hfma
healthcare financial management association

December 31, 2019

Joanne 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

RIN: 0936–AA10

Re: Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements

Dear Ms. Chiedi:

The Healthcare Financial Management Association (HFMA) would like to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the *Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements* (hereafter referred to as the Proposed Rule) published in the Federal Register on October 17, 2019.

HFMA is a professional organization of more than 49,000 individuals involved in various aspects of healthcare financial management. HFMA is committed to helping its members improve the management of and compliance with the numerous rules and regulations that govern the industry.

Introduction
HFMA would like to commend the OIG for its thorough analysis and discussion of the many issues related to the Anti-Kickback Statute (AKS) and Civil Monetary Penalties (CMPs) related to beneficiary inducements in the Proposed Rule. Our members broadly support the proposed changes and would like to comment on the proposals related to:

- Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency
- Local Transportation
- Cybersecurity Technology and Related Services
- Electronic Health Records
- Opportunities to Better Align Physician Self-Referral and Anti-Kickback Regulations

Below please find HFMA members' specific comments.

Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency

The OIG proposes to establish a new safe harbor (the "patient engagement and support safe harbor") at proposed paragraph 1001.952(hh) for patient engagement tools and supports furnished to improve quality, health outcomes, and efficiency provided by Value Based Enterprise participants (as defined in proposed paragraph 1001.952(ee)) to a specified target patient population. This safe harbor is intended to remove barriers from the anti-kickback statute and the beneficiary inducements Civil Monetary Penalties that impact provider's abilities to provide patients tools and supports.

HFMA members support a broad safe harbor for a range of activities to help improve the engagement of a targeted population that is covered under a value-based arrangement in their health care. This could include positive incentives for exhibiting desired behaviors – such as receiving an annual wellness visit, participating in a smoking cessation program, or seeking care from a lower cost provider (e.g., receiving imaging services in a freestanding setting as opposed to a hospital outpatient department) – or providing a means to address a barrier to adhering to a care plan beyond transportation – such as providing cooking classes, providing condition-specific groceries, providing condition-specific technology (e.g., electronic scales and/or internet service to facilitate data collection) or helping a patient afford their medications. In addition to the use of cash, gift cards, and reduced beneficiary cost sharing as a means to achieve patient engagement, we would encourage the safe harbor to include benefits like direct payments from the provider to utility companies and the direct provision of technology (e.g., electronic scales, iPads to provide continuing condition-specific education).

While HFMA members appreciate the need for an annual monetary cap on the value of patient engagements and support, we believe the proposed $500 is insufficient, particularly when attempting to address the needs of a socioeconomically challenged patient who suffers from multiple chronic conditions. **We recommend you increase it to $2,000 annually**. To address concerns about program integrity, we encourage you to work with the provider community to develop tiering criteria based on both the complexity of a patient's condition (e.g., the number of chronic conditions afflicting the patient) and socioeconomic factors that would limit eligibility to receive the maximum amount of support to those who truly need it.

Many of the waivers described above are currently available to HFMA members participating in Medicare Advanced Alternative Payment Models like the Next Gen ACO. However, our members report that few of these waivers – like the ability to reduce beneficiary cost sharing – are currently used. This is a result of the complex, administratively burdensome requirements imposed on those VBEs who do use them. As one member commented, "It seems like the OIG starts with a presumption of guilt when they design these waivers." **HFMA recommends that, moving forward, the OIG reduce the compliance requirements necessary to qualify for these exemptions from the AKS and CMP rules for participants in value-based arrangements.** As an example, HFMA members are strongly opposed to any requirement that they retrieve an item or good they provided a patient. We strongly believe this should be a business decision, based on the value and reusability of the good, made by each individual VBE or VBE participant.

Local Transportation
The rule proposes four changes in the use of transportation services for patients.

1) *Expansion of Mileage Limit for Patients Residing in Rural Areas*. The OIG is proposing to increase the limit on transportation of residents in rural communities from 25 to 75 miles of the healthcare provider.

   HFMA members strongly support this provision.

2) *Elimination of Distance Limit on Transportation of Discharged Patients*. The OIG proposes to eliminate any distance limit on transportation of a patient discharged after an inpatient stay, for both patients residing in urban or rural areas, if the transportation is to the patient's residence or another residence the patient chooses. The OIG is also considering protecting transportation to another healthcare facility. In addition, the OIG is considering when transportation home or to another facility should be protected when a patient has not been admitted to an inpatient facility, such as an emergency room or after a procedure at an ambulatory surgical center (ASC).

   HFMA members strongly support this provision. We encourage the OIG to include transportation to another healthcare facility, an ASC, or a physician's office (the latter two apply in cases where the patient has received care in an emergency department or other non-inpatient setting).

3) *Local Transportation for Health-Related, Nonmedical Purposes*. The OIG is considering nonmedical purposes in this safe harbor. The OIG notes that the proposed safe harbor for patient engagement and support offered by VBE participants includes transportation for health-related, nonmedical purposes but this protection is limited to VBE participants.

   HFMA members strongly support expanding this provision to providers not participating in a VBE. Transportation to and from medical care is a key barrier facing many socioeconomically challenged patients. Allowing non-VBE participants – especially safety net providers – to provide transportation to and from clinic visits to targeted patients has the potential to reduce ambulatory-sensitive utilization, improving outcomes and reducing the total cost of care. Providers who are not participating in a VBE will provide this service as part of their community benefit activities related to many health systems' mission to improve the health of their communities.

