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BY ELECTRONIC FILING – via regulations.gov

Daniel R. Levinson
Inspector General
Attn: Aaron Zajic
Office of Inspector General
Department of Health and Human Services
Room 5527 Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

Re: OIG-0936-P 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

Dear Mr. Levinson,

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the Department of Health & Human Services (HHS) Office of Inspector General (OIG) proposed rule: *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*.[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $71.4 billion in 2017 alone.

[1] 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. 84 Fed. Reg. 2340 (Feb. 6, 2019).

Antitrust Statement

At the outset of our comments, it is important to note that numerous questions in the proposed OIG safe harbor rule raise competitively sensitive topics for members and that PhRMA's advocacy activities on behalf of its members in responding to the proposed rule are limited by the antitrust laws and PhRMA's antitrust compliance policy. In particular, PhRMA as the trade association does not permit any discussion about members' current and future drug pricing strategies, relationships with customers, or anticipated responses in the marketplace to any proposed changes to law or regulation. PhRMA's comments have been prepared with these guidelines in mind and in compliance with the antitrust laws and thus set forth PhRMA's advocacy views regarding the proposed rule.

PhRMA supports fundamental policy changes to achieve solutions that will help patients and produce better, more efficient health care. **Accordingly, PhRMA supports the policies underlying OIG's proposed modifications to the safe harbors and our member companies are committed to working with OIG to facilitate implementation by 2020 so that Medicare Part D beneficiaries may see the benefit of these policies.** Rapid implementation of the reforms proposed by OIG will be challenging for manufacturers and other stakeholders, but we consider these changes too important to delay.

PhRMA believes the existing reimbursement system for medicines can be improved to result in more cost savings for patients and the Part D program. The changes proposed by OIG would help achieve that goal by more directly translating the benefits of competition to patients through lower cost sharing—instead of allowing plans and supply chain entities to primarily benefit—and discouraging the use of compensation to certain intermediaries based on a medicine's list price. These polices could have a transformative impact on Medicare Part D and assist patients in gaining appropriate access to their medicines.

Our comments below seek clarity on certain aspects of the policies and offer suggestions in alignment with this goal. We begin by summarizing key action items for OIG and the Centers for Medicare & Medicaid Services (CMS) that reflect PhRMA's proposed near-term implementation priorities and recommended technical revisions to the safe harbors. We believe these actions are critical to ensuring a smooth 2020 implementation of the proposed rule that advances OIG's stated policy goals. As set forth in the Table of Contents, the remainder of this letter offers detailed policy and legal comments and provides additional information to OIG and CMS in separate appendices.

Action Items for HHS

Near-Term Implementation Priorities for HHS. PhRMA urges OIG to finalize the proposed rule as quickly as possible in order to meet the proposed effective date of January 1, 2020. This timeline is aggressive but attainable and will ensure that beneficiaries begin to benefit from the proposed policy changes as soon as possible. However, this timeline will also require HHS to take steps to ensure a smooth transition during the 2020 plan bid cycle. We urge HHS, including OIG and CMS, to consider the following implementation recommendations, as described in greater detail in Section VI of our comments.

- *OIG must rescind the PBM references in connection with the GPO safe harbor in the 2003 Compliance Program Guidance for Pharmaceutical Manufacturers and issue revised guidance.* OIG must rescind its statements in the 2003 Compliance Program Guidance for Pharmaceutical Manufacturers (2003 Pharma CPG) stating that rebates and other payments to pharmacy benefit managers (PBMs) may be protected under the GPO safe harbor, as of the effective date of the final rule. OIG should issue revised guidance clarifying that OIG no longer recognizes the GPO safe harbor as a possible source of protection for rebates or other payments by manufacturers to PBMs.

- *Successful implementation will require OIG to take steps to ensure PBM compliance.* OIG must issue clear "bright-line" guidance in the preamble to the final rule stating OIG's expectations for industry-wide compliance with the federal Anti-Kickback Statute (AKS) as it relates to PBM-negotiated reductions in price on medicines and PBM service fee arrangements. As part of this guidance, we urge OIG to specifically address PBMs' compliance obligations under the proposed safe harbors. Over the longer term, OIG should develop PBM-specific compliance program guidance that specifies recommended compliance program elements common to all health care stakeholders, but with tailored guidance on the application of those elements to PBM arrangements that have the potential for abuse.

- *The final rule will represent a change in law that* ***must apply prospectively only.*** OIG must recognize and clarify in the final rule that the rule represents a change in law and must apply prospectively only as of the effective date of the final rule.

- *CMS should provide clear program guidance to ensure discounts are appropriately reflected in point-of-sale prices on January 1, 2020*. CMS must issue clear guidance to facilitate the electronic sharing of data to provide pharmacies with real-time information about beneficiary cost sharing, a mechanism to allow pharmacies to receive point-of-sale (POS) chargebacks, and time to establish the necessary contractual relationships with entities administering point-of-sale chargebacks.

- *CMS and OIG should closely coordinate on finalization of the proposed rule.* PhRMA urges OIG to be in close contact with CMS so that CMS is aware of the status of the rulemaking. We encourage CMS to make any necessary modifications to the annual Part D operations timeline to

help ensure that coverage begins on January 1, 2020 with beneficiary cost sharing reflecting any changes to the AKS safe harbors.

- *CMS should update its cost sharing rules to align with the proposed point-of-sale reductions in price safe harbor.* PhRMA urges CMS to finalize its definition of negotiated price in the Medicare Advantage (MA) and Part D proposed rule published on November 30, 2018. We believe additional CMS guidance after the definition in the proposed rule is finalized would be helpful to ensure that the point-of-sale reductions in price safe harbor works smoothly and as intended.

- *CMS should oversee plan actuarial equivalence determinations to ensure that beneficiaries with copayments receive the intended benefits of the rule through reduced cost sharing.* In conjunction with OIG revising the regulatory text to clarify that the "completely applied" prong of the POS reductions in price safe harbor is met if the beneficiary's cost sharing at the point-of-sale is less than or equal to the price of the medicine after the reduction in price has been applied, CMS should ensure, through ongoing oversight of Part D plan design, that plan sponsors under Part D and PBMs acting on their behalf reduce copayments *for the tier on which the prescribed medicine is placed* that maintains actuarial equivalence with the standard benefit design.

Important Technical Changes to the Proposed Regulations Are Needed to Accomplish HHS/OIG's Stated Goals. PhRMA urges OIG to implement a series of critical changes to the text of the proposed safe harbors. If OIG moves forward with finalization, these changes will be crucial to successful implementation and are necessary to effectuate what we understand to be OIG's intent in issuing the proposed rule. We urge OIG to consider these proposed technical changes, as described in greater detail in Section XIII of our comments and as reflected in our redlined safe harbor text in Appendix I.

Proposed Point-of-Sale Reductions in Price Safe Harbor: 42 C.F.R. § 1001.952(cc)

- *OIG must clarify the compliance obligations of each party*. Currently, the safe harbor could be interpreted to require the manufacturer to meet all of the standards of the safe harbor. Manufacturers do not have visibility into nor the ability to control many of the elements of safe harbor compliance. OIG therefore must revise the proposed safe harbor to specify the compliance obligations of each party to a point-of-sale price reduction arrangement and indicate that compliance with the proposed safe harbor is determined separately for each party, similar to OIG's approach in the discount safe harbor.

- *OIG should clarify how reductions in price must be applied to beneficiary cost sharing at the point-of-sale.* The language in the proposed safe harbor that requires the reduction in price to be "completely applied" to the "price . . . charged" to the beneficiary is unclear and should be clarified. We recommend OIG consider revising the regulatory text to reflect what appears to be OIG's intent, which is that the reduction in price must be applied to reduce the price that determines beneficiaries' cost sharing on their medicines at the point-of-sale. For beneficiaries with fixed copayments, the regulatory text should specify that the "completely applied" prong is met if the beneficiary's cost sharing at the point-of-sale is less than or equal to the price of the

medicine after the reduction in price has been applied. Further, as noted above and as described in greater detail in Section VI, CMS should ensure, through its ongoing oversight of Part D plan design, that plan sponsors under Part D and PBMs acting on their behalf reduce the copayments *for the tier on which the prescribed medicine is placed* that maintains actuarial equivalence with the standard benefit design.

- *Clearer standards are needed for point-of-sale chargeback administration and pharmacy payments.* Certain changes are needed to the safe harbor to ensure appropriate chargeback administration and payment to the dispensing pharmacy. Specifically, we recommend that OIG (i) require plans, PBMs, and any other entities involved in the administration of point-of-sale chargebacks to exchange information and/or cooperate as necessary to ensure full transparency and appropriate administration of point-of-sale chargebacks, (ii) require plans and PBMs to reimburse dispensing pharmacies such that pharmacies receive full payment reflective of the negotiated reimbursement from the plan or PBM, the point-of-sale chargeback from the manufacturer, and the beneficiary's cost sharing payment, (iii) specify that the point-of-sale chargeback is equal to the amount of the reduction in price negotiated between the manufacturer and the plan or PBM, and (iv) address the risk of potential confusion caused by use of the term "chargeback" elsewhere in the distribution channel by revising the proposed safe harbor to use a more specific term, such as "point-of-sale chargeback."

- *OIG should put safeguards in place around service fees for point-of-sale chargeback administration*. We recommend revising the proposed safe harbor to require any individual or entity administering point-of-sale chargebacks to meet the same compensation requirements set forth in the proposed PBM service fees safe harbor at 42 C.F.R. § 1001.952(dd), which requires compensation to be at fair market value, to be a fixed payment not based on the list price of a medicine, and to be a payment not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

Proposed PBM Service Fees Safe Harbor: 42 C.F.R. § 1001.952(dd)

- *A more specific definition of "PBM" is needed.* OIG must adopt a more specific definition of "PBM." Specifically, we recommend a functional definition of "PBM" that reflects the range of services PBMs offer and accounts for the complex corporate structures and vertically integrated arrangements between PBMs and other entities (e.g., health plans). The PBM definition should further distinguish between the functions of PBMs and GPOs to foreclose protection of PBM services arrangements under the GPO safe harbor. Consistent with our request noted above, OIG should, as of the effective date of the final rule, rescind its statements in the 2003 Pharma CPG stating that rebates and other payments to PBMs may be protected under the GPO safe harbor.

- *The safe harbor should apply to all PBM service fees from manufacturers.* We recommend that OIG broaden the policy goals of the safe harbor by removing the "related to" limitation, such that the proposed safe harbor can be used for all PBM services arrangements with manufacturers.

- *Guidance is needed on "arm's-length transaction."* PhRMA supports OIG's approach to requiring PBM service fees to be consistent with fair market value; however, OIG should provide guidance on certain issues related to fair market value compensation in an arm's-length transaction. Specifically, OIG should (i) clarify that PBMs are obligated to negotiate services arrangements in good faith based on the bona fide needs of manufacturers, (ii) clarify the scope of safe harbor protection available for arrangements in which a PBM provides services on behalf of an affiliated health plan, and (iii) clarify that individual health plans that do not provide pharmacy benefits management services to plan sponsors under Part D may not attempt to use the safe harbor to negotiate administrative fees from manufacturers.

- *Service fee negotiations must be de-coupled from formulary negotiations.* OIG should (i) revise the proposed safe harbor to expressly prohibit PBMs from tying service fees or other compensation from manufacturers to formulary placement or positioning unless such compensation is paid by the manufacturer in exchange for services a PBM performs on a manufacturer's behalf to support the safe and effective use of medicines, such as a risk evaluation and mitigation strategy requirement, and (ii) clarify that PBMs may not require manufacturers to pay chargeback administration fees, chargeback adjudication fees, or similar service fees as a condition of formulary placement or position.

- *OIG should clarify the compliance obligations of each party.* Similar to PhRMA's proposal for the POS reductions in price safe harbor, OIG should revise the proposed PBM service fees safe harbor to specify the compliance obligations of manufacturers and PBMs and indicate that compliance with the proposed safe harbor is determined separately for each party. Because manufacturers may not have visibility into or control over PBM decision-making, PBMs should be solely responsible for ensuring that service fee compensation is separate from and does not take into account formulary placement or position and for complying with applicable transparency and disclosure requirements.

- *OIG should clarify the "volume or value" standard.* Similar to PhRMA's proposed revisions to the POS reductions in price safe harbor, OIG should revise the proposed PBM service fees safe harbor to deem certain per-unit fees to PBMs as not taking into account the volume or value of referrals or other business generated between the parties.

- *Transparency is needed for PBM services and fees.* PhRMA supports OIG's proposal to require PBMs to disclose service fee arrangements. In addition, PhRMA recommends that OIG modify the POS reductions in price safe harbor to require any individual or entity administering chargebacks under that safe harbor to meet the same disclosure requirements applicable to PBM services arrangements under the PBM service fees safe harbor.

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I. Prescription Medicines Have Revolutionized Treatment of Disease and Reduced Overall Health Care Costs

Medicines have revolutionized the treatment of numerous serious health conditions, saving lives, improving quality of life, and reducing the need for hospitalization.[2] The U.S. is by far the global leader in the development of new medicines.[3] American patients benefit from earlier and wider access to new medicines compared to patients in other countries, where governments restrict access.[4] For example, nearly 90 percent of newly launched medicines from 2011 to 2017 were available in the U.S., compared to just two-thirds in the United Kingdom (U.K.), half in Canada and France, and one third in Australia.[5]

Continued advances in medicines are indispensable to addressing some of our society's biggest health and economic challenges.[6] Likewise, better use of medicines, such as improved adherence to needed treatments, offers the opportunity for better results for patients and an estimated $213 billion per year in health care savings.[7] Recent research by Harvard economists shows that more than half of the reduction in medical spending between 1999 and 2012 for elderly Americans was attributable to reductions in cardiovascular events, and that half of these improvements were directly due to the use of medicines.[8] Researchers have also found that every additional dollar spent on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes, and high cholesterol generates $3 to $10 dollars in savings on emergency room visits and inpatient hospitalizations.[9]

As medicines' role in effective health care has grown sharply and many new medicines have been brought to patients, retail and physician-administered medicines combined have remained a consistent 14 percent of total U.S. health spending.[10] Biopharmaceutical innovator companies, which develop the safe and

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[2] PhRMA. A decade of innovation in rare diseases: 2005-2015. 2015. Available at: http://phrma-docs.phrma.org/sites/default/files/pdf/PhRMA-Decade-of-Innovation-Rare-Diseases.pdf; Lacey MJ, Hanna GJ, Miller JD, et al. Impact of pharmaceutical innovation in HIV/AIDS treatment during the highly active antiretroviral therapy (HAART) era in the US, 1987-2010: an epidemiologic and cost-impact modeling case study. Truven Health Analytics, December 2014. Roebuck MC. Medical cost offsets from prescription drug utilization among Medicare beneficiaries. *Journal of Managed Care Pharmacy*. 2014;20(10):994-995; Afendulis CC, Chernew ME. State-level impacts of Medicare Part D. *American Journal of Managed Care*. 2011;17 Suppl 12:S.

[3] National Science Foundation, National Science Board, 2018. Available at: https://www.nsf.gov/statistics/2018/nsb20181/data/appendix; TEConomy for PhRMA, analysis of Pitchbook data. April 2018. Companies and Deals. PitchBook Data Inc.; European Commission. The 2016 EU industrial R&D Investment Scoreboard, 2016. Available at: http://iri.jrc.ec.europa.eu/scoreboard16.html.

[4] Zhang Y, Hana CH, Hernandez I. Comparing the Approval and Coverage Decisions of New Oncology Drugs in the United States and Other Selected Countries. *Journal of Managed Care Specialty Pharmacy*. 2017;23(2):247-254.

[5] PhRMA analysis of IQVIA data.

[6] Alzheimer's Association. Changing the trajectory of Alzheimer's disease: how a treatment by 2025 saves lives and dollars. 2015. Available at: https://www.alz.org/help-support/resources/publications/trajectory_report.

[7] IMS Institute for Healthcare Informatics. Avoidable costs in U.S. healthcare: the $200 billion opportunity from using medicines more responsibly. June 2013.

[8] Cutler DM, Ghosh K, Messer KL, et al. Explaining the Slowdown in Medical Spending Growth among the Elderly, 1999-2010. *Health Affairs*. 2019;38(2):222-229.

[9] Roebuck MC, Lieberman JN, Gemmill-Toyama M, et al. Medical Adherence Leads to Lower Health Care Use and Costs Despite Increased Drug Spending. *Health Affairs*; 2011;30(1):91-99.

[10] Altarum Institute. Projections of the prescription drug share of national health expenditures including non-retail. May 2018.

effective new medicines that improve patients' lives, receive less than half of the total amount spent in the U.S. on prescription medicines—accounting for about 7 percent of total health care spending in 2015.[11] Generic manufacturers receive and intermediaries in the pharmaceutical supply chain retain the other half of spending on medicines.[12]

The ability to bring important medical advances to patients while reducing overall health care costs is made possible by the highly competitive structure of the U.S. market.[13] Fierce market competition among medicines results in sizable discounts from brand manufacturers and shifts utilization from brand medicines to generics and biosimilars.[14] As a result of these forces:

- In 2017, total net drug spending grew just 0.6 percent, even as many new treatments reached patients.[15] In 2018, prices for brand-name medicines increased just 1.5 percent after discounts and rebates, lower than the rate of inflation.[16]

- In 7 of the last 10 years, net retail prescription drug costs grew more slowly than total health care costs—and, on average, spending for retail prescription medicines has grown more slowly than growth for other major types of care, and more slowly than total health expenditures.[17]

- In 2018, 90 percent of all prescriptions filled were generics, up from 80 percent in 2011.[18] IQVIA projects U.S. brand sales will be reduced by $95 billion due to competition from generics and biosimilars between 2019 and 2023.[19] There is no similar type of cost containment for other health care services.

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[11] Vandervelde A, Blalock E. The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholders. Berkeley Research Group. January 2017. Available at: http://www.thinkbrg.com/media/publication/863_Vandervelde_PhRMA-January-2017_WEB-FINAL.pdf.

[12] In some instances, middlemen who played no role in a medicine's development and took no risk in purchasing it are paid more than the company that developed a medicine through years of research and clinical trials. A recent study reports that for 20 medicines administered in hospital outpatient departments commercial insurers pay hospitals up to three and a half times the medicines' acquisition cost. The Moran Company. Hospital Charges and Reimbursement for Drugs: Analysis of Markups Relative to Acquisition Cost. October 2017. While these markups are recorded as spending on drugs that typically is attributed to manufacturers in policy debates, in fact this is spending that is determined by and goes to middlemen, not spending that either goes to or is determined by biopharmaceutical companies.

[13] Lichtenberg F. Benefits and Costs of Newer Drugs: An Update. NBER Working Paper No. 8996. June 2002. Available at: https://www.nber.org/papers/w8996.

[14] Generics and biosimilars are a form of cost containment that applies only to the biopharma sector. For instance, the price of one widely used statin dropped by about 92 percent from 2005 to 2013 when generic versions came to market. Over the same period, the average charge for percutaneous transluminal coronary angioplasty, a surgical procedure to treat cardiovascular disease, increased by almost 66 percent.

[15] IQVIA. 2017 Medicine Use and Spending in the U.S.: A Review of 207 and Outlook to 2022. April 2018. Available at: https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.

[16] IQVIA. The Global Use of Medicine in 2019 and Outlook to 2023. January 2019. Available at: https://www.iqvia.com/institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.

[17] PhRMA analysis of CMS 2016 National Health Care Expenditure Accounts. December 2017.

[18] Fein AJ. The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Drug Channels Institute. March 2019.

[19] IQVIA. The Global Use of Medicine in 2019 and Outlook to 2023. January 2019. Available at: https://www.iqvia.com/institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.

While growth of net spending for medicines has been lower than growth in other health care costs,[20] multiple data sources show that (i) growth in manufacturer rebates and discounts that lower payers' cost of medicines has been substantial and (ii) an increasing share of these discounts and rebates are retained by intermediaries involved in distributing or paying for medicines, rather than directly passed on to patients:

- Compared to list price growth, rebates and other discounts reduced average net price growth for brand medicines by nearly three-quarters in 2018.[21]

- The pharmaceutical supply and payment chain accounts for a significant share of prescription drug spending, retaining 40 percent of total spending on retail prescription medicines in 2016.[22]

- Manufacturers' gross-to-net reductions[23] have more than doubled since 2012, totaling more than $166 billion in 2018.[24]

II. The Existing Rebate System Drives a Widening Gap Between List and Net Prices, Increasing Cost Sharing for the Sickest Patients

Although the current drug distribution and payment system has successfully constrained overall spending on medicines, the underlying mechanics could work better for patients. Today's system has evolved over time with changes in drug benefits, as well as changes in the size, role, and structure of PBMs. Industry analysts, the Medicare Payment and Advisory Commission (MedPAC), and independent researchers have observed that in recent years, publicly reported list prices for medicines have increased more rapidly than the actual net prices paid by PBMs and insurers, resulting in a growing gap between list and net prices.[25]

As OIG notes, the current rebate framework may incentivize both PBMs and health plans to favor medicines that carry higher rebates.[26] These misaligned incentives may also be the result of the types of arrangements PBMs commonly negotiate with their health plan clients, which allow PBMs to retain a portion of negotiated rebates and / or other price concessions as compensation for their services pursuant

[20] PhRMA analysis of CMS 2016 National Health Care Expenditure Accounts. December 2017.
[21] IQVIA. The Global Use of Medicine in 2019 and Outlook to 2023. January 2019. Available at: https://www.iqvia.com/institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.
[22] The Pew Charitable Trusts. "The Prescription Drug Landscape, Explored." March 2019. Available at: https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored.
[23] Defined as "rebates, off-invoice discounts, copay assistance, price concessions, and other reductions like distribution fees, product returns, the 340B Drug Pricing Program, and more." Fein AJ. The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Drug Channels Institute. March 2019.
[24] Fein AJ. The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Drug Channels Institute. March 2019.
[25] IQVIA. 2017 Medicine Use and Spending in the U.S.: A Review of 207 and Outlook to 2022. April 2018. Available at: https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.
[26] 84 Fed. Reg. at 2341.

to their arrangements with those plans, or which may guarantee a minimum level of rebates to the plan sponsor.[27] Manufacturers are not party to these arrangements.

Under the Current Structure of the Medicare Part D Program, Many Patients Do Not Directly Benefit from Significant Price Negotiations in the Market Today

Increasingly, Medicare Part D patient cost sharing for medicines is based on prices that exceed health plans' actual costs. This is because health plans typically base patients' cost sharing at the pharmacy counter on a medicine's list price rather than the lower discounted price paid by the plan when patients face deductibles or coinsurance. In contrast, out-of-pocket spending for care received from doctors and hospitals in a health plan's provider network is based on negotiated rates.

