical standpoint, it is unclear how a Final Rule could be published in a timely in light of the quickly approaching June 3, 2019 bid submission date, and the large number of comments HHS must consider. Public comments on the Proposed Rule close on April 8, 2019. Following the public comment period, and as discussed more below, HHS must review thousands of public comments²⁵⁶ and publish a final rule well in

²⁵⁵ At a Drug Channels Institute event on March 21, 2019, HHS official John O'Brien stated that HHS plans to finish the safe harbor regulation before plan bids are due on June 3rd.

²⁵⁶ As of March 25, 2019, there were 18,309 public comments listed at regulations.gov on the Proposed Rule.

advance of the bid submission date. Even if HHS-OIG were able to review and respond to the thousands of comments in just 30 days, this would give Part D plans a mere 26 days to adjust their bids in time for the bid deadline.

This timeline also puts aside a host of other concerns. For example, under the Social Security Act, substantive rules must have a 30-day delayed effective date.²⁵⁷ As such, even if HHS-OIG were able to publish a final rule by May 8, 2019, the rule would not be “effective” until after the bid submission date. It is unclear under this scenario whether or not Part D plans could take the substance of a rule, not yet in effect, into account in calculating their bids. Other competing deadlines further muddy the waters. For example, the Final Call Letter must be published prior (April 1) to the close of the Proposed Rule comment period (April 8) and well in advance of the publication of any final rule.²⁵⁸ This means that CMS’ primary bid and rate setting guidance will be published more than a month before plans can expect to see any final rule.

- **The APA Requires that HHS-OIG Give Careful Consideration to Public Comments.** Based on statements from the Administration, it is concerning to hear hints that HHS has already determined it will move forward with publication of the Final Rule, notwithstanding a review of public comments. Such an approach is wholly inconsistent with rulemaking procedures under the APA.

The APA requirements regarding consideration of public comments and publication of a basis and purpose statement are set forth in 5 U.S.C. § 553(c) as follows:

After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule-making through submission of written data, views, or arguments with or without opportunity for oral presentation. *After consideration of the relevant matter presented*, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose.... (Emphasis added).

Courts interpreting this section of the APA have required the basis and purpose statement to be sufficiently detailed and informative to allow a searching judicial scrutiny of how and why the regulations were *actually* adopted. In particular, the statement must point to administrative determinations to allow a reviewing court to satisfy itself that none of the regulatory provisions were framed in an “arbitrary or capricious” manner.²⁵⁹ In addition to explaining the agency’s decision-making process, the statement must enable

A reviewing court [to] assure itself, not only that a diversity of informed opinion was heard, but that it was genuinely considered [W]here apparently significant information has been brought to [the agency’s] attention, or substantial issues of policy or gaps in its

²⁵⁷ 42 U.S.C. § 1395hh(e)(1)(B)(i). See also 5 U.S. Code § 553.

²⁵⁸ 42 U.S.C. § 1395w-24(a)(1).

²⁵⁹ See National Welfare Rights Org. v. Mathews, 533 F.2d 637, 648 (D.C.Cir.1976), citing Amoco Oil Co. v. EPA, 501 F.2d 722, 739 (D.C.Cir.1974).

reasoning raised, the statement of basis and purpose must indicate why the agency decided the criticisms were invalid. Boilerplate generalities brushing aside detailed criticism on the basis of agency "judgment" or "expertise" avail nothing; what is required is reasoned response, in which the agency points to particulars in the record which, when coupled with its reservoir of expertise, support its resolution of the controversy. (emphasis supplied).²⁶⁰

In cases where there is evidence that the agency has failed to genuinely consider the relevant issues raised by commenters, a Court can set aside an agency's action as "arbitrary and capricious."²⁶¹

Given the vast scope of issues raised in the Proposed Rule, and the growing list of public comments received in response, PCMA urges HHS to adhere to its statutory duty to review and take into account public comments received in response to the Proposed Rule. Given the amount of feedback we anticipate from stakeholders across the drug supply chain, we believe a January 1, 2020 effective date will be unrealistic if the agency wishes to truly abide by its duties under the APA.

PCMA Recommendation: A January 1, 2020 effective date is simply unrealistic if the Proposed Rule is implemented and finalized as written. As noted above, statutory deadlines and practical reality means that the creation of an entirely new rebating model is not possible within the allotted timeframe.

9. Feedback on CMS April 5, 2019 Memo From Seema Verma entitled "Guidance Regarding Part D Bids"

PCMA has reviewed the above-referenced CMS memo on guidance for Part D bids.²⁶² We truly appreciate the effort by CMS to provide plans some clarity amidst much confusion in the marketplace. We note that we are preparing these thoughts on April 5, so our comments do not reflect any further bidding guidance that may be forthcoming including on the call that CMS has scheduled with interested parties for Monday afternoon, April 8. In any event, we believe that the notion of a demonstration on risk-corridors is both important and directionally appropriate, as risk-corridors is one of the key aspects of the Proposed Rule that we urge HHS to address as part of any implementation effort in our comments. That said, "fixing" risk-corridors is one of many Part D regulatory and operational features where additional guidance is needed to implement a reconceived price concession system. We would hope that CMS would consider other risk-mitigation strategies. A more detailed list of what is needed in this regard is set forth in Table 4 in Section VI above.

