

VIA ELECTRONIC SUBMISSION

The Honorable Alex M. Azar II
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: 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 (OIG-0936-P)

Dear Secretary Azar:

The Robert J. Margolis, MD Center for Health Policy at Duke University (The Duke-Margolis Center) appreciates this opportunity to comment on the Department of Health and Human Services (HHS) Office of Inspector General's (OIG) proposed rule ("Proposed Rule") captioned above.

The Duke-Margolis Center was established in January 2016 with a founding gift from Duke University School of Medicine alumnus Robert J. Margolis and his wife Lisa, through the Robert and Lisa Margolis Family Foundation.

The Duke-Margolis Center brings together capabilities that generate and analyze evidence across the spectrum of policy to practice, supporting the triple aim of healthcare—improving the experience of care, the health of populations and reducing the per capita cost. The Duke-Margolis Center's activities reflect its broad multidisciplinary capabilities, fueled by Duke University's entrepreneurial culture. It is based at the Fuqua School of Business, with staff and offices in both Durham and Washington, DC, and collaborates with experts on healthcare policy and practice from across the country and around the world.

A core mission of the Duke-Margolis Center is to focus on increasing the value of biomedical innovation to patients—both through better health outcomes and lower overall healthcare costs.

The comments provided below are part of a broader analysis undertaken by the Value-Based Payment (VBP) for Medical Products Consortium (described below) of the current legal and regulatory environment and its potential impact on the expansion of VBP arrangements.

In this document, we discuss:

1. The growing importance of VBP arrangements for medical products.
2. The existing uncertainty under the Anti-kickback Statute (AKS) for VBP arrangements, the need for clarity on how VBPs will be protected under the Proposed Rule, and the need for a new VBP-specific safe harbor to protect these arrangements, particularly if the Proposed Rule is finalized.
3. Examples of VBP arrangements that may implicate the AKS under the Proposed Rule but should be protected.
4. Recommendations for providing more clarity for VBP arrangements and designing a VBP safe harbor to benefit patients.

1. The Importance of Value-Based Payment Arrangements for Medical Products

Biopharmaceutical and medical device innovation is broadly viewed a defining feature of the United States healthcare system. Rapid innovation in these industries promises to produce transformative therapies that will change the lives of patients with diseases previously considered intractable or in need of costly management.

Advances in innovation, however, are also reflected in the costs associated with medical products, which continue to rise. As a result, stakeholders are calling for new reimbursement models for biopharmaceutical and medical device products (together referred to as “medical products”) that help better align payments for these medical products with the value that they actually generate for patients.

In contrast to a fee-for-service (FFS) payment basis, in which total payments are generally tied to the volume and intensity of services, VBP arrangements for medical products are intended to align pricing and/or payments more closely to value in a population (e.g., outcomes relative to costs).

Implementation of VBP arrangements for medical products might be meaningfully viewed on a spectrum, beginning with payments that remain FFS-based but that are adjusted based on expected value, as determined by existing evidence (e.g., indication-based pricing). More advanced models exist along the spectrum and include outcomes-based contracts (OBCs) that link payments to a product’s actual performance or value in a patient or a population.

These VBP arrangements encourage greater coordination to improve outcomes and lower overall costs for the patient population treated, including but not limited to enabling the development of more robust evidence on how treatments work and how they can be improved in real-world settings.

VBP arrangements for medical products are still relatively early in implementation, however. Their slow development and adoption in the U.S. is attributable to numerous factors, including: the lack of consensus on what constitutes “value,” agreement on best measures, availability and

sharing of data, and other operational challenges. Regulatory and legislative policies can also have a significant impact on the shift from volume-based to evidence/outcomes-based payments.

In April 2017, The Duke-Margolis Center formed a first-of-its-kind consortium to address key practical issues in advancing VBP arrangements for pharmaceuticals, including gene therapies and gene editing technologies, and medical devices.

The Consortium Advisory Group—composed of patient advocates, payers, manufacturers, and providers, as well as experts on regulatory affairs, law, and policy—works to develop approaches to payment reform that support better outcomes for patients and better value across the system. The Consortium is providing practical solutions to legal and regulatory barriers, data and operational challenges, and financing for high-cost therapies.

2. Anti-Kickback Statute Uncertainty for Value-Based Payment Arrangements

I. Background

Compliance with the Anti-Kickback Statute (AKS) is an area of substantial concern for VBP arrangements. Because sharing valuable resources across organizations has understandably been perceived to increase the risk of fraud and abuse in volume-based, fee-for-service payment systems, the AKS and its safe harbors have generally viewed arrangements that involve care coordination and integration with skepticism due to the potential for increased volume billing. However, those concerns diminish for payments that are based on improving outcomes and lowering costs, which require healthcare organizations to work together in new ways to succeed in improving value rather than volume. As a result, the AKS and its existing safe harbors pose challenges for the implementation of VBP arrangements since their potential for increased value often depends on some degree of coordination and other types of resource sharing between the contracting parties.