Imagine a hypothetical Part D beneficiary who takes a medicine with a list price of $400. The patient's Part D plan has negotiated a 65 percent rebate, which substantially reduces the cost to the plan. However, because the beneficiary has not yet met her deductible, the plan does not provide any coverage for her prescription, and the beneficiary's bill reflects the medicine's full cost of $400. Despite paying nothing for this beneficiary's medicine, the Part D plan still collects the rebate, earning $260.[28]

Deductibles and coinsurance expose patients to undiscounted list prices and can create affordability challenges for many patients. In Medicare Part D, the increased use of complex, multi-tiered formularies and growing prevalence of coinsurance may expose patients to a disproportionately high share of the cost of their medicines. Today, the vast majority (93 percent) of PDPs use CMS-approved formularies with five coverage tiers, and 7 percent are now using a sixth tier.[29] While most Part D plans have historically applied coinsurance to specialty tier medicines, in recent years plans have increasingly extended coinsurance to medicines on lower tiers. As a result, the percentage of Part D drugs subject to coinsurance jumped by nearly 20 percentage points between 2016 and 2019. Today, 62 percent of all medicines covered by PDPs are covered on a coinsurance tier.[30]

Undiscounted Part D Cost Sharing Subsidies and Reinsurance Payments are Distorted by the Growing Gap Between List and Net Prices

The gap between list and net prices also has implications for federal spending on Medicare Part D low-income cost sharing subsidies and reinsurance payments. The government subsidizes the cost sharing of low-income subsidy (LIS) recipients, including deductible and coinsurance payments, that are tied to undiscounted prices. Since negotiated rebates are not factored in, government-subsidized cost sharing for the LIS is based on the full, undiscounted value of a medicine, rather than the discounted price paid by the Part D plan. OIG's proposal to reform the existing rebate system could significantly lower government spending on low-income cost sharing subsidies in Medicare Part D. According to Milliman, the proposed

[27] Roehrig C. The Impact of Prescription Drug Rebates on Health Plans and Consumers. April 2018. Available at: https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf.
[28] PhRMA. Follow the Dollar. November 2017. Available at: http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf.
[29] Avalere Health. 2019 Medicare Part D Formularies: An Initial Analysis. December 2018.
[30] *Id*.

reforms could reduce government overpayments on low-income cost sharing subsidies by as much as $118.5 billion over 10 years, depending on the underlying model assumptions.[31]

Today, beneficiaries progress through the Part D benefit based on spending levels tied to undiscounted prices. This results in more enrollees reaching catastrophic coverage—where the government pays 80 percent of beneficiaries' total drug spending—than if net spending were used to determine progression through the benefit. Actuaries note that OIG's proposed changes to the existing rebate system are likely to result in fewer Part D enrollees reaching the catastrophic phase of the benefit, which could result in reductions in federal reinsurance costs of more than $163 billion over 10 years.[32]

Reforming the Rebate System Could Reduce Costs and Improve Patients' Access to Medicines

CMS, MedPAC, and OIG have all suggested that PBMs may have incentives under the existing Part D framework to prefer medicines with high list prices and large rebates over lower cost alternatives.[33] In previous comment letters to HHS and CMS, PhRMA has advocated for policy changes that would put the current system on a more sustainable path to align the needs of patients and payers and has suggested the following guiding principles for government reform:[34]

- **Part D beneficiaries should benefit directly at the point-of-sale from negotiated rebates and other price concessions.** Patients in the deductible phase or facing coinsurance should pay cost sharing that reflects the steep discounts that many manufacturers provide to PBMs and payers. Their cost sharing should not be calculated based off the list price of the medicine.

- **Rebates should not be allocated solely to premiums.** Today, rebate dollars are typically directed to lowering premiums instead of reducing cost sharing for Part D beneficiaries who use prescription medicines. This means that beneficiaries who take medicines for which manufacturers pay large rebates to reduce the price of the product are subsidizing coverage for other beneficiaries—which is effectively a tax on the sick.[35] Government policies should encourage rebate dollars to flow back to beneficiaries taking prescription medicines directly at the point-of-sale.

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[31] Klaisner J, Holcomb K, Filipek T. Impact of Potential Changes to the Treatment of Manufacturer Rebates. Milliman. January 31, 2019. Available at: https://www.regulations.gov/docket?D=HHSIG-2019-0001.
[32] *Id.*
[33] 82 Fed. Reg. at 56336; Medicare Payment Advisory Commission. Report to the Congress: Medicare Payment Policy. Chapter 14: The Medicare Prescription Drug Program (Part D): Status Report. March 2018; 84 Fed. Reg. at 2341.
[34] PhRMA comment letter on proposed Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. January 16, 2018. Available at: http://phrma-docs.phrma.org/download.cfm?objectid=E7F44060-FB02-11E7-821C0050569A4B6C; PhRMA comment letter on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. July 16, 2018. Available at: http://phrma-docs.phrma.org/download.cfm?objectid=9583A320-8919-11E8-8DCF0050569A4B6C.
[35] Girod CS, Hart SK, Weltz S. 2017 Milliman Medical Index. May 2017. Milliman. Available at: http://www.milliman.com/uploadedFiles/insight/Periodicals/mmi/2017-milliman-medical-index.pdf.

- **Underlying incentives for compensation arrangements for pharmacy benefit managers should not be tied to price.** The current system permits rebates and compensation based on list price. Reforms to the current system should be made with an aim to move toward a PBM compensation structure that is not linked to price. If PBMs deliver substantial value, they should be entitled to compensation based on that value. However, to reduce the potential for misaligned PBM incentives, we support OIG's proposed changes to untether PBM rebates and compensation from a medicine's price.

PhRMA, as a trade association, is not involved in and cannot comment on the individual pricing decisions of our members. HHS has, however, noted its concerns that the current system—in which negotiated rebates are permitted to be tied to a percentage of list price—may deter decreases in list price.[36] Under the current system, the revenues PBMs earn on medicines could decline if the prices of medicines were to decrease.[37] Since PBMs can influence medicine affordability and availability through their decisions about formulary coverage, utilization management, and formulary tier placement (which establishes cost sharing), a hypothetical manufacturer's unilateral decision to lower list price could result in a PBM then taking action to significantly reduce formulary access for that manufacturer's medicine, which in turn could significantly impact affordability and access for patients taking that medicine.[38]

Similarly, OIG has observed that "[t]he prominence of rebate arrangements in the prescription drug supply chain has been cited as a potential barrier to lowering drug costs" and that under the current system, PBMs may have incentives to penalize manufacturers for reducing list prices, including removing medicines from the formulary or placing them on a less-preferred formulary tier.[39] Information published by industry analysts shows that similar penalties may exist if manufacturers attempt to lower list prices without modifying their contract terms to provide a corresponding increase in the rebates received by the PBM.[40] Adam Fein, an expert on the pharmaceutical supply chain, has also stated that it would be "difficult, perhaps impossible," to lower list prices because "cutting the list price means wholesalers make less money, pharmacies make less money, PBMs make less money and payers get fewer rebate dollars."[41]

Under the current system, PBMs commonly negotiate administrative fees with manufacturers that are based on a percentage of the list price of a medicine.[42] Between 2012 and 2016, the revenue PBMs

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[36] Alex Azar, HHS, Testimony Before the United States Senate Committee on Finance: Prescription Drug Affordability and Innovation: Addressing Challenges in Today's Market, June 26, 2018.; Alex Azar, HHS, Testimony Before the United States Senate Committee on Health, Education, Labor and Pensions: Full Committee Hearing: The Cost of Prescription Drugs: Examining the President's Blueprint 'American Patients First' to Lower Drug Prices, June 12, 2018.

[37] Johnson CY. In May, Trump predicted the pharmaceutical industry would cut prices in two weeks. It hasn't happened yet. *Washington Post.* June 26, 2018. Available at: https://www.washingtonpost.com/news/wonk/wp/2018/06/25/in-may-trump-predicted-the-pharmaceutical-industry-would-start-cutting-prices-in-two-weeks-its-been-three/?noredirect=on&utm_term=.82a4ec23bbb9.

[38] Nisen M. Pharma's Quieter Price War Continues. *Bloomberg Businessweek*. August 3, 2017. Available at: https://www.bloomberg.com/news/articles/2017-08-03/pbm-formularies-quieter-drug-price-war-continues.

[39] 84 Fed. Reg. at 2341.

[40] Gal A, Wilkes L. Biopharma and managed care: UNH reaches out to pharma to manage rebate change, but change is hard and pain will spread. Bernstein. February 8, 2019.

[41] Johnson C. In May, Trump predicted the pharmaceutical industry would cut prices in two weeks. It hasn't happened yet. *Washington Post.* June 25, 2018.

[42] 84 Fed. Reg. at 2344.

retained from administrative fees for retail prescription medicine increased by 352 percent, from $1.2 billion to $5.6 billion.[43] PhRMA supports OIG's proposal to discourage list price-based administrative fees by creating a new safe harbor that would protect fixed-dollar PBM fees that are based on a fair market value standard. This proposed change to the safe harbor would help to create appropriate incentives for PBMs that can result in cost savings to the Medicare Part D program.

III. If Finalized, the OIG Proposed Rule Could Lower Costs for Millions of Part D Beneficiaries

Health plans typically use some portion of negotiated rebates to reduce premiums for all enrollees, rather than to directly lower costs for patients facing high cost sharing due to deductibles and coinsurance. According to one actuarial firm, this results in a system of "reverse insurance," whereby payers require patients with high drug expenditures to pay more out of pocket, while rebate savings are spread out among all health plan enrollees in the form of lower premiums.[44] Asking sicker patients with high drug costs to subsidize premiums for healthier enrollees is the exact opposite of how health insurance is supposed to work. The proposed rule would help to put an end to this practice. As envisioned by the proposed rule, the reduction in price agreed to between manufacturers and PBMs or plan sponsors would need to be reflected in the Part D negotiated price, lowering out-of-pocket costs for non-low-income beneficiaries and federal low-income cost sharing subsidies. No longer would sicker beneficiaries overpay to reduce costs for insurers and healthier patients.

Beneficiaries Could See Substantial Decreases in Their Total Out-of-Pocket Costs

All six of the analyses included in the proposed rule by three separate groups of actuaries show significant cost sharing savings in total.[45] In the first year, estimated average savings in out-of-pocket expenditures range from $48 to $96 per member,[46] or $2.2 billion to $4.6 billion in savings across all beneficiaries.[47] In five of the six scenarios included in the proposed rule, aggregate savings from lower cost sharing would more than outweigh increases in premiums, with beneficiaries projected to save between $2 and $3 per member per month after accounting for the modest projected premium increases.[48]

For patients taking multiple medicines, including the millions of Part D beneficiaries with chronic diseases, the cost sharing savings could be even greater. For example, an analysis by Avalere Health shows that a typical Part D beneficiary with diabetes taking five medicines, including insulin, could experience a decline in annual out-of-pocket costs of $962. Even when accounting for a projected increase in Part D premiums of $6 per month, this beneficiary would still see total annual savings of

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[43] The Pew Charitable Trusts. "The Prescription Drug Landscape, Explored." March 2019. Available at: https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored.
[44] Girod CS, Hart SK, Weltz S. 2017 Milliman Medical Index. Milliman. May 2017. Available at: http://www.milliman.com/uploadedFiles/insight/Periodicals/mmi/2017-milliman-medical-index.pdf.
[45] 84 Fed. Reg. at 2358.
[46] *Id.*
[47] Centers for Medicare and Medicaid Services Office of the Actuary. Proposed Safe Harbor Regulation. August 30, 2018. Available at: https://www.regulations.gov/docket?D=HHSIG-2019-0001; Klaisner J, Holcomb K, Filipek T. Impact of Potential Changes to the Treatment of Manufacturer Rebates. Milliman. January 31, 2019. Available at: https://www.regulations.gov/docket?D=HHSIG-2019-0001.
[48] 84 Fed. Reg. at 2358.

nearly $900.[49] A Part D beneficiary with rheumatoid arthritis (RA) taking four medications, including a brand RA therapy, could see total annual savings of $844, whereas a Part D beneficiary with hepatitis C and taking two medications, including a direct-acting brand antiviral, could save over $3,300.[50]

Premium Increases Would be Manageable

The average Part D premium has been growing at a low rate since the program's inception and is substantially lower than initial projections. The basic Part D premium averages just $32.50 a month in 2019, over a dollar less than the average premium in 2018.[51] Government and independent actuaries estimate that average monthly premiums could rise by $3 to $6 in 2020 under the proposed rule,[52] a manageable increase and below the Congressional Budget Office's (CBO) initial estimate that monthly premiums would average $58 by 2013.[53] Milliman estimates that if rebates were converted to upfront discounts, as proposed in the new safe harbor, beneficiaries with cost sharing reductions of about $3 per month would save enough in 2020 from lower out-of-pocket costs to offset the average premium increase.[54]

All Beneficiaries Could See Improved Coverage Due to Lower Deductibles and Other Benefit Changes

The CMS Office of the Actuary (OACT) and Milliman both note that the proposed changes to the existing rebate system could result in changes to Part D benefit parameters, including the deductible, initial coverage limit (ICL), and out-of-pocket threshold. These parameters are adjusted each year based on the growth in Part D costs, and today that adjustment does not take rebates into account.[55] Under the proposed rule, the adjustment would change to being based on prices net of rebates.

If net prices were to become the standard for measuring program growth, there could be a large drop in the Part D benefit parameters beginning in 2021, resulting in a larger number of beneficiaries with cost sharing savings (including those taking only generic drugs). OACT estimates that by 2022, the deductible, the ICL, and the catastrophic threshold would all decrease by nearly 20 percent relative to current law.[56] Accounting for likely behavior changes by Part D plans, Milliman finds the reduction

[49] Calculations for PhRMA by Avalere Health. Calculations reflect the 2019 parameters for non-LIS beneficiaries in actual standalone PDPs. Proposed rule adjustments assume premium increases as projected by OACT and reduce each brand drug's negotiated price by its average non-Medicaid list-to-net discount as reported by SSR Health.
[50] *Id.*
[51] CMS. Medicare Part D Premiums Continue to Decline in 2019. July 2018. Available at: https://www.cms.gov/newsroom/press-releases/medicare-part-d-premiums-continue-decline-2019.
[52] 84 Fed. Reg. at 2358.
[53] Note that 2013 was the last year of the federal budget window at the time CBO prepared its initial analysis of the Medicare Modernization Act. Congressional Budget Office. A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit. July 2004. Available at: https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/07-21-medicare.pdf.
[54] Klaisner J, Holcomb K, Filipek T. Impact of Potential Changes to the Treatment of Manufacturer Rebates. Milliman. January 31, 2019. Available at: https://www.regulations.gov/docket?D=HHSIG-2019-0001.
[55] *Id.*
[56] 84 Fed. Reg. at 2358.

could be even greater, up to nearly 30 percent by 2022 and nearly 35 percent by 2029 depending on the scenario modeled.[57]

Additionally, to maintain actuarial value standards if cost sharing were based on net, rather than list prices, Milliman notes that plans may choose to reduce copays.[58] This change could generate additional savings for a large number of beneficiaries, including those taking only generics.

IV. Reforms Proposed by OIG Could Strengthen the Market Dynamics Underlying the Part D Program and Reverse Erosion of the Program's Effective Actuarial Value

High Cost Sharing, Not Premiums, Drives Affordability Challenges in Part D

Plans' practice of using savings from negotiated rebates to keep premiums low has led to a system in which chronically ill beneficiaries subsidize the premiums of healthier enrollees, which is the opposite of how health insurance is supposed to work. The greatest benefits of the proposed reforms would likely flow to chronically ill beneficiaries with high drug spending, especially those who are currently paying coinsurance based on undiscounted prices. For a few additional dollars a month in premium costs, healthier beneficiaries would also gain the security of knowing they had meaningful drug coverage if and when they got sick.

The Value of Part D Coverage Has Begun to Erode for Beneficiaries with Chronic Conditions

Part D is structured so that under the standard benefit design, non-LIS beneficiaries are expected to pay an average of 25 percent of their brand drug costs up to the ICL and in the coverage gap and 5 percent in the catastrophic phase in 2019. At the time Part D was implemented, CMS believed plan sponsors would apply a portion of the rebate savings negotiated for a medicine directly at the point-of-sale, thereby lowering the cost sharing for beneficiaries taking that medicine. Instead, CMS has observed that plans seldom share rebate savings directly with beneficiaries.[59]

New research from Milliman shows that the effective actuarial value of Part D coverage for beneficiaries taking medicines with large rebates, such as insulin and oral anti-diabetes medications, has decreased since the start of the program.[60] Rebate growth has created a steadily widening gap in the share of total costs paid by beneficiaries on a gross vs. net basis (i.e., before and after rebates are factored in). As a share of net costs, actual beneficiary cost sharing for medicines with large rebates is projected to be higher than intended under the standard benefit design.

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[57] Holcomb K, Klein M. Impact of Manufacturer Rebate Proposed Rule on Part D Benefit Parameters. Milliman. March 29, 2018. Available at: http://www.milliman.com/insight/2019/Impact-of-manufacturer-rebate-proposed-rule-on-Part-D-benefit-parameters/.

[58] Klaisner J, Holcomb K, Filipek T. Impact of Potential Changes to the Treatment of Manufacturer Rebates. Milliman. January 31, 2019. Available at: https://www.regulations.gov/docket?D=HHSIG-2019-0001.

[59] 82 Fed. Reg. at 56336.

[60] Holcomb K, Klein M. Medicare Part D Diabetic Member Cost-Sharing: Impact on Non-Low Income Members. Milliman. February 2019. Available at: http://www.milliman.com/uploadedFiles/insight/2019/medicare-part-d-diabetic-cost-sharing.pdf.

As shown in Table 1, Milliman estimates that on the basis of net drug cost, non-LIS insulin users will pay an average of 46 percent of drug costs in the initial coverage phase and 47 percent in the coverage gap in 2020, rather than the intended 25 percent. Under the status quo, Milliman projects that by 2026 beneficiaries will pay an average of 51 percent of their net drug costs in the initial coverage phase and 53 percent in the coverage gap, more than twice the expected share of 25 percent. Furthermore, by 2026, Milliman estimates that non-LIS beneficiaries who fill insulin prescriptions in the deductible phase will pay an average of 201 percent of the plan's net cost, more than twice what their Part D plan would pay for those same medicines.

Table 1: Share of Drug Spending Paid by Non-LIS Insulin Users on a Gross (Pre-Rebate) and Net (Post-Rebate) Basis, by Benefit Phase[61]

	Deductible Phase		Initial Coverage Phase		Coverage Gap Phase		Catastrophic Phase		All Phases	
	Gross	Net	Gross	Net	Gross	Net	Gross	Net	Gross	Net
2008	100%	106%	25%	26%	100%	106%	5%	6%	46%	49%
2011	100%	108%	25%	27%	57%	62%	5%	6%	32%	35%
2014	100%	120%	25%	30%	51%	62%	5%	7%	30%	36%
2017	100%	149%	25%	38%	41%	63%	5%	8%	27%	41%
2020	100%	182%	25%	46%	25%	47%	5%	11%	23%	43%
2023	100%	192%	25%	49%	25%	50%	5%	11%	23%	46%
2026	100%	201%	25%	51%	25%	53%	5%	12%	23%	49%

Milliman's analysis demonstrates that in the absence of change, the value of Part D coverage will likely continue to erode over time. As beneficiaries effectively bear a higher and higher percentage of the cost of their medicines, their Part D coverage will be worth less. All else equal, the Part D benefit is expected to cover 62 percent of spending for all non-low-income beneficiaries on gross basis in 2020, but would provide coverage for 73 percent of spending if beneficiary out-of-pocket costs were instead calculated based on net prices.[62] Changes proposed by OIG could significantly lower out-of-pocket costs for beneficiaries, especially those with diabetes and other chronic conditions, and help ensure that patients do not pay more for their medicines than their Part D plans.

Competitive Incentives Are Key to the Long-Term Sustainability and Affordability of Part D

The success of the Part D program is attributable to the incentives that drive competition among plan sponsors. Those incentives result from and are directly proportional to plans' responsibility for managing costs and the possibility of financial rewards for keeping costs low. CMS, MedPAC, actuaries, and economists have all raised questions about the incentives created by allowing plans to apply aggregate rebate savings at the end of the year to lower premiums and whether plans have begun to overemphasize

[61] *Id.*
[62] *Id.*

low premiums at the expense of benefit designs that are affordable for high-cost beneficiaries with significant chronic or life-threatening conditions.[63]

Today, Part D plans are only responsible for covering a small portion of drug costs for beneficiaries in three of the four phases of the benefit (i.e., in the deductible, coverage gap, and catastrophic phases, plans are liable for 0 percent, 5 percent, and 15 percent, respectively, for non-LIS beneficiaries and 0 percent, 0 percent, and 15 percent, respectively, for LIS beneficiaries), yet they still collect and retain rebates for each prescription filled during this time. Plan sponsors, according to CMS, "are able to offset their already limited liability in the catastrophic phase by capturing additional rebates from manufacturers" which may result in "weak incentives, and, in some cases even, no incentive, to lower prices at the point-of-sale or to choose lower net cost alternatives to high cost-highly rebated drugs when available."[64] In addition, CMS has reported that Part D plan bids do not always reflect accurate rebate estimates and the actual rebates collected by plans and PBMs consistently exceed the projected rebates submitted during the bid process. Economists have also observed that relative to actual spending, plans systematically bid too low on the amount of spending expected in catastrophic coverage, while bidding too high for expected spending in the other phases of the benefit.[65] These systematic trends in plan sponsors' bidding practices suggest that plans have engaged in a pattern of keeping premiums low by shifting risk to the government.

Underbidding on catastrophic spending allows plan sponsors to suppress growth in premiums, while still receiving reimbursement for a large share of their actual incurred catastrophic coverage costs through additional reinsurance payments made during reconciliation. Since retrospective reconciliation payments are not reflected in plan sponsors' bids, this allows plans with high reinsurance costs to continue offering low premiums. A higher share of Part D payments in 2016 were made through retrospective reconciliation, rather than the prospective risk-based capitation system, which suggests that plan sponsors' liability for managing the benefit may be shrinking.[66]

If finalized, the OIG proposed rule is expected to decrease the share of Part D costs that occur in the catastrophic phase of the benefit[67]—where the government bears the majority of the risk—and increase the share of benefit spending that occurs in the initial coverage phase, where plans are most at risk for beneficiaries' drug spending. Requiring Part D plans to bear risk for a larger share of benefit spending further strengthens the incentives for payers to negotiate and manage costs. As MedPAC has noted: "Plan sponsors bear insurance risk for the benefit spending of their enrollees. When competing plans bear risk, they have incentives to offer benefits that are attractive to beneficiaries and yet manage spending so that

[63] 82 Fed. Reg. at 56336; MedPAC. Report to the Congress: Medicare and the Health Care Delivery System. Chapter 6: Sharing Risk in Medicare Part D. June 2015; Jung J, Feldman R. Growing Reinsurance Payments Weaken Competitive Bidding in Medicare Part D. *Health Services Research*. 2018;53(6):4371-4380.
[64] 82 Fed. Reg. at 56421.
[65] Jung J, Feldman R. Growing Reinsurance Payments Weaken Competitive Bidding in Medicare Part D. *Health Services Research*. 2018;53(6):4371-4380; MedPAC. Report to the Congress: Medicare and the Health Care Delivery System. Chapter 6: Sharing Risk in Medicare Part D. June 2015.
[66] MedPAC. Report to the Congress: Medicare Payment Policy. Chapter 14: The Medicare Prescription Drug Program (Part D): Status Report. March 2018.
[67] 84 Fed. Reg. at 2341 at 2360.

premiums remain affordable."[68] On the flip side, MedPAC has also observed that "evidence suggests that sponsors have been less successful at cost containment when they were at less risk for benefit spending."[69]

PhRMA supports the policy proposed by OIG aimed at changing the existing rebate system. It could more appropriately align plans' incentives to compete and innovate to provide appropriate, sustainable coverage for sicker, costlier beneficiaries, thereby strengthening the competitive dynamics that have made the Part D program a success.