²⁶⁰ *Natural Resources Defense Council, Inc., v. United States Nuclear Regulatory Commission*, 547 F.2d 633 (D.C.Cir.1976).

²⁶¹ See *Bedford County Memorial Hospital v. Heckler*, 583 F. Supp. 367 (1984).

²⁶² See <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2019-Apr-5th.pdf>.

However, we have a number of questions about the scope of the April 5, 2019 memo and related concerns, which we list below.

- The memo only addresses Part D bids. We assume this is meant to be applicable to MA-PD bids as well.
- Likewise, we assume the demonstration is available to MA-PDs as well as Part D stand-alone plans.
- The memo is silent on any relief for Medicaid managed care organizations
- We assume the April 5th memo is consistent with the position of the HHS Secretary as well as the OIG with regard to the effective date of any safe harbor changes, as they were not copied or referenced in the memo
- With respect to the demonstration, we appreciate that CMS will provide further guidance on how it will work. Some initial questions include: In order to qualify for the demonstration, would the plan have had to bid for 2020 as if the safe harbor rule was in effect? How does participation in this relate to participation in other pending Part D demonstrations (e.g. can a participant in the pending Part D reinsurance demonstration also participate in this one, as well?) Are there dollar limits on how much can be paid under the demonstration and what is the authority for the demonstration?
- The language in the April 5, 2019 memo about the bids being subject to the AKS laws and regulation “in effect as of the bid submission deadline” remains unclear and still leaves uncertainty in the marketplace. In other words, if the rebate safe harbor rule is published in final form on May 2, 2019, with a 30 day effective date, then would the bids (due June 3, 2019) still have to reflect those final rules? It would be very helpful if CMS could confirm that this type of scenario is not still a possibility.

Finally, the April 5, 2019 memo does not address the fundamental disconnect between OIG safe harbors and the CMS regulatory construct. Specifically, even if bids assume that safe harbor rules have not changed, it does not mean that safe harbor changes may still take effect 2020 with criminal penalties for non-compliance. Simply put, under this scenario, while bids would be based on one set of rules, the actual operations would be performed under another set of rules. To the extent that this is a possible outcome, it would obviously be untenable. To avoid this scenario, we would strongly urge OIG to accompany any final rule with a statement of non-enforcement of the revised safe harbors for two years.

PCMA Recommendation: PCMA recommends that CMS continue to consider additional risk-mitigation strategies along the lines of the April 5 memo. PCMA recommends that OIG accompany any final rule with a statement of non-enforcement of the revised safe harbors for two years.

Section IX. Further Legal Concerns Including the Relationship to Existing Safe Harbors Need to be Addressed

Under the current drug supply chain, manufacturers negotiate discounts and rebates on prescription drugs with Part D plan sponsors and Medicaid managed care organizations (typically through their contracted PBMs). These rebating arrangements are deeply embedded in the supply chain and are frequently credited with the overwhelming success of the Part D program.²⁶³ Moreover, HHS has clarified in previous regulations and guidance that such arrangements, if properly structured, can be protected by a number of safe harbors.²⁶⁴

In the Proposed Rule, HHS proposes to amend its longstanding protection for certain rebate arrangements under the discount safe harbor under § 1001.952(h), and to create two new safe harbors in paragraphs (cc) and (dd) to protect a narrower range of PBM rebates and service fees. These amendments to existing safe harbor protection raise a number of novel legal questions, as discussed below.

1. In the Proposed Rule, HHS fails to discuss the impact on existing safe harbors

As noted above, HHS has long taken the position that safe harbor protection for rebates may be available under a number of different safe harbors, if properly structured. In the Proposed Rule, HHS generally fails to discuss the applicability of these other, existing safe harbors (e.g., the managed care safe harbor, the personal services safe harbor, the GPO safe harbor) to rebate arrangements.²⁶⁵ Absent future rulemaking and subject to any existing statutory exceptions that may provide protection for ongoing arrangements,²⁶⁶ it is PCMA's strong belief that manufacturers, plans, and PBMs can continue to structure their agreements using existing safe harbor protection for rebate arrangements, notwithstanding HHS's current proposal to amend the discount safe harbor. Thus, given the longstanding protection for rebates under these other

²⁶³ CMS's Chief Actuary, in the 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund ("Medicare Trustees Report"), credited rebates with lowering costs in the Part D program. CMS said, "[t]his upward revision to projected rebates is a major reason for decreases in overall Part D costs compared to 2017." 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds (June 5, 2018) at 143.

