



April 8, 2019

Aaron Zajic
Office of Inspector General
U.S. Department of Health and Human Services
Room 5527, Cohen Building
330 Independence Ave. SW
Washington, DC 20201

RE: Comment on the Proposed Rule for the 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 Fees (OIG-0936-P)

Dear Mr. Zajic:

The Association for Accessible Medicines (AAM) and the Biosimilars Council (the Council) appreciate the opportunity to provide comments in response to the agency's proposed rule for the *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 Fees* [OIG-0936-P]. AAM and the Council work to expand patient access to safe, quality, and effective FDA-approved generic and biosimilar medicines. This includes promoting a positive regulatory, reimbursement, political, and policy environment for and supporting education about the safety and effectiveness of generics and biosimilars. As manufacturers of nine out of every 10 small molecule prescriptions dispensed in the U.S., our members are integral parts of the health care system for America's patients.¹

Generic and biosimilar medicines play a critical role in reducing drug prices for beneficiaries and federal health programs alike. The Administration should ensure that federal programs encourage the use of lower-cost therapeutically equivalent generics and biosimilars to increase pharmaceutical competition and reduce patient out-of-pocket costs. We believe the proposed rule is an important step toward such goal.

We applaud the Administration's continued commitment to innovative, market-based solutions to the national problem of high drug prices as exemplified by both this proposed rule, and the Advanced Notice and Call Letter draft for Medicare Advantage and Part D plans for calendar year 2020 ("the Draft Call Letter").² We support eliminating opaque back-end rebates on branded drugs in the Medicare and

¹ Association for Accessible Medicines (AAM), *2018 Generic Drug Access & Savings in the U.S.* Available online: <http://RxAccessReport.us>.

² CMS. Part II of the 2020 Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part D Payment Policies (the Advance Notice) and Draft Call Letter. Released January 30, 2019. Available at: <https://go.cms.gov/2sWmV4d>. AAM commented that CMS should ensure that generics and biosimilars are

Medicaid programs to increase patient access to cost-effective generics and biosimilars. The core mission of the generics and biosimilar medicines industry is to provide access to medicines while reducing prescription drug spending for both the government and beneficiaries. This was also the Congressional intent in enacting the 1984 Hatch-Waxman Act³ and the 2009 Biologics Price Competition and Innovation Act (BPCIA)⁴.

Increasing plan and patient adoption of more affordable generic and biosimilar medicines is vital in order to achieve the Administration's goals of lowering patient out-of-pocket costs and reducing federal spending on prescription drugs. In 2017 alone, competition from generic medicines saved more than \$265 billion for the U.S. health care system, including \$82.7 billion in savings for the Medicare program.⁵ Indeed, it has been well-documented that the dispensing of generics in Medicare Part D has produced significant savings to the federal government and Part D beneficiaries.^{6,7} Importantly, reports have also shown that additional savings could be achieved with greater generic substitution and competition among specialty and biologic products.^{8,9} Moreover, Part D beneficiary out-of-pocket costs remain high in drug classes that have few or no generic or therapeutic alternatives.

Increased adoption of biosimilars could significantly reduce Medicare drug spending. Brand biologics account for 95 percent of specialty drug spending in Medicare Part D, and specialty drug net prices increased at an average annual rate of 5.8 percent between 2010 and 2018—nearly six times the rate of inflation during that period.¹⁰ In contrast, biosimilars are, on average, priced 47 percent lower than their biologic competitors.¹¹

The Office of Inspector General (OIG) correctly highlights in the proposed rule that the current brand drug rebate system incentivizes utilization of products with higher list prices. Brand drug rebates provide

immediately included on more favorable formulary tiers with lower beneficiary cost-sharing. In the final Call Letter for calendar year 2020 released on April 1, 2019, CMS did not adopt these proposed formulary policies, citing opposition from Part D sponsors but did note that it would “continue to encourage Part D sponsors to prioritize formulary placement for generics and biosimilars through favorable tier placement relative to branded products.” CMS also noted “instances when Part D sponsors are not including generic alternatives” or “are not achieving optimal generic substitution.” AAM and the Council believe the goals of this proposed rule will not be achieved unless OIG and CMS ensure that any competing generic or biosimilar medicines with a lower net cost are included in the plan formulary in a lower cost-sharing, preferred formulary tier.

³ Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417 (1984).

⁴ Biologics Price Competition and Innovation Act (Public Law 111-148).

⁵ Association for Accessible Medicines (AAM), *2018 Generic Drug Access & Savings in the U.S.* Available online: <http://RxAccessReport.us>.

⁶ Sheingold S and Nguyen NX. Impacts of Generic Competition and Benefit Management Practices on Spending for Prescription Drugs: Evidence from Medicare's Part D Benefit. *Medicaid and Medicare Research Review*; 2014:4(1).

⁷ Congressional Budget Office (CBO). *Effects of Using Generic Drugs on Medicare's Prescription Drug Spending*. September 2010. Available online: <https://www.cbo.gov/publication/21800?index=11838>.

⁸ HHS Assistant Secretary for Planning and Evaluation (ASPE). Data Point: Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D. July 23, 2018.

⁹ Avalere Health. Medicare Part D Generic Drug Tiering Request for Comment: Implications for Patient Out-of-Pocket Spending and Part D Plan Costs." February 28, 2019. Available at: <https://bit.ly/2IDOdqG>.

¹⁰ CBO, *Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid*. (slide presentation) March 2019. Available at: <https://www.cbo.gov/publication/55041>.

¹¹ AAM Analysis of IQVIA WAC Data, February 2019.

a financial incentive for PBMs and plans to make formulary decisions based on rebate potential rather than on total net cost/reimbursement for a drug product. This burdens patients with higher cost-sharing and stifles competition from generics and biosimilars.

Thus, AAM and the Council generally support the proposal to remove the safe harbor protection for rebates paid by manufacturers to Medicare and Medicaid plans and/or their PBM agents. However, we note that the proposal's goal of increasing adoption of lower cost generic and biosimilar medicines will be incomplete without also finalizing CMS' proposal included in the 2020 Draft Call Letter to restrict brand and generic drugs to respective brand and generic tiers. Taken together, these proposals would decrease cost sharing for beneficiaries, incentivize lower list prices, and allow for greater competition among pharmaceutical manufacturers.¹²

Accordingly, we encourage OIG to:

1. Prohibit manufacturers from conditioning point-of-sale reductions in price on formulary requirements with respect to plan coverage of a competing generic or biosimilar drug, including requirements not to cover a generic or biosimilar or that it only be covered in a non-advantageous formulary tier;
2. Remove safe harbor protection for rebates paid to Medicare Advantage plans with respect to their coverage of Part B drugs, in favor of POS discounts on such drugs;
3. Explicitly prohibit "swapping" arrangements related to commercial, Medicare, and Medicaid business from safe harbor transactions;
4. Ensure that value-based contracts are not used to block competition;
5. Confirm that point-of-sale discounts are not permitted to operate like brand drug copayment coupons;
6. Maintain protection for purchase discounts traditionally available to wholesalers and pharmacies; and
7. Ensure that payments for chargeback processing are at fair market value and not "disguised kickbacks" related to formulary placement/exclusive arrangements.

Finalize the Proposal to Remove Safe Harbor Protection For Brand Drug Rebates And Ensure That Rebates Can Not Be Used to Block Lower-Cost Competition

Plans and PBMs rely on manufacturer rebates to reduce their net costs for pharmaceuticals. Unfortunately, this can create a perverse incentive favoring the use of high-cost brand drugs. The consequences are particularly notable in the biosimilars market. For example, infliximab biosimilars have been excluded from payor coverage and are unable to garner significant market share relative to the reference product. This is despite being on the market for over two years and with an Average Sales Price (ASP) 20 percent lower than the brand and a Wholesale Acquisition Cost (WAC) that is an average of 27 percent lower.¹³ As a result, multiple stakeholders have sued the brand manufacturer of

¹² In the final Call Letter for calendar year 2020 released on April 1, 2019, CMS did not adopt proposed formulary policies we suggested related to generic and biosimilar formulary coverage and tier placement, citing opposition from Part D sponsors. We believe the goals of this proposed rule will not be achieved unless OIG and CMS ensure that any competing generic or biosimilar medicines with a lower net cost are included in the plan formulary in a lower cost-sharing, preferred formulary tier.

