

Health Innovation Caucus  
U.S. House of Representatives  
Washington, D.C. 20515

**RE: REQUEST FOR INFORMATION ON PHYSICIAN SELF-REFERRAL,  
ANTI-KICKBACK, AND MEDICAID BEST PRICE STATUTES**

Dear Innovation Caucus Members:

The Robert J. Margolis, MD Center for Health Policy at Duke University (The Duke-Margolis Center) appreciates this opportunity to respond to the Health Innovation Caucus's request for information regarding recent updates to the Physician Self-Referral, Anti-Kickback, and Medicaid Best Price statutes and opportunities to modernize and improve these statutes. The recently finalized rules for each represent progress in providing greater clarity and protection to stakeholders seeking to engage in value-based arrangements and contribute to improvements in patient experience and health care quality, more appropriate use of medical technologies, and reductions in health care spending. Opportunities remain to further improve and modernize these statutes so they are more inclusive of key stakeholders involved in value-based care and more responsive to the challenges certain stakeholder groups face when seeking to enter value-based arrangements.

Drawing from the Center's ongoing payment and delivery reform work, we've compiled points of feedback on the recently finalized rules regarding the Physician Self-Referral, Anti-Kickback, and Medicaid Best Price statutes and identified several opportunities to modernize and improve these statutes. Specifically, we recommend:

- the Physician Self-Referral statute include a Physician Self-Referral exception for small and rural providers;
- the Anti-Kickback statute include greater flexibility for small and rural providers regarding how the contribution requirement for the Care Coordination Arrangements safe harbor is paid, specifies that medical product manufacturers are eligible for safe harbor protection for value-based arrangements involving providers, and includes a safe harbor for medical product value-based payment arrangements between payers and manufacturers; and
- the bundled sales methodology for Best Price calculation, under the Medicaid Best Price statute, accommodates value-based arrangements involving small patient populations.

The Duke-Margolis Center ("the Center") is uniquely positioned to provide this feedback. Established with a founding gift through the Robert and Lisa Margolis Family Foundation, the Center brings together capabilities that generate and analyze evidence across the spectrum of policy to practice, supporting the triple aim of health care: improving the experience of care, the health of populations, and reducing the per capita cost. The Center's activities reflect its broad multidisciplinary capabilities, fueled by Duke University's entrepreneurial culture. With staff

and offices in both Durham, North Carolina, and Washington, DC, the Center collaborates with experts on health care policy and practice from across the country and around the world.

The mission of the Duke-Margolis Center is to improve health and the value of health care through practical, innovative, and evidence-based policy solutions. The Center's work includes identifying effective delivery and payment reform approaches that support the transition to value-based care and collaborating with expert stakeholders to identify pathways to increase the value of biomedical innovation to patients – both through better health outcomes and lower overall health care spending.

The comments provided in this letter are informed by the Center's work related to the operations and effectiveness of accountable care organizations (ACOs), the development of payment models for specific specialties and populations, the responsiveness of value-based payment models to the COVID-19 pandemic, and the operations, effectiveness, and implementation of value-based payment arrangements for pharmaceuticals, including gene therapies and gene editing technologies, and medical devices.

**I. Feedback on finalized rules for the Physician Self-Referral and Anti-Kickback Statutes and suggested changes to modernize these statutes**

Under a fee-for-service (FFS) payment system, the Physician Self-Referral (PSR) regulations and Anti-Kickback Statute (AKS) serve a critical purpose of avoiding waste and incentives for inappropriate or excessive treatment. Regulators have viewed coordination and the sharing of valuable resources across organizations under a FFS payment system as posing an increased risk of fraud and abuse, and have consequently adopted narrow exceptions and safe harbors with expected benefits that exceed any adverse impacts on innovative care models and care coordination and integration. However, as providers and manufacturers move toward assuming greater financial risk in their payment arrangements, there are fewer incentives and opportunities to engage in behaviors that lead to excess federal spending and inappropriate overuse of services and medical products for patients. As payments shift from being based on volume to being based on achieving better outcomes and lowering total costs, with greater financial risk tied to limiting costs, the PSR and AKS regulations designed for FFS constitute increasingly significant barriers to the adoption of new health care models that achieve the policy goals of better health care with more sustainable spending.