²⁶⁴ See 68 Fed. Reg. 23,731, 23,736 (May 5, 2003) ("Any rebates or other payments by drug manufacturers to PBMs that are based on, or otherwise related to, the PBM's customers' purchases potentially implicate the anti-kickback statute. Protection is available by structuring such arrangements to fit in the GPO safe harbor at 42 CFR 1001.952 (j).... In addition, arrangements with PBMs that assume risk may raise different issues; depending on the circumstances, protection for such arrangements may be available under the managed care safe harbors at 42 CFR 1001.952 (m), (t) and (u).")

²⁶⁵ The Proposed Rule does briefly indicate that PBM service fees may be eligible for safe harbor protection under other, existing safe harbors. See 84 Fed. Reg. 2,349 (February 6, 2019) ("The Department recognizes the possibility that certain types of remuneration that manufacturers might pay to PBMs either would not implicate the anti-kickback statute or could be protected under another existing safe harbor. However, this proposed new safe harbor would provide a pathway, specific to PBMs, to protect remuneration in the form of flat fee service fees that would be low risk if they meet specified criteria.")

²⁶⁶ Removing or altering the treatment of existing regulatory safe harbors, each previously subject to notice-and-comment rulemaking procedures, would clearly, under this definition, constitute a legislative rule and fall subject to the APA's notice-and-comment rulemaking procedures.

safe harbors, plans, PBMs, and manufacturers intend to continue to rely upon those that provide protection for properly structured arrangements that rely on manufacturer rebates.

PCMA Recommendation: Given the diversity of arrangements that occur in the marketplace today, various safe harbors may be available to PBMs that protect certain rebating arrangements. Given that HHS has not proposed to amend such safe harbors, they remain available and legally protected.

2. By focusing exclusively on PBM rebates, HHS may inadvertently be encouraging the development of new, unintended discounts in the drug supply chain

In the Proposed Rule, HHS fails to discuss how - and to what extent - other actors in the drug supply chain will be prevented from engaging in future rebate arrangements and supplanting the critical and cost-saving role PBMs currently play in the marketplace. In particular, the Proposed Rule appears to unfairly target only PBMs, ignoring the role of other intermediaries (such as wholesalers), creating an uneven playing field and opening up the possibility of rebates being administered by other entities. HHS has expressed “concern” regarding the risks of rebates overall. However, HHS does not propose to establish a comprehensive regulatory scheme to eliminate or regulate rebate arrangements. Instead, it proposes only to disrupt the practice of PBM-administered rebates, while leaving untouched the role of other intermediaries. This narrow approach fails to address the specific “concern” HHS raises at all.

Indeed, in the Proposed Rule HHS clarifies that it *does not* intend to disrupt other discounting/rebating practices in the current drug supply chain:

The Department intends for the discount safe harbor to continue to protect discounts on prescription pharmaceutical products offered to other entities, including, but not limited to, wholesalers, hospitals, physicians, pharmacies, and third-party payors in other Federal health care programs.²⁶⁷

In other words, rather than identifying a problematic practice (although we strongly dispute this characterization, as noted elsewhere in these comments), HHS in the Proposed Rule targets a particular *actor* in the drug supply chain, leaving open a very real possibility that the practice it seeks to discourage will simply be performed by another entity.²⁶⁸

We note that over the last decade and a half, Congress and CMS have developed a comprehensive regulatory construct for Part D that incorporates the role of PBMs and accounts

²⁶⁷ 84 Fed. Reg. 2,348, February 6, 2019

²⁶⁸ To the extent HHS’s focus is on the elimination of “spread pricing” the actuarial analyses it commissioned acknowledge that spread pricing, in other parts of the drug supply chain, would continue: “In terms of the supply chain flow, the wholesaler would still purchase products from manufacturers at a discount relative to the list price and sell to pharmacies on a spread.” See Milliman, 2019, “Impact of Potential Changes to the Treatment of Manufacturer Rebates.”

for the existing flow of money in the system. So, for example, DIR reporting fields take into account PBM-retained rebates and require those rebates to be reflected in plan bids. By permitting and facilitating the activities of new, inexperienced actors, such as wholesalers, into this role, the HHS is not only causing a tremendous amount of uncertainty, but also introducing a completely unregulated entity to the Part D program. The introduction of a new participant in pharmacy financial transactions could require new regulation and guidance regarding program integrity. To be clear, however, CMS currently has *no* regulatory authority over the drug supply distribution chain, including over wholesalers.

Indeed, HHS apparently foresees this exact situation occurring, noting: “We also seek comment on the ability of wholesalers to facilitate chargebacks to pharmacies in a timely fashion, replacing PBMs rebates with manufacturer discounts routed through wholesalers, and other concerns related to disrupting the relationship between pharmacies and PBMs.”²⁶⁹

While HHS may intend that these transactions occur using the protection of the newly created safe harbor at paragraph (cc), which requires that the “total payment to the pharmacy for the prescription pharmaceutical product is at least equal to the price agreed upon in writing between” the plan and the manufacturer, what is to prevent manufacturers, wholesalers, and pharmacies from structuring these transactions under the existing discount safe harbor? This leaves open the troubling proposition that, if properly structured under the existing discount safe harbor, chargebacks *would not* need to be reflected entirely at the point-of-sale, and there would be no requirement that wholesalers pass through at the point-of-sale all chargebacks. Should HHS-OIG proceed with its Proposed Rule, it must account for unintended consequences and avoid unfairly targeting a single actor in the drug supply chain.