4) *Use of Ride-Sharing Services*. The final rule establishing the local transportation safe harbor (81 FR 88387), included patient transportation provided via a taxi in the safe harbor as long as all other requirements were met. The OIG notes that although it did not explicitly refer to ride-sharing services, for purposes of the safe harbor, it considers ride-sharing services similar to taxis.

   HFMA members strongly support the OIG's clarification that ride-sharing services are similar to taxis.

Cybersecurity Technology and Related Services
OIG proposes a new safe harbor to protect donations of certain cybersecurity technology and related services at a new §1001.952(jj). The proposed safe harbor is based on comments and suggestions offered by stakeholders, and OIG believes it could help improve cybersecurity in the healthcare industry, where an attack on the weakest link of an interconnected health information technology (IT) system poses risks to the protection of patient records and the transmission capabilities within the entire system.

The proposed safe harbor would prohibit a potential recipient or the potential recipient's practice from making receipt of the technology or services, or the amount and nature of the technology or services, a condition of doing business with the donor.

The OIG is not proposing to require a recipient contribution under the cybersecurity safe harbor because it seeks to remove a barrier to donations that improve cybersecurity in the healthcare industry. It does not believe that a minimum contribution requirement is necessary or practical. Because the level of services might vary by recipient and over time, some physician practices, particularly those in rural areas, might not be able to make the required contribution, which would threaten cybersecurity of the systems in which they participate. Similarly, if donors were to aggregate costs of cybersecurity updates across recipients, determining pro-rata contributions may become unworkable.

HFMA members strongly support this proposal and the OIG's implicit acknowledgement that smaller practices partnering with larger health systems can pose a significant security risk to the network. We greatly appreciate the OIG's not proposing to require a minimum contribution to the cybersecurity technology and related services provided. Any level of contribution is not practical for many small practices, given their economics.

Electronic Health Records
In this rule, the OIG proposes changes to the electronic health records (EHR) safe harbor and notes that CMS is proposing parallel changes to the EHR exception under the physician self-referral regulations. The OIG has aimed to be as consistent as possible with the CMS proposed rule and will consider comments submitted to CMS on these issues. It may also "take additional actions" when crafting the final rule.

In general, HFMA members support these changes.

15% Recipient Contribution. Currently, §1001.952(y) requires that as a condition to the EHR safe harbor, the recipient must pay 15% of the donor's cost of the technology. The OIG is aware of the burden on recipients associated with the 15% contribution, particularly on small and rural practices, and that application of the contribution to upgrades and updates is restrictive and cumbersome and may act as a barrier to adoption. No formal proposals regarding the 15% contribution are made in this rule, and the OIG is considering retaining the requirement without change in the final rule.

HFMA members strongly encourage the OIG to eliminate the 15% contribution requirement. As discussed above, for many smaller practices, even a nominal contribution to the costs of an EHR system implementation and ongoing maintenance is prohibitive. This gap in the health IT network diminishes the ability of a delivery system to coordinate care, reduce avoidable utilization, and improve outcomes.

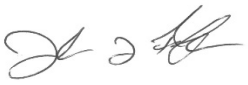
Opportunities to Better Align Physician Self-Referral and Anti-Kickback Regulations
CMS's proposed rule related to physician self-referral regulations (i.e., the Stark rule) includes three exceptions for value-based arrangements in which the value-based enterprise is at full financial risk, the physician has meaningful downside risk, and a general exception for value-based arrangements. The OIG's proposed AKS rule includes similar exceptions.

However, in the proposed AKS rule, remuneration must be provided by the VBE to a VBE participant, while the proposed Stark rule also protects payments between VBE participants. **HFMA members strongly encourage the OIG to modify the AKS final rule to mirror the Stark proposed rule and allow payments between VBE participants.**

HFMA looks forward to any opportunity to provide assistance or comments to support CMS's efforts to refine and improve regulations related to the anti-kickback statute and civil monetary penalties. As an organization, we take pride in our long history of providing balanced, objective financial technical expertise to Congress, CMS, and advisory groups.

We are at your service to help CMS gain a balanced perspective on this complex issue. If you have additional questions, you may reach me or Richard Gundling, Senior Vice President of HFMA's Washington, DC, office, at (202) 296-2920. The Association and I look forward to working with you.

Sincerely,



Joseph J. Fifer, FHFMA, CPA
President and Chief Executive Officer
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About HFMA

HFMA is the nation's leading membership organization for more than 49,000 healthcare financial management professionals. Our members are widely diverse, employed by hospitals, integrated delivery systems, managed care organizations, ambulatory and long-term care facilities, physician practices, accounting and consulting firms and insurance companies. Members' positions include chief executive officer, chief financial officer, controller, patient accounts manager, accountant and consultant.

HFMA is a nonpartisan professional practice organization. As part of its education, information and professional development services, HFMA develops and promotes ethical, high-quality healthcare finance practices. HFMA works with a broad cross-section of stakeholders to improve the healthcare industry by identifying and bridging gaps in knowledge, best practices, and standards.