Part D Plans and PBMs Will Continue to Leverage their Market Power to Negotiate Price Concessions

The U.S. pharmaceutical market is structured to take advantage of savings from brand competition and from generics. Three large PBMs manage over 75 percent of all prescriptions filled[70] and—as evidenced by the steady growth in rebates in year after year—they leverage this market power in their negotiations with manufacturers. In recent years, PBMs have further enhanced their negotiating leverage through a series of consolidations, mergers, and vertical integration with health plans and pharmacies.[71]

If the proposed rule is finalized, Milliman and OACT anticipate that Part D plans and PBMs will continue to negotiate with manufacturers for coverage of medicines and preferred formulary placement.[72] PhRMA is hopeful that the proposed reforms could more appropriately align payers' incentives to provide coverage for lower cost therapies and medicines that offer the best value for beneficiaries.

Actuarial analyses included in the regulatory impact section of the proposed rule support an expectation that manufacturers, plans, and PBMs will negotiate formulary-based reductions in price going forward. Specifically, Milliman notes that "manufacturers may be pushed to provide higher price concessions to keep the net plan sponsor liability closer to the current liability after rebates, rather than maintaining the current net allowed cost after rebates" and that formulary controls instituted by plans and PBMs could lead manufacturers to offer price concessions that are larger than rebates offered today:

> As formulary control tightens, manufacturers may offer additional price concessions to PBMs or plan sponsors (which could be even greater than the equivalent rebate arrangements today) to keep their products on formulary. . . . [I]n a market without rebates, manufacturers of higher-cost products may need to negotiate larger price concessions with PBMs to

[68] MedPAC. Report to the Congress: Medicare and the Health Care Delivery System. June 2015. Available at: http://www.medpac.gov/docs/default-source/reports/chapter-6-sharing-risk-in-medicare-part-d-june-2015-report-.pdf?sfvrsn=0.
[69] *Id.*
[70] Fein AJ. The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Drug Channels Institute. March 2019.
[71] The Pew Charitable Trusts. "The Prescription Drug Landscape, Explored." March 2019. Available at: https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored.
[72] Milliman. Impact of Potential Changes to the Treatment of Manufacturer Rebates, at 12 (Jan. 31, 2019), available at: https://www.regulations.gov/document?D=HHSIG-2019-0001-0002; CMS Office of the Actuary. Proposed Safe Harbor Regulation at 3 (Aug. 30, 2018), available at: https://www.regulations.gov/document?D=HHSIG-2019-0001-0004.

> secure formulary access or risk losing formulary status to a lower-cost alternative.[73]

Similarly, OACT assumed manufacturers would continue to negotiate competitively to determine placement of medicines on plan and PBM formularies:

> Another key assumption is how much of the remaining rebates would be converted into the chargeback system versus used to lower list prices. Because manufacturers would still need negotiating power to determine formulary position among competitors, and because a chargeback would offer more flexibility to vary prices by market, we believe the majority of rebates would be converted to a chargeback.[74]

We support the premise underlying these analyses: namely, under the proposed rule, pharmaceutical manufacturers may negotiate point-of-sale reductions in price based on formulary status or other conditions.[75] We support the belief shared by HHS that formulary designs and other controls are useful tools to help reduce costs for beneficiaries: "If Part D plans changed their benefit structures (e.g., increased formulary controls, greater use of generic drugs), and sought to prevent or ameliorate premium increases, they may be able to obtain additional price concessions from manufacturers."[76] We share HHS's point of view that "the pricing decisions of drug companies, and negotiations between manufacturers and PBMs will determine how plan sponsors make formulary decisions that determine whether or not beneficiaries pay more or less in out-of-pocket costs."[77]

OIG's proposed reforms to the rebate system are likely to redefine the competitive landscape for payers and reshape the contracting relationships between key stakeholders.[78] For example, Milliman has noted that the proposed rule may promote increased uptake of generics and biosimilars, which in turn could encourage more biosimilar launches.[79] With the proposed reforms, PBMs and Part D plans will have even

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[73] Klaisner J, Holcomb K, Filipek T. Impact of Potential Changes to the Treatment of Manufacturer Rebates. Milliman. January 31, 2019, at 12. Available at: https://www.regulations.gov/document?D=HHSIG-2019-0001-0002.

[74] CMS Office of the Actuary. Proposed Safe Harbor Regulation at 3 (Aug. 30, 2018). Available at: https://www.regulations.gov/document?D=HHSIG-2019-0001-0004.

[75] To this end, we have suggested language in the proposed safe harbor text below that is based on the proper disclosure tenet of the existing discount safe harbor, but adapted to fit a point-of-sale discount given to a purchaser as the existing safe harbor has historically been used to protect.

[76] 84 Fed. Reg. at 2356.

[77] 84 Fed. Reg. at 2355.

[78] The proposed rule addresses the existing rebate framework, which OIG and others have noted may incentivize PBMs and insurers to favor medicines that carry higher rebates. Outside of the U.S., these dynamics do not exist – PBMs do not negotiate price concessions on behalf of private payers and patients do not pay cost sharing based on prices that exceed the net cost to their insurers. In countries where these specific dynamics are absent, net price transparency is not likely to have similar benefits.

[79] Klaisner J, Holcomb K, Filipek T. Impact of Potential Changes to the Treatment of Manufacturer Rebates. Milliman. January 31, 2019, at 12. Available at: https://www.regulations.gov/document?D=HHSIG-2019-0001-0002.; Bell D, Carioto J, Hayes M. An End to Manufacturer Rebates as We Know Them Today? Milliman. February 15, 2019. Available at: http://www.milliman.com/insight/2019/An-end-to-manufacturer-rebates-as-we-know-them-today/.

stronger program incentives to engage in competitive negotiations to manage Part D benefit costs, which could drive beneficial and robust competition. Plans may be particularly incentivized to manage costs in order to minimize any expected increase in premiums stemming from the proposed rule, as premiums and plan design are key tools for Part D plans to attract enrollment.[80] As HHS Secretary Azar's Senior Advisor for Drug Pricing Reform recently noted, "projections of premium increases operate from the unrealistic assumption that Part D plans won't do what everyone who knows the market expects them to do, which is find a way to hold down premiums, through increased use of generics, tougher negotiation, or reduced overhead."[81]

V. Government Actuaries Overestimate Cost of Proposed Reforms Because They Do Not Account for Other Changes Likely to Occur in the Market

As noted in the proposed rule, OACT estimates that OIG's proposal could increase federal outlays for Medicare Part D by $196 billion over 10 years.[82] However, OACT's analysis assumes no behavioral changes by Part D plans, noting instead that "it is difficult to predict manufacturer and Part D plan behavior in response to this regulation."[83]

A more comprehensive analysis by the actuaries at Milliman notes that "it is critical to consider possible behavioral impacts" from the changes in the proposed rule because "all stakeholders would likely change behavior as a result."[84]

Federal Impact Projections Vary Substantially Based on Modeling Assumptions

The proposed rule includes impact analyses on federal Part D outlays conducted by OACT and two independent actuarial firms (Milliman and Wakely Consulting Group) for HHS. The analyses by OACT and Milliman include 10-year federal outlay projections for 2020 to 2029, whereas the analysis by Wakely includes estimates for only 2020.

OACT's analysis models only one scenario, which as noted above did not account for behavioral responses by plans or beneficiaries. In contrast, Milliman considered seven different scenarios, six of which estimated the impact of various behavioral changes by Part D plan sponsors, beneficiaries, and manufacturers. These included Part D plan sponsors imposing tighter formulary management, changes in net drug spending due to higher / lower discounts than under current law, a decrease in brand drug cost trend, higher beneficiary utilization, and increased pharmacy rebates.

[80] Klaisner J, Holcomb K, Filipek T. Impact of Potential Changes to the Treatment of Manufacturer Rebates. Milliman. January 31, 2019. Available at: https://www.regulations.gov/docket?D=HHSIG-2019-0001.
[81] O'Brien J. Patients need transparency and relief from high drug costs, not defense of the status quo. March 11, 2019. https://www.hhs.gov/blog/2019/03/11/patients-need-transparency-and-relief-from-high-drug-costs.html.
[82] 84 Fed. Reg. at 2358.
[83] 84 Fed. Reg. at 2344.
[84] Klaisner J, Holcomb K, Filipek T. Impact of Potential Changes to the Treatment of Manufacturer Rebates. Milliman. January 31, 2019 (emphasis added). Available at: https://www.regulations.gov/docket?D=HHSIG-2019-0001.

In four of the six scenarios where Milliman accounted for behavioral changes, federal Part D costs associated with the proposed reforms decreased relative to current law, saving the government an estimated $23 billion to $100 billion over the 10-year period.[85] The remaining two scenarios did not report net savings to the federal government, but Milliman's cost projections were much lower than those estimated by OACT.[86]

Proposed Rebate Reforms Could Significantly Reduce Federal Spending on Part D Cost Sharing Subsidies and Reinsurance

OIG's proposal to reform the rebate system could significantly lower federal spending on low-income cost sharing subsidies. Today, when LIS beneficiaries are in the deductible phase or are charged coinsurance for their prescriptions, their government-subsidized cost sharing is based on the full, undiscounted price of a medicine, rather than the discounted price paid by the Part D plan. Milliman finds that the proposed reforms could reduce federal government overpayments on low-income cost sharing subsidies by as much as $118.5 billion over 10 years, savings which were incorporated in Milliman's overall estimates of the change in federal Part D outlays.[87]

The proposed changes are also likely to result in fewer Part D enrollees reaching the catastrophic phase of the benefit, where the federal government pays 80 percent of beneficiaries' total drug spending. OACT estimates that federal reinsurance costs could decline by more than $20 billion over 10 years as a result.[88] Estimates from Milliman, which take likely behavioral changes into account, indicate that the 10-year reduction in federal reinsurance costs could exceed $163 billion.[89]

Actuaries Expect that the Proposed Rule Would Drive Behavioral Changes that Could Lower Costs for Part D Plans and the Government

If the proposed rule is finalized, plan sponsors who wish to hold down premiums to attract enrollees would have to use their negotiating power to manage costs, rather than leveraging rebate dollars.[90] According to actuaries, plans with large LIS populations could be further incentivized to submit low bids in order to preserve eligibility for auto-assignment of LIS enrollees.[91] Milliman anticipates that pharmaceutical manufacturers may see increased pressure from payers during contracting negotiations due to a shift in plans' formulary strategies and increased emphasis on covering generic medications and

[85] *Id.*
[86] *Id.*
[87] Klaisner J, Holcomb K, Filipek T. Impact of Potential Changes to the Treatment of Manufacturer Rebates. Milliman. January 31, 2019. Available at: https://www.regulations.gov/docket?D=HHSIG-2019-0001.
[88] 84 Fed. Reg. at 2360.
[89] Klaisner J, Holcomb K, Filipek T. Impact of Potential Changes to the Treatment of Manufacturer Rebates. Milliman. January 31, 2019. Available at: https://www.regulations.gov/docket?D=HHSIG-2019-0001.
[90] *Id.*
[91] Pyenson B, Kwong A. A World Without Rebates? How Will the Part D Market React to the New Proposed Safe Harbor for Rebates? Milliman. March 27, 2019. Available at: http://www.milliman.com/insight/2019/A-world-without-rebates-How-will-the-Part-D-market-react-to-the-new-proposed-safe-harbor-for-rebates/.

brand medicines with lower point-of-sale costs. Milliman also observes that manufacturers "may have more success marketing biosimilars in Part D if manufacturer rebates are eliminated."[92]

While actuaries expect that the proposed reforms will encourage plans to leverage their control over formularies to negotiate discounts on brand medicines, plans may also attempt to narrow formularies in order to deter high-cost beneficiaries from enrolling, and it may be difficult to distinguish cost controls from attempts at favorable selection.[93] Efforts to discourage enrollment by certain eligible beneficiaries would violate Part D's nondiscrimination requirement[94] and we would urge CMS to continue to closely monitor plan formulary submissions to protect beneficiaries from being discriminated against on the basis of their health status. A more detailed discussion of the actions CMS could take to ensure the proposed changes to the safe harbors are implemented in a manner consistent with the non-discrimination requirement in the Part D statute can be found in Section VI of this comment letter.

Cost Estimates Do Not Account for Offsetting Savings in Medicare Parts A and B

While the Part D benefit has helped countless seniors access needed medications, beneficiaries facing high cost sharing for medicines still face challenges accessing the treatments they need, preventing optimal adherence and resulting in treatment abandonment. Despite evidence of the benefits of medicine, between 23 percent and 38 percent of Medicare beneficiaries with chronic diseases are not adherent to therapy.[95] Nonadherence accounts for up to 4 percent, 7 percent, 9 percent, and 11 percent of total health care expenditures for hyperlipidemia, diabetes, heart failure, and hypertension, respectively.[96]

An analysis by Amundsen Consulting shows that 38 percent of all new specialty prescriptions filled by Part D beneficiaries beginning therapy for the first time were abandoned at the pharmacy in 2016, and that the likelihood of abandonment was strongly associated with out-of-pocket cost.[97] When beneficiary cost sharing exceeded $250, 71 percent of new specialty prescriptions were abandoned. This level of cost sharing was not uncommon, as nearly 40 percent of all new Part D prescriptions for specialty medicines had cost sharing of more than $250.

If finalized, the proposed rule could significantly lower beneficiary cost sharing, particularly for brand medicines that currently carry rebates. This lower cost sharing should help to improve beneficiary adherence; a decision by OptumRx to apply point-of-sale discounts to fully-insured plans in the commercial market in 2019 resulted in as much as a 16 percent improvement in adherence in the first two

[92] Klaisner J, Holcomb K, Filipek T. Impact of Potential Changes to the Treatment of Manufacturer Rebates. Milliman. January. 31, 2019. Available at: https://www.regulations.gov/docket?D=HHSIG-2019-0001.
[93] Pyenson B, Kwong A. A World Without Rebates? How Will the Part D Market React to the New Proposed Safe Harbor for Rebates? Milliman. March 27, 2019. Available at: http://www.milliman.com/insight/2019/A-world-without-rebates-How-will-the-Part-D-market-react-to-the-new-proposed-safe-harbor-for-rebates/.
[94] Social Security Act § 1860D-11(e)(2)(D)(1) (the Secretary may approve a Part D plan only if the plan design is not "likely to substantially discourage enrollment by certain part D eligible individuals under the plan").
[95] Lloyd JT, Maresh S, Powers CA, et al. How Much Does Medication Nonadherence Cost the Medicare Fee-For-Service Program? *Medical Care*. 2019;57(3):218-224.
[96] *Id.*
[97] Amundsen Consulting. Medicare Part D Abandonment: Deep Dive into Branded Product Abandonment. November 2017.

months alone.[98] However, neither Milliman nor OACT's impact estimates account for likely savings in Medicare Parts A and B due to better adherence to medicines and a subsequent reduction in hospitalizations and in the use of other medical services. Reducing beneficiaries' financial burdens could help achieve the health benefits and cost savings available through improved adherence to needed treatments and reduced abandonment of prescriptions at the pharmacy counter.[99] As CBO has affirmed, medication adherence plays an important role in reducing the use of other health care services in Medicare.[100] On the other hand, medication nonadherence is associated with poor clinical outcomes and higher overall health care costs.[101]

Analysis by IHS Markit indicates that passing through a share of rebates just for diabetes medicines alone could reduce overall health care spending (including Parts A and B) for Medicare beneficiaries with diabetes by $20 billion over the next 10 years.[102] Similarly, other research shows that if the 25 percent of beneficiaries with hypertension who were nonadherent were to become adherent, Medicare could save $13.7 billion annually, avoiding over 100,000 emergency department visits and 7 million inpatient hospital days.[103] In a recent Health Affairs study, Harvard economists reported that 56 percent of the reduction in medical spending between 1999 and 2012 for Americans ages 65 and older was attributable to reductions in cardiovascular events, and that half of these improvements were directly due to the use of medicines.[104]

VI. Implementation is Possible for 2020 but Would Require CMS and OIG to Work Quickly to Ensure Clear Rules of the Road for Manufacturers, Part D Plans, and Supply Chain Entities

If finalized, the OIG proposed rule could lower costs for beneficiaries and address the existing incentives that may contribute to PBM and plan sponsor priorities for formulary decision-making.[105] Given these benefits, PhRMA urges OIG to finalize this rule as expeditiously as possible, such that savings from negotiated discounts may be passed on to beneficiaries. The January 1, 2020 timeline is aggressive but attainable and will ensure that beneficiaries begin to benefit from the proposed policy changes as soon as

[98] Optum. Successful Prescription Drug Discount Program Expands to Benefit More Consumers at Point-of-Sale. March 12, 2019. Available at: https://www.optum.com/about/news/successful-prescription-drug-discount-program.html.

[99] Goldman DP, Joyce GF, Escarce JJ, et al. Pharmacy Benefits and the Use of Drugs by the Chronically Ill. *JAMA*. 2004;291(19):2344-2350.; Doshi JA, Li P, Ladage VP, et al. Impact of Cost Sharing on Specialty Drug Utilization and Outcomes: A Review of the Evidence and Future Directions. *American Journal of Managed Care.* 2016;22(3):188-197.

[100] Congressional Budget Office. Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services. November 2012. Available at: https://www.cbo.gov/sites/default/files/112th-congress-2011-2012/reports/MedicalOffsets_One-col.pdf.

[101] Boswell KA, Cook CL, Burch SP, et al. Associating Medication Adherence with Improved Outcomes: A Systematic Literature Review. *American Journal of Managed Care*. 2012;4(4):e97-e108.

[102] Su W, Dall T. Passing a Portion of Negotiated Rebates Through to Seniors with Diabetes Can Improve Adherence and Generate Savings in Medicare. IHS Markit. May 14, 2018.

[103] Lloyd JT, Maresh S, Powers CA, et al. How Much Does Medication Nonadherence Cost the Medicare Fee-For-Service Program? *Medical Care*. 2019;57(3):218-224.

[104] Cutler DM, Ghosh K, Messer KL, et al. Explaining the Slowdown in Medical Spending Growth Among the Elderly, 1999-2010. *Health Affairs*. 2019;38(2):222-229.

[105] Klaisner J, Holcomb K, Filipek T. Impact of Potential Changes to the Treatment of Manufacturer Rebates. Milliman. January 31, 2019. Available at: https://www.regulations.gov/docket?D=HHSIG-2019-0001.

possible. As discussed below, this timeline will also require that both OIG and CMS take steps to ensure a smooth transition during the 2020 plan bid cycle. Manufacturers, PBMs, pharmacies, and other stakeholders will need to work in tandem and with clear guidance to effectuate changes in time for January 1, 2020. Our specific recommendations regarding implementation are outlined below.

OIG Must Rescind the PBM References in Connection with the GPO Safe Harbor in the 2003 Compliance Program Guidance for Pharmaceutical Manufacturers and Issue Revised Guidance

OIG did not address in the proposed rule whether or how the proposed safe harbors would align with OIG's statements in the 2003 Pharma CPG that rebates and other payments by pharmaceutical manufacturers to PBMs could be structured to fit within the GPO safe harbor. Specifically, in the section of the 2003 Pharma CPG titled "Payments to PBMs," OIG stated the following:

> 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 C.F.R. § 1001.952(j). That safe harbor requires, among other things, that the payments be authorized in advance by the PBM's customer and that all amounts actually paid to the PBM on account of the customer's purchases be disclosed in writing at least annually to the customer.[106]

To eliminate stakeholder confusion and foreclose alternate safe harbor protection for retrospective rebates and percentage-based service fees, OIG should issue new guidance rescinding its statements in the 2003 Pharma CPG and clarifying that OIG no longer recognizes the GPO safe harbor as a possible source of protection for rebates or other payments by manufacturers to PBMs.

Assuming the safe harbors are finalized as proposed, we ask that OIG clarify in revised guidance that the above-quoted statements in the "Payments to PBMs" section in the 2003 Pharma CPG have been superseded and replaced by OIG's new guidance on point-of-sale reductions in price and PBM service fees upon the effective date of the final rule. If the proposed rule is to have any meaningful impact on delinking supply chain payments from a medicine's price, OIG must foreclose the use of pre-existing safe harbor guidance that would allow PBMs to use the GPO safe harbor to maintain the status quo.

Successful Implementation Will Require that OIG Take Steps to Ensure PBM Compliance

While PhRMA supports implementing the rule for the 2020 plan year, we emphasize that successful implementation on this timeline will require that OIG issue affirmative, clear guidance to encourage PBM compliance with the proposed safe harbors. As we noted in our comments to the Blueprint,[107] ongoing industry consolidation and an imbalance in enforcement scrutiny over the last decade have emboldened

[106] 68 Fed. Reg. at 23736.
[107] PhRMA, Comment Letter on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, 24. Jul. 16, 2018. Available at: https://www.phrma.org/public-communication/rfi-comments-on-hhs-blueprint-to-lower-drug-prices-and-reduce-out-of-pocket-costs.

PBMs to use their considerable market power to dictate contracting terms to individual pharmaceutical manufacturers. To promote rapid adoption and implementation of the final rule, we recommend OIG issue clear bright-line guidance for affected stakeholders, including our suggestions below, regarding OIG's compliance and timing expectations.

Manufacturers have long been committed to compliance and have had the benefit of receiving detailed compliance program guidance from OIG. This industry context has driven manufacturers to further embrace corporate cultures that emphasize AKS compliance. Although OIG has issued compliance guidance specific to many entities, including pharmaceutical manufacturers, it has never issued PBM-specific compliance guidance.

We suggest that OIG can improve the likelihood of success of the proposed rule's aims to foster strong negotiations that result in arrangements supported by the safe harbors by taking action as follows: (i) issue near-term "bright-line" guidance stating OIG's expectations specific to PBMs under the proposed safe harbors, and (ii) issue a compliance program guidance specific to PBMs.

- In the near term, OIG could state clearly in the preamble to the final rule that the agency expects industry-wide compliance with the AKS as it relates to PBM-negotiated reductions in price on medicines and PBM service fee arrangements. Timely renegotiation will be important to ensure an orderly transition for plans and beneficiaries for the 2020 plan year.

- To ensure the rule effectively achieves HHS's stated goals, OIG could provide bright-line guidance that it will subject PBMs to heightened scrutiny for any discount or services arrangements that PBMs solicit in exchange for placement of pharmaceutical manufacturers' medicines on Medicare Part D formularies *that do not fit within the four corners of one of the proposed safe harbors*.

- Over the longer term, PhRMA urges OIG to issue further guidance that communicates to PBMs the importance of complying with applicable health care fraud and abuse laws, including the proposed safe harbors. As part of this longer-term effort, OIG should promulgate comprehensive compliance program guidance for PBMs that is similar to OIG's 2003 Pharma CPG.[108] PhRMA believes it will be critical for OIG to issue compliance guidance to PBMs that specifies recommended compliance program elements common to all health care stakeholders, but with tailored guidance on the application of those elements to PBM arrangements that have the potential for abuse. We believe it is important for OIG to describe specifically the arrangements and other PBM business activities that could increase potential enforcement risk under applicable health care fraud and abuse laws.

In addition, as part of this long-term effort, we suggest that OIG, the Department of Justice (DOJ), and CMS should implement a mechanism through which manufacturers and other industry stakeholders can obtain interpretive and other guidance on implementation of the new system contemplated by the

[108] OIG, Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23734 (May 5, 2003).

proposed safe harbors that is more timely and accessible than OIG's existing advisory opinion process. Such a mechanism could also include the ability to report suspected non-compliance. We recognize that this would be time and resource intensive and may require additional authority or funding. We would be pleased to offer ideas regarding the potential establishment of such a mechanism, including authority and funding, upon your request.