PCMA Recommendation: The Proposed Rule wholly fails to take into account the gaps left by excluding only PBM-administered rebates from the discount safe harbor. If the Proposed Rule is finalized, HHS should clarify that wholesalers or other intermediaries may not facilitate rebates under the existing discount safe harbor.

3. The proposed changes to the discount safe harbor must address, and avoid disrupting, discounts to PBM or plan-owned pharmacies

In the preamble to the Proposed Rule, HHS states that it intends for the discount safe harbor to continue to protect pharmacy discounts.²⁷⁰ However, the proposed amendment to the discount safe harbor at § 1001.952(h) to exclude certain rebates, would have the unintended consequence of also excluding pharmacy purchase discounts received by any mail pharmacy, specialty pharmacy or retail pharmacy owned by a Part D plan, Medicaid MCO, or their PBM,

²⁶⁹ See 84 Fed. Reg. at 2,361 (February 6, 2019).

²⁷⁰ See 84 Fed. Reg. at 2,348 (February 6, 2019) (“The Department intends for the discount safe harbor to continue to protect discounts on prescription pharmaceutical products offered to other entities, including, but not limited to, wholesalers, hospitals, physicians, pharmacies, and third-party payors in other Federal health care programs.”) (Emphasis added).

regardless of whether these discounts are dependent on formulary placement. These discounts are provided to the buyer in its capacity of a dispensing pharmacy, and not in the capacity of a formulary manager. If this exclusion is not clarified in any final rule, antitrust concerns over class-of-trade pricing could prevent manufacturers from offering purchase discounts to *any* mail pharmacy, specialty pharmacy or retail pharmacy (e.g., if a manufacturer is unable to offer purchase discounts to PBM-owned specialty pharmacy, the manufacturer would not offer purchase discounts to any specialty pharmacy).

Should HHS proceed with finalizing the Proposed Rule, it should correct this problem by adding the following text to the proposed exclusion (viii): “*or unless it is a price reduction or rebate to a pharmacy or other provider that is not dependent on the formulary placement of the prescription pharmaceutical product.*” Absent such a clarification, the rule may have the unintended consequence of eliminating pharmacy discounts.

PCMA Recommendation: HHS should ensure that any revisions to the safe harbor regulations appropriately account for all consequences and actors, to ensure that the behavior it seeks to limit or ban is not simply performed elsewhere in the supply chain.

4. The proposed safe harbor for PBM service fees will fail protect some important transactions, while unnecessarily disclosing confidential information

In the Proposed Rule at §1001.952(dd), HHS proposes to establish a new safe harbor to protect certain fair market value service fees paid by pharmaceutical manufacturers to PBMs. While PCMA appreciates the recognition of the value-added services the PBMs provide throughout the drug supply chain, we believe the proposed safe harbor as written may constrain the provision of these services. In particular, HHS proposes that PBM service fees must be “fixed,” rather than based on a percentage of sales or other variable. While PCMA recognizes the value in moving away from fees based on list price or even the number of prescriptions, as worded the safe harbor may exclude arrangements in which manufacturers are compensated for the volume of work they perform (which may correlate with the number of claims) and in which payment varies over time. For example, HHS should allow PBMs the flexibility to be paid less per claim with an increased number of prescription claims, in recognition of certain fixed costs associated with any provision of services.

Finally, PCMA objects to the disclosure requirements associated with the proposed safe harbor. In particular, PBMs and their client Part D plan sponsors already engage in arm’s length negotiations over a whole series of terms, including what is disclosed and not disclosed. It is unnecessary, burdensome, and troubling for HHS to step in between these negotiations to mandate such disclosure.

PCMA Recommendation: If HHS finalizes the Proposed Rule and the new safe harbor for PBM service fees, it should consider and take into account the range of different contracting options that manufacturers and PBMs may engage in.

Part 3: PCMA's Alternative to the Proposed Rule

In light of the numerous issues raised in Part 2 of these comments, PCMA is clearly troubled by the range of adverse consequences of the Proposed Rule. To the extent HHS intends to proceed in finalizing the rule, we offer in this part our comments on an alternative approach that we believe is not only more viable for a 2020 implementation deadline, but also would mitigate to varying degrees the concerns and barriers we have previously identified in these comments. Below, we provide background on this alternative approach, detail a possible viable scenario for implementation for 2020, provide some perspective on how the alternative policy mitigates at least to some extent the concerns we have identified with the Proposed Rule, and then provide alternative regulatory language for an appropriate revision to the discount safe harbor.