¹³ CMS ASP Pricing Files. April 2019.; AAM Analysis of IQVIA NSP Market Share February 2019.

Remicade alleging use of exclusionary contracts and bundled rebates conditioned on multi-year biosimilar exclusion.¹⁴ This is not an isolated example. Pegfilgrastim biosimilars' average WAC is 32 percent lower than the reference product, have a 10 percent lower ASP and have also been unable to garner market share from the brand.¹⁵

Generic drug manufacturers typically do not provide rebates to PBMs, but rather compete through lower list prices and discounts provided to wholesalers, pharmacies and other purchasers of their products, such as hospitals (referred to as purchase discounts). Generic medicines enter the market at a significantly lower price to purchasers than the brand product and typically experience rapid price declines. In fact, generic drugs are launching at a greater discount, declining in price, and ultimately reaching a lower price point than at any time in the last 20 years.¹⁶

Competition in the pharmaceutical marketplace from generic and biosimilar medicines provides America's patients with relief from monopoly prices for branded drugs. However, although the net cost of a generic or biosimilar product is generally lower than the net cost (after rebate) of the brand, the value of high rebates on brand drugs, combined with the impacts of beneficiary cost-sharing differences and Part D subsidies/program design, may cause plans to give equivalent or preferential tier placement to higher-cost brand drugs. The result is lower patient access to safe, effective, and cost-efficient generic and biosimilar products, higher out-of-pocket spending, and increased program/taxpayer costs.

This practice, whereby brand manufacturers can limit access to therapeutically equivalent generics and biosimilars by conditioning brand rebates on plan or PBM exclusion of a generic or biosimilar competitor, is a result of the distorted incentives of the rebate system. These "rebate traps" threaten the viability of the generic and biosimilar markets. They occur when, upon entry of a biosimilar or complex generic, a reference manufacturer (who has significant market share due to more than a decade of exclusivity) threatens to remove the rebates provided to payors unless the generic or biosimilar are effectively excluded from lower formulary tiers or the entire formulary. Some brand manufacturers have even threatened to withdraw the rebates on a bundle or portfolio of unrelated products if the contracted entity utilizes a biosimilar or generic in place of the reference product.¹⁷

In such a situation, an insurer must decide whether to keep the lower-priced competitor off its formulary or pay the full, non-rebated list price for the reference product. The rebate trap can pressure plans to cover only the reference product, to protect the plan's access to the rebates. In a market free from rebate traps, a plan may be able to use cost-sharing or utilization management to steer new patients towards the most cost-effective treatment.

The following table shows a hypothetical example of the rebate trap in practice. The scenario involves withdrawal of a rebate for the reference biologic that was previously available upon coverage of a

¹⁴ Center for Biosimilars. "Walgreen, Kroger File Antitrust Suit Against J&J, Janssen Over Remicade". June 11, 2018. Available: <https://bit.ly/2u76AKg>.

¹⁵ CMS ASP Pricing Files. April 2019.; AAM Analysis of IQVIA NSP Market Share February 2019.

¹⁶ IQVIA Institute for Human Data Science Analysis conducted for AAM (1994-2014). Data reflects pricing trends for newly introduced generic products separated by year.

¹⁷ USA Today: "Pfizer accuses Johnson & Johnson of 'anticompetitive practices' in lawsuit." September 20, 2017. Available at: <https://usat.ly/2xgWxFW>.

biosimilar. This “trap” acts as a significant disincentive to add a biosimilar to the formulary or carry the product, making it difficult for the biosimilar to gain any significant market share.

	Pre-Biosimilar	Post-Biosimilar	
		50% of Patients Switch	100% of Patients Switch
Reference biologic list price, US \$	50,000	50,000	50,000
Reference biologic postrebate price, US \$	25,000	NA (no longer offering rebate)	NA (no longer offering rebate)
Biosimilar price, US \$	NA	10,000	10,000
Patients taking branded biologic, No.	1,000	500	0
Patients taking biosimilar, No.	NA	500	1,000
Payer cost, US \$	25,000,000	30,000,000	10,000,000

Source: Hakim A, Ross JS. Obstacles to the Adoption of Biosimilars for Chronic Diseases. JAMA. 2017;317(21):2163–2164. doi:10.1001/jama.2017.5202

If a biosimilar manufacturer does not believe it will be able to wrestle any of the market away from the reference product, it has little incentive to invest in the development of these products in the first place. This dynamic creates a significant incentive for the plan to block the adoption or coverage of the generic or biosimilar in order to retain the brand rebate.