The Final Rule Will Represent a Change in Law That Must Apply Prospectively Only

While PhRMA firmly supports finalizing the proposed rule effective for the 2020 plan year, for all of the important policy reasons described above, it is critically important that OIG recognize and clarify that the final rule would represent a change in the law that must apply *prospectively only* as of the effective dates set out in the final rule.

"A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required."[109] As the Supreme Court has explained, "[e]lementary considerations of fairness dictate that individuals should have an opportunity to know what the law is and to conform their conduct accordingly; settled expectations should not be lightly disrupted."[110] Consequently, an agency cannot enforce a new interpretation of a statute or rule retroactively to impose liability on a party that did not have fair notice of the agency's interpretation.[111] Indeed, the relevant case law clearly reflects that "fundamental anti-retroactivity principles" are "Rule of Law 101."[112] These considerations apply with particular force in criminal matters—retroactively expanding criminal liability without due notice violates the most basic principles on which our criminal justice system is based and would, quite simply, violate every notion of fundamental fairness.[113]

The proposed rule cannot be applied retroactively to arrangements in place prior to the effective dates set forth in any final rule, for the reasons set forth below. First, the proposed rule expressly acknowledges that the revisions it proposes to the discount safe harbor would narrow the scope of that safe harbor. OIG explains that the proposed rule would:

> amend the existing discount safe harbor so that it would *no longer* protect price reductions from manufacturers to plan sponsors under Medicare Part D or Medicaid MCOs, either directly or through PBMs acting under contract with plan sponsors under Medicare Part D or Medicaid MCOs, in

[109] *FCC v. Fox Television Stations*, 567 U.S. 239, 253 (2012).
[110] *Landsgraf v. USI Film Prods*., 511 U.S. 244, 265 (1994).
[111] *See, e.g., Fox*, 567 U.S. at 253-54 (Due Process prevents an agency from applying a new interpretation of a statute retroactively to parties who had "no notice" that the agency deemed the conduct unlawful); Christopher v. SmithKline Beecham Corp., 567 U.S. 142, 156 (2012) (rejecting agency's interpretation of a regulation that resulted in "unfair surprise" to regulated parties).
[112] *PHH Corp. v. Consumer Fin. Prot. Bureau*, 839 F.3d 1, 48 (D.C. Cir. 2016), *vacated on other grounds* (Feb. 16, 2017), on *reh'g en banc*, 881 F.3d 75 (D.C. Cir. 2018).
[113] *See United States v. Lanier*, 520 U.S. 259, 266 (1997) (explaining that this basic due process principle of fair warning incorporates both the prohibition on vague criminal laws and the rule of lenity, which "ensures fair warning by so resolving ambiguity in a criminal statute as to apply it only to conduct clearly covered"); *see also United States v. Pennsylvania Indus. Chem. Corp.*, 411 U.S. 655, 674 (1973).

> connection with the sale or purchase of prescription pharmaceutical products, unless the reduction in price is required by law.[114]

Likewise, elsewhere in the proposed rule, OIG states: "[T]his amendment, if finalized, [would] be effective on January 1, 2020. We are mindful that many entities may be using the current discount safe harbor to protect financial arrangements that no longer would meet the definition of 'discount' under this proposed change."[115] These statements appropriately recognize that the proposed rule, if finalized, reflects a change in law, and we appreciate that OIG has proposed a prospective compliance date consistent with that fact, which PhRMA firmly supports.

Second, OIG has well-documented its awareness of existing PBM rebates in numerous reports and studies and has plainly permitted such arrangements to persist and proliferate. OIG acknowledged the PBM rebating system in studies published as far back as 2010 and 2011 without criticism or concern regarding potential abuse.[116] OIG was also aware of CMS's published report "Medicare Part D – Direct and Indirect Remuneration," and did not issue any additional guidance or fraud alerts relating to rebates at the time, suggesting that such arrangements continued to be permissible.

Finally, it is important to bear in mind that the Part D rebate framework that OIG now seeks to address through reforms to the safe harbors was established and bolstered by the regulations of other agencies within HHS. Specifically, the CMS Medicare Part D regulatory definition of "direct and indirect remuneration," which expressly includes, in relevant part:

> . . . discounts, chargebacks or rebates . . . or other price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by an intermediary contracting organization with which the Part D plan has contracted, regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the Part D sponsor and regardless of the terms of the contract between the plan sponsor and the intermediary contracting organization.[117]

Since the establishment of the Medicare Part D program, CMS has never placed limits or minimum pass through requirements on PBMs or plan sponsors with respect to such remuneration. We believe the record shows that rebates are currently an integral part of the Part D program that are recognized by agency regulations.

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[114] 84 Fed. Reg. at 2347 (emphasis added).
[115] 84 Fed. Reg. at 2348.
[116] *See, e.g.*, OIG, Memorandum Report: Medicare Part D Pharmacy Discounts for 2008, OEI-02-10-00120 (Nov. 17, 2010) ("It is important to note that pharmacy discounts are distinct from drug manufacturer rebates. . . . *Drug manufacturers provide rebates to sponsors when they encourage beneficiaries to use certain drugs*.") (emphasis added); OIG, Concerns with Rebates in the Medicare Part D Program, OEI-02-08-00050 (Mar. 2011) ("[S]elected sponsors reported that their PBMs collected fees from drug manufacturers that were not always pass on to the Part D program.").
[117] 42 C.F.R. § 423.308.

Moreover, by OIG's own admission, in giving the Department the authority to protect certain arrangements and payment practices under the Anti-Kickback Statute, Congress intended the safe harbor regulations to be updated periodically to reflect changing business practices and technologies in the health care industry.[118] For the past several years, pharmaceutical manufacturers have actively solicited guidance from OIG regarding payments to PBMs for utilization covered under Part D and regarding value-based rebate arrangements, including through the OIG's annual solicitation process for new safe harbors and special fraud alerts,[119] with no response or additional guidance from OIG on these issues. Particularly in light of this history, this rulemaking does not change the legality of conduct that took place, or that takes place, before the effective date of the final rule.[120]

Thus, for the reasons outlined above, and while we applaud OIG for issuing the proposed rule with an implementation schedule set to impact the 2020 plan year, PhRMA requests that OIG expressly clarify, for the avoidance of any doubt, that any final rule is a change in the law and applies prospectively only as of the effective dates set out in the final rule.[121]

Finally, we request that, consistent with OIG precedent[122] involving significant changes to the safe harbor regulations, OIG exercise its enforcement discretion as manufacturers, Part D plan sponsors, PBMs, and other stakeholders with existing contractual arrangements work to implement the proposed rule with reasonable diligence once it becomes final. The proposed rule affects the core of a complex set of existing contracting and regulatory arrangements between multiple stakeholders, with drug pricing and contractual arrangements being key inputs in formulary design, financial projections, and underwriting. We are committed to timely implementation of the rule if it is finalized, but our efforts to ensure compliance will require greater speed than is typical in today's market. Systematic changes needed to accommodate the new point-of-sale discounts for beneficiaries will likewise require effort in how they are configured initially and then continued diligence over time to make changes that will best ensure success.

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[118] 84 Fed. Reg. at 2345.

[119] *See e.g.*, PhRMA, Comment Letter on Solicitation of New Safe Harbors and Special Fraud Alerts (OIG-127-N) (Feb. 26, 2018), available at: https://www.regulations.gov/document?D=HHSIG-2018-0001-0014; Eli Lilly & Co., Comment Letter on Solicitation of New Safe Harbors and Special Fraud Alerts (OIG-125-N) (Feb. 24, 2017), available at: https://www.regulations.gov/document?D=HHSIG-2017-0001-0005; Eli Lilly and Co., Comment Letter on Solicitation of New Safe Harbors and Special Fraud Alerts (OIG-125-N) (Feb. 14, 2017), available at: https://www.regulations.gov/document?D=HHSIG-2017-0001-0002; PhRMA, Comment Letter on Solicitation of New Safe Harbors and Special Fraud Alerts (OIG-125-N) (Feb. 27, 2017), available at: https://www.regulations.gov/document?D=HHSIG-2017-0001-0007; PhRMA, Comment Letter on Solicitation of New Safe Harbors and Special Fraud Alerts (OIG-112-N) (Feb. 19, 2008).

[120] *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) (because the "'power to require readjustments for the past is [a] drastic'" power, the Secretary generally lacks authority to promulgate retroactive rules and "courts should be reluctant to find such authority absent an express statutory grant").

[121] PhRMA respectfully requests further clarification that any written arrangements in existence prior to January 1, 2020 and requiring payment for rebates set in advance, and which are earned prior to January 1, 2020 but not yet paid by such date, may be lawfully paid and received after January 1, 2020.

[122] *See, e.g.,* preamble to 1991 Final Rule, 56 Fed. Reg. 35952, 35955 (Jul. 29, 1991) ("In the event that they [health care providers] now find that the arrangement does not comply fully with a particular safe harbor provision and are working with diligence and good faith to restructure it so that it does comply, we will use our discretion to be fair to the parties to such arrangements."); *see also*, preamble to 1999 Final Rule, at 64 FR 63521 ("We are not setting a specific 'grace period,' as we believe that the reasonable time period for restructuring an arrangement will vary depending on the type and complexity of the arrangement.").

Clear Program Guidance Will Need to Be Established to Ensure Discounts Are Appropriately Reflected in Point-of-Sale Prices on January 1, 2020

If rebates were replaced by POS reductions in price contemplated by the proposed rule, it would require changes to today's system to quickly reimburse pharmacies for the amount of the manufacturer discount. To account for the POS reductions in price contemplated by the proposed rule, OIG envisions that, in addition to payments from PBMs and cost sharing collected from beneficiaries—both of which would be based on a new lower point-of-sale price inclusive of all negotiated discounts—pharmacy reimbursement will be comprised of a third payment, in the form of a POS "chargeback."

To process claims for each beneficiary by January 1, 2020, clear program guidance from CMS will be needed prior to implementation. In particular, we request that CMS coordinate with stakeholders to ensure that all parties have access to the data necessary to effectuate and validate a system of POS chargebacks. CMS should also issue program guidance to facilitate any necessary systems changes and enable the electronic sharing of data to provide pharmacies with real-time information about beneficiary cost sharing, a mechanism to allow pharmacies to receive POS chargebacks, and time to establish the necessary contractual relationships with entities administering POS chargebacks.

The current system is also not designed to quickly reimburse pharmacies for the reduction in price negotiated between manufacturers and payers. Under the current system, rebates are typically paid by manufacturers to plan sponsors on a periodic basis and are reconciled on an aggregate level. Under the system envisioned by the proposed rule, discounts would be administered at an individual, per-prescription level by pharmacies, and POS chargebacks would be required to flow directly or indirectly from manufacturers to pharmacies to make up for the difference after accounting for PBM payments and beneficiary cost sharing. Regardless of the entity administering the POS chargeback, this would require the transmission of additional information to the pharmacy at the point-of-sale. Therefore, we respectfully request that CMS engage with the National Council for Prescription Drug Programs (NCPDP) to update the telecommunication standard that governs transactions between pharmacies and PBMs and plan sponsors in order to create a new, separately identifiable field to record the value of POS chargebacks. This fundamental data element will ensure transparency of the POS chargeback amount, giving all stakeholders the ability to verify that the appropriate value of POS chargebacks was paid, and that the system envisioned by the proposed rule is being applied effectively.

Pharmacies play a unique and crucial role in the pharmaceutical supply chain. While some pharmacies are part of large, well-resourced corporations, there are an estimated 21,909 independent community pharmacies in the United States, representing 35 percent of the retail pharmacy marketplace. Community pharmacies should not be burdened by transition to upfront discounts. Independent and small-chain pharmacies would likely have financial difficulty waiting to be reimbursed in full for the prescriptions they dispense. Ensuring that pharmacies are not financially burdened by the proposed changes to the existing rebate system is particularly important given how often community pharmacies serve more rural areas.[123]

[123] Seventy-five percent of community pharmacies serve population areas of 50,000 or fewer. National Community Pharmacists Association. 2018 NCPA Digest. October 8, 2018.

CMS Guidance on Timelines and Processes Will Be Necessary for Successful Implementation of the Safe Harbor Changes.

By statute, Part D plan sponsors must submit bids for the 2020 plan year by the first Monday in June, which in 2019 falls on June 3rd.[124] It is, of course, unclear to PhRMA and other stakeholders whether the OIG proposed rule will be finalized before or after that date. While we encourage OIG to thoughtfully consider feedback from all stakeholders, we emphasize that OIG should finalize the proposed rule as quickly as possible to help facilitate the transition process.

If the rule is finalized, price concessions may need to be renegotiated across thousands of medicines. A 2011 HHS study on rebates in the Medicare Part D program examined agreements for a small sample of plan sponsors and found that "in total, the 6 sponsors or their PBMs had 531 contracts with manufacturers"—an average of nearly 90 agreements per plan sponsor.[125] Each of these many agreements presumably will need to be examined under the new safe harbor for a point-of-sale reduction in price. Ensuring that these plans are able to renegotiate and make decisions on their formularies in a timely manner would be important for the success of these changes.

As OIG works to finalize the rule, we urge OIG to be in close contact with CMS so that CMS is aware of the status of the process. We appreciate that CMS has issued guidance to clarify that plans should submit bids "in a form and manner that is consistent with the Anti-Kickback Statue law and regulations in effect as of the bid submission deadline," has announced a demonstration project "to test an efficient transition for beneficiaries and plan" should the proposed rule be finalized, and has provided an additional update window in August 2019 to accommodate changes to formularies.[126] We encourage CMS to make any necessary modifications to the annual Part D operations timeline to help ensure that coverage begins on January 1, 2020 with beneficiary cost sharing reflecting any changes to the AKS safe harbors.

We Urge CMS to Update Its Definition of Negotiated Price to Realize the Beneficiary Cost Sharing Goals of the Proposed OIG Safe Harbor

To "replace [rebates from manufacturers to PBMs] with discounts provided to beneficiaries at the point-of-sale"—which HHS identifies as "[t]he intent of this rule"[127]—we urge CMS to update its regulations and guidance governing Part D beneficiary cost sharing to align with the proposed OIG safe harbor. We believe that CMS can help ensure that beneficiaries benefit directly from negotiated discounts through its interpretation of "negotiated price." Negotiated price, set out in statute and interpreted by CMS through

[124] § 423.265(b)(1).
[125] Nudelman, Jodi et al., "Concerns with Rebates in the Medicare Part D Program," *Department of Health and Human Services, Office of the Inspector General*, March 2011, p. 8. Available at https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.
[126] Centers for Medicare & Medicaid Services. Guidance Regarding Part D Bids. April 5, 2019; Centers for Medicare & Medicaid Services. Guidance Regarding Part D Bids. April 5, 2019; Centers for Medicare & Medicaid Services, 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.
[127] 84 Fed. Reg. at 2353.

regulations and guidance, is the price that is used to determine a beneficiary's cost sharing at the point-of-sale, including any coinsurance.[128]

Negotiated price generally has been defined by CMS as the total payment a pharmacy negotiates with the Part D plan sponsor (or its contracting PBM) to receive for covered Part D drugs.[129] For the beneficiary to receive the benefit of the reduction in price as contemplated in the POS reductions in price safe harbor, that discount must be applied to reduce the Part D negotiated price on which the beneficiary's cost sharing is based in each phase of the benefit. The current definition of "negotiated price" should be revised to include non-pharmacy (i.e., manufacturer) price concessions and other forms of direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale.[130] For example, if a manufacturer and plan negotiate a $20 discount on a $100 drug, then that $20 should reduce the drug's negotiated price from $100 to $80. If a beneficiary has 20 percent coinsurance, then that beneficiary would pay $16 (20 percent of $80).

To achieve the objectives of the proposed POS reductions in price safe harbor, manufacturer discounts must be used to reduce the pharmacy's negotiated price to ensure that beneficiaries obtain the benefit of the discounts through reduced cost sharing payments. To this end, CMS should finalize its proposed definition of negotiated price in its Part D proposed rule.[131] This proposed definition would clarify that discounts from manufacturers should be applied as a reduction to the price negotiated between the plan or PBM and the pharmacy. This is an important step toward establishing the conditions for the POS reductions in price safe harbor to generate beneficiary savings and we urge CMS to take this step quickly. We believe additional CMS guidance issued promptly after the POS reductions in price safe harbor rule is finalized would be helpful to ensure that the safe harbor takes effect smoothly and as intended.

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[128] Social Security Act 1860D-2(d)(1)(B). *See also*, 82 Fed. Reg. 56336, 56420 (Nov. 28, 2017) ("Beneficiary cost-sharing . . . is generally calculated as a percentage of the negotiated price . . . . Although this is especially true when a Part D drug is subject to coinsurance, it is also true when a drug is subject to a copay [because of Part D actuarial equivalence rules]."

[129] 42 C.F.R § 423.100.

[130] The definition of "negotiated price" used in the statutory provisions for the coverage gap discount program (CGDP) is based on the regulatory definition of negotiated prices that was in effect at the time the CGDP was implemented in 2010. SSA § 1860D-14A(g)(6). The regulation at that time defined negotiated price very similarly to the definition proposed in the Part D proposed rule (83 Fed. Reg. 62152 (Nov. 30, 2018)), and states that negotiated price is "reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale." 42 C.F.R. § 423.100 (2010).

[131] CMS stated in a 2018 proposed rule that it was considering a revised negotiated price definition providing in part that negotiated price "Is reduced by non-pharmacy [i.e., manufacturer] price concessions and other direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale." 83 Fed. Reg. 62152, 62179 (Nov. 30, 2018) (emphasis added). It is less clear how price concessions from manufacturers would be treated under the new framework in light of the current definition of negotiated prices, which are identified as amounts : "(1) The Part D sponsor [or PBM] … and …pharmacy … have negotiated as the amount such [pharmacy] will receive, in total, for a particular drug. (2) Are inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale; and (3) Include any dispensing fees; but (4) Excludes additional contingent amounts . . . [that] increase prices and cannot reasonably be determined at the point-of-sale. (5) Must not be rebated back to the Part D sponsor [[or PBM] . . . in full or in part." 42 CFR § 423.100.

CMS Should Oversee Plan Actuarial Equivalence Determinations to Ensure that Beneficiaries with Copayments Receive the Intended Benefits of the Rule Through Reduced Cost Sharing

As explained further below in Section XIII, the impact of the rule on beneficiaries with fixed copayments requires greater clarity, due to the way the legal standards are crafted. In the proposed rule, OIG notes that "[p]atients with fixed co-payments may not see changes in their cost sharing at the point-of-sale outside of the deductible, coverage gap, or catastrophic phases of their benefits."[132] Milliman's actuarial analyses further concluded that "[m]embers with copayments may not see cost sharing savings if the value of the copayment remains the same and does not exceed the new POS cost of the medication, though the value of the copayment may in fact change due to actuarial equivalence requirements in Part D."[133]

In later sections of this letter, PhRMA addresses this issue and asks OIG to clarify in the regulatory text that, in the case of fixed copayments, the "completely applied" prong of the safe harbor is met if the beneficiary's cost sharing at the point-of-sale is less than or equal to the price of the medicine *after* the reduction in price has been applied.

However, beyond this change to the proposed regulatory text, to ensure that Medicare Part D beneficiaries with copayment obligations[134] on their branded medicines receive the benefits of negotiated reductions in price on those medicines, PhRMA respectfully urges CMS, through its ongoing oversight of Part D plan design, to ensure that plan sponsors under Part D and PBMs acting on their behalf reduce the copayments *for the tier on which the prescribed medicine is placed* that maintains actuarial equivalence with the standard benefit design. Under existing Part D actuarial equivalence testing requirements, plans must require members to pay 25 percent of costs before reaching the initial coverage limit, and average cost sharing in remaining phases of the Part D benefit must be actuarially equivalent to the percentage required for the defined standard benefit.[135] As Milliman found in its actuarial analyses, "[i]f the POS cost for brand[] [medicines] decreases, a copayment will become a larger percentage of costs, which may cause a plan to fail the equivalence test unless it reduces cost sharing on that tier *or another tier*" such that the average out-of-pocket obligation for the member remains at or below 25 percent across all tiers.[136]

Because a plan may reduce cost sharing on that tier "or another tier," PhRMA believes that CMS oversight is essential to ensuring that the policy goals of the proposed rule are realized with respect to reducing beneficiaries' out-of-pocket costs for brand medicines. Failure to do so could result in scenarios where PBMs / plans take the reductions in price from branded medications and apply them to other tiers

[132] 84 Fed. Reg. at 2353.
[133] Klaisner J, Holcomb K, Filipek T. Impact of Potential Changes to the Treatment of Manufacturer Rebates. Milliman. January 31, 2019. Available at: https://www.regulations.gov/docket?D=HHSIG-2019-0001.
[134] The term copayment here does not refer to LIS copayments or statutorily required copayments, but rather to copayments that are set by the Part D plan sponsor.
[135] CMS. Instructions for Completing the Prescription Drug Plan Bid Pricing Tool for Contract Year 2019. April 6, 2018. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Bid-Pricing-Tools-and-Instructions-Items/BPT2019.html.
[136] Klaisner J, Holcomb K, Filipek T. Impact of Potential Changes to the Treatment of Manufacturer Rebates. Milliman. January 31, 2019. (emphasis added) Available at: https://www.regulations.gov/docket?D=HHSIG-2019-0001.

so that beneficiaries using those medications do not obtain any benefit from the reduction in price obtained by the PBMs / plans from the pharmaceutical manufacturer, thus frustrating the intent of the OIG final rule.

Updated Educational Resources Will Help Beneficiaries Better Navigate Plan Choices Under the Changes Proposed by the OIG.

The new safe harbors proposed by OIG will lead to changes in the cost sharing and premiums that beneficiaries will face in 2020. If the rule is finalized, we suggest that CMS raise awareness of the coming changes to Part D plans and encourage beneficiaries to take a fresh look at their covered benefits. Specifically, CMS should educate beneficiaries that their cost sharing for prescription medicines may be very different than it was in prior years and that beneficiaries should utilize Plan Finder to make the best choice for their needs. We therefore suggest that CMS develop and issue a carefully crafted education plan to reduce confusion and ensure that beneficiaries are empowered to take advantage of this new cost saving opportunity.

The New OIG Safe Harbors Should be Accompanied by Enhanced CMS Enforcement of the Non-Discrimination Protections in Medicare Part D

CMS should expect that the changes OIG is proposing will lead to increased pressure on plans to manage costs and minimize premium increases. We urge CMS to closely monitor Part D plan benefit design to ensure that plans are not restricting access to medicines in ways that would violate the non-discrimination protections in the Part D program. CMS is prohibited from approving any Part D plan with a design that is "likely to substantially discourage enrollment by certain [Medicare beneficiaries]."[137] We would urge CMS to heighten its formulary reviews—looking at exclusions, utilization management criteria, and cost sharing—to identify plans that may be attempting to manipulate a formulary with the aim of avoiding the enrollment of beneficiaries with certain medical conditions or taking medications in particular therapeutic classes.

