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October 26, 2018

Susan Edwards
Office of the Inspector General
Department of Health and Human Services
Attention: OIG-0803-N, Room 5513
Cohen Building
330 Independence Avenue SW
Washington, DC 20201

RE: Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP [OIG-0803-N]

Dear Ms. Edwards:

The American College of Cardiology (ACC) is pleased to submit comments in response to the request for information (RFI) from the Office of the Inspector General for the Department of Health and Human Services (OIG) regarding the anti-kickback statute (AKS) and beneficiary inducements civil monetary penalties (CMP) as published in the *Federal Register* on Aug. 27, 2018. The ACC envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned *JACC Journals,* operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions.

General comments

Clinicians, particularly cardiovascular care team members, are primarily motivated by one goal: providing high quality patient care to ensure the best possible outcome to each patient. The healthcare system must provide clinicians with the appropriate time, resources and support structure to provide optimal care. In today's age of innovation, many are developing novel models for doing so. Unfortunately, existing regulatory and administrative burdens often make it difficult for them to provide the requisite care under the current framework, let alone new models that incorporate digital health solutions and other more recent advances. Instead, a clinician's time is often split between patient care and navigating the hurdles imposed within the regulatory landscape. The College welcomes this Administration's examination of those administrative burdens, particularly with respect to the fraud and abuse statutes. The ACC looks forward to reviewing the promised proposal to revise the physician self-referral (Stark) regulations later this year, as well as the anticipated proposal to revise

the CMP regulations to be issued in spring 2019. While this RFI specifically addresses the beneficiary inducements provisions of the CMP, the College hopes that the 2019 proposal will address the CMP in its entirety, enabling an examination of other troublesome provisions.

Statutory and regulatory harmonization

Like the physician self-referral (Stark) law, the AKS and beneficiary inducements CMP predate the interest in shifting from a fee-for-service based system to one that rewards clinicians based on the value of the care furnished. As such, many of the existing laws are predicated on old notions of healthcare and either prevent or disincentivize clinicians from developing novel methods of delivering care. Care coordination is prioritized in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA); yet, the regulatory schema implementing the AKS, Stark law and beneficiary inducements CMP are all fashioned for a fee-for-service based system. In some cases, these actively prevent the coordination of care across settings and/or specialties. To that end, **the ACC urges the OIG to work closely with the Centers for Medicare and Medicaid Services (CMS) to harmonize the regulatory schema implementing the various laws, taking congressional intent into consideration. Additionally, the College recommends that OIG ensure harmonization across the safe harbors and exceptions to the AKS and beneficiary inducements CMP.**

Care coordination

Alternative payment models

Alternative payment models have significant potential to enhance patient care and lower healthcare costs. The College believes that clinician-led alternative payment models should be afforded opportunities to explore novel approaches for achieving these goals. These models should be:

- Patient centric, with a focus on patient engagement
- Innovative
- Flexible
- Enable and encourage coordination across specialties and sites of care
- Quality-focused
- In risk-based arrangements, provide clinicians with the tools necessary to be successful

These goals are operationalized in the models described in a November 2017 *JAMA Cardiology* article, entitled "Payment Reform to Enhance Collaboration of Primary Care and Cardiology: A Review."[1] The College recommends that the OIG review these models to identify and remedy obstructions created by the AKS and beneficiary inducements CMP.

The ACC has urged CMS to create an exception to the Stark law similar to that which is outlined in the Medicare Care Coordination Improvement Act of 2017 (H.R. 4206/S. 2051). This bipartisan, bicameral legislation would substantially improve care coordination for patients, improve health outcomes and restrain costs by allowing physicians to participate in alternative payment models. Congress explicitly recognized the Stark Law and AKS as a barrier to care coordination when it authorized the HHS Secretary to waive the self-referral and anti-kickback prohibitions for accountable care organizations (ACOs). To

[1] Farmer, SA et al. "Payment Reform to Enhance Collaboration of Primary Care and Cardiology: A Review." *JAMA Cardiology*. 2018;3(1):77-83.

that end, **the ACC urges the OIG to examine AKS and existing safe harbors to ensure that the activities permitted under this legislation would also be permitted under the AKS.**

Financial alignment

In order to best serve patients within a risk-bearing structure and drive value for patients and the healthcare system, there must be mechanisms that allow for some degree of financial alignment between hospitals/health systems and clinicians. Under these circumstances, such incentives encourage clinicians toward practices that improve patient outcomes while reducing total medical costs. In 2008 CMS took the first steps towards issuing a gainsharing exception to the Stark rule by including a discussion of one in the proposed CY 2009 Medicare physician fee schedule. Unfortunately, that effort stalled for a variety of reasons. That should not prevent the OIG from undertaking such an effort. Both independent and integrated cardiovascular groups have explored options for assisting hospitals and health systems in addressing workflow inefficiencies and operating expense reductions. However, these efforts have floundered as a result of interpretations of the AKS and gainsharing provisions of the CMP. Consequently, ideal models are not available, forcing the use of arcane approaches (with proxy and process outcome variables) instead. These models are suboptimal and usually do not result in the best outcome for the healthcare system. Even in situations involving cardiologists working as employees of hospitals and/or health systems, the compliance regulations inhibit a direct approach.