This pricing decision can impact the prices paid for other products, too, given the use of these bundled arrangements. These aggressive negotiation tactics, which block lower-priced biosimilar and complex generic medicines from being available to patients, also discourage future investment in developing new biosimilar and complex generic products.¹⁸ Both HHS Secretary Alex Azar and former FDA Commissioner Gottlieb have criticized the use of “rebate traps” and have made persistent efforts to increase the competitiveness of the market. Former FDA Commissioner Gottlieb specifically noted:

“Manufacturers are using several schemes to hamstring biosimilar competition... restrictive contracting, rebating, and distribution agreements deter coverage and reimbursement...the net result is a lopsided playing field that disincentives biosimilar developers from making the sizable investment in bringing such products to market. I am concerned this will lead to reduced competition in the long-run and unsustainable costs.”¹⁹

Modify the Safe Harbor Protecting Point-of-Sale Price Reductions to Exclude Protection for Point-of-Sale Discounts Conditioned on Formulary Requirements with Respect to Plan Coverage of a Competing Generic or Biosimilar Drug

Exclusionary Arrangements/Contracts Threaten the Market for Generic and Biosimilar Products

Current brand drug rebating strategies threaten access to effective and cost-efficient generic and biosimilar products. These strategies include the use of exclusionary agreements – contracts with plan

¹⁸ Biosimilar Development: “Why So Slow? Demystifying the Barriers to U.S. Biosimilar Adoption.” Available at: <https://bit.ly/2BxnHbj>. Accessed: May 15, 2018.

¹⁹ CNBC Interview of FDA Commissioner Gottlieb, March 28, 2018. Available at: <https://cnb.cx/2pNVVlh>.

sponsors or PBMs that condition rebates on the plan or the PBM's exclusive placement of the brand or biologic product on formulary or tiers with lower cost sharing to the detriment of patient access to a generic or biosimilar competitor with a lower net cost.

However, the proposed rule does not address exclusionary arrangements. These arrangements would have a similar negative effect on the market as back-end rebates: higher government spending and beneficiary out-of-pocket costs. AAM and the Council recommend that OIG eliminate safe harbor protection for point-of-sale price reductions conditioned on exclusive or preferred formulary placement when there are generic or biosimilar competitors.

Bundled Discounts Improperly Protect Brand Drugs with Generic Competition and Disadvantage the Generic Drug Market

“Stacked” or “bundled” rebates are the most pernicious form of exclusionary contracts. In these contracts, the manufacturer of an originator product conditions rebates or discounts for a range of products produced by that manufacturer (the “bundle”) on the contracted entity covering a biosimilar or generic in an equivalent or less favorable manner than the brand drug—or not covering the biosimilar or generic at all. This bundling can lead to higher spending for beneficiaries and can improperly restrict access to lower-cost generics and biosimilars.²⁰ AAM and the Council recommend that OIG eliminate safe harbor protection for bundled point-of-sale price reductions containing any formulary requirements relating to coverage of a generic or biosimilar.

Multi-Year Contracts Delay Generic and Biosimilar Access and Adoption and Thwart Competition

While multi-year discount arrangements are not inherently concerning, they can be when used in an anticompetitive manner. However, once a brand drug product loses patent exclusivity and a generic enters the market, the generic is typically significantly cheaper than the brand drug. But the proposal would not prevent brand manufacturers from anticipating generic or biosimilar competition and seeking to delay it through multi-year formulary contracts that continue after the introduction of a lower cost generic or biosimilar product to the market. Under a multi-year contract, a plan sponsor or PBM may not be able to add the generic or biosimilar to formulary or prefer the generic drug without violating the terms of its multi-year rebate or discount agreement. This runs counter to the OIG's goal of preventing arrangements that increase costs for the government and beneficiaries. Therefore, AAM and the Council recommend that OIG eliminate safe harbor protection for point-of-sale price reductions for multi-year formulary arrangements.