1. Background on Proposed Alternative

Should HHS feel compelled to finalize any changes to the safe harbor treatment of rebates effective January 2020, the only way that such a policy has a chance of being implemented under this short timeframe would be to rely on existing infrastructure and systems already in place and operated by PBMs, as subcontractors to Part D plans. Under the alternative approach discussed above, in lieu of the proposed chargeback approach, PBMs would administer prescription drug benefits in the form of price concessions required to be passed through at the POS.

PBMs are already administering POS price concessions in the commercial market, and at least one is doing so in Medicare. With the modifications and critical guidance outlined below, similar systems could be supported for Medicare. Unlike other participants in the supply chain, PBMs have the pertinent information to administer POS price concessions in real time at POS without disrupting beneficiary access: they know the details of the enrollee's plan, including cost-sharing, the enrollee's stage of the benefit, and the price concessions negotiated with the manufacturer. Unlike the chargeback system contemplated in the Proposed Rule, PBMs' systems do not have to be built from the ground up, but are highly efficient and operate in milliseconds to determine enrollee eligibility and cost-sharing, and adjudicate claims. Moreover, Part D's prompt pay requirement means that PBMs assure that pharmacies are paid, in full, within 14 days.

Under this proposed "price concessions at POS" alternative, pharmacies would be paid as they are today at a negotiated amount based on WAC or another amount related to list price, rather than a lower amount reflecting a manufacturer discount that they would then have to collect from the manufacturer at a later date through a "chargeback." Using the existing PBM-facilitated system would make this process seamless for pharmacies and for beneficiaries. It would also prevent the pharmacies from having to "hold the float" for an indeterminate length of time as they gathered the needed data to submit for a chargeback to the manufacturer.

This alternative approach is in contrast to a system envisioned by the Proposed Rule in which a yet-to-be-determined third-party administers chargebacks within some newly created infrastructure. Such a new system apparently could be operated by entities not subject to CMS's current regulatory reach with respect to any aspect of operations, including audits or prompt pay requirements. It would duplicate, not replace, PBM operations, as PBMs would still have to determine eligibility, calculate cost-sharing, and calculate payment amounts, as well as audit pharmacies to ensure their compliance with contracts. In addition, a non-PBM entity administering a chargeback would have to obtain from the PBM this data, none of which is currently shared, and the National Council for Prescription Drug Programs (NCPDP) would have to develop new data standards to facilitate these transactions. This anticipated process would be long, costly, and complicated.²⁷¹ PBM, pharmacy, and the existing switch systems would all have to be modified to accommodate these newly layered-on and additive transactions. A new entity not only would add complexity but would also add costs, whereas the existing systems are efficient and highly functional and could be altered to administer price concessions at POS.

There is another major advantage to having the PBM administer the POS price concessions; namely, that they would be able to address the not uncommon situation where manufacturers turn back claims that did not process as claims eligible for a rebate. There may be a number of reasons for the rejection of the rebate on claims, including: (a) the claim was run as a non-340B claim but was then submitted by the pharmacy as a 340B claim; (b) the claim was a duplicate; or (c) the enrollee was no longer enrolled in the plan. For purposes of this discussion, we refer to these circumstances as "non-collectable rebates."

As noted earlier in these comments, the Federal Trade Commission (FTC) and others have expressed concern over the complete transparency of discounts and rebates in the drug supply chain. Under the proposed alternative (and unlike the policy contained in the Proposed Rule), CMS would know the percentage of collectable rebates that a PBM was passing through at POS, but the market would not. By not handing over to other parties in the supply chain (wholesalers and pharmacies) the exact amount of negotiated price concessions, with even a few points uncertainty about the exact amount of price concessions, the market to some degree could avoid the tacit collusion among manufacturers that would otherwise result from a chargeback system administered by other entities. A reconciliation process could be employed to ensure that the estimate of the collectable rebates and the exact amount of collectable rebates were trued up and that the plans retained the incentive to estimate as accurately as possible what rebates would be "collectable" or "non-collectable". This process, administered by

²⁷¹ We reiterate our concern about the lack of cost considerations in the Proposed Rule for this kind of new infrastructure. The Proposed Rule estimates costs for standing up such a new system as only \$53.5 million and \$10.8 million in first-year costs to change their business practices and update IT systems to comply with the new rules. However, PCMA's comments above (see pages 47-54) provide a rationale for a more realistic estimate of nearly \$2 billion to make these updates, in the first year alone.

PBMs, would also ensure that beneficiaries would not be at risk for paying cost-sharing that was reduced by a rebate not rightly owed to them through no fault of their own.

Of course, the OIG would have to provide guidance on whether it would consider a Part D plan to have offered a kickback if it erroneously provided a rebate at POS to a beneficiary on a claim for which later the manufacturer refused to pay a price concession (the rebatable drugs that are subsequently determined to be not eligible for a rebate and therefore non-collectable). Likewise, CMS will have to provide guidance on how these claims are to be reported for audit purposes, and how the amounts erroneously paid to enrollees due to non-collectable rebates should be collected from them.