Beneficiaries with chronic illnesses such as diabetes, cardiovascular disease, chronic respiratory disorders, HIV, and mental health conditions are particularly vulnerable to this type of discrimination because their prescription drug needs are relatively predictable by Part D plan sponsors. If CMS finds evidence of discriminatory benefit design, it must ensure the formularies in question are strengthened ahead of open enrollment. If OIG's proposed changes are implemented for the 2020 plan year, CMS will undoubtedly have many workstreams underway to ensure its policies are aligned with the changes OIG is proposing. Strengthening formulary reviews should be seen as a crucial step by CMS towards ensuring the new OIG policy is implemented in a manner consistent with the Part D statute. Without strong plan oversight, there is a risk that plans could narrow their formularies in ways that discriminate against beneficiaries, which could lead to restricted access and result in increased medical costs.[138]

[137] SSA § 1860D-11 (e)(2)(D)(i).
[138] Yujin Park, et al. The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review. *Journal of Managed Care & Specialty Pharmacy*. August 2017; 23:8.

CMS Should Issue Guidance to Protect Medicaid Programs by Ensuring Manufacturer Point-of-Sale Chargebacks Do Not Result in Lower Average Manufacturer Prices

The proposed rule contemplates manufacturers making point-of-sale chargeback payments to retail pharmacies in lieu of manufacturer rebates to Part D plans and PBMs acting on their behalf. Statutory Medicaid rebates are calculated by manufacturers based on a formula that relies on the average manufacturer price (AMP) of a drug. Generally, AMPs reflect the average net price of manufacturers' direct sales of a drug to retail community pharmacies (RCPs) and indirect sales to RCPs through wholesalers.[139] The statutory definition of AMP does not include manufacturer sales, discounts, or concessions to PBMs or insurers, such as Part D plans, or beneficiaries. But the statute does have a "catchall" provision requiring that rebates, discounts, payments, or "financial transactions" that are not otherwise addressed and that are received by or "passed through" to RCPs be included in AMP.

Given that CMS has the authority to exclude POS chargebacks from AMP, we strongly recommend CMS issue clarification regarding the treatment of POS chargeback payments for AMP reporting. The proposed rule acknowledges this, stating that the rule, if finalized, may result in a reduced AMP and that HHS may issue guidance to "clarify the treatment of POS chargebacks in calculation of AMP and Best Price."[140] We agree that if POS chargebacks under the new POS reductions in price safe harbor are included in the calculation of AMP, this could reduce AMP and in turn lower statutory Medicaid rebates for certain products. A lower AMP would also likely reduce Federal Upper Limits (FULs), which limit Medicaid payments to pharmacies for multiple source drugs. PhRMA does *not* think that lowering AMP and therefore lowering statutory Medicaid rebates would be a desirable outcome.

To avoid this result, PhRMA strongly encourages CMS to issue guidance once the rule is finalized and prior to the rule going into effect, on how POS chargebacks should be treated for AMP and Best Price purposes as it would help clarify to all stakeholders CMS' intentions and make clear manufacturer price reporting obligations. Because of the unintended possibility of chargebacks potentially lowering AMP and therefore lowering statutory Medicaid rebates, we urge CMS to issue guidance specifying that POS chargebacks used to lower Part D beneficiary cost sharing are excluded from a drug's AMP calculation, and to do so as soon as a final rule is published to avoid a period of confusion.

The Medicaid statute also excludes from Best Price "any prices charged which are negotiated with a prescription drug plan under part D of [Medicare], [or] by an MA-PD plan . . . with respect to covered part D drugs . . . on behalf [of Part D-eligible individuals]."[141] Thus POS chargebacks under the proposed safe harbor would fall within this Best Price exemption because they would be discounts negotiated with a Part D plan sponsor (or a PBM acting on its behalf) with respect to Part D drugs and on behalf of plan enrollees.

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[139] 42 U.S.C. § 1396r-8(k)(1)(SSA § 1927(k)(1). Drugs that are infused, injected, inhaled, instilled, or implanted and are not generally dispensed through a retail community pharmacy have a special AMP formula that includes many sales and price concessions that are not included in standard AMP (so that an AMP for these "5i" drugs can be calculated). 42 U.S.C.§ 1396r-8(k)(1)(A)(i)(IV)(SSA § 1927(k)(1)(A)(i)(IV)).
[140] 84 Fed. Reg. at 2344, 2351.
[141] SSA § 1927(c)(1)(C)(i)(VI).

Appendix II outlines the legal bases for excluding POS chargebacks from AMP. CMS has authority to issue this guidance and could take the position (as it has in the past) that AMP excludes these discounts that go through pharmacies but pharmacies are only "conduits" transmitting the discount to others, or that are made available only through certain state and federal government providers and programs. This rationale could apply to Part D. We urge CMS to issue this guidance in a timely manner so that states and manufacturers are aware of this clarification as soon as the rule is finalized. We note that for most states the 2020 fiscal year begins on July 1, 2019. It would therefore be helpful for CMS to announce as soon as possible its intention to issue this guidance. Such an announcement would help states plan their FY 2020 budgets.

VII. The Antitrust Laws Do Not Pose an Obstacle to Implementation of the Proposed Rule

Some stakeholders have pointed to the antitrust laws and long-running antitrust litigation to suggest that antitrust issues could hinder implementation of the proposed rule. Stakeholders point specifically to the Robinson-Patman Act (RPA) and the *In re Brand Name Prescription Drugs Antitrust Litigation* involving drug manufacturers, wholesalers, and pharmacies, which spanned over two decades. The RPA focuses on price discrimination—involving any dimension of price—and does not distinguish between upfront discounts and rebates.

The Robinson-Patman Act, 15 U.S.C. § 13, was enacted in 1936. Its primary purpose was to prevent large businesses from extracting more favorable terms and prices than those that would be available to smaller businesses, although it applies to discrimination against companies of all sizes. The RPA makes it illegal for a manufacturer to discriminate in price between two purchasers that compete for the resale of a product if certain requirements are met.[142] For example, it would be unlawful for a prescription pharmaceutical manufacturer to contemporaneously charge different prices[143] for the same drug to Customer A and Customer B if Customers A and B (or the customers of Customers A and B) compete to resell the drug and the difference in prices causes an injury to competition between them, unless an affirmative defense applies.[144] The "price" for RPA purposes is the effective price after all discounts, rebates, and credits have been taken into account.[145] In short, the Act applies regardless of whether Customer A is charged 10 percent less than Customer B at the time of purchase, or Customer A subsequently is given a 10 percent rebate not given to Customer B.

At bottom, the antitrust laws apply equally to upfront discounts and retrospective rebates. The *In re Brand Name Prescription Drugs Antitrust Litigation*, long-running litigation cited by some stakeholders, did not result in any change in the ability of a prescription drug manufacturer to offer an upfront discount. The *Brand Name Prescription Drugs* litigation did not challenge the legality of upfront discounts

[142] 15 U.S.C. §13(a).
[143] Even if a customer purchases through a wholesaler, if the manufacturer is controlling the price to the wholesaler's customers, the RPA applies. *Drug Mart Pharmacy Corp. v. American Home Products Corp.*, 427 F. Supp. 2d 385 (E.D.N.Y. Jan. 25, 2007).
[144] There are a number of defenses to Robinson-Patman liability. For example, it is an affirmative defense for a seller to demonstrate that the lower price was offered "in good faith to meet an equally low price of a competitor…" 15 U.S.C. §13(b).
[145] *See e.g.*, *Conoco v. Inman Oil Co., Inc.*, 774 F.2d 895, 902 (8th Cir. 1985) ("[P]rice under the Robinson-Patman Act is the 'net price' received by the seller").

generally. Plaintiffs were challenging the alleged refusal of drug manufacturers to offer the same discounts to all classes of trade. Nor did the settlements in the *Brand Name Prescription Drugs* litigation change the applicability of the RPA to differential pharmaceutical pricing for those settling manufacturers. The legality of differential pricing—during the *Brand Name Prescription Drugs* litigation and still today—is governed by the Robinson-Patman Act. The requirements for RPA liability were not changed by the *In re Brand Name Prescription Drugs Antitrust Litigation* instituted in the early 1990s. In the 1990s, retail pharmacies filed suit against pharmaceutical manufacturers and wholesalers in what became the long-running *Brand Name Prescription Drugs* litigation. The retail pharmacy plaintiffs claimed that drug manufacturers and wholesalers had conspired to deny them discounts in violation of Section 1 of the Sherman Act, which prohibits agreements in restraint of trade,[146] and refused to provide discounts available to other customers in violation of the RPA. A class was certified, and the class action focused on the conspiracy claims under Section 1 of the Sherman Act. Several drug manufacturers settled with the class and committed not to refuse discounts to retail pharmacies based on their retailer status and to provide the same discounts to retail pharmacies and buying groups that demonstrated the same ability to affect market share as managed care customers.[147] Although the claims that were settled were Sherman Act claims, the settlements specifically reserved the defendants' rights to take any pricing action that was permitted under the Robinson-Patman Act.[148] Thus, the settlement did not change—even for the settling defendants— how the RPA applied to pharmaceutical pricing. According to news reports, the settlements had a three-year term, meaning that the settlements expired almost 20 years ago. Other non-settling manufacturer defendants ultimately prevailed against the class on the Sherman Act Section 1 claims following an eight-week trial after which the trial court granted judgment as a matter of law for defendants.[149]

Several retail pharmacy plaintiffs had opted out of the class action. Following the unsuccessful litigation of the class case against defendants, the cases of the opt-out plaintiffs were remanded and litigation continued on both Sherman Act and Robinson-Patman Act claims.[150] Over 20 years after the original suits were filed, the Second Circuit affirmed the district court's grant of summary judgment in favor of defendants on the RPA claims of one group of opt-out plaintiffs finding that plaintiffs had failed to demonstrate competitive injury.[151]

Neither the Robinson-Patman Act nor the *Brand Name Prescription Drugs* litigation prevents prescription pharmaceutical manufacturers from offering upfront discounts. Although the proposed rule incentivizes a shift from retrospective rebates towards upfront discounts for prescription medicines, rebates do not

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[146] 15 U.S.C. §1.
[147] *In re Brand Name Prescription Drug Antitrust Litig.*, 1996 U.S. Dist. LEXIS 8817 (June 24, 1996).
[148] Although the settlement agreement is not available on the court's docket, it was reported that the settlement stated that "nothing 'shall prevent any settling defendant from taking, or declining to take, any action if permitted under the Robinson-Patman Act…or relying upon any defenses permitted by, or exemptions from, that statute.'" The Pink Sheet, *Rx Pricing Suit Settlement Would Exclude Existing Managed Care Contracts from Pharmacy Claims for Access to Discounts; Abbott, Ciba Out of Settlement* (May 13, 1996).
[149] *In re Brand Name Prescription Drugs Antitrust Litig.*, No. 94 C 897, 2000 U.S. Dist. LEXIS 1750, *2 (Feb. 9, 2000). The Seventh Circuit affirmed the district court's dismissal of an industry-wide antitrust conspiracy, but remanded with respect to the specific question of whether the manufacturers had agreed to link price increases to the Consumer Price Index. *Id.* The district court dismissed the remaining claims on remand. *Id.* at *15.
[150] *Cash & Henderson Drugs, Inc. v. Johnson & Johnson*, 799 F.3d 202 (2d Cir. 2015).
[151] *Id.* at 208-09. The plaintiffs had previously settled their claims under Section 1 of the Sherman Act.

occupy a unique position insulated from antitrust scrutiny. The applicability of the antitrust laws to differential pricing apply equally to both upfront discounts and retrospective rebates.

VIII. The Proposed Rule May Impact the Continued Adoption of Value-Based Arrangements, Highlighting the Need for Permanent Regulatory Reforms to Address Existing Barriers

PhRMA supports the continued expansion of value-based arrangements (also known as "results- or value-based contracts") for medicines within Medicare Part D and Medicaid programs. However, we do have concerns that the proposed safe harbor reforms could limit certain types of value-based contracts and recognize that manufacturers and payers could face unique challenges in renegotiating those arrangements. As such, we welcome the opportunity to continue engaging with OIG to promote the continued development and adoption of contracts that link price to performance.

PhRMA considers value-based contracts for biopharmaceuticals to be voluntary arrangements between manufacturers and other private entities, such as health plans or risk-bearing providers, in which the price or price concession for a prescription medicine is linked to value as determined by the contracting entities. These arrangements can reduce payers' cost exposure for treatment failures by allowing the manufacturer to share financial risk with the payer. By aligning payments for medicines more directly with their value in improving meaningful health outcomes and / or reducing the need for other health care services (such as hospitalizations), value-based arrangements make biopharmaceutical manufacturers accountable for the results their products achieve in a concrete way and can help improve patients' health and maximize the benefits of health care spending.

Benefits of Value-Based Contracts

Existing value-based contracts focused on clinical results have been adopted and are utilized to promote patient access to medicines that encourage better disease management. One such arrangement, for example, links the payment for a medicine that treats type 2 diabetes directly to the outcomes experienced by patients and ultimately, the total cost of care.[152] Value-based contracts also can increase patient access to new therapies, including breakthrough medications for rare and devastating diseases, which could ultimately improve patient outcomes. A payer that might otherwise decline to cover a new medicine (or that would only cover the medicine with significant utilization management restrictions or high cost sharing) due to uncertainties about the expected percentage of its patient population who would benefit might increase access to the medicine if the manufacturer shared the risks of the medicine's performance. By reducing a payer's risks (e.g., agreeing to pay a large rebate on units of the medicine used by enrollees who do not respond or achieve a specified outcome, so that the payer cannot end up paying a high net price in cases of suboptimal value), these agreements may make medicines more accessible to patients who will benefit from them and increase competition in relevant therapeutic classes.[153]

[152] Prime Therapeutics. Prime Therapeutics and Boehringer Ingelheim Enter Into Outcomes-Based Contract for Jardiance. January 29, 2018. Available at: https://www.primetherapeutics.com/en/news/pressreleases/2018/jardiance-carecenterecontract-release.html.

[153] Staley L. A Drug's Worth: Why Federal Law Makes It Hard to Pay for Pharmaceutical Performance. *Boston University Law Review*.2018;98(1):303-334. ("Tying reimbursement to health outcomes presents new opportunities for competition with rival manufacturers. . . . [A] manufacturer that can demonstrate sustained health benefits in post-market studies may distinguish itself from competitors.").

The short-term benefits of value-based contracts fall into three categories:

- **VBCs can improve patient outcomes.** Because these arrangements allow manufacturers to reduce payers' risk for suboptimal outcomes or offer new types of discounts that may not be available today, payers may be able to provide broader access to innovative medicines. Value-based contracts may also allow payers or manufacturers to provide more support for appropriate use of medicines by patients. These changes are improving patient outcomes—a payer survey conducted by Avalere Health found that 44 percent of payers engaged in outcomes-based contracts experienced improvements in patient outcomes. [154]

- **VBCs can lower patients' out-of-pocket costs.** From 2015 to 2017, patient copays were 28 percent lower for certain plans that announced a value-based contract compared to the market average. Although data was not detailed enough to directly link lower cost sharing to the arrangement, the results provide a clear indication that such contracts may have led to lower patient cost sharing.[155] Researchers have also found that value-based arrangements can improve patient access to medicines.[156]

- **VBCs can reduce costs for the health care system.** Value-based contracts can reduce costs for the health care system. For example, if new VBCs can improve the use of medicines for diabetes and help reduce the burden of this disease in the United States by only five percent, this could save $9 billion annually in direct medical costs, and improve productivity by an additional $3.4 billion. This would save the U.S. health care system more than $12 billion annually.[157]

In the longer term, if the number and scope of results-based contracts increases, they will likely generate more information on the effects of different products and treatment regimens on different patient populations and subpopulations.[158] Real world evidence on how different treatments affect patients with a certain disease (or subgroups of patients with a certain disease) will be available both to providers and patients making individualized, patient-centered treatment decisions, and to payers developing formularies and coverage policies. Over time, this evidence should shift utilization toward medicines with greater clinical value and greater ability to reduce hospitalizations and other costly services, resulting in better health outcomes and lower overall health care spending.

Encouraging the expansion of value-based contracts provides a sound, market-based alternative to reforms that replace market competition with government price-setting. As seen from many countries in

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[154] Avalere Health. Payer Perspectives on Outcomes-Based Contracting: Avalere 360. May 22, 2017.
[155] PhRMA. Delivering Results for Patients: The Value of Value-Based Contracts. February 2018.
[156] See, for example, description of Entresto and Repatha contracts in: Seely E and Kesselheim A. "Outcomes-Based Pharmaceutical Contracts: An Answer to High U.S. Drug Spending?" Commonwealth Fund. Issue Brief. September 2017.
[157] PhRMA. Delivering Results for Patients: The Value of Value-Based Contracts. February 2018.
[158] For example, one study conducted in Sweden concluded that "stakeholders benefited from analysis of real-world (postmarket) data (in addition to pre-launch, trial-based data)" collected under a value-based pricing agreement. *See* Deloitte, Value-based Pricing for Pharmaceuticals: Implications of the Shift from Volume to Value. 2012. Available at: http://deloitte.wsj.com/cfo/files/2012/09/ValueBasedPricingPharma.pdf.

Europe, public policies that reference one-size-fits-all cost-effectiveness thresholds or government-enforced "arbitration" have the effect of hindering patient access to needed treatments and chilling continued biopharmaceutical progress. The OIG proposed rule offers a strong step forward in improving the United States' market-based health care system and improving patient affordability.

Requests for Additional Guidance and Clarity for Value-Based Contracts

The preamble to the proposed rule states that "[t]he 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."[159] However, if finalized, the proposal would fundamentally impact those value-based contracts that are currently rebate-based. Moreover, there remain many questions about how certain types of value-based contracts, particularly those contingent on outcomes, might need to be restructured in a point-of-sale price reduction model. Manufacturers and plan sponsors will face significant burdens in reconceptualizing and renegotiating these types of arrangements, even beyond the burden of renegotiating rebate arrangements more generally. PhRMA respectfully requests that OIG consider providing future flexibility to manufacturers and payers in negotiating these types of arrangements, ideally before or contemporaneously with the effective date of any final rule. We would emphasize that any new safe harbor should benefit patients and strike the right balance between allowing flexibility for value-based arrangements while not undermining the policies underlying the current proposed rule.

PhRMA requests that in finalizing the proposed rule, OIG describe and clarify what "existing protections for value-based arrangements" are available, as referenced in the preamble. This is the precise issue on which PhRMA has been seeking clarity and guidance from OIG for years, as part of OIG's annual solicitation process and recent "regulatory sprint" request for information. While many types of value-based arrangements may fit within existing safe harbors, a lack of clarity in the safe harbors, variable interpretation by courts, aggressive *qui tam* relators and enforcement officials, and the outdated nature of the safe harbors creates uncertainty that discourages some payers, providers, and manufacturers from embracing value-based agreements. Clear guidance addressing value-based arrangements would create greater certainty and could encourage payers, providers, and manufacturers to develop and support additional value-based contracting models. Specifically, PhRMA is seeking clarity around existing protections for reductions in price conditioned on value or outcomes measures and services offered to support administration of value-based arrangements.

PhRMA is concerned that, in the absence of additional guidance clarifying continued or new available safe harbor protections, the proposed rule could chill the expansion of value-based arrangements and discourage the development of new arrangements. We appreciate OIG's recent request for information seeking input on how to address regulatory provisions that may act as barriers to value-based arrangements.[160] It is important that the AKS safe harbors continue to evolve to support new arrangements that, if properly structured, could help improve health outcomes, promote competition, and contain overall health care spending without raising risk of fraud and abuse. We continue to seek creation of a new safe harbor to clearly protect value-based arrangements for medicines under the Anti-Kickback

[159] 84 Fed. Reg. at 2348.
[160] 83 Fed. Reg. 43607 (Apr. 27, 2018).

Statute, including the services needed to administer such arrangements. PhRMA has made this recommendation to OIG in both 2017 and 2018 and continues to support a new safe harbor in light of the current proposed rule.[161]

Given HHS's goal of moving from fee-for-service payments toward payment methods that reward quality and cost savings, PhRMA encourages OIG as well as HHS to make permanent regulatory reforms that address barriers that inhibit value-based arrangements.

IX. Proposed Point-of-Sale Reductions in Price Safe Harbor for Medicaid Managed Care Organizations Needs Additional Clarification for Implementation

As stated earlier, PhRMA supports overall market reforms that benefit patients and lower out-of-pocket costs for prescription medicines. We strongly support the application of the proposed PBM service fees safe harbor to Medicaid MCOs to help address the lack of PBM transparency and potential misaligned incentives with respect to PBM fees. The proposed PBM service fees safe harbor should apply to manufacturer service fees offered to PBMs, regardless of the type of plan the PBM serves. We also agree that the vast majority of manufacturer rebates in Medicaid (comprised of the statutory and state supplemental rebates) according to OIG, would not be impacted by the proposed rule.[162]

However, PhRMA has questions about how the proposed POS reductions in price safe harbor would operate for Medicaid MCOs and patients in a way that helps HHS achieve its policy goals. Patient cost sharing in Medicaid is already nominal (and may not be collected in some instances) and the level of cost sharing is set at fixed values that are largely not tied to the list price of medicines. In light of these facts, additional clarity is needed with respect to the POS reductions in price safe harbor in the context of Medicaid. Specifically, the proposed rule does not clearly address Medicaid cost sharing in the context of the new POS reductions in price safe harbor, which, as currently drafted, stipulates that the value of reduction in price from manufacturers to Medicaid MCOs must be completely applied to the price charged to the beneficiary at the point-of-sale.

With respect to the POS reductions in price safe harbor, OIG must provide clear guidance, either in regulatory text or the preamble, as to what conditions a reduction in price would need to meet to satisfy the requirement to be "completely applied" to the price of a medicine at the point-of-sale for a Medicaid enrollee who pays a copayment or who does not pay cost sharing. Manufacturers, Medicaid MCOs and their PBMs, and states would need clarity on how the reduction in price would be applied to a copayment which will likely be lower than the reduction in price, and clarity on the specific obligations a manufacturer must satisfy in order to be eligible for safe harbor protection. Given the demands on HHS and OIG to finalize and implement the proposed changes to the Part D program, where many beneficiaries need relief from high cost-sharing obligations, the agency's efforts may be more efficiently exercised if focused on ensuring a smooth and successful implementation for the 2020 Part D benefit year.

[161] PhRMA comments to OIG-125-N, Solicitation of New Safe Harbors and Special Fraud Alerts, February 2017; PhRMA comments to OIG-127-N Solicitation of New Safe Harbors and Special Fraud Alerts, February 2018.
[162] 84 Fed. Reg. at 2344.

X. OIG Should Clarify Duplicate Discount Arrangements and Manufacturer Compliance with the POS Reductions in Price Safe Harbor

As a threshold matter, 42 U.S.C. § 256b(a)(5)(A) prohibits 340B covered entities from "request[ing] payment under [the Medicaid program] with respect to a drug that is subject to [a 340B Pharmaceutical Pricing Agreement] if the medicine is subject to the payment of a rebate to the State under [the Medicaid Drug Rebate Statute]."[163] This provision makes duplicate discounting prohibited by law and reflects the common sense principle that discounts should not be paid twice on the same utilization due to unattended overlap between the 340B program and Medicaid.