Safe Harbor Protection Should also be Removed with Respect to Brand Manufacturer Rebates for Part B Drugs Covered under Medicare Advantage Plans

The proposed rule also solicited comments on whether this exclusion should apply to rebates on drugs and biologics covered under other aspects of Medicare.²¹ AAM urges OIG to similarly remove safe harbor protection for brand manufacturer rebates paid to Medicare Advantage plans with respect to Part B drugs and biologics, at least once generic drugs or biosimilars are available. Biosimilars are often covered as Part B products rather than under Part D because they are administered by a physician. In order to realize the promise of biosimilar competition, they must compete on a level playing field. The

²⁰ FDA Head: On Board with ‘Right To Try’. MEDPAGETODAY. Available at: <https://bit.ly/2J1bNjX>.

²¹ 84 Fed. Reg. at 2347.

same anticompetitive effects related to brand rebates described above can apply in the context of a Medicare Advantage plan's treatment for Medicare Part B drugs. Accordingly, AAM supports a further limitation on safe harbor protection with respect to Part B/Medicare Advantage rebates. This limitation is particularly important for Medicare Advantage and Medicare Advantage Prescription Drug (MA-PD) plans, given the utilization management flexibility of Medicare plans.²²

Eliminate Safe Harbor for Point-of-Sale Price Reductions when there is a Generic or Biosimilar Competitor unless the Generic or Biosimilar is Placed on a Lower Formulary Tier

As explained earlier, rebates are commonly used by brand manufacturers to gain preferred tier or formulary placement for their brand drugs relative to competitors. As a result, plans increasingly have been putting lower cost generics on higher formulary tiers that command higher beneficiary cost sharing. The removal of the safe harbor in this proposed rule would be an important first step towards protecting generics from being blocked from formulary. However, the proposed rule falls short as nothing would preclude brand manufacturers from conditioning point-of-sale price reductions on formulary placement and positioning related to a competing generic or biosimilar product.

Recent data indicates that generic drugs are increasingly being placed on higher tiers with higher cost-sharing, sometimes in a disadvantaged position compared to the higher cost brand reference drug. A 2018 Avalere Health report found that between 2011 and 2015, the percent of generic drugs placed on tier 1—the lowest cost-sharing tier available for patients—fell from 71 to 19 percent.²³ The shift of generics to higher tiers occurred equally among both high and low-cost generics even though prices for generic drugs generally declined between 2006 and 2017.²⁴ Similarly, the OIG recently found that between 2011 and 2015, reimbursement for Part D brand drugs increased by 77 percent, despite a 17 percent decrease in the number of prescriptions for these drugs.²⁵ A more recent report from Avalere found that between 2016 and 2018, plans increasingly shifted generics from tier 2 to tier 4, resulting in even higher cost-sharing for generics.²⁶ Meanwhile, as patients spent more out-of-pocket, federal payments for catastrophic coverage under Part D more than tripled to \$33.2 billion between 2010 and 2015.²⁷

AAM and the Council are concerned that branded drug manufacturers will continue their current anticompetitive rebate practices using the new point-of-sale reductions by tying the point-of-sale reductions to formulary positioning of a branded product related to generics and biosimilars. As such, we recommend that OIG eliminate safe harbor for the point-of-sale price reduction for a branded

²² CMS Notice to Medicare Advantage Organizations. "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage." August 7, 2018. Available: <https://go.cms.gov/2M2h21m>.

²³ Avalere Health: "Generic Drugs in Medicare Part D: Trends in Tier Structure and Placement." May 22, 2018). Available at: <https://bit.ly/2kx8clP>.

²⁴ *Ibid.*; Medicare Payment Advisory Commission (MedPAC) Report to Congress: Medicare Payment Policy. Ch. 14: The Medicare Prescription Drug Program (Part D) Status report. March 2019. Available at: <https://bit.ly/2Tlbugn>.

²⁵ HHS Office of Inspector General (OIG), Increases in Reimbursement for Brand-Name Drugs in Part D (2018).

²⁶ Avalere Health: Medicare Part D Generic Drug Tiering Request for Comment: Implications for Patient Out-of-Pocket Spending and Part D Plan Costs." February 28, 2019. Available at: <https://bit.ly/2IDOdqG>.