Removing regulatory obstacles that hinder the shift to value-based payment has been a major concern for this Administration, as reflected in the RFIs issued by the OIG and the Center for Medicare & Medicaid Services (CMS) in 2018 concerning changes to the AKS and Stark Law, respectively, to better enable stakeholder participation in value-based models on the care delivery side. The Administration has further stated that this issue remains a key priority for 2019 and has acknowledged that the Stark Law, AKS, and other healthcare fraud and abuse regulations may prevent value-based care participation.

Under the existing AKS discount safe harbor, stakeholders have some flexibility to engage in VBP arrangements by allowing payers and manufacturers to link payment, in the form of rebates, to measures relating to a drug's impact on outcomes, utilization, and spending for affected populations of patients. However, this safe harbor also includes several elements, such as a requirement that, in some circumstances, the benefit from the discount must be realized within a maximum two years, which may hinder VBP arrangements. This highlights why a VBP safe harbor is needed for manufacturer-payer/provider arrangements even if the amendments contained

in the Proposed Rule are not finalized. But as discussed in further detail below, the proposed modifications to the discount safe harbor could significantly compound existing regulatory challenges in the shift of payments from volume to value. We do not believe that erecting further barriers to VBP arrangements is the Administration's intent.

To facilitate healthcare reform and the increasing transition towards value-based reimbursement, we believe that it is crucial that any AKS reforms for drug rebates are implemented in a way that advances the Administration's goals of promoting VBP arrangements, while preserving the AKS' central purpose of limiting fraud and abuse in federal healthcare programs. We believe that an appropriately-crafted safe harbor specific to VBP arrangements would be the best approach to achieving these two goals. A safe harbor specific to VBP arrangements would be particularly helpful for enrollees in public programs who depend on effective medicines, since VBP arrangements could encourage greater adoption of personalized medicine, improved medication adherence, greater development of robust real-world data and evidence, and other benefits that would increase the value of medications and care.

II. The Proposed Rule Has an Unintended Negative Impact on Value-Based Payment Arrangements

On January 31, 2019, HHS released the Proposed Rule that proposes to amend the current regulatory "Discount Safe Harbor" to eliminate protection for rebates in the context of Part D and Medicaid Managed Care Organizations (MCOs). The Proposed Rule would also introduce two new safe harbors.

In the Proposed Rule, HHS states that:

"The Department does not intend for this proposal to have any effect on existing protections for value-based arrangements between manufacturers and plan sponsors under Medicare Part D and Medicaid MCOs." (84 Fed. Reg. at 2348 (Feb. 6, 2019)).

While we appreciate the OIG's statement that it does not intend for the Proposed Rule to adversely impact VBP arrangements, we are concerned that the OIG provides little detail on how existing and future Medicare/Medicaid VBP arrangements would be protected, to the extent that they rely on the discount safe harbor as currently drafted. Therefore, despite its best intentions, the Proposed Rule could in fact inject significant uncertainty as to the treatment of VBP arrangements that involve rebate mechanisms, which in turn, could consequently have a broader chilling effect on stakeholders' appetite to pursue VBP arrangements. VBP-related rebates that are explicitly linked to the performance of a drug have the purpose of improving patient outcomes and care while aligning spend with value and are therefore inherently different from rebates that are simply linked to volume. For this reason, VBP-related rebates should not be discouraged by the Proposed Rule, as it effectively appears to do, despite the OIG's intention.

Additionally, we are concerned about the Proposed Rule's potential impact on Medicaid supplemental rebates, particularly in the context of Colorado's, Michigan's, and Oklahoma's efforts to align supplemental rebates with clinical outcomes and value. While CMS has expressed its commitment to giving states the flexibility they need to improve patient care and make healthcare more affordable and better aligned with value by allowing these states to implement supplemental rebate agreements involving VBP, the Proposed Rule may have the unintended consequence of discouraging or actually disallowing such arrangements given that such supplemental rebates are not "required by law" in the same way the mandatory minimum rebates are required by section 1927(c) of the Social Security Act.

3. Illustrative Examples of VBP Arrangements that Would Be Inhibited by the Proposed Rule

In this section, we provide two scenarios in which a drug manufacturer and a payer enter into a VBP arrangement that is likely to be discouraged by the Proposed Rule but, if allowed to be implemented, would have a positive impact on patient outcomes and healthcare utilization and costs.

Scenario 1: A payer has an arrangement with a manufacturer in which the manufacturer provides a discount of 30% of the drug's list price, which is fully passed on to plan members at the point of sale. The product's real-world performance is uncertain, so the manufacturer agrees in advance, in writing, to an additional 40% rebate if the drug does not achieve specified measure(s) of adherence, utilization, or outcomes related to the condition treated. The measures might be obtained on individually treated patients in the plan, or calculated across all relevant patients in the population.