2. Implementation of Proposed Alternative

As noted above, PBMs can already collect and pass along price concessions under Medicare Part D at the POS. For this to work, rebates must be knowable and passed along to beneficiaries at POS on a drug-specific basis for drugs for which there are rebates. Contract arrangements that allow for amounts that cannot be accurately estimated at POS would no longer qualify under the discount safe harbor rules (subject to dealing with the non-collectable rebates, as noted above).

In order to accomplish this for the 2020 Part D benefit year, additional adjustments will be required to address timing of implementation based on details needed from CMS for Part D plan sponsors. Specifically, PBMs can implement a POS price concession in Part D for 2020 to the extent that Part D plans get information on key details for both bidding and operational purposes. Further information on the details needed in each of these arenas for effective and smooth implementation of POS drug price concessions is outlined below.²⁷²

a. Required CMS 2020 Bid Development Guidance and Timing

- Finalized 2020 bid instructions applicable to all plans must be timely, clear and unambiguous related to bid assumptions around the final OIG rebate rule content and effective date.
- Issues that must be addressed in the guidance include whether POS price concessions count towards a patient's TrOOP, how they apply to copays, and how they apply in all phases of the benefit.
- Assuming the final HHS rebate rule is issued with an effective date that does not permit timely incorporation into the current bids due on June 3, but the date *does*

²⁷² The list of implementation issues in this section represents what we understand from our PBM members is the absolute minimum information that Part D plans would need to know with respect to bidding and operations to make the alternative viable for 2020. To the extent that CMS is able to address additional items, such as those on set forth in our list in Part 2, Section VI (Table 4), that would be helpful and beyond appreciated. Ideally, CMS would provide for some process, albeit abbreviated, pursuant to which stakeholders would be able to comment on both the bidding and operational guidance listed above.

provide for an effective date that would allow for timely incorporation into bids by a date on or around July 1, CMS should plan to reopen the bids so they can be modified as appropriate and re-submitted by July 1.²⁷³

- With respect to current PBM-manufacturer contracts, CMS needs to affirmatively state that it does not expect contract rebate rates to be renegotiated as that would not be feasible in the truncated period of time.

b. Required CMS Operational Guidance and Timing

- *Beneficiary Tools and Materials:*
 - Plans must have technical guidance on Medicare Plan Finder (MPF) submission requirements to be prepared for the 2020 annual enrollment period. MPF and similar tools utilized by plan sponsors must be updated to display cost-sharing based on the POS price inclusive of rebates/price concessions to allow beneficiaries to make an informed purchasing decision.
 - Plans must have technical guidance on revisions required to reflect the new construct in beneficiary marketing and enrollment materials, above and beyond basic educational materials explaining the changes (including Annual Notice of Changes (ANOC), Evidence of Coverage (EOC), and Explanation of Benefits (EOB)).
- *Formulary Changes*
 - CMS must issue technical guidance on permissible formulary changes and permissible tiering arrangements, including whether and how the formulary review process will change.
- *Timing*
 - The necessary CMS operational guidance would also need to be issued in final form on or around June 3, so that plans could immediately turn to preparing their revised bids as soon as they file their original bids due June 3.

c. Additional Guidance including on Benefit Design

There are a significant number of additional guidance areas that would be helpful to make the alternative discussed here viable for effective implementation in 2020. While we understand that content for these arenas may take longer to develop, we would urge CMS address these concerns at least directionally as soon as possible. Some of the key areas we believe fall in this bracket include:

- *De Minimis Premium for LIS*
 - The 2020 De Minimis Premium Policy for Low-Income Subsidy (LIS) eligible beneficiaries should be increased to avoid massive program-wide enrollment disruption, including mass plan changes for LIS members. Specifically, CMS

²⁷³ We suggest CMS retain the June 3 bid due date under current rules, in case there are unanticipated problems with the second round of bids, which, as noted, would be scheduled for submission on or around July 1.

should consider allowing a fourth plan offering.

- *Risk Corridors*
 - To ensure a sufficient number of bids will be received, CMS will need to address the increased risks and uncertainty created by the new Part D rebate model, possibly by narrowing the Part D risk corridors for 2020 to manage the transition.
- *Risk Adjustment*
 - Risk adjustment is used to calculate the bid amounts themselves so the RxHCC model will need to be recalibrated to reflect the new applicable costs associated with high- rebate versus low-rebate classes, and to somewhat protect plans against the expectation of adverse selection caused by the visibility of the discounts. Our alternative assumes that the rebates at POS are put in place for Medicare only.
- *Exclusion of Medicaid*
 - As discussed elsewhere these comments, we believe that Medicaid should be excluded from the final safe harbor rule. Given that Medicaid beneficiaries have fixed, nominal cost-sharing, it is entirely unclear how POS price concessions even would work. In addition, the wide variation in state Medicaid programs makes uniform implementation quite difficult and unachievable within the proposed timeline, while making the assessment of the Proposed Rule's impact even more uncertain.

