



**VIA ELECTRONIC DELIVERY**

April 8, 2019

Office of Inspector General  
Department of Health and Human Services  
Attn: **OIG-0936-P**  
Room 5527  
Cohen Building  
330 Independence Ave, SW  
Washington, DC 20201

**Re: Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees.**

I am writing on behalf of the Biotechnology Innovation Organization (BIO) relating to The Department of Health and Human Services Office of Inspector General's (HHS & OIG) proposed regulation to eliminate safe harbor protection for certain rebates in the Medicare Part D and Medicaid programs and to create new safe harbor protection for point-of-sale reductions in price and certain pharmacy benefit management service fees.<sup>1</sup>

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics yield not only improved health outcomes, but also reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

**Introduction**

As BIO noted in its initial statement welcoming the release of this proposed rule, we firmly believe that the rebates drugmakers provide insurers and other middlemen should be used to lower what patients pay out-of-pocket for prescriptions. This proposed rule, if finalized, would be a significant step forward in achieving our desire to ensure patients are the beneficiaries of at least some of the \$166 billion in rebates, discounts, and other price

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<sup>1</sup> 84 Fed. Reg. 2340 (Feb. 6, 2019).

concessions our member companies, and the biopharmaceutical industry at large, annually pay into the healthcare system in the United States.<sup>2</sup>

Fundamentally, BIO supports the proposed rule in its effort to streamline reimbursement for medications by focusing more on the patient, rather than the complicated system of middlemen that pervade the U.S. supply chain for prescription medications. This issue was put on display most vividly at a recent Senate Finance Committee hearing on drug pricing, where several biopharmaceutical executives reinforced a need for the supply chain to decrease reliance on hidden rebates as one of many proposals to address concerns surrounding drug pricing in the United States.

In short, changes to the rebate system in favor of transparency and patient cost sharing relief are important, and we urge HHS to continue exploring options consistent with some of the technical comments expressed during this commenting period. Consistent with the foregoing, BIO does have some suggestions for HHS for changes and clarifications that would ultimately allow for smoother implementation and more durable reforms. Set forth below are our suggested modifications, which we are happy to discuss with OIG further in person if necessary.

#### **I. We Agree with CMS that Point-of-Sale Price Reductions Will Promote Strong Negotiations for Formulary Placement**

BIO agrees with HHS that negotiations for point-of-sale price reductions offered by manufacturers on prescription pharmaceutical products payable under Medicare Part D or managed Medicaid under the finalized point-of-sale price reduction safe harbor that are contingent on preferred placement on the plan's formulary or PDL (or on similar terms such as lack of utilization management restrictions) are important to the success of the rule. HHS states that "[t]his proposed rule seeks to eliminate rebates so that manufacturers will have an incentive to lower list prices and PBMs will have more incentive to negotiate greater discounts from manufacturers."<sup>3</sup> We recognize that negotiating point-of-sale discounts contingent on formulary placement will be an important tool for Part D plans and Medicaid MCOs (or their PBMs) under the new safe harbor and provide an opportunity to lower patient out-of-pocket expenses at the point of sale. BIO understands that maintaining protection from Anti-Kickback Statute (AKS) liability for point-of-sale (POS) price reductions contingent on formulary placement is consistent with HHS's long-standing recognition that Part D plans or Medicaid MCOs (and their PBMs) have offered preferred formulary placement as an incentive for manufacturers to pay rebates.

In the Proposed Rule, HHS explains that it believes "discounts are distinct from across-the-board price reductions offered to all buyers where the inducement that is made is so diffuse that it does not appear intended to encourage a particular buyer to purchase or order a particular good or service."<sup>4</sup> By noting this distinction, HHS acknowledges that lower list prices, while helpful for lowering overall costs, might not go far enough. HHS seeks to create the new safe

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<sup>2</sup> See *The Gross to Net Bubble Reached a Record \$166 Billion in 2018*, Drug Channels, available at: <https://www.drugchannels.net/2019/04/the-gross-to-net-bubble-reached-record.html>.

<sup>3</sup> 84 Fed. Reg. at 2352.