If the Proposed Rule is finalized as is it is currently written, it appears that the second rebate (40%) would not warrant protection under the discount safe harbor because it does not represent a flat fee paid to the PBM, nor is it passed through at the point-of-sale. There may also be no other safe harbor that adequately protects this arrangement.

Scenario 2: A payer enters into a subscription/population-based arrangement with a manufacturer where the manufacturer agrees to provide a drug at a pre-specified price for a relevant population of patients, in exchange for a commitment from the payer to exclusive or near-exclusive formulary placement of that specified drug. In addition, the manufacturer agrees to an outcome-based rebate to the plan if certain outcome measures agreed on in advance are not met.

This arrangement would also appear to violate the AKS because the fixed price and potential outcome-based rebate in exchange for exclusive use of the manufacturer's product could be interpreted as remuneration (the outcome-based rebate) in exchange for arranging the furnishing of an item (through exclusive formulary placement) payable by a federal healthcare program. This scenario may be particularly relevant to Medicaid, where states—including Louisiana and Washington—are developing or have implemented population-based payment contracts and supplemental rebates related to outcomes for Hepatitis C treatments and potentially other drugs.

4. **Recommendations: More Clarity from the Administration Is Needed to Continue to Develop and Implement VBP Arrangements—Develop a VBP Safe Harbor**

Consistent with our goal of encouraging the development and implementation of diverse VBP arrangements to drive better patient outcomes, improve affordability of crucial medicines and care, and reduce system-wide costs, we propose the development of a new VBP-specific safe harbor to enable VBP arrangements for drug payments to continue and expand.

One of the main goals of the Proposed Rule is to promote patient benefits by seeking to end the “gross-to-net bubble” in which patients do not benefit from the significant rebates flowing between drug makers and payers since patient cost-sharing at the point-of-sale is based on the drug’s list price and not the negotiated price that is the net of rebates and other price concessions after the point-of-sale.

As broadly recognized by stakeholders across the healthcare industry, one of the most important ways to provide more benefits to patients is to improve their healthcare outcomes, as well as to align their spending with value. Properly designed VBP arrangements can advance these objectives in various ways, such as by reducing patient spending on drugs to which they do not respond and by increasing access to therapies that would otherwise remain unaffordable under the prevailing payment system. Moreover, the existence of a robust VBP environment could further spur innovation that responds to the increasing importance of “value” in the healthcare landscape. Therefore, we urge the OIG to create a new safe harbor that specifically protects VBP arrangements and allows them to realize their potential benefits to patients.

We believe that a new VBP safe harbor should be broad enough in scope to protect rebates associated with a medical product’s failure to achieve pre-specified outcomes that would have offered a cognizable benefit, such as a reduction in total healthcare costs and/or avoidance of disease complications. The VBP safe harbor protection should extend beyond information set forth in a product’s label, to include such extensions as longer-term outcomes or effects in particular subpopulations of patients. The VBP safe harbor should not be overly prescriptive in such a way that leaves no room or flexibility for future VBP designs that are not yet in existence, especially given that VBP arrangements remain in their infancy and continue to evolve in complexity. For example, VBPs may increasingly leverage sophisticated healthcare information technology, including artificial intelligence, to collect and analyze relevant data, which would presumably require increased financial and operational coordination between the relevant parties.

At the same time, the new safe harbor should be narrow enough so that it does not allow for ostensible value-based arrangements that are little more than vehicles for volume-based rebates.

To illustrate this point, we offer the following example:

Scenario 3: A payer has an arrangement with a manufacturer where the manufacturer agrees to provide a rebate based on a performance measure achieved by treated patients. However, the

performance measure is unrelated to, or not plausibly influenced by, more effective, higher-value use of the drug in question. For example, consider a VBP arrangement for a cholesterol-lowering drug that links payment to a reduction in short term all-cause mortality for the population using the drug. Since the drug would not be expected to influence short-term mortality significantly, it is likely that the contract amounts to a volume-based rebate. In contrast, a VBP arrangement where the rebate is tied to improvements in medication adherence, achievement of significant reductions in blood cholesterol levels, and/or lower longer-term cardiac event rates in the at-risk population, could support higher-value care for patients with poorly controlled cholesterol levels. Such payment arrangements should not be prohibited under the AKS and should be explicitly protected by a new VBP-specific safe harbor.

In other words, the safe harbor should be limited to rebates that are based on measures that could be reasonably influenced by the effective use of the drug.

The Duke-Margolis Center appreciates the OIG's consideration of our comments, and the Administration's support for advancing high-value, affordable healthcare. We and our colleagues would be pleased to provide more information on these issues if that would be helpful.

Sincerely,

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