3. How the Alternative will Mitigate to Varying Degrees the Concerns Addressed in Part 2 of these comments

We believe that, with appropriate implementation, the alternative should serve to mitigate to at least some extent many of the concerns identified herein with the Proposed Rule. Below we briefly summarize many of the key problems articulated in Part 2 of these comments and note how the alternative should directionally alleviate the issues of concern.

a. Policy

- The Proposed Rule would lead to increases in net drug prices, beneficiary out-of-pocket spending, and federal spending. However, the alternative would mitigate these effects somewhat by providing PBMs with the ongoing opportunity to limit the ability of manufacturers to set prices at high levels through price concession negotiations.
- Under the alternative, the structure of the negotiations between plans and PBMs on one side, and manufacturers on the other, would be less upended, posing less risk and disruption to the successes of the Part D program.
- The alternative would not undermine formulary-based price concessions, which have provided significant savings to enrollees, payers, and taxpayers without raising risks.

b. Transparency

- The Proposed Rule fails to consider the negative impact of too much cost transparency on overall net drug prices.
- By passing along only collectable rebate amounts to a more limited set of stakeholders (pharmacies), the alternative would reduce the likelihood that price concessions would be uncovered by other supply chain actors, while giving HHS access to these price concession amounts.

c. Beneficiary Access

- The Proposed Rule does not adequately consider the likely harm to beneficiaries caused by the increases in premium and resultant disruptions in enrollment and lapses in coverage. In its report accompanying the Proposed Rule, OACT finds that premiums would rise by 25% over ten years, based in part of its assumptions surrounding manufacturers being able to retain current price concessions.
- To understand the effects of our alternative on premiums, cost-sharing and federal spending, PCMA commissioned Milliman to conduct an analysis of applying manufacturer rebates at POS, among other policy proposals, to match the timeframe contemplated in the Proposed Rule (2020-2029). The analysis included other current policy proposals, separately and in combination with manufacturer rebates at POS, which PCMA expected would have strong interactions with the manufacturer rebates at POS proposal.²⁷⁴ This analysis finds that with 100% of manufacturer rebates applied at POS and no other policy changes, premiums would increase by 15% over ten years (assuming no other changes in stakeholder behavior).
- The Proposed Rule fails to account for the likely formulary and drug utilization changes, which could negatively harm beneficiaries. The alternative should not result in possible scenarios where access to drugs could be limited by formulary placement, since the fundamentals around PBM negotiations with manufacturers are not changing.
- Due to these improvements, beneficiary confusion and dissatisfaction with Part D should be mitigated.

d. Cost/Regulatory Analysis

- HHS does not accurately estimate the excessive administrative burden that these new requirements would impose on the private sector and Medicare beneficiaries. The alternative would impose significantly less administrative burden since it would build on PBM systems already in place.

²⁷⁴ Milliman, "Impact of Potential Medicare Part D Program Changes: How Potential Part D Program Changes Could Affect Stakeholder Costs." April 5, 2019. Available at https://www.pcmamet.org/wp-content/uploads/2019/04/Part-D-Program-Changes_FINAL.pdf.

- With respect to transfers, HHS's analysis demonstrates that the Proposed Rule is a windfall for manufacturers, harming beneficiaries and taxpayers. The Milliman analysis cited above evaluating the application of manufacturer rebates at POS indicates that under such a change, beneficiary cost-sharing would still be reduced by 13% (\$42.1 billion over ten years), but that federal spending would rise only moderately by \$48.1 billion (4%) over ten years. Manufacturer rebates at POS have a more moderate effect on federal spending because they do not necessarily allow manufacturers to reset their pricing strategies. Under a manufacturer rebates at POS model, PBMs will have a better chance to keep current net costs constant.

e. Legal Considerations

- The Proposed Rule fails to consider that current antitrust law will prevent and disincentive manufacturers from offering differential discounts and/or discounts as deep as current rebates. The alternative may lessen this risk as it would allow for the continuation of rebates without these disincentives.
- Such a fundamental change to the regulatory underpinning of the Part D should have undergone a more deliberate process, in coordination with CMS. The proposed timetable and content for the alternative provides for engagement by HHS's subject matter experts in the guidance process, so should limit at least to some extent the unintended consequences and risks.

4. Changes to Proposed Rule to Reflect the Alternative

To facilitate HHS' consideration of the alternative, we have set forth below the proposed regulatory changes to the proposed safe harbors to accommodate the alternative as set forth above. Please note that the language is redlined from the current version as proposed.

PART 1001—[AMENDED]

1. The authority citation for part 1001 continues to read as follows: Authority: 42 U.S.C. 1302; 1320a–7; 1320a–7b; 1395u(j); 1395u(k); 1395w– 104(e)(6), 1395y(d); 1395y(e); 1395cc(b)(2)(D), (E), and (F); 1395hh; 1842(j)(1)(D)(iv), 1842(k)(1), and sec. 2455, Pub. L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note).