The final rules for the PSR and AKS from December 2020 (“AKS Final Rule” and “PSR Final Rule”) provide greater clarity on existing regulations and offer new exceptions and safe harbors for value-based arrangements. The new exceptions under the PSR Final Rule, new and updated safe harbors under the AKS Final Rule, and increased regulatory flexibility afforded to those taking on greater risk open up opportunities for greater participation in value-based arrangements.

There remain, however, significant issues regarding the feasibility of the PSR exception and AKS safe harbor requirements for specific stakeholder groups and the exclusion of other stakeholder groups (namely medical product manufacturers) from the newly-created value-based

AKS safe harbor protections (please see Table 1). We believe there are legislative and/or regulatory opportunities to enhance these new protections to allow stakeholders to continue to develop and implement value-based arrangements that facilitate the participation of more providers, especially small and rural providers, and the implementation of value-based arrangements that include medical products, especially those involving significant risk-sharing by manufacturers.

**Table 1. Overview of PSR & AKS Challenges and Recommendations**

<i>Remaining Challenges with PSR and AKS</i>	<i>Recommendations</i>
PSR exception and AKS safe harbor requirements are likely too burdensome for small and rural providers	<ul style="list-style-type: none"> <li>• Establish a PSR exception for small and rural providers (PSR)</li> <li>• Amend the contribution requirement for the Care Coordination Arrangements safe harbor to provide small and rural providers more flexibility in how the contribution is paid (AKS)</li> </ul>
Exclusion of medical product manufacturers from AKS value-based safe harbor protections limits	<ul style="list-style-type: none"> <li>• Allow medical product manufacturers to be eligible for value-based arrangement safe harbor protection (AKS)</li> <li>• Create a safe harbor for medical product value-based payment arrangements between payers and manufacturers (AKS)</li> </ul>

**a. Physician Self-Referral**

The exceptions finalized for the PSR represent a significant step forward in removing regulatory barriers to physician engagement in value-based arrangements. The exception categories – Full Risk, Meaningful Downside Financial Risk to the Physicians, and Value-Based Arrangements – reflect the continuum of financial risk assumption observed across the health care landscape and will extend exception protections to a greater number of physicians. Additionally, the reduction of the proposed 25% financial risk threshold to 10% in the Meaningful Downside Financial Risk to Physicians exception and removal of the 15% contribution requirement of nonmonetary compensation under the Value-Based Arrangements exception will both further extend the application of these exceptions. The wider the application of these exceptions, the greater the likelihood they will contribute to greater movement toward value-based care.

However, the finalized exceptions may still represent barriers to value-based arrangement participation for certain providers, specifically small and rural providers. For this reason, we recommend:

**Recommendation 1: Establish a Physician Self-Referral exception for small and rural providers**

Small and rural providers typically operate under lower profit margins and fewer cash reserves than larger, urban providers, leaving them with limited resources to invest in the infrastructure needed to engage and succeed in value-based arrangements.<sup>1,2,3</sup> The impact of the COVID-19 pandemic has only further eroded the financial status of small and rural providers and exacerbated their challenges to entering value-based arrangements.<sup>4,5</sup>

The Value-Based Arrangements exception, which has no financial risk assumption requirement, is meant to be an option for small and rural providers. However, the Centers for Medicare and Medicaid (CMS) received comments expressing concern that the complexity of the value-based exceptions and definitions would still be challenging for these provider groups (pg. 19).<sup>6</sup> Commenters suggested either limiting the number of value-based exception requirements for rural and small physician practices or establishing a separate exception altogether for these groups. CMS was not persuaded such changes were warranted, but we recommend further consideration of these comments and suggestions.

A separate exception for these types of providers could be designed to accommodate the unique needs of small and rural providers. Elements such as including in the exception a “phase-in period” similar to the Full Financial Risk exception to allow small and rural providers to accept support from their value-based arrangement partners would help allow providers time to develop the infrastructure necessary to succeed under a value-based arrangement. Additional safeguards would need to be developed for this exception given the providers’ lack of financial risk, but such effort would be worthwhile if it helped minimize barriers to smaller and rural providers’ participation in value-based arrangements.

