



December 27, 2019

Joanne M. Chiedi, Acting Inspector General  
Office of Inspector General  
Department of Health and Human Services  
Attention: OIG-0936-AA10-P  
Room 5521, Cohen Building  
330 Independence Avenue  
SW, Washington, DC 20201

Dear Acting Inspector General Chiedi:

On behalf of the American Academy of Family Physicians (AAFP), which represents 134,600 family physicians and medical students across the country, I write in response to the [proposed rule](#) titled, “Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements” as published by the Office of Inspector General (OIG) in the October 17, 2019 *Federal Register*.

The AAFP is committed to transforming the Medicare program into one that prioritizes the delivery of high-quality, patient-centered, and efficient care. As we have previously stated, and literature supports, achieving meaningful transformation of our health care system starts with creating such a system based in foundational primary care – and one which supports an increased investment in primary care to sustain its’ transformation.

As the agency refines these policies, we wish to share the AAFP’s [position](#) that it is improper for physicians to receive payment from an entity, including non-monetary items of value, to induce or reward the generation of business by that entity. This policy is not intended to preclude any safe harbors defined within the context of the Federal Anti-Kickback legislation, Stark legislation, accountable care organization contracts, bundled episodes of care payment, or other similar business arrangements, such as legal gain sharing agreements or risk contracts.

The AAFP appreciates the opportunity to comment on proposals to revise safe harbors under the anti-kickback statute and civil monetary penalty rules regarding beneficiary inducements. The AAFP commends OIG for breaking down barriers to value-based care, particularly barriers that make it difficult for independent practices and physicians to move away from fee-for-service (FFS). While supportive of the intent and direction of the proposed safe harbors, the AAFP remains concerned about the level of administrative burden required to comply with these proposed requirements, especially on small and rural practices. By reducing or not creating new administrative burden, OIG can support the patient-physician relationship and let physicians focus on an individual patient’s welfare and, more broadly, on protecting public health.

Below are comments on portions of the proposed rule most applicable to family medicine.

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C. Care Coordination Arrangements to Improve Quality, Health Outcomes and Efficiency  
*Summary*

OIG proposes a new safe harbor that would protect in-kind remuneration exchanged between qualifying Value-Based Enterprise (VBE) participants with value-based arrangements that satisfy certain requirements. One of the proposed requirements of the safe harbor is that the recipient must pay at least 15% of the offeror's total cost for the in-kind remuneration.

OIG is considering for the final rule whether it should require a more specific methodology for determining value and is alternatively considering contribution amounts ranging from 5 to 35% and whether it should require different contribution amounts for different types of remuneration or different recipients.

*AAFP Response*

The AAFP opposes the contribution requirement from the recipient to receive protection under the current electronic health record safe harbor. The contribution requirement adds unnecessary burden and complexity and is potentially cost prohibitive. The contribution requirement adds burden by requiring the contribution amount to be set in writing and mandating ongoing monitoring and tracking of contribution amounts to ensure compliance.

Finally, we are also opposed to proposals that would have contribution amounts range from 5 to 35% contribution and vary contribution amounts for different types of remuneration. As with the contribution requirement, these proposals add further complexity and burden on the practice of medicine.

D. Value-Based Arrangements with Substantial Downside Risk  
*Summary*

The OIG proposes a new safe harbor for certain value-based arrangements of a VBE that assumes substantial downside financial risk from a payer. It would protect both monetary and in-kind remuneration but would not protect an ownership or investment interest in the VBE. As proposed, the VBE would be required to be at substantial downside financial risk if it is subject to risk pursuant to one of the following methods:

- Shared savings with a repayment obligation to the payer of at least 40% of any shared losses, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent that such data is unavailable, evidence-based, comparable expenditures;
- A repayment obligation to the payer under an episodic or bundled payment arrangement of at least 20% of any total loss, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures;
- A prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population, where such payment is determined based upon a review of historical expenditures, or to the extent such data is unavailable, evidence-based comparable expenditures; or
- A partial capitated payment from the payer for a set of items and services for the target patient population where such capitated payment reflects a discount equal to at least 60% of the total expected FFS payments based on historical expenditures, or to the extent such data is unavailable, evidence-based comparable expenditures of the VBE participants to the value-based arrangement.