<sup>4</sup> 84 Fed. Reg. at 2348.

harbor for point-of-sale price reductions under the belief that manufacturer discounting will occur, but in order for that safe harbor to be most effective, formulary placement needs to be offered in return for the discounts. HHS also states that “[i]f 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.”<sup>5</sup> HHS further points out 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.”<sup>6</sup>

In line with past implicit recognition of the provision of rebates for formulary placement and in line with HHS’s statements regarding incentivizing discounting in the Proposed Rule. BIO appreciates that HHS within the Proposed Rule emphasizes the need for encouraging POS discounts as long as the incentives to provide discounts do not create undue risks, stating that:

As we describe throughout this preamble, point-of-sale reductions in price pose less risk to Medicare Part D, Medicaid MCOs, and beneficiaries than the current rebate system .... In that regard, we are soliciting comments on the extent to which the safe harbor, if finalized, would incentivize manufacturers to provide point-of-sale discounts. We are considering whether and, if so, how the proposed safe harbor conditions should be modified to encourage these point-of-sale price reductions without posing any undue risk to programs or patients.<sup>7</sup>

BIO supports this balanced approach and HHS’s appreciation of the need to permit incentives for manufacturers to provide POS discounts. We also agree with HHS that these discounts—particularly in the context of all the reforms associated with the HHS proposal—pose less risk to Part D and managed Medicaid than the current rebate system. For example, the risk that WAC-based PBM rebates and administrative fees would cause PBMs to favor drugs with high WACs in making formulary decisions has been a serious concern to HHS and the Administration, expressed in the Administration’s Drug Pricing Blueprint as well as the Proposed Rule. As such, more specifically favoring flat dollar discounts that must be shared with plan enrollees at the point of sale to hinge on a drug’s formulary status is highly unlikely to create risks of PBMs making inappropriate formulary decisions that fail to promote the best interests of plan beneficiaries and sponsors.

## **II. Exclusion of Supplemental Rebates from the Proposed Rule**

With respect to the proposed new safe harbor for point-of-sale price reductions, HHS proposes that the price reduction could not involve a rebate, unless “the full value of the reduction in price is provided to the dispensing pharmacy through a chargeback or a series of chargebacks, or the rebate is required by law.”<sup>8</sup> As one example of such rebates that are

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<sup>5</sup> 84 Fed. Reg. at 2356.

<sup>6</sup> 84 Fed. Reg. at 2355.

<sup>7</sup> 84 Fed. Reg. at 2348 (emphasis added).

<sup>8</sup> 84 Fed. Reg. at 2349.

“required by law,” HHS cites “supplemental rebates negotiated between states and manufacturers.”<sup>9</sup> HHS explains that it is aware that many states and manufacturers have negotiated supplemental rebates, and proposes that those rebates would not be affected by the Proposed Rule.

BIO agrees with HHS that supplemental rebates negotiated between manufacturers and states should not be affected by the Proposed Rule. As HHS understands, many states have enacted a state statutory provision that generally permits the state and manufacturer to enter into a supplemental rebate agreement, pursuant to which the manufacturer generally remits a supplemental rebate to the state for each unit of the manufacturer’s product subject to the agreement that is provided to state Medicaid recipients.<sup>10</sup> Manufacturers remit the supplemental rebate to the state under this agreement, in addition to the mandatory rebates received by the state under the National Medicaid Drug Rebate Agreement, pursuant to Social Security Act (SSA) Section 1927. Under this current supplemental rebate structure, states may be able to negotiate better prices than would otherwise be available for pharmaceutical products for Medicaid recipients in their state, and the rebate dollars are paid directly from the manufacturer to the state and shared with the federal government.

In light of the direct payments of rebate dollars from manufacturers to the states, the supplemental rebate system, as currently structured, does not pose the same risks as the current rebate structure related to Part D plans or Medicaid MCOs (or their PBMs). Further, the narrowed discount safe harbor relates only to rebates paid to Part D plan sponsors, Medicaid MCOs, and their PBMs (not states), and HHS states explicitly that it does not intend for this proposed change to affect supplemental Medicaid rebates to states. In fact, HHS has encouraged states to establish supplemental rebate programs and to collect supplemental rebates on their Medicaid drug utilization.<sup>11</sup> For these reasons, BIO supports HHS’s proposal to exclude supplemental rebates from the Proposed Rule.