This same principle should be applied to POS reductions in price. Indeed, due to timing issues, POS reductions in price under the proposed safe harbor could potentially lead to a high rate of duplicate discounts if pharmacies dispense a medicine purchased under the section 340B program[164] to a plan beneficiary. This concern is particularly relevant in the 340B contract pharmacy setting, where pharmacies often do not identify 340B-discounted medicines until after the medicine has been dispensed,[165] at which point the POS reduction in price already would have been applied to the price of the medicine. Consequently, a risk would exist for substantial combined 340B / POS price reduction discounts, as 340B discounts on brand medicines generally can be very large. The 340B law's ceiling price formula sets the 340B discount at the Medicaid unit rebate amount (URA),[166] which has been estimated at 63 percent of AMP on average.[167] Some drugs have even higher 340B discounts, with the extreme case being "penny priced" drugs (which have a 340B discount approaching 100 percent). We do not believe it is OIG's intent that manufacturers should risk incurring an undue financial loss on each prescription that generates both 340B discounts and POS reductions in price.

Today, manufacturers may contract with plans to ensure the manufacturer avoids paying both a 340B discount and a statutory Medicaid rebate. Similarly, manufacturers may contract with plans to ensure that the manufacturer does not pay a 340B discount in addition to discounts or rebates on contracted utilization (including Part D). While not a perfect solution, it provides manufacturers some ability to prevent payment of duplicate discounts.

If the POS reductions in price safe harbor extends to Medicaid MCOs, PhRMA is particularly concerned about the potential for duplicate discounts in managed Medicaid due to the Medicaid program vulnerabilities that OIG has previously highlighted.[168] Specifically, the Government Accountability Office (GAO) has recently warned that the Health Resources and Services Administration's (HRSA) duplicate discount prevention guidance does not address duplicate discounts on Medicaid managed care

[163] 42 U.S.C. § 256b(a)(5)(A); Section 1927(j)(1) of the Social Security Act.
[164] 42 U.S.C. § 256b (PHS Act § 340B).
[165] OIG, Contract Pharmacy Arrangements in the 340B Program (2014), 9, 14.
[166] 42 U.S.C. § 256(a)(1)–(2). The 340B ceiling price formula is the drug's Average Manufacturer Price (AMP) minus its URA.
[167] Congressional Budget Office, Options for Reducing the Deficit 2017-2026, 255 ("in 2013 ... the average statutory rebate under Medicaid, weighted by the dollar amount of drug purchases, was 63 percent of the AMP").
[168] OIG, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates (June 2016)("to identify 340B drug claims and correctly collect rebates for MCO drugs, most States use methods that identify providers using 340B-purchased drugs. However, we found that these provider-level methods may not accurately identify all individual 340B drug claims, creating a risk of duplicate discounts").

utilization and therefore manufacturers are at risk of erroneously being subject to 340B / Medicaid rebate duplicate discounts in the Medicaid managed care context.[169] A POS reduction in price to Medicaid MCOs for enrollees getting 340B medicines could subject manufacturers to a risk of multiple discounts. Accordingly, we request that OIG clarify that manufacturers may continue traditional duplicate discount avoidance arrangements, and that doing so will not put the safe-harbored status of a POS price reduction arrangement at risk.

Likewise, to reduce this 340B duplicate discount risk for Part D utilization, it is important for OIG to make clear that the new POS reductions in price safe harbor is not intended to require that manufacturers pay chargebacks for Part D POS reductions in price when doing so would generate 340B duplicate discounts. We also believe it is important for OIG to clarify that the POS reductions in price safe harbor is not intended to prevent written arrangements aimed at avoiding 340B duplicate discounts. Nothing in the proposed rule suggests that this type of private contracting to avoid duplicate discounts cannot continue under the new POS reductions in price safe harbor, but nor does the proposed rule make explicit that manufacturers may enter into arrangements to avoid duplicate discounting under the POS reductions in price safe harbor.

Therefore, consistent with the policy goals of 42 U.S.C. § 256b(a)(5)(A), we ask that OIG clarify that the conditions of the POS reductions in price safe harbor are met when there are contractual arrangements between a manufacturer, a plan sponsor (or PBM acting on its behalf), a third-party intermediary, or a pharmacy, to avoid duplicate discounts being paid on the same prescription. In addition, the final rule should clarify that, in the event that a POS reduction in price is not completely applied to the price of a medicine as a result of such contractual provisions aimed at preventing or recouping duplicate discounts, this would not remove the parties' arrangement from protection under the POS reductions in price safe harbor. Without such OIG guidance, a possibility exists that the transition to POS reductions in price could inadvertently increase 340B duplicate discounts, which would have increasing repercussions as the 340B program itself continues to grow.[170]

In sum, it is critical that HHS address duplicate discounts as a program integrity issue that threatens both Part D and Medicaid to avoid further exacerbating market distortions. OIG has previously recommended methods to identify 340B claims.[171] We think this will be even more important under a POS discount system, and we urge HHS to work with stakeholders on a solution to protect the integrity of the federal health care programs.

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[169] GAO, 340B Drug Discounts: Program Improvements Needed on Federal Oversight of Compliance at 340B Contract Pharmacies (July 2018), 40 ("federal law directs [HHS] to develop detailed guidance describing methodologies and options for avoiding duplicate discounts. Until HRSA develops guidance and includes an assessment of the potential for duplicate discounts in Medicaid managed care as part of its audits, the agency does not have assurance that covered entities' efforts are effectively preventing noncompliance. As a result, manufacturers are at risk of being required to erroneously provide duplicate discounts for Medicaid prescriptions") (footnote omitted).

[170] *See, e.g.*, Berkeley Research Group, Measuring the Relative Size of the 340B program: 2017 Update (July 2018)(reporting that since 2010 the 340B program has expanded at an average annual rate of just under 21 percent, and that in 2017 340B (valued at wholesale acquisition cost) exceeded Medicare Part B reimbursement for drugs).

[171] OIG, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates. June 2016. Available at: https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf.

XI. In Future Rulemaking, HHS and OIG May Wish to Consider Expanding Proposed Safe Harbor Protection for Fixed Service Fees to Other Supply Chain Entities

We applaud OIG's proposal to create a new safe harbor for flat fees to PBMs that are not based on a percentage of sales.[172] As noted above, we think other changes—including partial rescission of OIG's 2003 Pharma CPG—will be necessary to effectuate this policy change for PBMs, but we support OIG in the policy underlying this proposal. This bold move, combined with other changes in the proposed rule, could help to correct some of the misaligned incentives in our current system.

It is important to note that the current system permits compensation to other supply chain entities—such as wholesalers and pharmacies—based on the list price of a medicine. All participants in the pharmaceutical supply chain—including wholesalers, pharmacies, and PBMs—deliver substantial value and should be entitled to compensation based on that value. However, we suggest that in future policymaking, HHS consider extending the policy reflected in the proposed PBM service fees safe harbor to incentivize (or perhaps even require) fixed manufacturer fees to other supply chain entities.

There are several reasons we suggest deferring changes to the safe harbors governing fees for other supply chain entities to future rulemaking. First, we do not want to add additional complexity to the OIG's goal of completely implementing the proposed rule by 2020. While we believe this goal is attainable, we are reluctant to add to the changes that will be required to meet this deadline. Second, including these changes in future policymaking would give HHS and other relevant policymakers the opportunity to solicit feedback and carefully consider the potential impact of these changes on other entities in the supply chain. As discussed earlier in our comments, we believe any changes to the current system should seek to avoid unintentionally harming community pharmacies. Third, waiting for future rulemaking will allow HHS to learn from the implementation of the proposed safe harbors before imposing similar requirements on other stakeholders.

We are not suggesting that OIG ignore other supply chain entities altogether. Given the vertical integration among PBMs with health plans and pharmacies, the OIG final rule should include a carefully constructed definition of PBM. We discuss this in detail later in our letter and are concerned that PBMs may be able to subvert the goals of the proposed rule without a carefully constructed and complete definition of PBMs.

XII. OIG Does Not Need to Extend Safe Harbor Reforms to Medicare Part B Fee-for-Service

OIG should not extend the proposed changes in this rule to physician-administered medicines under Medicare Part B. The Average Sales Price (ASP) metric used to reimburse providers for drugs under Part B represents a true net price that already captures rebates and discounts provided by manufacturers in the commercial market. Because beneficiary coinsurance (established in statute at 20 percent for most drugs and biologicals under Medicare Part B)[173] is based on ASP,[174] beneficiaries already benefit from the discounts and rebates that manufacturers give on physician-administered drugs, and extension of the proposed rule is unnecessary.

[172] 84 Fed. Reg. at 2342.
[173] SSA § 1833(a)(1)(S).
[174] SSA § 1847A(b).

In addition, more than 87 percent of Medicare Part B fee-for-service (FFS) beneficiaries are already enrolled in supplemental coverage that helps to defray their out-of-pocket costs for Part B medicines, an option that is not available for Part D plans.[175] This makes the extension of the proposed rule's changes superfluous in this context. However, there is less clarity in the Medicare Advantage (MA) program regarding levels of beneficiary cost sharing for physician-administered medicines relative to other services provided by MA plans. While we do not believe it is necessary to apply this proposed rule to physician-administered medicines, we do recommend that the OIG evaluate how MA plans are reflecting potential savings on Part B covered medicines in beneficiary cost sharing.

The number of seniors enrolled in MA plans has nearly doubled over the past decade.[176] According to the Kaiser Family Foundation, nearly 1 in 3 Medicare beneficiaries is enrolled in an MA plan.[177] Additionally, the vast majority of MA plans require 20 percent cost sharing for Part B medicines, even though MA plans have flexibility in how they design benefits. A handful of plans (30 out of 1030) require less than 20 percent cost sharing; however, 97 percent of non-special needs plans have 20 percent coinsurance for coverage of medicines for plan beneficiaries.[178] The majority of beneficiaries in MA plans are subjected to the same percentage of cost sharing as FFS beneficiaries. However, for MA plans, there is limited information about the price on which that coinsurance is based.

As MA plans become more and more responsible for how Medicare beneficiaries access Part B benefits, particularly physician-administered medicines, oversight into how plan design is serving beneficiaries in need of Part B medicines becomes increasingly important. Before considering extending the changes proposed in this rule, OIG should evaluate beneficiary cost sharing for Part B medicines in MA plans.

XIII. A Series of Important Technical Changes to the Proposed Regulations is Needed to Accomplish HHS/OIG's Stated Goals

Proposed Point-of-Sale Reductions in Price Safe Harbor: 42 C.F.R. § 1001.952(cc)

PhRMA strongly supports HHS's efforts to ensure that Part D beneficiaries receive the financial benefits of negotiated discounts between manufacturers, plan sponsors, and PBMs through reduced out-of-pocket costs on their medicines at the pharmacy counter. As PhRMA has noted here and in prior comments to HHS, applying negotiated reductions in price to the price that determines beneficiary cost sharing at the point-of-sale could significantly reduce out-of-pocket costs and improve access to medicines while strengthening the protections and ensuring the long-term sustainability of the Part D program. The proposed POS reductions in price safe harbor would fundamentally shift Medicare Part D away from a retrospective rebate-driven model toward a model that encourages upfront discounts that are reflected in the prices for medicines that are used to determine beneficiaries' cost sharing payments at the point-of-sale. Our comments below reflect technical revisions intended to strengthen the safe harbor and advance

[175] Avalere Analysis for PhRMA. Medicare Part B Supplemental Coverage Analysis. November 2018.
[176] Henry J Kaiser Family Foundation. A Dozen Facts About Medicare Advantage. Available at: https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage/.
[177] *Id*.
[178] Avalere analysis for PhRMA of Part C Cost Sharing on Part B Drugs. January 2019.

HHS's goal of transitioning to a point-of-sale discount model. A full markup of PhRMA's suggested revisions to the POS reductions in price safe harbor is included in Appendix I.

- OIG Should Clarify the Obligations of Each Party to a POS Price Reduction Arrangement

It is critical to the successful implementation and operationalization of the safe harbor that OIG specify, within the safe harbor text, the compliance obligations of each party to a POS price reduction arrangement consistent with the structure of the existing discount safe harbor. As proposed, the POS reductions in price safe harbor requires only manufacturers to comply with the specified conditions in order for a POS price reduction arrangement to receive safe harbor protection; however, manufacturers may not have sufficient information, visibility, or control to ensure that the various requirements of the safe harbor are appropriately operationalized.

Specifically, the safe harbor excludes from the definition of remuneration "a reduction in the price charged by a manufacturer for a prescription pharmaceutical product . . ., provided the *manufacturer meets* the following conditions with regard to that reduction in price."[179] OIG further suggests that manufacturers are responsible for compliance with the proposed safe harbor in the preamble: "Under the proposed new safe harbor, *a manufacturer* could offer a reduction in price on a particular prescription pharmaceutical product to a plan sponsor under Medicare Part D, to a Medicaid MCO, or through a PBM acting under contract with either *if certain conditions are met*."[180]

PhRMA urges OIG to revise the language of the proposed safe harbor to assign obligations to each relevant party as appropriate to their role in the chargeback administration process. Such an approach would be consistent with the allocation of responsibilities to various parties under the discount safe harbor.[181] Manufacturers, PBMs, plans, and chargeback administrators each will play a critical role in meeting the policy goals OIG hopes to achieve with the POS reductions in price safe harbor. As currently drafted, the POS reductions in price safe harbor places an undue and inequitable burden on manufacturers to ensure point-of-sale chargeback arrangements comply with the safe harbor when, in fact, manufacturers will have only privity of contract with PBMs, plans, and/or chargeback administrators. It will be the responsibility of the plans, PBMs, and chargeback administrators to ensure the point-of-sale reductions in price are completely applied to reduce the price that determines the beneficiary's cost sharing on medicines at the point-of-sale. While manufacturers can make contractual requirements to this effect, manufacturers will not have any direct role at the point-of-sale. That responsibility thus appropriately lies with the parties responsible for ensuring the reduction in price is completely applied to reduce the cost of medicines for beneficiaries. It would belie principles of fairness, and potentially

[179] 84 Fed. Reg. at 2363 (proposed to be codified at 42 C.F.R. § 1001.952(cc)(1)) (emphasis added).
[180] 84 Fed. Reg. at 2349 (emphasis added).
[181] *See* 84 Fed. Reg. at 2346 ("In response to requests from stakeholders, in the July 21, 1994, *Federal Register*, OIG proposed a number of clarifications to the discount safe harbor. For instance, OIG proposed to divide the relevant parties into three groups (buyers, sellers, and offerors) in order to delineate the different obligations individuals or entities must meet to receive protection under the discount safe harbor."). While we recognize that the discount safe harbor has come under scrutiny as being confusing and difficult to implement, it is our sense that it is ambiguity in the terms "seller," "buyer," and "offeror" under the discount safe harbor that give rise to confusion, not the construct of assigning specific, appropriate obligations to each party to a transaction.

undermine OIG's policy goals, if manufacturers alone were to be responsible for ensuring safe harbor compliance for point-of-sale reductions in price.

We do not believe this is OIG's intent. To address this risk and to encourage all parties to a POS price reduction arrangement to perform their obligations under the safe harbor, we respectfully urge OIG to delineate specific obligations that individuals and entities must meet. Under our proposed revisions:

- Manufacturers would be responsible for (i) setting reductions in price in advance with plans and PBMs, and (ii) providing reductions in price to dispensing pharmacies, directly or indirectly, through a point-of-sale chargeback or a series of point-of-sale chargebacks.

- Plans and PBMs would be responsible for (i) ensuring the appropriate exchange of information, including information about the manufacturer's reduction in price and negotiated price, with dispensing pharmacies per the terms of the contract with the PBM or plan, and (ii) ensuring the reduction in price is "completely applied" to reduce the price that determines the beneficiary's cost sharing on the medicine at the point-of-sale.

- Plans, PBMs, and/or chargeback administrators would be responsible for providing total payments to the dispensing pharmacy in the amount agreed upon by the pharmacy and the plan and/or PBM, which would include the payment agreed upon by the pharmacy from the plan or PBM, the point-of-sale chargeback or series of point-of-sale chargebacks from the manufacturer, and the beneficiary cost sharing payment.

Under this approach, if an individual or entity satisfies applicable conditions under the safe harbor, safe harbor protection would be afforded to that party regardless of whether other parties to the arrangement comply with safe harbor conditions applicable to their activities under the arrangement. No party to the transaction would be permitted to impede the other from meeting its own obligations, consistent with the requirements OIG has previously adopted under the discount safe harbor.

This change to the safe harbor text is critical to ensure that beneficiaries receive the appropriate pass through of manufacturer discounts, as manufacturers do not have any direct role at the point-of-sale. As noted above, that responsibility appropriately lies with the plans and PBMs, and that must be clarified and appropriately reflected in the safe harbor text.[182]

[182] If OIG chooses not to adopt PhRMA's suggested revisions to the POS reductions in price safe harbor, we respectfully urge OIG to, at a minimum, clarify that manufacturers are responsible for complying with the requirements under proposed paragraphs (cc)(1)(i) and (cc)(1)(ii) of the safe harbor and that plan sponsors under Part D and PBMs acting under contract with such plan sponsors are responsible for complying with the requirements under proposed paragraph (cc)(1)(iii) of the safe harbor. OIG should further clarify (i) that a party will receive protection under paragraph (cc) if it fulfills its own obligations under the safe harbor, regardless of whether any other party fulfills its obligations under the safe harbor, and (ii) that technical errors affecting complete application of the reduction in price at the point of sale will not affect manufacturers' compliance with applicable safe harbor requirements.

- OIG Should Clarify How Reductions in Price are to be Applied to Beneficiary Cost Sharing at the Point-of-Sale

PhRMA recommends that OIG clarify the proposed regulatory text that requires a reduction in price to be "completely applied to the price" of the medicine "charged to the beneficiary at the point-of-sale," in order to make abundantly clear how the reduction in price must be applied with respect to beneficiary cost sharing under the safe harbor.[183] In the preamble, OIG clarifies that the "reduction in price must be completely reflected in the price the pharmacy charges to the beneficiary at the point-of-sale."[184] Despite OIG's clarification that the reduction in price must be "completely reflected" in the price charged to the beneficiary at the pharmacy counter, we believe the regulatory text could benefit from a more direct statement of what we understand to be OIG's intent: **that the negotiated reduction in the price of a medicine must be completely applied *to reduce the price that determines the beneficiary's cost sharing* on that medicine at the point-of-sale**.

While this standard is relatively straightforward in its application to beneficiaries with coinsurance, OIG should clarify how the standard applies with respect to beneficiaries with fixed copayments. In the proposed rule, OIG notes that "[p]atients with fixed co-payments may not see changes in their cost sharing at the point-of-sale outside of the deductible, coverage gap, or catastrophic phases of their benefits."[185] Milliman's actuarial analyses further concluded that "[m]embers with copayments may not see cost sharing savings if the value of the copayment remains the same and does not exceed the new POS cost of the medication, though the value of the copayment may in fact change due to actuarial equivalence requirements in Part D."[186]

PhRMA is concerned that, if OIG does not address this issue more specifically, beneficiaries with fixed copayments may not receive the benefit of negotiated reductions in price on their medicines, thus undoing a key policy goal of the proposed rule that PhRMA supports. There are two relevant categories of beneficiaries owing copayments for purposes of this standard: (i) those whose copayment amount would be greater than the price of the medicine after the reduction in price has been applied, and (ii) those whose copayment amount would be less than the price of the medicine after the reduction in price has been applied. For beneficiaries in the first group, existing Medicare Part D guidance would require that the beneficiary be charged not their copayment amount, but instead the lower negotiated price—the price after the reduction in price has been applied.[187]

We ask OIG to clarify in the regulatory text that, in the case of fixed copayments, the "completely applied" prong is met if the beneficiary's cost sharing at the point-of-sale is less than or equal to the price of the medicine *after* the reduction in price has been applied. In other words, beneficiaries in the first

[183] 84 Fed. Reg. at 2363 (proposed to be codified at 42 C.F.R. § 1001.952(cc)(1)(iii)).
[184] 84 Fed. Reg. at 2349.
[185] 84 Fed. Reg. at 2353.
[186] Klaisner J, Holcomb K, Filipek T. Impact of Potential Changes to the Treatment of Manufacturer Rebates. Milliman. January 31, 2019. Available at: https://www.regulations.gov/docket?D=HHSIG-2019-0001.
[187] Letter from Seema Verma, Administrator, Centers for Medicare & Medicaid Services, to Part D Plan Sponsors, Unacceptable Pharmacy Gag Clauses (May 17, 2018). Available at: https://downloads.cms.gov/files/2018-05-17.pdf.

group would pay the lower negotiated price and beneficiaries in the second group would pay their fixed copayment amount.

Furthermore, as described previously in this letter, to ensure that Medicare Part D beneficiaries with copayment obligations[188] on their branded medicines receive the benefits of negotiated reductions in price on those medicines, PhRMA respectfully urges CMS, through its ongoing oversight of Part D plan design, to ensure that plan sponsors under Part D and PBMs acting on their behalf reduce the copayments *for the tier on which the prescribed medicine is placed* that maintains actuarial equivalence with the standard benefit design.

Because this is a particularly complex issue, we encourage OIG to revise the proposed regulatory text itself to improve clarity, include more explanatory text in the preamble to the final rule to clarify the standard, include hypothetical numerical examples of scenarios that would meet this prong of the safe harbor, and work closely with CMS on issuance of appropriate actuarial equivalence requirements.

- OIG Should Provide Clearer Standards for Point-of-Sale Chargeback Payments to Dispensing Pharmacies

PhRMA recommends that OIG incorporate a number of limited, technical revisions to the proposed POS reductions in price safe harbor to ensure that dispensing pharmacies receive full payment for medicines they dispense to beneficiaries and to avoid potential scenarios in which pharmacies would suffer a loss for dispensing medicines to Medicare Part D beneficiaries.

First, we recommend that OIG consider clarifying the reference to the "chargeback" payment made by manufacturers to dispensing pharmacies under the proposed safe harbor. The term "chargeback" alone is a term of art used in other supply chain contexts. As a common example, wholesalers regularly submit chargebacks to pharmaceutical manufacturers for transactions in which the manufacturer's contracted rates to purchasers are below the wholesaler's acquisition cost. OIG should clarify the reference to "chargeback" in the context of the revised safe harbors to minimize the risk of confusion. Thus, PhRMA suggests referring to such payments as "point-of-sale chargebacks." Regardless of whether OIG adopts this proposed alternative or another term, PhRMA believes it is important to distinguish chargebacks under the proposed POS reductions in price safe harbor from wholesaler and other chargebacks used elsewhere in the pharmaceutical supply chain.[189]

Second, we recommend that OIG add to subparagraph (1)(ii) a requirement that the plan sponsor under Medicare Part D or a PBM acting under contract with such plan sponsor, or any other entity involved in the administration of point-of-sale chargebacks, be required to exchange information and/or cooperate, as necessary, to ensure full transparency among the parties and appropriate administration of point-of-sale chargebacks.

[188] The term copayment here does not refer to LIS copayments or statutorily required copayments, but rather to copayments that are set by the Part D plan sponsor.

[189] Moreover, we interpret the safe harbor standards regarding point-of-sale chargebacks not to take into account any procurement-based discounts that may be provided to the dispensing pharmacy.

Third, we recommend that OIG include clarifying language in the POS reductions in price safe harbor to ensure that dispensing pharmacies receive full payment for dispensed medicines where appropriate, consistent with OIG's stated intent in the preamble to the proposed rule. Under the proposed POS reductions in price safe harbor, the definition of a "chargeback" would require a total payment to the pharmacy that is *at least equal* to the price agreed upon in writing between the manufacturer and the plan sponsor under Medicare Part D, the Medicaid MCO, or the PBM acting under contract with either.[190] In the preamble to the proposed rule, OIG clarifies that "total payment to the pharmacy (*i.e.*, cost sharing from the beneficiary, payment from the Part D plan or Medicaid MCO, and any chargeback) [must] be at least equal to the price agreed upon between the manufacturer of that drug and the Part D Plan or Medicaid MCO, or a PBM acting under contract with either."[191] PhRMA is concerned that the proposed definition of "chargeback," as currently drafted, does not align with the intent of the proposed rule and could protect arrangements under which dispensing pharmacies do not receive payments sufficient to cover the pharmacies' costs of acquiring medicines. This could result in situations where pharmacies suffer a loss for dispensing medicines to Medicare Part D beneficiaries and, in time, result in delays to or denials in access for medicines for such beneficiaries.