In addition, the VBE participant must meaningfully share in the VBE's substantial downside financial risk for providing or arranging for items and services for the target patient population. OIG proposes that the VBE participant "meaningfully shares" in the VBE's substantial downside financial risk if the value-based arrangement contains one of the following:

1. A risk-sharing payment pursuant to which the VBE participant is at risk for 8% of the amount for which the VBE is at risk under its agreement with the applicable payer (e.g., an 8% withhold, recoupment payment, or shared losses payment);
2. A partial or full capitated payment or similar payment methodology; or
3. In the case of a VBE participant that is a physician, a payment that meets the requirements of the physician self-referral laws regulatory exception for value-based arrangements with meaningful downside financial risk.

#### *AAFP Response*

While the AAFP supports the addition of this safe harbor, we urge OIG to be consistent in application of definitions and risk-taking standards across programs. We believe it would be most appropriate for this exception to focus on the amount of risk assumed by the entity rather than the clinician, like the assessment of "more than nominal risk" for an advanced alternative payment model (APM).

We urge OIG and CMS to work together to adopt a common definition of risk for the proposed Anti-Kickback Statute safe harbor for arrangements requiring "substantial downside financial risk" and the proposed physician self-referral exception for arrangements requiring "meaningful financial risk."

### G. CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives

#### *Summary*

OIG proposes a new safe harbor to permit remuneration:

- Between and among parties to arrangements under a model or other initiative being tested or expanded by the Innovation Center under section 1115A of the Act and the Medicare Shared Savings Program under section 1899 of the Act; and
- In the form of incentives and supports provided by CMS model participants and their agents under a CMS-sponsored model to patients covered by the CMS-sponsored model.

#### *AAFP Response*

We support the additional clarity and uniformity that comes from the proposed safe harbor, which essentially acts as an umbrella policy sitting over all the models currently being tested by CMS. This provides important clarity for current and future Innovation Center model participants.

### H. Cybersecurity Technology and Related Services

#### *Summary*

OIG proposes to protect nonmonetary remuneration in the form of certain types of cybersecurity technology and services. "Cybersecurity" is proposed to mean the process of protecting information by preventing, detecting, and responding to cyberattacks. The new exception would protect nonmonetary remuneration in the form of certain types of cybersecurity technology and related services and would cover any software or other type of information technology (excluding hardware).

OIG is considering, but not proposing, to require a recipient contribution if the donation includes hardware. This contribution requirement could be 15% or another contribution amount. OIG is considering excepting small and rural practices and is interested in comments on this approach, including how “small and rural practices” should be defined.

#### *AAFP Response*

While the AAFP supports the addition of this exception, we also urge clarification that the exception should not be used to support intentional or unintentional anti-competitive behavior. We support CMS’ decision not to require the recipient to contribute toward the cost of the item or service. This could be a disincentive for independent practices and physicians, given that the potential magnitude of the cost and the administrative burden associated with tracking and calculating the cost of the item/service. If OIG does require a contribution, we urge you to consider a comparable investment across provider types rather than a flat percentage that does not account for the unique circumstances of particular providers.

### I. Electronic Health Records

#### *Summary*

OIG proposes to update the existing exception for electronic health records items and services to align with other regulations. OIG proposes to prohibit the donor (or any person on the donor’s behalf) from engaging in a practice constituting information blocking, as defined in section 3022 of the *Public Health Service Act*, in connection with the donated items or services. While OIG is not proposing specific amendments to the existing 15% contribution requirement, it is soliciting comments on alternative requirements.

One alternative is whether and how OIG should eliminate or reduce the 15% contribution requirement for a specific subset of recipients, such as small or rural practices. If such flexibility is recommended, OIG is soliciting comments on how “small or rural practices” should be defined.

#### *AAFP Response*

The AAFP strongly supports the addition of specific language preventing donors from engaging in information blocking. We urge CMS to consider additional AAFP suggestions to address information blocking that we suggested in a June 3, 2019 [letter](#).

On the definition of “small and rural practices,” we urge CMS to be consistent with other standards it has already adopted in other programs. To that end, we suggest that CMS use the definition of “small practice” used in the Quality Payment Program – a Tax Identification Number or virtual group associated with 15 or fewer clinicians.

We appreciate the opportunity to provide these comments. Please contact Robert Bennett, Federal Regulatory Manager, at 202-655-4908 or [rbennett@aaafp.org](mailto:rbennett@aaafp.org) with any questions.

Sincerely,



John S. Cullen, MD, FAAFP  
Board Chair