²⁷ HHS OIG, High Price Drugs Are Increasing Federal Payments for Medicare Part D Catastrophic Coverage (2017).

pharmaceutical if there is a competing generic or biosimilar with a lower net cost unless the generic or biosimilar is included in the plan formulary in a lower, preferred formulary tier.

Explicitly Prohibit “Swapping” Arrangements Related to Commercial and Medicare/Medicaid Business

“Swapping” occurs when a supplier, such as a pharmaceutical manufacturer, offers a substantial discount or rebate for one or more products related to a plan issuer’s commercial business in exchange for favorable coverage or formulary placement across all of the issuer’s products including Medicare and Medicaid business. This can effectively mean that commercial discounts are being used to gain favorable Medicare or Medicaid coverage. OIG has historically stated that “swapping” arrangements do implicate the AKS. However, existing regulatory and statutory text do not state this explicitly.

AAM and the Council recommend OIG clarify, in regulatory text, that any “swapping”-style arrangement would not be protected under any safe harbors or exclusions from AKS liability, including the proposed safe harbors.

Ensure Value-Based Arrangements are Not Used to Block Competition

OIG states that the proposed rule is not intended to impact current or future value-based arrangements (VBAs), and the Administration has consistently supported VBAs as innovative contracting arrangements. However, it is important to establish clear guardrails to prevent brand drug manufacturers from using VBAs as an avenue to block use of lower-cost generics or biosimilars. For example, a manufacturer might create a risk-sharing arrangement that includes a post point-of-sale price reduction tied to an inconsequential or easily satisfied value assessment that effectively acts like a rebate.

AAM and the Council urge OIG to protect against anticompetitive VBAs that effectively frustrate this proposed rule. OIG should make clear that VBAs tied to conditions that block generic or biosimilar formulary/tier coverage do not fall under an AKS safe harbor.

Maintain Protection for Purchase Discounts

In the preamble to the proposed rule, OIG states:

“The Department intends for the discount safe harbor to continue to protect discounts on prescription pharmaceutical products offered to other entities [other than Part D plan sponsors, Medicaid Managed Care Organizations (MCOs) or their PBMs], including, but not limited to, wholesalers, hospitals, physicians, pharmacies, and third-party payors in other Federal health care programs.”²⁸

HHS specifically solicits comment on whether the proposed safe harbor text excludes reductions in price not consistent with this intent.

We believe that the proposed amendment could inadvertently restrict purchase discounts for which HHS intends to preserve safe harbor protection. The amendment as drafted would remove protection for:

²⁸ 84 Fed. Reg. at 2348.

“A reduction in price or other remuneration from a manufacturer in connection with the sale or purchase of a prescription pharmaceutical product to [a Part D plan sponsor, Medicaid MCO or PBM acting under contract with either], unless it is a price reduction or rebate that is required by law.”

We are concerned that the proposed language could be read to remove protection for common purchase discounts that generic or biosimilar manufacturers provide to wholesalers or pharmacies, if those discounted products are later dispensed by the pharmacy to a Part D or Medicaid MCO enrollee. Specifically, such discounts could be construed as being made “in connection with” a “sale” of a product (from the manufacturer to the wholesaler or pharmacy) and a “purchase” (by the Part D plan, Medicaid MCO, or PBM) of that product from the pharmacy. Given how important purchase discounts are to competition between generic and biosimilar manufacturers, frequently resulting in large reductions from those products’ already-low list prices, it is critical that discount safe harbor protections clarify that discounts to wholesalers are protected.²⁹

Ensure That the Final Rule Does Not Inadvertently Permit Point-of-Sale Price Reductions to Operate Like a Branded Drug Manufacturer Coupon Program for Medicare and Medicaid Beneficiaries

While we believe it is clear from OIG’s discussion of the proposed rule and from the current statutory prohibition that HHS does not have this intent, we are concerned that the proposed safe harbor could be read to allow point-of-sale price reductions to operate in a manner similar to brand drug manufacturer coupon programs—a practice considered to implicate the AKS by OIG.^{30,31} As such, we recommend that the safe harbor language be revised to ensure this unintended result is prevented.