**b. Anti-Kickback**

As with the PSR Final Rule’s set of value-based exceptions, the AKS Final Rule’s tiered framework for the three value-based harbors – Care Coordination Arrangements, Value-Based Arrangements with Substantial Downside Financial Risk, Value-Based Arrangements with Full Financial Risk – reflects the reality that the amount of financial risk assumed under value-based arrangements exists on a continuum. Rewarding the assumption of financial risk with greater regulatory flexibility is a meaningful approach to encouraging advancement along that continuum of risk. In addition, the final rule’s reduction of the financial risk requirement for the

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<sup>1</sup> <https://www.caplinc.org/images/stories/Resources/reports/Report-CA-Health-Centers-Financial-and-Operational-Performance-Analysis-2011-2014.pdf>

<sup>2</sup> [https://www.ivantageindex.com/wp-content/uploads/2020/02/CCRH\\_Vulnerability-Research\\_FINAL-02.14.20.pdf](https://www.ivantageindex.com/wp-content/uploads/2020/02/CCRH_Vulnerability-Research_FINAL-02.14.20.pdf)

<sup>3</sup> <https://www.gao.gov/assets/690/681541.pdf>

<sup>4</sup> <https://www.healthaffairs.org/doi/10.1377/hblog20200429.583513/full/>

<sup>5</sup> <https://www.pccpc.org/2020/11/23/primary-care-covid-19-round-23-survey>

<sup>6</sup> <https://www.federalregister.gov/documents/2020/12/02/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations>

Substantial Downside Financial Risk safe harbor will help encourage more providers to advance to this level of financial risk so they may access regulatory flexibilities. As with the PSR exceptions, the new AKS safe harbors still contain requirements that will likely keep small and rural providers from being able to access their protections. For this reason, we recommend:

***Recommendation 2: Amend the contribution requirement for the Care Coordination Arrangements safe harbor to provide small and rural providers more flexibility in how the contribution is paid***

The Care Coordination Arrangement safe harbor, intentionally designed for the types of value-based arrangements small and rural providers will likely participate in initially, contains a recipient contribution requirement (pg. 41).<sup>7</sup> This requires all recipients to pay 15% of the offeror's costs or 15% of the fair market value of the remuneration *in advance* of receiving the in-kind remuneration (pgs. 41, 56).<sup>8</sup> As mentioned above, small and rural providers generally have access to limited capital and therefore limited ability to make advance payments on remuneration.

The contribution requirement is an important safeguard against fraud and abuse and OIG declined to lower the 15% threshold in response to comments, but we believe greater flexibility should be implemented with respect to the structure of contribution repayment. For example, the in-advance percentage component could be lowered to 5% and a new component could be added to require repayment of the remaining 10% over the first 12 months of the value-based arrangement to achieve the total 15% total contribution requirement. Such flexibility would make this requirement easier to meet for the groups of providers this safe harbor was specifically designed to include.

***Recommendation 3: Medical product manufacturers should be eligible for safe harbor protection for value-based arrangements involving providers***

While the AKS Final Rule creates safe harbors for risk sharing and care coordination efforts between participants in a value-based arrangement, it generally excludes medical product manufacturers from the group of entities that are eligible for protection.

While we support the OIG's intent to limit potential industry fraud in the AKS Final Rule, we believe that concerns about program misuse and increased volume billings—that the AKS aims to prevent—diminish when value-based payments require outcome improvements and meeting spending targets. This reduces the need for the AKS' restrictions that apply in volume-based arrangements.

In addition, the OIG denied commentators' requests to include manufacturers in the finalized value-based safe harbors because manufacturers are not as likely as other entities to be involved

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<sup>7</sup> <https://www.federalregister.gov/documents/2020/12/02/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations>

<sup>8</sup> <https://www.federalregister.gov/documents/2020/12/02/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations>

with front line care coordination. However, the OIG's assumptions that provide the basis for excluding manufacturers from the finalized safe harbors and the payment and regulatory regimes that go along with these assumptions have contributed to limited manufacturer participation in care coordination and support for higher-value treatment decisions.

Value-based arrangements that include providers, payers, *and* medical product manufacturers have significantly greater potential to improve outcomes for the patient population treated, compared to provider-payer relationships that seek to move away from volume-based payment while still requiring volume-based payment methods for medical products.

Manufacturers' specific expertise and ability to develop and target programs involving their products, such as care coordination, risk prediction, remote monitoring, and more, may provide resources that fill important gaps in care coordination and data collection that providers and payers could not address alone in trying to achieve more value in care delivery and from particular medical products. Such manufacturer participation would need to be accompanied by a shift to substantial manufacturer accountability (financial risk sharing) for achieving spending benchmarks for the affected populations.