### **III. Clarifying the Application of the Proposed Safe Harbor for Point-of-Sale Price Reductions to Beneficiary Cost-Sharing**

In the Proposed Rule, HHS does not offer guidance regarding how point-of-sale price reductions would be applied to beneficiary cost sharing. BIO would appreciate additional guidance regarding how manufacturer point-of-sale price reductions would be applied to beneficiary cost sharing, both when the beneficiary’s cost sharing obligation is less than the manufacturer price reduction and when it is more.

In particular, BIO encourages HHS to issue guidance regarding the application of point-of-sale price reductions to beneficiary coinsurance and to beneficiary copayments. For example, under many Medicaid MCO plans, a beneficiary may have zero, or very low, copayments. HHS

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<sup>9</sup> 84 Fed. Reg. at 2344, 2348.

<sup>10</sup> See e.g., Tex. Gov’t Code § 531.070; Cal. Welf. & Inst. Code § 14105.33.

<sup>11</sup> HHS, OIG, States’ Collection of Offset and Supplemental Medicaid Rebates 13 (Dec. 2014) (recommending that CMS consider encouraging “all states to establish supplemental rebate programs.”).

should clarify how a manufacturer price reduction that exceeds the beneficiary's copayment is applied to that copayment amount.

#### **IV. Maintaining Broad Safe Harbor Protection for PBM Services**

In the Proposed Rule, HHS proposes a new safe harbor to protect “a pharmaceutical manufacturer’s payment for services that a PBM furnishes to the pharmaceutical manufacturer.”<sup>12</sup> BIO supports the creation of a Safe Harbor for the protection of services provided by a PBM to a manufacturer. BIO further supports the HHS proposal that to be protected under the Safe Harbor the payments must be a “fixed payment, not based on a percentage of sales (which includes fees based on a percentage of sales or a percentage of the price of a manufacturer’s product).<sup>13</sup>

In the Proposed Rule, HHS then goes on to state that the proposed safe harbor would protect those services that “relate in some way” to the PBM’s arrangements with health plans. Although HHS states that it does not propose to define “PBM services,” HHS does enumerate a list of services that potentially “relate to” PBM’s arrangement with health plans, such as “contracting with a network of pharmacies; establishing payment levels for network pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; performing drug utilization review; and operating disease management programs.”<sup>14</sup> HHS has asked for comments on its proposal to limit this safe harbor to the services that relate to the PBM’s arrangements to provide pharmacy benefit management services to the health plans. BIO believes that the safe harbor for PBM services should protect from Anti-Kickback Statute liability all *bona fide* services provided to a manufacturer by a PBM.<sup>15</sup> Without this specific change, we are concerned that the language in the proposed rule will cause confusion between PBM services being provided to the manufacturer as distinguished from the PBM services being provided to a plan or other stakeholder.

Additionally, without limiting the scope of the protection offered by the proposed safe harbor to *bona fide* service fees, it is possible that intermediaries may seek to reallocate lost rebate revenue and shift costs by conversion to service fees. If this happened, the benefit of a payment from the manufacturer to the intermediary would not go to the patient but instead to the intermediary. In other words, if HHS incentivizes the negotiation of service fees over discounts through the language of the safe harbor, it is possible that patients would see less financial benefit, as the fees are not passed on to them. For these reasons, we recommend that HHS finalize that the proposed safe harbor for PBM services protects only *bona fide* services provided to a manufacturer by a PBM.

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<sup>12</sup> 84 Fed. Reg. at 2349.

<sup>13</sup> 84 Fed. Reg. at 2350.

<sup>14</sup> 84 Fed. Reg. at 2350.

<sup>15</sup> See 42 C.F.R. § 447.502 for the definition of “*bona fide* service fee.” In the Covered Outpatient Drug Final Rule published in 2016, CMS reiterated the definition of *bona fide* service fees, stating that a *bona fide* service is “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.” CMS, Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5169, 5347 (Feb. 1, 2016).