Specifically, subsection (cc)(1)(iii) of the proposed new safe harbor sets forth the following requirement:

- (iii) The reduction in price must be completely applied to the price of the prescription pharmaceutical product charged to the beneficiary at the point-of-sale.³²

We are concerned that the foregoing reference to the “price of the prescription pharmaceutical product charged to the beneficiary” might be read to mean that a point-of-sale price reduction would be applied only, or first, to the cost-sharing amount otherwise payable by the beneficiary (e.g., their copayment or coinsurance amount), rather than to the entire price of the drug. If so, a brand drug manufacturer might provide a point-of-sales price reduction that would pay the beneficiary’s copayment or coinsurance amount, incentivizing use of the brand over lower-priced generics and biosimilars still subject to a copayment or coinsurance amount.

²⁹ Cf. 81 Fed. Reg. 5170, 5227 (Feb. 1, 2016) (recognizing distinction between retail pharmacy purchase discounts and payor rebates in connection with Medicaid rebate program average manufacturer price reporting rules).

³⁰ See, e.g., OIG Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons (Sept. 2014) (emphasizing need for coupon programs to maintain effective processes for administering federal program patient “carve outs”).

³¹ OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed.Reg. 70623, 70625 (Nov. 22, 2005).

³² 84 Fed.Reg. at 2363.

We recognize that this is not the intent of the proposed rule. Accordingly, we recommend that OIG ensure that the new safe harbor does not inadvertently permit co-payment coupons for federal health care program beneficiaries.

Ensure That Payments for Chargeback Processing Related to Point-of-Sale Price Reductions are at Fair Market Value and Not “Disguised Kickbacks” Related to Formulary Placement or Exclusive Arrangements

One of the operational challenges under the new safe harbor will be ensuring that pharmacies can collect payment for chargebacks associated with point-of-sale price reductions. HHS has not defined which entity or entities would process chargebacks.

Whichever entity or entities end up administering the chargebacks will likely charge manufacturers a fair market value fee to process such chargebacks. It is important for the OIG to set parameters for how fair market value is or can be defined. This is critical to ensure that manufacturers do not use these chargeback fees as a way of recreating the current rebating arrangements that OIG has proposed to remove from safe harbor protection through chargeback administration fees.

AAM and the Council recommend that OIG limit the ability of brand drug manufacturers to structure fees to mimic rebates. We recommend that OIG prescribe a form for a chargeback administration fee, such as a per chargeback, and also that OIG mandate that chargeback administration fees not vary substantially by manufacturer or by drug. Such chargeback administration fees should reflect only the cost of administering the chargeback. Generic and biosimilar manufacturers could be disadvantaged in negotiations with plans if brand manufacturers can pay high fees to health plans and/or their PBMs that are explicitly or implicitly related to formulary placement, resulting in diminished patient access to affordable medicines.

Conclusion

We commend HHS for its bold approach to addressing the entrenched rebate system that creates a perverse incentive for higher brand drug prices. As the proposed safe harbor rule highlights, increasing formulary controls and generic utilization would enhance Part D plans’ ability to negotiate to achieve lower drug prices and would likely lead to a decrease in beneficiary and federal spending on premiums, as envisioned by the President’s Blueprint. HHS should employ all the levers and oversight powers at its disposal to ensure taxpayers and the greatest number of beneficiaries benefit from lower list prices and the value of FDA-approved generics and biosimilars. These measures would ensure increased, fairer competition in the pharmaceutical market and reduced spending for both government programs and beneficiaries alike.

The shift to generics would also further the Administration's goals to promote a robust biosimilar and specialty generic market and lower beneficiary cost-sharing. Additionally, these changes would promote savings for the broader Medicare program as more patients not only use lower-cost generics but also experience lower medical costs as a result of better care and medication management.³³

We appreciate the opportunity to provide these comments. If you have any additional questions, please do not hesitate to contact me at (202) 249-7100 or Christine.Simmon@accessiblemeds.org.

Sincerely,

A handwritten signature in blue ink, appearing to read "C. M. S.", with a stylized flourish at the end.

Christine Simmon

Senior Vice President Policy & Strategic Alliances, AAM

Executive Director, Biosimilars Council

³³ CBO. Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services. November 2012. Available at: <https://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf>.