As experience and capacity to implement care delivery payment reforms increase, contracts could move toward direct alignment of both provider and medical product payments with value produced for patients and the health system – i.e., accountability for better patient outcomes and for limiting total spending. These arrangements could prove especially effective if adopted by health systems or different providers that are aligned through their own value-based arrangements, giving them the ability to coordinate patient care. Many provider-led value-based arrangements, which initiatives such as the Regulatory Sprint<sup>9</sup> and the AKS Final Rule aim to support, could become more effective with the inclusion of medical products. Such arrangements could include, for example, provisions to share in either excess costs or cost-savings (e.g., the manufacturer will receive a share of cost savings and share in excess costs with the provider for procedures using the manufacturer's equipment), or agreements that the manufacturer will reimburse for the cost of treatment if certain goals are not met.

We, therefore, urge Congress to incorporate medical product manufacturers under the protection of the value-based arrangement safe harbors for health care providers.

***Recommendation 4: A safe harbor should be created for medical product value-based payment arrangements between payers and manufacturers***

The AKS's existing safe harbors do not generally accommodate medical product payment arrangements that shift away from FFS to models in which product reimbursement depends on measures of value. The Discount Safe Harbor, for example, provides stakeholders with some flexibility to engage in value-based payment 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

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<sup>9</sup> <https://www.govinfo.gov/content/pkg/FR-2018-12-14/pdf/2018-27162.pdf>

includes several restrictions, such as a requirement that, in some circumstances, the benefit from the discount must be realized within a maximum of two years. This might significantly hinder value-based payment arrangements, especially for some gene and other transformative therapies where the durability is only confirmed over a significantly longer<sup>10</sup> time horizon.

Moreover, and perhaps most importantly, in November 2020, the OIG finalized a rule<sup>11</sup> that modifies the AKS Discount safe harbor to expressly exclude manufacturer rebates paid to Medicare Part D plans (“the Rebate Rule”), thereby further limiting the application of this safe harbor for value-based payment arrangements taking place between manufacturers and Part D plans. Because the Rebate Rule could inject significant uncertainty as to the treatment of value-based payment arrangements that involve rebate mechanisms, it could have a broader chilling effect on stakeholders’ appetite to pursue value-based payment arrangements.

Value-based 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. Because value-based rebates are effectively discouraged by the Rebate Rule, rendering the Discount safe harbor inapplicable to many value-based payment arrangements, it is now even more critical to create a safe harbor that protects value-based payment arrangements between payers and manufacturers.

The importance of value/outcomes-based arrangements for medical products was recognized in the AKS proposed rule, where it was noted that:

*“We may also consider specifically tailored safe harbor protection for value-based contracting and outcomes-based contracting for the purchase of pharmaceutical products (and potentially other types of products) in future rulemaking.”*  
(p. 55 of the AKS proposed rule).

We strongly support the further development of the approach reflected in this statement and believe that Congress should develop a statutory value-based payment safe harbor to enable value-based payment arrangements for medical product payments to expand and move further away from FFS. Alternatively, because Congress has already provided the OIG with broad authority to establish safe harbors, it could make the AKS more amenable to value-based payment arrangements by directing the OIG to issue or revise existing safe harbors to support these arrangements.

To facilitate health care reform and the increasing transition towards value-based reimbursement, we believe that it is crucial that any AKS reforms be implemented in a way that (1) advances Congress and the Administration’s goals of promoting value-based payment

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<sup>10</sup> <https://www.forbes.com/sites/joshuacohen/2019/04/12/how-are-gene-therapies-going-to-get-paid-for/#1f7d5b832090>

<sup>11</sup> <https://www.federalregister.gov/documents/2020/11/30/2020-25841/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>

arrangements, while (2) preserving the AKS' central purpose of limiting fraud and abuse in federal health care programs.

Recognizing concerns related to the realization of spending reduction from these arrangements and supporting the OIG's general approach of creating safe harbors that reflect a sliding scale of risk assumption in the health care providers' context, we believe that a similar approach could also be pursued for value-based payment arrangements for medical products, where advanced value-based payment arrangements that represent a very substantial shift away from FFS payments could be protected by a more flexible safe harbor, whereas limited risk arrangements could be protected by a more limited safe harbor.

In conclusion, we recommend the development of a safe harbor framework that encourages value-based payment arrangements for medical products that represent a significant enough shift from FFS to warrant relief from traditional AKS restrictions.