Further, to avoid revenue generation shifting among related-party affiliates, we urge HHS to define “PBM” in a way that accounts for the commonly integrated business lines that pervade the supply chain – such as integrated health plans, PBM-owned mail order pharmacies, specialty pharmacies, and data aggregators. PBMs should be prohibited from tying formulary status to the purchase of services covered under this new safe harbor. Moreover, HHS should evaluate Part D plan submissions to explore ways to enhance those reviews to ensure against non-discriminatory behavior resulting from this proposal. Specifically, we are concerned that practices could evolve that begin to severely restrict access on formulary tiers or that involve significant utilization management that ultimately limits patient access and severely restricts patient choice.

**V. Clarification to the Proposed Safe Harbor Requirement that an Arrangement May Not Take into Account the Volume or Value of Business Otherwise Generated Between the Parties**

As proposed, the third sub-condition for an arrangement protected under the proposed safe harbor for PBM service fees is that the service fees contemplated by the arrangement must not be determined in a manner that takes into account the volume or value of any referrals or any business otherwise generated between the parties.<sup>16</sup> With respect to this sub-condition, the Proposed Rule solicits comments on any arrangements between PBMs and manufacturers that take into account the volume or value of referrals or business otherwise generated, but that would nevertheless pose a low risk of fraud and abuse.<sup>17</sup>

BIO recommends that HHS specifically exempt from this sub-condition any arrangement that involves varying numbers of transactions, provided that the fee for each individual transaction is fixed in advance and consistent with fair market value in an arm’s-length transaction. By way of example, suppose a PBM enters into an arrangement that involves a variable number of transactions, ranging from 10 transactions to 100 transactions each month. Under this arrangement, it is logical that the manufacturer pay the PBM on a per-transaction basis (i.e., a flat dollar amount per transaction). In this case, the aggregate service fee payment would vary month over month and year over year, depending on the business generated between the parties: the transactions. Further, the fair market value of the services at issue may well vary depending on the volume of services the PBM provides. For example, the fair market value of 100 units of service would likely exceed the fair market value of 10 units of service, creating a potential conflict between the “volume or value” requirement and the requirement for a fair market value fee. To facilitate practical service fee arrangements between manufacturers and PBMs, BIO recommends that HHS clarify that this type of arrangement, despite taking into account the business generated between the parties, presents a low risk of fraud and abuse and is therefore protected under the proposed safe harbor. Alternatively, HHS could clarify that the requirement that fees under a particular contract should not be determined in a manner that takes into account the volume or value of business “otherwise” generated between the parties does not preclude per-unit fees based on the volume or value of services provided by the PBM under that contract.

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<sup>16</sup> 84 Fed. Reg. at 2350.

<sup>17</sup> 84 Fed. Reg. at 2350.

## VI. Definition of Fair Market Value

As proposed, one part of the second sub-condition for an arrangement protected under the proposed safe harbor for PBM service fees is that the service fees contemplated by the arrangement must be consistent with fair market value (FMV) in an arm's-length transaction.<sup>18</sup> HHS does not propose a specific definition of FMV in the Proposed Rule. BIO agrees with HHS's decision to refrain from adopting such a definition. In particular, BIO recommends that HHS adopt the same approach to defining "fair market value" that it took in the 2016 Final Rule regarding covered outpatient drugs (2016 AMP Final Rule) in the context of "*bona fide* service fees." In the 2016 AMP Final Rule, HHS states that it believes "that manufacturers should retain flexibility in determining whether service fees are paid at fair market value in light of the constant changes in the pharmaceutical marketplace."<sup>19</sup> HHS determined, at that time, that it would not "mandat[e] a specific method or provid[e] further guidance on fair market value."<sup>20</sup> With respect to the proposed safe harbor for PBM service fees, HHS should adopt a similarly flexible approach to fair market value evaluation methodology.