Thus, PhRMA urges OIG to remove the language stating that the total payment to the pharmacy must be "at least equal" to the price agreed upon between the manufacturer and the plan / PBM, as this language could lead to gaming by PBMs and plans and result in situations where pharmacies dispense medicines to Medicare Part D beneficiaries at a loss. Instead, we suggest requiring in the text of the safe harbor that the total payment to the dispensing pharmacy must be the amount agreed upon by the pharmacy and the plan or PBM that includes, consistent with OIG's preamble guidance above, (i) the payment to the pharmacy from the plan or PBM, (ii) the point-of-sale chargeback due from the manufacturer under the safe harbor, and (iii) the beneficiary cost sharing payment. This approach would make clear that pharmacies should be made whole for their acquisition costs plus an appropriate dispensing fee.

Fourth, we recommend that OIG expressly clarify that the point-of-sale chargeback is a payment to the dispensing pharmacy that is equal to the reduction in price negotiated between the manufacturer and the plan or PBM. If incorporated as part of the revisions to the safe harbor text we recommend above, PhRMA believes this revised definition of a point-of-sale chargeback more clearly captures OIG's intent, as indicated in the preamble text quoted above, and in OIG's statement that "[t]he . . . chargeback[] . . . make[s] pharmacies whole for the difference between acquisition cost, plan payment, and beneficiary out-of-pocket payment . . . ."[192]

A markup showing these suggested changes is included in Appendix I.

- <u>OIG Should Implement Standards to Address Fees for Point-of-Sale Chargeback Administration</u>

PhRMA recommends that OIG include in the proposed safe harbor a requirement that compensation received by any individual or entity to administer a point-of-sale chargeback must meet the same compensation requirements set forth in the proposed PBM service fees safe harbor at 42 C.F.R. §

[190] *See* 84 Fed. Reg. at 2363 (proposed to be codified at 42 C.F.R. § 1001.952(cc)(2)(ii)).
[191] 84 Fed. Reg. at 2349.
[192] 84 Fed. Reg. at 2361.

1001.952(dd). Specifically, OIG should require fees for point-of-sale chargeback administration to be (i) consistent with fair market value in an arm's-length transaction, (ii) be a fixed payment, not based on a percentage of sales or the price of a medicine, and (iii) not be determined in a manner that takes into account the value of any referrals or business otherwise generated between the parties, nor the volume of any such referrals, subject to the safeguards as explained in greater detail in connection with the volume or value requirement under the proposed PBM service fees safe harbor.

We believe establishing specific compensation requirements for chargeback administration provides clarity to all entities and further delinks intermediary compensation from the price of medicines by prohibiting *any* individual or entity from receiving compensation for point-of-sale chargeback administration that is tied to the price of a medicine. Moreover, inclusion of a volume or value limitation would improve the alignment of incentives for PBMs or their related or affiliated entities administering point-of-sale chargebacks. We believe such a limitation will discourage PBMs from attempting to negotiate such fees based on the placement or positioning of a manufacturer's medicines on formulary.

As described further below, PhRMA believes a volume and value limitation is a critical feature of OIG's proposed PBM service fees safe harbor. However, PhRMA recommends an enhancement to this limitation that will provide appropriate flexibility to pay fair market value compensation for chargeback administration while avoiding the potential for abusive arrangements. Specifically, PhRMA requests that OIG deem fair market value, per-unit chargeback administration fees as not taking into account the volume or value of referrals or other business generated if they contain the following safeguards, which are taken from existing OIG advisory opinions:

- When measured individually and not in the aggregate, the fee does not take into account the volume or value of referrals or other business generated between the parties;

- When measured individually and in the aggregate, the fee reflects the fair market value of the actual services provided;

- The fee takes into account only the services that are necessary for the individual or entity to perform chargeback administration services and does not include amounts attributable to ancillary services that such individuals and entities do not provide under the arrangement or that are not integral to performing chargeback administration services; and

- The fee is assessed for each unit of service[193] and regardless of whether the service is in the form of one or multiple chargebacks.

In the past, OIG has recognized the foregoing safeguards as providing sufficient protection from abusive arrangements. Specifically, there is precedent for OIG determining that certain per-unit service fees present a low risk of fraud and abuse in connection with the AKS. For example, in Advisory Opinion 10-14, OIG favorably reviewed a proposed arrangement under which a company providing sleep disorder

[193] One example of a relevant "unit of service" may be "each prescription dispensed for which a chargeback is processed," although there may be other appropriate ways to define a unit of service.

diagnostic testing and related services proposed to charge a hospital a set per-test fee that the company certified was negotiated through an arm's-length bargaining process, consistent with fair market value, and did not take into account the volume or value of any referrals or other business generated by the hospital.[194] The requesting company certified that the per-test fee was "determined in a manner that takes into account only items and services integral to furnishing [the] . . . services . . . ."[195] In considering the arrangement, OIG stated that, "[i]n the aggregate, per-test fees are inherently reflective of the value or volume of services."[196] Nevertheless, OIG found that such fees were "less likely to be remuneration to induce referrals" for the following reasons:

> [T]he per-test fees were arrived at through arm's-length negotiations; the per-test fee amount is consistent with fair market value in an arm's-length transaction; and the per-test fee, taken individually and not in the aggregate, does not take into account the volume or value of referrals or other business generated between the parties. Further, the per-test fee takes into account only items and services provided by [the company] that are necessary to perform [the] . . . services . . . and does not include amounts attributable to ancillary services and supplies that [the company] does not provide under the Arrangement . . . or other items or services not integral to furnishing [the services] . . . .[197]

Similarly, in Advisory Opinion 11-18, OIG favorably reviewed a proposed arrangement in which the requestor provided web-based business services to physician practices and charged certain transaction-based fees for referrals made and received using the requestor's service.[198] In reviewing the per-transaction fees, OIG reasoned that the fees "would—both individually and in the aggregate—reflect the fair market value of the actual services the Requestor would provide . . . , [t]he services would provide value that is unrelated to inducing referrals," and the fees charged for the services "would not vary based on the value of the items or services" provided to federal health care program beneficiaries.[199] OIG further noted that, although the arrangement would involve a transaction fee on a "per-click" basis, such a pricing model was reasonable under the circumstances, in part, because the requestor would assess the fee each time an ordering health professional made a referral regardless of whether a beneficiary actually received items or services payable by a federal health care program.[200] Moreover, the fees charged reflected the work the requestor must perform with each requested service.[201]

We urge OIG to recognize the safeguards we have listed above as providing sufficient protection from fraud and abuse, consistent with prior advisory opinions. We believe chargeback administration service compensation is fairly tied to the number of chargebacks processed by the administrator, and that the

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[194] OIG, Adv. Op. No. 10-14 at 3 (Aug. 30, 2010).
[195] *Id.*
[196] *Id.* at 8.
[197] *Id.*
[198] OIG, Adv. Op. No. 11-18 at 6 (Nov. 30, 2011).
[199] *Id.* at 10-11.
[200] *Id.* at 11.
[201] *Id.*

safeguards noted above are consistent with those recognized by OIG in the past as resulting in low risk of abusive arrangements based on volume or value.[202]

Finally, we ask OIG to clarify that PBMs may not require pharmaceutical manufacturers to pay chargeback administration fees, chargeback adjudication fees, or similar service fees as a condition for formulary placement or position. This could have a chilling effect on third party chargeback administrators entering into the market.

- OIG Should Ensure Consistent Use of the Term "Reduction in Price" Throughout the POS Reductions in Price Safe Harbor

PhRMA respectfully recommends that OIG consistently use the term "reduction in price" within the POS reductions in price safe harbor to better effectuate the stated goals of this provision, ensure consistency with other portions of the proposed rule, and to provide clarity for manufacturers and other regulated parties. We believe this change would be consistent with OIG's intent, as the revised language would align with OIG's preamble discussion of the requirement under the proposed safe harbor.[203]

For example, while OIG uses the term "reduced price" in the regulatory text, OIG describes this provision in the preamble using the term "reduction in price," stating that "the *reduction in price* would have to be set in advance with the plan sponsor under Medicare Part D, a Medicaid MCO, or a PBM."[204] OIG further states that "'set in advance' would mean that the terms of the *reduction in price* would be fixed and disclosed in writing . . . ."[205]

Similarly, OIG's use of the terms "sale" and price "charged" in the regulatory text introduce some level of ambiguity. As OIG knows, the pharmaceutical supply chain is complex, and there could be disagreement among stakeholders as to the entities and transactions implicated by these terms (and, consequently, potential gaming by PBMs or other stakeholders). Instead, we think the term "reduction in price" reflects the actual delta—the remuneration—that the proposed safe harbor is intending to protect. Using this term consistently would make the safe harbor more precise and clear.

In addition, by using the term "reduction in price," OIG would be clarifying that, for purposes of complying with the "set in advance" requirement under the safe harbor, manufacturers would be permitted to set in advance the *reduction* in price (i.e., the discount). PhRMA believes this revised language is consistent with the operation of an upfront discount model and clarifies the information that must be fixed, disclosed to plans, and provided to dispensing pharmacies under the proposed safe harbor.

[202] We recommend that OIG should adopt a similar approach with respect to PBM service fees, as explained more fully below.
[203] Similarly, for consistency and clarity, we recommend the term "reduction in price" be used consistently in OIG's proposed text for 42 C.F.R. § 1001.952(h)(5)(viii), rather than "reduced price."
[204] 84 Fed. Reg. at 2349 (emphasis added).
[205] *Id.*

A full markup showing consistent usage of the term "reduction in price" throughout the POS reductions in price safe harbor is included in Appendix I.

- OIG Should Provide Guidance Clarifying that PBMs May Not Tie Formulary Placement or Positioning to Procurement-Based Discounts from Manufacturers

As an initial matter, PhRMA does not interpret the proposed POS reductions in price safe harbor, or the inclusion of owned, affiliated, or related entities in the PBM definition (as explained in greater detail below) to affect the ability of entities to continue to receive procurement-based discounts, such as discounts negotiated by PBM-affiliated specialty pharmacies. In the preamble to the final rule, OIG notes:

> 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. We solicit comments regarding whether the proposed regulatory text amending the discount safe harbor (when read in conjunction with the proposed new safe harbor at 42 CFR 1001.952(cc)) excludes reductions in price not contemplated by the proposed amendment.[206]

Because the proposed changes to the discount safe harbor at 1001.952(h)(5)(viii) exclude from discount safe harbor protection only those reductions in price offered "in connection with" a sale or purchase to a plan sponsor, or to a PBM "acting under contract with" a sponsor, we interpret procurement-based discounts to be outside of this exclusion and to potentially remain within the ambit of the discount safe harbor. Thus, we interpret the proposed revisions to retain potential discount safe harbor protection for PBM-affiliated entities, such as specialty pharmacies, that obtain procurement-based discounts on medicines.

That being said, however, because PBMs continue to become more diverse in business structure, with an increasing number of affiliated and related entities, we respectfully request that OIG make clear that PBMs may not tie (implicitly or explicitly) placement or positioning of the manufacturer's medicines on the PBM's formulary to such manufacturer procurement-based discounts that may be paid to PBM-affiliated specialty pharmacies or other PBM-affiliated entities.

[206] 84 Fed. Reg. at 2348.

Proposed PBM Service Fees Safe Harbor: 42 C.F.R. § 1001.952(dd)

We also applaud OIG for proposing the PBM service fees safe harbor. The PBM service fees safe harbor would be an important first step in delinking payment to intermediaries from the list price of medicines by requiring service fees that manufacturers pay to PBMs to be fixed payments negotiated at arm's length and consistent with fair market value and not based on a percentage of list price, among other requirements. Our comments below reflect critical technical revisions that would strengthen the protections of the safe harbor and advance HHS's goal of delinking PBM compensation from list price. A full markup of PhRMA's suggested revisions to the PBM service fees safe harbor is included in Appendix I.

- OIG Should Codify a Clear Functional Definition of "Pharmacy Benefit Manager"

While we appreciate OIG's proposal to retain some flexibility as PBM services evolve over time, we urge OIG to codify a carefully considered PBM definition that provides clarity to regulated entities and minimizes the risk of potential abuse.

Specifically, we recommend that OIG adopt a functional definition of "PBM" that reflects the range of specified services that PBMs offer, accounts for complex corporate structures and ongoing vertical integration of PBMs into or with other entities, and reduces the potential for abuse. The definition we propose below is similar to definitions that have been codified in various states[207] and reflects the broad range of services that PBMs currently offer to health plans and manufacturers while affording flexibility as the PBM business model evolves over time.

> "Pharmacy Benefit Manager" means any person, business, or other entity that, pursuant to a written agreement with plan sponsors under Medicare Part D, either directly or through an intermediary, acts as a price negotiator on behalf of plan sponsors under Medicare Part D or manages the prescription drug benefits provided by plan sponsors under Medicare Part D, including but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, controlling the cost of covered prescription drugs, or the provision of services related thereto. Under this definition, any person, business, or other entity that carries out one or more of the activities above or any entity that is owned, affiliated, or related under a common ownership structure with such a person, business, or entity is a "pharmacy benefit manager." Such entity is not a purchasing agent and therefore is not a GPO as defined in paragraph (j) of this section.

[207] *See, e.g.*, Cal. Health & Safety Code § 1385.001; Md. Code Ann., Ins. § 15-1601; Tex. Health & Safety Code § 1385.001; Wash. Rev. Code § 19.340.010.

In the absence of our recommended clarifications, PBMs could easily adjust their business practices or shift their corporate structures to avoid being considered "PBMs" for purpose of the regulation, thus undermining the important policy goals of the proposed rule.

- OIG Should Clearly Distinguish PBMs from GPOs

Our proposed definition of "PBM" recognizes the distinct role of PBMs and GPOs in the marketplace and proposes to clarify that a PBM is not a GPO as that term is defined in the GPO safe harbor. Under the GPO safe harbor, a GPO is defined as an entity "authorized to act as a *purchasing agent* for a group of individuals or entities . . . ."[208] As a threshold matter, GPOs generally represent members that take physical possession of medicines. Common examples of GPO members include hospitals and physician practices. By contrast, PBMs function as "price negotiators" and, unlike GPOs, do not represent members that purchase and take possession of medicines; rather, PBMs represent only health plans that reimburse pharmacies for dispensing medicines to the plans' enrollees. We encourage OIG to emphasize this distinction between PBMs and GPOs to avoid confusion over the similar, but distinct, roles of these types of intermediaries in the pharmaceutical supply chain, and to foreclose attempts by PBMs to seek protection for arrangements under the GPO safe harbor.

This proposed distinction is complementary to our recommendation in Section VI above regarding OIG's 2003 Pharma CPG. Indeed, by codifying this proposed definition and rescinding the provisions of the 2003 Pharma CPG addressing PBMs' use of the GPO safe harbor to protect rebates and other payments from manufacturers, OIG would make clear its view that PBMs are distinct from GPOs and, therefore, PBMs may not seek to protect manufacturer rebates and other payments using the GPO safe harbor.

- OIG Should Broaden the PBM Service Fees Safe Harbor to Apply to All PBM Services Arrangements with Manufacturers

As stated elsewhere in our comments, the proposed safe harbor would make meaningful progress toward delinking intermediary compensation from the price of medicines. However, PhRMA is concerned that the "related to" language unduly limits the scope of the safe harbor and could present risk of gaming, as PBMs could solicit potentially abusive service arrangements from manufacturers on the basis that such services are "unrelated to" the pharmacy benefit management services that the PBM furnishes to health plans. Accordingly, PhRMA urges OIG to remove this limitation and thus broaden the scope of the PBM service fees safe harbor to apply to *all manufacturer service fee payments to PBMs*.

PhRMA suggests this change because manufacturers may contract with PBMs for services that may not clearly "relate to" the pharmacy benefits management services that the PBM furnishes to health plans. In addition, the "related to" requirement would be difficult to administer and could be subject to abuse by PBMs. OIG's list of PBM services to plans is helpful, but it is neither comprehensive nor would it keep pace with future developments in the industry and PBMs' evolving business models. Taken together, the "related to" limitation will result in uncertainty in service fee negotiations between PBMs and manufacturers (with PBMs arguing safe harbor compliance is inapplicable for services that fail the "related to" standard) and would result in a vague standard.

[208] 42 C.F.R. § 1001.952(j)(2).

Indeed, PhRMA believes that it is critical for OIG to provide "bright-line" standards that facilitate *long-term* compliance with the proposed safe harbors. Given the potential ambiguities in the "related to" standard, we respectfully urge OIG to remove the "related to" limitation and codify a broadly applicable safe harbor that advances HHS's goal of delinking intermediary compensation from list price, no matter the underlying services that are being provided to a manufacturer by a PBM.

- OIG Should Provide Additional Guidance on Issues Related to Fair Market Value in an Arm's-Length Transaction

PhRMA supports OIG's implementation of a fair market value standard for PBM service fees to manufacturers. It is critical that PBM service fees not only be delinked from the price of a medicine, but also that such fees represent fair market value for itemized services actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the services arrangement. We recognize OIG's rationale for declining to define "fair market value," consistent with its approach in the personal services and management contracts safe harbor,[209] and manufacturer government price reporting requirements.[210] We believe it is important for OIG to maintain this consistency and believe the other controls in the proposed safe harbor, subject to our additional recommendations below, will help to achieve OIG's policy goals.

First, PhRMA requests that OIG provide guidance in the preamble to the final rule to clarify PBMs' obligations to negotiate services arrangements with manufacturers in good faith based on a manufacturer's bona fide needs. PhRMA is concerned that, absent clear guidance specifying examples of improper negotiating tactics that would not be "at arm's length," within the meaning of the safe harbor, the applicable requirements will be vague.

Accordingly, OIG should provide bright-line guidance to clarify that safe harbor protection is available for only those service fee arrangements that are negotiated in good faith for itemized services that the PBM offers individually, not as a fixed bundle. OIG should also clarify in guidance that PBMs are required to provide a line-item fee for each service provided to a manufacturer and allow manufacturers to choose individual services. Such a requirement could mirror CMS's requirement for bona fide service fees, as set forth in the 2016 final rule addressing requirements under the Medicaid Drug Rebate Program.[211] Specifically, CMS requires that the fee be for "a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement."[212]

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[209] 42 C.F.R. § 1001.952(d)(5).
[210] CMS, Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170, 5180 (Feb. 1, 2016) (". . . [W]e believe the determination of fair market value is by nature subjective and many factors can contribute to its determination, and as a result, it can be a range of values. Therefore, we believe that any documentation can be used, provided that it makes clear the methodologies or factors the manufacturer used in making its fair market value determination. We expect such determination of fair market value and documentation be made contemporaneously with the manufacturer's agreement to pay the fee.").
[211] CMS, Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5169 (Feb. 1, 2016).
[212] 81 Fed. Reg. at 5347.

Second, PhRMA requests that OIG issue guidance to clarify the scope of protection available under the PBM service fees safe harbor for arrangements in which a PBM provides pharmacy benefits management services on behalf of an affiliated health plan. Health plans contracting with unaffiliated PBMs must negotiate for the provision of pharmacy benefits management services as part of an arm's-length transaction and determine fair market value compensation for the PBM's services. Under the proposed rule, it is unclear whether PBMs may seek fees for services to affiliated health plans and what additional compliance obligations, if any, may apply to such arrangements.

Third, PhRMA urges OIG to issue guidance to clarify that individual health plans not providing pharmacy benefits management services to plan sponsors under Medicare Part D may not negotiate on their own behalf with manufacturers to seek administrative fees or other compensation for services described in the definition of "PBM." Absent this clarification, PhRMA is concerned that health plans performing certain services referenced in the PBM definition may assert that manufacturers should pay additional service fees for a plan's services because the plan, in its view, satisfies the proposed safe harbor definition of a "PBM."

- OIG Should Prohibit the Tying of PBM Service Fees to Formulary Placement or Position

In order for the safe harbor to achieve HHS's policy goals, PhRMA believes it is critical that OIG revise the proposed PBM service fees safe harbor to expressly prohibit PBMs from tying service fees to placement or positioning of a manufacturer's medicines on a PBM's (or its contracted plan's) formulary, unless the associated services are requested by the manufacturer to be performed on its behalf to support the safe and effective use of the medicines (e.g., when a drug subject to a risk evaluation and mitigation strategy requirement by the Food and Drug Administration or a similar voluntary safety program established by the manufacturer requires the PBM to perform a service at the request of the manufacturer).

The PBM service fees safe harbor advances HHS's effort to delink channel intermediary compensation from the price of medicines. In our view, negotiations for formulary placement and positioning should be driven by the clinical profile of the medicine, its value, and reductions in price in compliance with the proposed POS reductions in price safe harbor. Requiring that PBMs decouple formulary placement and positioning from service fee negotiations would help to ensure that the above factors are appropriately driving formulary decision-making.

Further, as described above in the discussion of chargeback administration, we ask OIG to clarify that where a third-party entity unrelated to a PBM is being paid to perform POS chargeback administration services, PBMs may not require pharmaceutical manufacturers to pay chargeback administration fees, chargeback adjudication fees, or similar service fees as a condition for formulary placement or position, due to the potential chilling effect on third party chargeback administrators entering into the market.

- OIG Should Clarify the Obligations of Each Party under the PBM Service Fees Safe Harbor

We further request that OIG specify the compliance obligations of each party under the safe harbor. We acknowledge that certain conditions in the proposed safe harbor, such as a written agreement covering all

of the PBM services and compensation that meets certain standards, require both PBMs and manufacturers to perform. However, there are provisions in the safe harbor, as initially proposed and as contemplated by our proposed revisions, that place clear obligations and reasonable limitations on PBMs. Specifically, PBMs and plans are in control of formularies, not manufacturers; therefore, under the proposed safe harbor, PBMs are the only party in a position to ensure that service fee compensation to the PBM is separate from and does not take into account formulary placement or position. PBMs are also the only entity in a position to provide transparency to manufacturers and health plans with respect to the services to and fees from the manufacturer.

As explained above in the context of the POS reductions in price safe harbor, we are concerned that PBM non-compliance with applicable safe harbor requirements could cause services arrangements to fall outside the safe harbor and outside the control of manufacturers, thereby exposing manufacturers to AKS risk. To address this risk and to encourage all parties to a PBM services arrangement to perform their obligations under the safe harbor, we respectfully urge OIG to delineate specific obligations that manufacturers and PBMs must meet. If a manufacturer or PBM satisfies applicable conditions under the safe harbor, safe harbor protection would be afforded to that party regardless of whether other party to the arrangement complies with safe harbor conditions applicable to their activities under the arrangement.