## **II. Feedback on improving Medicaid Best Price to facilitate value-based arrangements for treatments**

On December 21, 2020, CMS issued a Final Rule<sup>12</sup> that finalized a proposal from June 2020 to support value-based payment arrangements for pharmaceutical products and in particular, finalized its proposal to allow value-based payment arrangements to qualify as a bundled sale for the purposes of calculating Medicaid best price (Best Price).

Under the existing rules, a very low payment for a single patient for whom a treatment does not work could become the new Best Price for the entire Medicaid market, even if the therapy does achieve its pre-specified outcomes for all other patients under the value-based payment arrangement. This uncertainty currently deters drug manufacturers and payers from pursuing innovative payment arrangements that could encourage more effective use of treatments, reduce medical costs, and generate value for patients.

Duke-Margolis appreciates CMS's acknowledgment in the Final Rule of these challenges that are posed for value-based payment arrangements by the existing Best Price rules, and for providing, for the first time, specific solutions for addressing the determination of Best Price in the context of value-based payments, meant to increase the adoption of new payment models for pharmaceuticals that are accountable to making significant improvements in patient health.

Value-based payment contracts require the bundling of a higher net price when a drug works, with a lower net price when it does not. To that end, we have proposed<sup>13</sup> using the regulatory bundled sales provision so that Best Price would be calculated as a weighted average across the different drug prices included in the single bundled contract. That is, in the context of value-based payment contracting, the bundled sales provision would allocate the price for a product

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<sup>12</sup> <https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf>

<sup>13</sup> <https://healthpolicy.duke.edu/news/clarifying-medicaid-best-price-regulations-context-value-based-payment-arrangements>



across sales and different reporting periods for a population under the same contract (e.g., the outcome-based prices across multiple quarters if an outcome is tracked quarterly). We are highly supportive of this finalized Best Price reporting methodology that will improve certainty about the regulatory implications of value-based payment arrangements, keeping the Best Price regulation up to date with marketplace developments, while continuing to support states' ability to obtain the best available prices in the marketplace.

**Recommendation 5: The bundled sales methodology for Best Price calculation should accommodate value-based arrangements involving small patient populations**

We would like to offer a refinement to the bundled sales application in value-based payment arrangements for cases where the number of patients covered by an individual contract is so low as to make the average price unreliable. This is relevant for pharmaceutical products such as gene therapies for very rare conditions, where an outcome for a single patient can dramatically affect the weighted average rebate in a given value-based payment contract. In such cases, we propose that Best Price could potentially be calculated using the bundled sales mechanism over a set of contracts with aligned outcome provisions, or even on a national level, to help determine it more reliably. This change could potentially be made legislatively in the event that CMS might face statutory limitations.

While we recognize that CMS has finalized the multiple Best Prices option in part to address reporting Best Price in contracts for small populations, we believe that there are challenges associated with this policy that we laid out in our comment letter.<sup>14</sup> As we described, our main concern with the multiple Best Prices policy is that states would only be entitled to the lowest price available absent a value-based payment arrangement, *i.e.*, the traditional FFS Best Price, for Medicaid patients that are not included in the state-adopted value-based payment arrangement, therefore, potentially not supplying the state with the best marketplace prices for many of its Medicaid beneficiaries. Similarly, if states decline to adopt the value-based payment arrangement, they would only be receiving a Best Price that is based on the traditional FFS formula absent any value-based payment arrangement and not a weighted average, bundled sales calculation. This means that if states do not have the capacity to enter into a value-based payment arrangement, and indeed, states are limited in their ability to enter into these contracts,<sup>15</sup> they would be losing out on a value-based Best Price.

Instead of implementing the multiple Best Prices mechanism, our comment letter offers recommendations for creating a federal framework to better enable states to enter into value-based payment arrangements with manufacturers.

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<sup>14</sup> <https://beta.regulations.gov/comment/CMS-2020-0072-16454>

<sup>15</sup> <https://healthpolicy.duke.edu/sites/default/files/2020-07/Novel%20State%20Payment%20Models%20Final%20Revised%20091219.pdf>

In conclusion, more action is needed to allow stakeholders to continue to develop and implement value-based payment arrangements that include medical products to help deliver on their promise.

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The Duke-Margolis Center appreciates the Health Innovation Caucus considering our comments, and their continued action to support advancing high-value, affordable health care. We and our colleagues would be pleased to provide more information on these issues if that would be helpful. These comments are those of the authors at Duke-Margolis and are not necessarily reflective of the view of Duke University leadership, staff, or other affiliated individuals or organizations.

Sincerely,

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