## VII. Impact on Value Based Payment Arrangements

We appreciate HHS' acknowledgement in the proposed rule that value based payment arrangements are an important component of the evolving reimbursement landscape for prescription medicines. In part, by acknowledging HHS' intention that the proposed rule will not impact "existing protections for value-based arrangements" the Agency recognizes that these arrangements are playing an increasingly important role in the American healthcare system.<sup>21</sup> In fact, in a survey of payers conducted by The Health Care Payment Learning & Action Network, it was reported that in 2017 34% of payments across all markets were wrapped into some form of value-based arrangement – up from 29% in 2016.<sup>22</sup> Clearly these programs are growing, and we hope the system can continue to find ways to incentivize their adoption.

BIO is concerned, however, that the blanket prohibitions imposed by the revision of the Discount Safe Harbor will have unintended impacts on future value-based agreements in the Part D and Medicaid space. Specifically, many evolving value-based regimes rely on outcomes data for long-term treatment durability and/or disease endpoints that are reconciled between the manufacturer and the contracting counter-party at some point after the treatment is provided and payment is arranged. In many circumstances, if a product does not produce the anticipated outcome, then the manufacturer may be contractually obligated to refund some portion of the payment price — something that might be viewed as a rebate depending upon how the arrangement is structured. In these cases, while the endpoint and mandated post-payment refund are fixed in advance and set forth in an agreement, it may be difficult to ensure that the arrangement is appropriately structured to comply with the discount safe harbor to the AKS.

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<sup>18</sup> 84 Fed. Reg. at 2350.

<sup>19</sup> Final Rule with Comment Period, Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170, 5179 (Feb. 1, 2016)

<sup>20</sup> 81 Fed. Reg. at 5180. HHS has taken the same approach to FMV in the context of *bona fide* service fees excluded from Average Sales Price (ASP) calculations.

<sup>21</sup> 83 Fed. Reg. at 2348.

<sup>22</sup> See <http://hcp-lan.org/workproducts/apm-methodology-2018.pdf>

Critically, the long-term success of innovative value arrangements is crucial to patient health. Therefore, BIO strongly recommends that HHS promulgate a safe harbor for value-based arrangements through a future rulemaking process. One avenue for HHS' consideration is the recently announced Patient Affordability and Value Efficiency Act co-sponsored by Senators Cassidy and Warner.<sup>23</sup> Formal safe harbor protection for a variety of value-based arrangements, accompanied by protections for necessary data transfers and adherence counseling, may well offer the most promising avenue to solidify value-based payment arrangements within the healthcare lexicon. Nevertheless, we urge HHS to consider steps it could take short of this legislative vehicle to bridge the enforcement gap until a long-term solution can be finalized. Perhaps more flexibility in program guidance or more specific guidance within this final rule regarding how post-treatment outcomes arrangements can be structured to avoid the enforcement pitfalls could keep from chilling properly structured and low risk value-based arrangements.

### **VIII. Revising the Proposed Definition of “Chargeback”**

In the Proposed Rule, HHS's definition of “chargeback” requires that the manufacturer make a payment to the pharmacy such that the payment to the pharmacy is “at least equal” to the price agreed upon between the manufacturer and the Part D plan sponsor, Medicaid MCO, or PBM.<sup>24</sup> Based on this language, it is our understanding the HHS intends to ensure that the pharmacy receives sufficient payments to account for the pharmacy's medicine acquisition costs. But we believe that the language, as proposed, does not account for pharmacy costs to dispense medicines, and the language that indicates that the payments to the pharmacy are “at least equal” to the price agreed upon between the pharmacy and the plan/PBM could result in situations where the pharmacy is not made whole.

Therefore, we urge HHS to finalize that the payment to the pharmacy is the amount agreed upon between the manufacturer and the Part D plan sponsor, Medicaid MCO, or PBM, and that it “includes” the payment to the pharmacy from the plan or PBM, the manufacturer chargeback, and then beneficiary cost sharing amount. In this way, HHS would clarify that the intent of the safe harbor for point-of-sale price reductions is to make the pharmacy financially whole.