2. Section 1001.952 is amended by revising paragraphs (h)(5)(vi) and (vii) and adding paragraphs (h)(5)(viii), (h)(6) through (10), (cc), and (dd) to read as follows:

§ 1001.952 Exceptions.

* * * * *

(h) * * *

(5) * * *

(vi) Services provided in accordance with a personal or management services contract;

(vii) Other remuneration, in cash or in kind, not explicitly described in this paragraph (h)(5); or

or to a pharmacy benefit manager acting under contract with such plan sponsor under Medicare Part D, unless it is a price reduction or rebate that is required by law.

(6) For purposes of this paragraph (h), the term *manufacturer* carries the meaning ascribed to it in Social Security Act section 1927(k)(5).

(7) For purposes of this paragraph (h), the terms *wholesaler* and *distributor* are used interchangeably and carry the same meaning as the term “wholesaler” defined in Social Security Act section 1927(k)(11).

(8) For purposes of this paragraph (h), the term *pharmacy benefit manager* or *PBM* means any entity that provides pharmacy benefits management on behalf of a health benefits plan that manages prescription drug coverage.

(9) For purposes of this paragraph (h), a *prescription pharmaceutical product* is either a drug or a biological as those terms are defined in Social Security Act section 1927(k)(2)(A), (B), and (C).

* * * * *

(cc) *Point-of-sale reductions in price or rebate arrangements for prescription pharmaceutical products.*

(1) As used in section 1128B of the Act, “remuneration” does not include –

(i) a point-of-sale price reduction arrangement; or

(ii) a point-of-sale rebate arrangement.

(2) For purposes of this paragraph (cc), a point-of-sale price reduction arrangement means an arrangement under which a reduction in the price charged by a manufacturer for a prescription pharmaceutical product that is payable, in whole or in part, by a plan sponsor under Medicare Part D, provided the manufacturer meets the following conditions with regard to that reduction in price:

(i) The reduced price must be set in advance with a plan sponsor under Medicare Part D, or the PBM acting under contract with such plan sponsor;

(ii) The sale does not involve a rebate unless the full value of the reduction in price is provided to the dispensing pharmacy through a chargeback or series of chargebacks, or is required by law; and

(iii) The reduction in price must be completely applied to the price of the prescription pharmaceutical product charged to the beneficiary at the point of sale.

(3) For purposes of this paragraph (cc), a point-of-sale rebate arrangement means an arrangement that meets the following requirements:

(i) The arrangement must involve a specific prescription pharmaceutical product for which a rebate is negotiated between a pharmacy benefit manager and a manufacturer;

(ii) The prescription pharmaceutical product must be payable, in whole or in part, by a plan sponsor under Medicare Part D; and

(iii) The amount of the rebate must be a fixed price that is known and determined in advance between a manufacturer and a plan sponsor under Medicare Part D or the PBM acting under

contract with such plan sponsor such that the entire amount of the rebate can be applied to the price of the prescription pharmaceutical product charged to the beneficiary at the point of sale.

(2)(i) For purposes of this paragraph (cc), the terms *manufacturer*, *pharmacy benefit manager* or *PBM*, *prescription pharmaceutical product*, and *rebate* have the meanings ascribed to them in paragraph (h) of this section.

(ii) For purposes of this paragraph (cc)(2), a *chargeback* is a payment made directly or indirectly by a manufacturer to a dispensing pharmacy so that the total payment to the pharmacy for the prescription pharmaceutical product is at least equal to the price agreed upon in writing between the Plan Sponsor under Part D or a PBM acting under contract with such sponsor, and the manufacturer of the prescription pharmaceutical product.

(dd) *PBM service fees*. As used in section 1128B of the Act, “remuneration” does not include any payment by a pharmaceutical manufacturer to a pharmacy benefit manager (PBM) for services the PBM provides to the pharmaceutical manufacturer related to the pharmacy benefit management services that the PBM furnishes to one or more health plans as long as the following conditions are met:

(1) The PBM must have a written agreement with the pharmaceutical manufacturer that covers all of the services the PBM provides to the manufacturer in connection with the PBM’s arrangements with health plans for the term of the agreement and specifies each of the services to be provided by the PBM and the compensation associated with such services.

(2) The compensation paid to the PBM must:

(i) Be consistent with fair market value in an arm’s-length transaction;

(ii) Be a fixed payment, not based on a percentage of sales; and

(iii) Not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties, or between the manufacturer and the PBM’s health plans, for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.

(3) The PBM must disclose in writing to each health plan with which it contracts at least annually, and to the Secretary upon request, the services rendered to each pharmaceutical manufacturer related to the PBM’s arrangements to furnish pharmacy benefit management services to the health plan.

(4) For purposes of safe harbor in this paragraph (dd), the terms *manufacturer*, *pharmacy benefit manager* or *PBM*, and *prescription pharmaceutical product* have the meanings ascribed to them in paragraph (h) of this section, and health plan has the meaning ascribed to it in paragraph (l) of this section.