- OIG Should Clarify the "Volume or Value" Standard

We appreciate OIG's long-standing concern with compensation arrangements that take into account the volume or value of any referrals or other business generated between the parties. As OIG has noted in prior guidance, in certain circumstances, per-unit based fees can be inherently reflective of the volume or value of referrals and increase the risk of fraud and abuse. We note, however, that certain services arrangements between pharmaceutical manufacturers and PBMs may include fees that vary on a per-unit basis, such as a per-transaction or per-prescription fee, but which are arrived at through arm's-length negotiations, are consistent with fair market value, and, taken individually and not in the aggregate, do not take into account the volume or value of referrals or other business generated between the parties. To promote flexibility in the use of fee arrangements that present a low risk of fraud and abuse under the PBM service fees safe harbor, PhRMA recommends that OIG include criteria to deem certain arrangements not to take in to account the volume or value of any referrals or other business generated by the parties.

Fair market value, per-unit fees are appropriate and present low risk of abuse if proper safeguards are incorporated into the safe harbor. For example, as OIG noted in the preamble to the proposed rule, manufacturers may receive data services from PBMs to help prevent duplicate discounts on 340B claims.[213] If the proposed rule is finalized, manufacturers may also compensate PBMs, among other entities, to administer chargebacks required by the POS reductions in price safe harbor. As discussed above in the section pertaining to fees for chargeback administration, to the extent fees for PBM services are structured on a fair market value, per-unit basis, such as a flat per-prescription or per-transaction fee, PhRMA is concerned that, without changes to the proposed regulatory text and issuance of further guidance, such compensation could be viewed as taking into account the volume or value of referrals or

[213] 84 Fed. Reg. at 2349-50.

business otherwise generated between the parties and, therefore, causing the arrangement to fall outside the PBM service fees safe harbor.

Thus, PhRMA believes OIG should consider factors identified in Advisory Opinions 10-14 and 11-18 to amend the proposed safe harbor to deem certain fair market value, arm's-length per-unit fees as not taking into account the volume or value of referrals or other business generated between the parties. Consistent with OIG's analyses in those opinions, the proposed safe harbor requires compensation paid to a PBM to be consistent with fair market value in an arm's-length transaction.[214] The safe harbor should further deem per-unit fee arrangements as not taking into account the volume or value of referrals or other business generated if they contain the following safeguards, which are consistent with existing OIG Advisory Opinions:

- When measured individually and not in the aggregate, the fee does not take into account the volume or value of referrals or other business generated between the parties;

- When measured individually and in the aggregate, the fee reflects the fair market value of the actual services provided;

- The fee takes into account only the services that are necessary for PBMs to perform agreed-upon services on behalf of manufacturers and does not include amounts attributable to ancillary services that PBMs do not provide under the arrangement or that are not integral to performing the agreed-upon services on behalf of the manufacturer; and

- The fee is assessed for each unit of service.[215]

These proposed safeguards would allow per-unit fees that reflect fair market value as negotiated at arm's-length for *each individual service* that a PBM provides to a manufacturer but that do not vary based on the aggregate value of items or services that might ultimately be provided to federal health care program beneficiaries or other business generated between the parties. This proposed revision to the safe harbor recognizes that PBMs may provide bona fide services to manufacturers that can be reasonably reflected in a per-unit fee that increases PBM compensation proportionally with the volume of services provided and the amount of work performed. While per-unit service fees might vary for transaction types that are not similarly situated,[216] OIG should clarify in preamble guidance that PBM service fees structured on a per-unit basis should not vary across similarly situated transaction types.

- <u>OIG Should Require Greater Transparency of PBM Services and Fees</u>

PhRMA supports full transparency with respect to PBM service fee arrangements. PBMs should be required to disclose their fee arrangements with both manufacturers and plans. Such service fee

[214] 84 Fed. Reg. at 2363 (proposed to be codified at 42 C.F.R. § 1001.952(dd)(2)(iii).
[215] One example of a relevant "unit of service" may be "each prescription dispensed," although there may be other appropriate ways to define a unit of service.
[216] For example, variations across products types based on bona fide distinctions, or based on the size or scope of the PBM engaging in the transaction.

arrangements should also be disclosed to the Secretary. Consistent with OIG's statement in the proposed rule, health plans (and manufacturers) "may not always know the services . . . PBMs are providing"[217] to the other party. OIG's proposals to require disclosure of service fee arrangements is a good first step toward increasing PBM transparency, allowing plans to "better . . . identify and protect themselves from conflicts of interest,"[218] and minimize risk of fraud and abuse.[219]

While we generally support OIG's proposal for PBM service fee transparency, we would caution that duplicative services may not always constitute "double dipping." For example, in the context of data, PBMs may provide the same data to more than one entity, and such data could represent value to each recipient, even if the data is also received by others.[220] We encourage OIG to consider that duplication or overlap, standing alone, may not necessarily indicate that an arrangement is fraudulent or abusive. Rigorous transparency standards, such as those described above, however, may help the Secretary identify instances of potential PBM fraud and abuse.

In addition, in connection with our discussion of chargeback administration fees above, PhRMA recommends that OIG similarly modify the POS reductions in price safe harbor to require any individual or entity administering chargebacks under that safe harbor to meet the same disclosure requirements that apply to PBM services arrangements under the PBM service fees safe harbor. Specifically, OIG should require any chargeback administrator, as a condition of the safe harbor, to disclose to the manufacturer and to the plan sponsor annually and to HHS the service fee arrangement for chargeback administration services rendered under the safe harbor.

XIV. Federal Policymaking to Address Commercial Market Rebates Should be Undertaken Outside of the Anti-Kickback Statute

As reflected in our comments here and in our prior comments to HHS, PhRMA supports policies that allow beneficiaries to share in negotiated price concessions on their medicines at the point-of-sale. While there have been efforts among certain plans and PBMs to offer rebate pass through models in the commercial insurance market, the reach of these programs has been limited to date.[221] If OIG finalizes the proposed rule, manufacturers will face one set of legal requirements for discounts and formulary terms under certain federal health care programs and a different set of requirements applicable in the commercial market. Given that the laws affecting the commercial insurance market will not change as a result of the final rule, we share the following comments on "swapping."

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[217] 84 Fed. Reg. at 2344.
[218] *Id.*
[219] In addition, we respectfully request that OIG work closely with CMS to update its DIR guidance to require the reporting of these fees in a way that is consistent with the new safe harbor and ensures appropriate transparency for the fees.
[220] As an analogous example, while movie production is a sunk cost for the movie studio, such studio can charge each person who views the movie, and value is conferred to each of those viewers.
[221] UnitedHealthcare Will Expand a Drug Discount Program Aimed at Lowering Consumer Costs. *The New York Times*. March 12, 2019. Aetna to Offer Point-of-Sale Pharmacy Rebates to Three Million Customers. *Managed Care*. March 27, 2018; Johnson CY. UnitedHealthcare Will Provide Drug Rebates Directly to Members in Some Plans. *The Washington Post*. March 6, 2018.

In the preamble to the proposed rule, OIG makes several statements regarding arrangements in which parties "carve out" federal health care program utilization from questionable financial arrangements. For example, OIG stated:

> [I]f a manufacturer offered a rebate on a product to an insurer for its private pay plans conditioned (explicitly or implicitly) on the product's favorable formulary placement across all plans (including Part D plans), such a rebate could be remuneration that would implicate the anti-kickback statute and would not be protected by the current discount safe harbor or by the provisions of this proposed rulemaking.[222]

HHS further stated in a separate fact sheet summarizing the proposed rule that:

> Longstanding OIG rules exclude from safe harbor protection price reductions offered to one payor but not to Medicare or Medicaid, particularly when such discounts serve as inducements for the purchase of federally reimbursable products. Such arrangements implicate, and may violate, the anti-kickback statute by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business . . . . This rule exercises HHS' regulatory authority to address the rebate system as it relates to federal healthcare programs.[223]

We request that OIG recognize that offering rebates to commercial plans that are not offered to Medicare, Medicaid, or another federal health care program, in itself, is not sufficient to give rise to impermissible and illegal "swapping" under the federal Anti-Kickback Statute. Instead, the activity that would be improper, according to OIG's "swapping" guidance, is if there was an explicit *quid pro quo* with respect to federal and non-federal books of business.

Further, we respectfully request that OIG acknowledge that the "longstanding OIG rules" referenced in the Fact Sheet accompanying the proposed rule, which "exclude from safe harbor protection price reductions offered to one payor but not to Medicare or Medicaid," do not apply when manufacturers offer price concessions on medicines in the commercial market that are not also offered under a federal health care program. More specifically, we seek OIG's acknowledgement that OIG rules relating to swapping do not apply so long as there is no *quid pro quo* between a manufacturer price concession offered on a plan's or PBM's commercial utilization and a price concession offered on such plan's or PBM's federal health care program utilization.

HHS should not attempt to achieve policymaking goals in the commercial market through the criminal federal AKS. To the extent there is future policymaking to achieve rebate reform in the commercial

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[222] 84 Fed. Reg. at 2347.

[223] OIG. Fact Sheet: Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients at 3. Jan. 31, 2019. Available at: https://www.hhs.gov/sites/default/files/20190131-fact-sheet.pdf.

market, it would be more appropriately accomplished through regulatory or legislative reforms outside of OIG's AKS authority. We note that the commercial market is complex and is governed by different statutes and state and federal agencies. Any changes to the current commercial market rebate system should be undertaken carefully and incorporate feedback from a range of stakeholders.

XV. Appendix I: Suggested Revisions to Proposed Regulatory Text

§ 1001.952 Exceptions.

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(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

(viii) A reduction in price or other remuneration from a manufacturer in connection with utilization ~~the sale or purchase~~ of a prescription pharmaceutical product by a beneficiary of ~~to~~ a plan sponsor under Medicare Part D~~, a Medicaid Managed Care Organization as defined in section 1903(m) of the Act,~~[224] or to a pharmacy benefit manager acting under contract with a plan sponsor under Medicare Part D~~, or Medicaid Managed Care Organization,~~ unless it is a ~~price~~ reduction in price 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 person, business, or other entity that, pursuant to a written agreement with plan sponsors under Medicare Part D, either directly or through an intermediary, acts as a price negotiator on behalf of plan sponsors under Medicare Part D or manages the prescription drug benefits provided by plan sponsors under Medicare Part D, including but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, controlling the cost of covered prescription drugs, or the provision of services related thereto. Under this definition, any person, business, or other entity that carries out one or more of the activities above, or any entity that is owned, affiliated, or related under a common ownership structure with such a person, business, or entity, is a "pharmacy benefit manager." Such entity is not a purchasing agent and therefore is not a GPO as defined in paragraph (j) of this section ~~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).

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[224] Assuming Medicaid MCOs are removed from the final POS reductions in price safe harbor at 42 C.F.R. § 1001.952(cc) and remain protected under the existing discount safe harbor, we recommend striking references to Medicaid MCOs throughout the revised safe harbors.

~~(10) For purposes of this paragraph (h), the term *Medicaid Managed Care Organization* or *Medicaid MCO* carries the meaning ascribed to it in section 1903(m) of the Social Security Act.~~

§ 1001.952 Exceptions.
* * * * *

(cc) *Point-of-sale reductions in price for prescription pharmaceutical products*. (1) As used in section 1128B of the Act, "remuneration" does not include 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 ~~or a Medicaid Managed Care Organization,~~[225] or by a PBM acting under contract with such plan sponsor, ~~provided the manufacturer meets the following conditions with regard to that reduction in price~~ for a manufacturer, as long as the manufacturer complies with the applicable standards of paragraph (cc)(1)(i) and (ii); for a plan sponsor under Medicare Part D or a PBM acting under contract with such plan sponsor as long as that entity complies with the applicable standards of paragraph (cc)(1)(ii) and (iii); and for an individual or entity that administers a point-of-sale chargeback or a series of point-of-sale chargebacks as long as such individual or entity complies with the applicable standards of paragraph (cc)(1)(iv) and (v):

(i) The ~~reduced price~~ reduction in price must be set in advance by the manufacturer and ~~with~~ a plan sponsor under Medicare Part D~~, a Medicaid MCO,~~ or the PBM acting under contract with ~~either~~ such plan sponsor;

(ii) The ~~sale~~ reduction in price:

(I) D~~d~~oes not involve a rebate unless the full value of the reduction in price is provided to the dispensing pharmacy by the manufacturer directly or indirectly through a point-of-sale chargeback or series of point-of-sale chargebacks (with any necessary exchange of information or other cooperation by the plan sponsor under Medicare Part D, a PBM acting under contract with such plan sponsor, or other entity), or is required by law; and

(II) Does not involve supplying one prescription pharmaceutical product without charge or at a reduced charge to induce the purchase of a different prescription pharmaceutical product, unless the reduced charges applicable to each such product meet the requirements of paragraph (cc)(1)(i) and the reduced charges attributable to each product are fully disclosed by the plan sponsor under Part D to the Federal health care program; and

(iii) The plan sponsor under Medicare Part D or the PBM acting under contract with such plan sponsor must ensure that:

(I) The reduction in price on the prescription pharmaceutical product must be completely applied to ~~the price of the prescription pharmaceutical product charged to the beneficiary at the point-of-sale~~ reduce the price that determines the beneficiary's cost sharing on such product at the point-of-sale. If the beneficiary owes a copayment, the requirements of

[225] Assuming Medicaid MCOs are removed from the final POS reductions in price safe harbor at 42 C.F.R. § 1001.952(cc) and remain protected under the existing discount safe harbor, we recommend striking references to Medicaid MCOs throughout the revised safe harbors.

this paragraph (1)(iii)(I) are met if the beneficiary's cost sharing at the point-of-sale is less than or equal to the reduced price of such product; and

(II) The total payment for the prescription pharmaceutical product to the dispensing pharmacy is an amount agreed upon by the pharmacy and the plan sponsor under Part D or a PBM acting under contract with such plan sponsor, and includes:

(aa) The payment to the pharmacy from the plan sponsor under Part D or PBM acting for such plan sponsor,

(bb) The point-of-sale chargeback or series of point-of-sale chargebacks due from the manufacturer under paragraph (cc)(1)(ii), and

(cc) The beneficiary cost sharing payment; and

(iv) The compensation received by any individual or entity to administer a point-of-sale chargeback or series of point-of-sale chargebacks under this paragraph must be consistent with fair market value in an arm's-length transaction and be a fixed payment not based on a percentage of sales or the volume or value of any referrals or business otherwise generated between or among the parties. For purposes of this paragraph (cc)(1)(iv), the determination is deemed not to take into account the volume or value of referrals or business otherwise generated between or among the parties, if the following conditions are met:

(I) When measured individually and not in the aggregate, the fee does not take into account the volume or value of referrals or other business generated between the parties,

(II) When measured individually and in the aggregate, the fee reflects the fair market value of the actual services provided,

(III) The fee takes into account only services that are necessary for the individual or entity to perform chargeback administration services and does not include amounts attributable to ancillary services that such individuals and entities do not provide under the arrangement or that are not integral to performing chargeback administration services, and

(IV) The fee is assessed for each prescription dispensed, and regardless of whether the service is in the form of one chargeback or a series of chargebacks; and

(v) An individual or entity that administers a point-of-sale chargeback or a series of point-of-sale chargebacks must disclose in writing to the manufacturer and the plan sponsor under Medicare Part D and to the Secretary at least annually the service fee arrangement for chargeback administration services rendered under this paragraph.

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

(ii) For purposes of this paragraph (cc), a *point-of-sale* *chargeback* is a payment equal to the reduction in price for a prescription pharmaceutical product negotiated by the manufacturer and the plan sponsor under Medicare Part D ~~or the Medicaid Managed Care Organization,~~ or by the PBM acting under contract with such plan sponsor ~~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, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product~~.

(3) A party will receive the protection of this paragraph (cc) if it fulfills its own obligations under this paragraph (those obligations that are identified above as obligations for that party to carry out) and does not impede any other party from meeting its own obligations, even if any other party does not fulfill its own obligations.

§ 1001.952 Exceptions.

* * * * *

(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~~ for a PBM, as long as the PBM complies with paragraph (dd), and for a manufacturer, as long as the manufacturer complies with the applicable standards of paragraph (dd)(1) and (2): ~~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~~ for any 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. For purposes of this paragraph (dd)(2)(iii), the determination is deemed not to take into account the volume or value of referrals or business otherwise generated between the parties, or between the manufacturer and the PBM's health plans, if the following conditions are met:

(I) When measured individually and not in the aggregate, the fee does not take into account the volume or value of referrals or other business generated between the parties;

(II) When measured individually and in the aggregate, the fee reflects the fair market value of the actual services provided;

(III) The fee takes into account only services that are necessary for the PBM to perform agreed-upon services on behalf of the manufacturer and does not include amounts attributable to ancillary services that the PBM does not provide under the arrangement or that are not integral to performing the agreed-upon services on behalf of the manufacturer; and

(IV) The fee is assessed for each unit of service.

(3) The compensation paid to the PBM must be separate from and shall not be a condition of the placement or position of a prescription pharmaceutical product of the manufacturer on a formulary of the PBM or any health plan to which the PBM furnishes pharmacy benefit management services.

(~~3~~ 4) The PBM must disclose in writing to each health plan with which it contracts and to the Secretary at least annually, ~~and to the Secretary upon request,~~ the service fee arrangement for the services rendered to ~~each~~ the pharmaceutical manufacturer related to the PBM's arrangements to furnish pharmacy benefit management services to the health plan.

(5) The PBM must disclose in writing to the manufacturer and to the Secretary at least annually the service fee arrangement for the services rendered to the PBM's health plans.

(~~4~~ 6) 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.

(7) A party will receive the protection of this paragraph (dd) if it fulfills its own obligations under this paragraph (those obligations that are identified above as obligations for that party to carry out) and does not impede any other party from meeting its own obligations, even if any other party does not fulfill its own obligations.

XVI. Appendix II: Bases for CMS Guidance Preventing POS Chargebacks to Retail Community Pharmacies from Reducing AMPs

Under the proposed safe harbor for POS reductions in price, manufacturers would provide these reductions in price through POS "chargebacks" paid to pharmacies that dispense the drug to Part D plan or Medicaid MCO enrollees.[226] We focus on Part D POS discount arrangements, but the principles outlined below would also apply in the Medicaid MCO context, if Medicaid MCOs are included in the final POS safe harbor.

Chargeback payments could arguably be included in AMP -- "standard" AMP in particular[227] -- due to a catchall provision added to the Medicaid rebate statute in 2010. After specifying whether certain sales or price concessions are included in/excluded from AMP, the statute states that AMP incudes "any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies [RCPs]."[228] While a POS chargeback transmitted through an RCP could potentially implicate this catchall language, CMS has good grounds to exclude POS chargebacks from AMP, and could thus issue guidance to that effect. Such guidance would help to avoid reductions in AMPs, FULs,[229] and Medicaid rebates.

Transactions Where the Pharmacy Receives No Benefit and Instead Acts Only as a Conduit Are Excluded From AMP

The catchall language in SSA § 1927(k)(1)(B)(ii) does not apply where a discount flows through a pharmacy without providing any benefit to the pharmacy; i.e., where the pharmacy is simply a "conduit" for a discount to another party. For example, in its 2016 AMP final rule, CMS described situations where pharmacies act solely as conduits transmitting a manufacturer discount to a beneficiary, stating that these discounts are excluded from AMP:

> Comment: . . . [A] commenter requested that CMS confirm that when a pharmacy extends a manufacturer-sponsored discount to a patient, and the manufacturer then reimburses the pharmacy for the exact amount of that patient discount, the reimbursement transactions with the pharmacy should be excluded from AMP . . . because the entire benefit of the discount flows through to the patient and there is no discount to the pharmacy. . . .
> Response: We agree that when a pharmacy is simply a conduit to passing a discount through to the beneficiary, those manufacturer-to-pharmacy transactions are excluded from AMP and best price.[230]

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[226] Proposed 42 CFR §1001.952(cc)(1)(ii),(2)(ii).
[227] We focus on standard AMP because the regulations specifically exclude from 5i AMP "[a]ny prices charged which are negotiated by a [Part D plan] … for covered Part D drugs." 42 C.F.R. § 447.504(e)(8). Because manufacturer chargeback payments to a Part D plan's network pharmacies would reflect the POS discounts negotiated with a Part D plan sponsor (or its PBM), they should fall within this exclusion.
[228] Social Security Act (SSA) § 1927(k)(1)(B)(ii)(emphasis added).
[229] FULs are 175% of the volume-weighted average AMP for a group of multiple source drugs or (if higher) the National Average Drug Acquisition Cost for the group. 42 C.F.R. § 447.514.
[230] 81 Fed. Reg. 5170, 5254-55 (Feb. 1, 2016)(emphasis added).

CMS similarly stated:

> [A] benefit provided to a patient, even if it is provided at the pharmacy counter, is not a discount, rebate, payment or other financial transactions received by or passed through to the [RCP] that must be included in AMP in accordance with section 1927(k)(1)(B)(ii) of the Act.[231]

Arrangements described by the proposed safe harbor are analogous: the pharmacy would simply be transmitting the manufacturer discount to the beneficiary and the Part D plan sponsor or its PBM. If a manufacturer discount goes entirely to beneficiaries and the Part D plan/PBM via the plan's network pharmacies, the pharmacies are merely conduits for the discount. Thus, POS chargeback payments could be excluded from AMP (assuming the final rule chargeback provisions are similar to those in the proposed rule) under the conduit principle.

Part D POS Chargebacks Fall Under CMS' Longstanding Policy that Government Program Prices Are Excluded From AMP

Another basis for excluding a POS chargeback from AMP is CMS' longstanding position that AMP excludes prices to government programs and payers. CMS has emphasized that the 2010 statutory changes to the AMP definition should not "be read to disregard CMS' longstanding position to exclude prices made available only through certain State and Federal government providers and programs from AMP."[232] CMS explained, "[m]anufacturers that provide discounts or rebates to government programs and payers generally do not make these discounts or rebates available to [RCPs] or wholesalers that distribute to [RCPs]," and therefore "AMP shall exclude . . . the discounts or rebates provided to government programs and payers, because they are not [RCPs] or wholesalers that distribute drugs to [RCPs]."[233]

Further, CMS specifically noted that this principle applies in the Part D context:

> Comment: A few commenters noted that the broad inclusion of insurers in the calculation of AMP for 5i drugs not generally dispensed through [RCPs] could be read to include discounts to entities that are ineligible for best price, such as Medicare Part D plans and SPAPs. The commenters urged CMS to exclude all best price exempt discounts from the calculation of AMP for 5i drugs . . . to ensure that the resulting AMP figure is not skewed lower by these best price exempt transactions. . . . .
>
> Response: . . . [P]ayments received, and discounts and rebates provided to, government programs, including Part D and SPAPs, should be excluded from . . . AMP for 5i drugs . .

[231] 81 Fed. Reg. at 5235 (emphasis added).
[232] 81 Fed. Reg. at 5246.
[233] 81 Fed. Reg. at 5246.

> .. [M]anufacturers should exclude Medicare Part D and SPAP government prices, discounts, and rebates when determining AMP for 5i drugs . . .[234]

The "government program" exclusion would therefore apply to POS chargebacks negotiated with Part D plan sponsors or their PBMs that are only triggered when the drug is dispensed to Part D plan enrollees (not when the drug is dispensed to the general public). This exclusion would be an additional ground for guidance excluding POS chargebacks from AMP.

* * *

[234] 81 Fed. Reg. at 5248-49. This is the basis for the 5i AMP exclusion for "any prices charged which are negotiated by a [Part D plan] . . . for covered Part D drugs" at 42 C.F.R. § 447.504(e)(8).

On behalf of PhRMA and our member companies, thank you for consideration of these comments. We look forward to working with you to address the many important issues discussed in the proposed rule.

Sincerely,

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