### **IX. Changes to the Current Regulatory Discount Safe Harbor Must be Solely Prospective**

Based upon an interpretation of the preamble to the Proposed Rule, BIO understands HHS to be prospectively changing the scope of the regulatory discount AKS safe-harbor protections. To provide important clarity for all stakeholders, BIO recommends that HHS make explicit that all changes to the AKS safe harbors are prospective in nature only and will not be applied retroactively to activities preceding the effective date of the final rule. Moreover, we respectfully request that HHS consider enforcement discretion for stakeholders as they work

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<sup>23</sup> See <https://www.cassidy.senate.gov/imo/media/doc/PAVE%20Act.pdf>.

<sup>24</sup> See 84 Fed. Reg. at 2363.

diligently to address implementation challenges in the course of timely and good-faith implementation of the proposed rule.

Notwithstanding some ambiguous discussion in a footnote to the preamble of the proposed rule, BIO sees the proposed rule as articulating a *change* in the way that rebates to Part D plans and Medicaid MCOs should be treated under the AKS and associated safe-harbors. For example, the Proposed Rule proposed to “update” the regulatory discount safe harbor and requests feedback on the financial arrangements that “no longer” would meet the definition of a “discount” under the proposed changes.<sup>25</sup> And HHS acknowledges the historical interpretation of the AKS safe-harbors and their applicability to rebate arrangements. HHS’s rule is “offer[ing] bright line guidance” about the treatment of rebate arrangements between manufacturers and PBMs that have been a central attribute of Medicare Part D since its inception.

The signal that HHS is changing the scope of the relevant AKS safe-harbors is supported by the Department’s historical treatment of rebate arrangements. Numerous examples exist of HHS’s knowledge of these arrangements as it has on multiple occasions published guidance instructing how they should be handled. HHS has stated explicitly that PBM-retained rebates benefit the plan sponsor (and Part D) as well as rebates that the PBM passes through to the plan sponsor. For example, in response to a comment asking HHS for clarification, for purposes of DIR reporting, about the classification of rebates retained by a PBM, HHS stated that:

Rebates received from a manufacturer, whether directly or indirectly through a PBM, are price concessions that reduce the drug costs incurred by the Part D sponsor and therefore, are considered direct and indirect remuneration (DIR). To the extent that rebates are retained by a PBM, the dollar amount retained by the PBM represents an administrative fee which the Part D sponsor has paid to the PBM. Thus, the Part D sponsor essentially uses the remuneration from the manufacturer that the PBM retains to pay a portion of the Part D plan’s administrative costs. As a result, when developing Part D bids, Part D sponsors should report this amount as an administrative cost.<sup>26</sup>

HHS has also implicitly and explicitly recognized the current use of rebate arrangements through its Medicare Part D direct and indirect remuneration (DIR) reporting requirements, which require Part D plans to report all DIR associated with their plan, including rebates and other price concessions received by PBMs on behalf of Part D plan sponsors (specifically including “PBM Retained Rebates”).<sup>27</sup> For example, the instructions for DIR #1, “PBM

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<sup>25</sup> See 84 Fed. Reg. at 2340, 2343, 2348.

<sup>26</sup> CMS, Final Rule, Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions 74 Fed. Reg. 1494, 1513 (Jan. 12, 2009) (emphasis added).

<sup>27</sup> Per CMS’s instructions, “DIR is any form of price concession, received either by the Part D sponsor or by an intermediary contracting organization (a Pharmacy Benefits Manager, or PBM, for instance) with which the sponsor has contracted, from any source (including manufacturers, pharmacies, enrollees, or any other person or entity) that serves to decrease the costs incurred under the Part D plan by the Part D sponsor, either directly or indirectly. Thus, DIR includes discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal action, and other price concessions or similar benefits.” See CMS Final Medicare Part D DIR Reporting Requirements for 2017 (May 30, 2018); see also 42 C.F.R. § 423.308.

Retained Rebates,” instruct plans to “not include any rebates passed through to the Part D sponsor [which are reported in another field]...[and i]nclude all manufacturer rebate associated with the Medicare prescription drug benefit retained by the PBM and not passed through to the plan sponsor.”<sup>28</sup>

Through DIR reporting, CMS collects information about manufacturer rebates related to Part D plans.<sup>29</sup> Specifically, DIR reports must include information about rebates and other price concessions received by PBMs and Part D plans from manufacturers.<sup>30</sup> This information includes the portions of a rebate retained by a PBM, and the rebates paid to the PBM for “Formulary Access/Tier Placement,” which is defined as “rebates received for inclusion of a drug on the plan’s formulary or favorable tier placement.”<sup>31</sup> By collecting this information, HHS necessarily understands, and therefore has implicitly approved, PBMs negotiating and collecting rebates under the current Medicare Part D system.

In light of HHS’s intent to change the scope of the AKS safe-harbors in the proposed rule, and HHS’s long-standing recognition that rebate arrangements between manufacturers and Part D plans (and their PBMs) have been a central feature of the healthcare system in the U.S. protected under the regulatory discount safe harbor, we urge the Department to make explicit the prospective application of the changes to the regulatory discount safe harbor. Further, HHS should make clear that any existing written arrangements 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 said date, may be lawfully paid and received post-January 1, 2020.

Finally, we request that, as was done in 1991 and again in 1999 when significant changes to the safe harbor regulations were made,<sup>32</sup> OIG exercise its enforcement discretion while manufacturers, Part D plan sponsors, PBMs, MCOs and other stakeholders with existing

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<sup>28</sup> CMS, Final Medicare Part D DIR Reporting Requirements for 2017, 20 (May 30, 2018).

<sup>29</sup> See generally CMS, 2014 Part D Rebate Summary for All Brand Name Drugs, available at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/PartD\\_Rebates.html](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/PartD_Rebates.html).

<sup>30</sup> Per CMS’s instructions, “DIR is any form of price concession, received either by the Part D sponsor or by an intermediary contracting organization (*a Pharmacy Benefits Manager, or PBM, for instance*) with which the sponsor has contracted, from any source (including manufacturers, pharmacies, enrollees, or any other person or entity) that serves to decrease the costs incurred under the Part D plan by the Part D sponsor, either directly or indirectly. Thus, DIR includes discounts, chargebacks, *rebates*, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal action, and other price concessions or similar benefits.” See CMS Final Medicare Part D DIR Reporting Requirements for 2017 (May 30, 2018) (emphasis added). See also 42 C.F.R. § 423.308.

<sup>31</sup> CMS Final Medicare Part D DIR Reporting Requirements for 2017 (May 30, 2018) (emphasis added) (“Such price concessions must be reported as DIR in the Summary and Detailed DIR Reports *regardless of whether the intermediary contracting organization retains all or a portion of the price concession or passes through the entire amount to the sponsor*”). Additionally, “PBM retained rebates” are specifically listed as “Remuneration Considered DIR.” *Id.*

<sup>32</sup> See, e.g., preamble to 1991 Final Rule, at 56 FR 35955 (“This regulation is intended to provide a formula for avoiding risk in the future.”); 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.”)

contractual arrangements work to implement the proposed rule. The proposed rule affects the core of a complex set of existing contracting and regulatory arrangements between multiple stakeholders, and where drug pricing and contractual arrangements drive formulary design, financial projections, and underwriting. Implementation will be difficult, but we are committed to timely implementation of the rule if it is finalized; however, our efforts to ensure compliance will require new types and forms of arrangements and fast implementation that may introduce unforeseen complexities through no fault of the parties acting in good faith. Accordingly, we seek an acknowledgment that our diligence, compliance-minded efforts will be viewed with fairness by OIG in the future.

### **Conclusion**

As stated at the outset, BIO and our members believe that finalization of this proposed rule would be a critical step forward in helping to facilitate better patient access to the significant price reductions passed along by our members into the US supply chain. And while our technical comments, if adopted by HHS, will help streamline implementation of the rule and ensure it can be operated effectively, we nevertheless support both the finalization of the rule and the implementation deadlines set forth in the proposal. We look forward to working with HHS as this proposal advances to completion and would be happy to discuss more in-depth any of our suggestions.

Please do not hesitate to contact us with follow-up questions.

Sincerely,

/S/

John A. Murphy III

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