To its credit, the OIG has issued a number of Advisory Opinions permitting gainsharing in certain limited situations. However, given the limitations regarding the broad applicability of Advisory Opinions and the narrow nature of the fact patterns described in the existing Advisory Opinions, it is difficult for clinicians or hospitals to have any degree of comfort when entering into gainsharing arrangements without asking for their own Advisory Opinion. Furthermore, seeking an Advisory Opinion from the OIG is costly and burdensome for both the individual or entity seeking the opinion and the government. **To that end, the College urges the OIG to issue a safe harbor to the AKS that would allow clinicians, hospitals and health systems to work together to control costs for the benefit of patients. Additionally, the ACC strongly recommends that the OIG work with CMS to develop language that would permit such arrangements under other fraud and abuse statutes, such as the Stark law and CMP, ensuring a consistent approach across agencies.**

Social determinants of health

Given the similar intent behind the AKS and beneficiary inducements CMP, the ACC believes that it is also critical for the OIG to examine potential barriers to the creation of ACOs and alternative payment models by the beneficiary inducements CMP. Among the concerns clinicians have raised regarding the move to a value-based payment system is that they will be held accountable for outcomes that may be influenced by social risk and other factors beyond their control. For instance, slowing the progress of diabetes frequently requires addressing its co-morbid conditions, including obesity. Clinicians can encourage patients to address obesity in many ways, but the patient may face personal and structural barriers, such as a lack of healthy food options, to achieving weight reduction. Studies have indicated that patients may respond to financial incentives to lose weight. However, under the existing regulations, these beneficiary engagement activities could constitute improper beneficiary inducements. The OIG has recognized the importance of patient assistance in some instances, such as documented financial need, reductions in copayments by hospitals for certain outpatient department services, certain coupon or rebate programs and others. **The ACC urges the OIG to re-examine the beneficiary inducements CMP safe harbor regarding the promotion of access to care and low risk threshold**

considering the interest in increasing care coordination and holding clinicians accountable for patient outcomes. As part of this re-examination, the College recommends that the OIG consider expanding the safe harbor to address the provision of certain needs that may impede a beneficiary's ability to seek care or affect care outcomes – food, clothing, transportation to and from healthcare-related visits, as well as encouragements to seek medically necessary care or to take medically necessary actions to address a patient's health, in situations where there is demonstrated need. This need could be financial, health-related or other situation that affects a patient's ability to seek care. While it is understood that some limits will need to be imposed, the College believes the potential benefits to patients would outweigh the harms if such a safe harbor were carefully crafted.

Disease management incentives

The OIG has recognized the difficulty that patients with financial need may face in accessing care and allows for the waiver of coinsurance in certain circumstances where financial need has been demonstrated. The College believes there are other circumstances under which it would medically benefit the patient to waive such fees without such action serving as an inducement that would harm the patient or the Medicare or Medicaid programs. For instance, novel models of care coordination and disease management may ultimately generate an increased number of clinician visits to facilitate the coordination and closer management of the disease or condition, which may result in additional coinsurance payments by the beneficiary. The burden imposed by the increased number of visits coupled with the greater total cost to the patient may disincentivize patients from participating in such models or lead to decisions to withdraw from a program. **To encourage medically beneficial participation in such programs, incentives for patients to remain within a participating provider's system or network, such as coinsurance waivers, should be permitted.** The ACC urges the OIG to consider the development of a safe harbor that would allow for such waivers or to expand an existing waiver to include such circumstances.

Digital health

Among the key precepts of care coordination are patient-centric design and shared engagement in patient care. To further these goals, clinicians should be encouraged to develop and adopt tools that assist patients in managing their own disease. This will enable patients to take ownership over their care and outcomes. For example, a healthcare provider might be interested in furnishing patients with access to technology for no cost, including those where studies have demonstrated benefit of technology, as a mechanism for engaging patients in management of their disease, while allowing others to access the technology at a cost. Such an app could allow patients to track basic metrics to assist in managing their disease, reducing hospital admissions or addressing disease progression. This could ultimately lead to improved patient outcomes and higher quality of life for patients, while potentially reducing Medicare and Medicaid costs. **Under current law, the provision of apps and similar tools by a clinician, hospital or health system exclusively to their own patients at no cost to those patients could be considered a violation of the AKS and the beneficiary inducements CMP. The College believes that creating a safe harbor to allow for the provision of such tools will enable patients and clinicians to form partnerships, rather than traditional paternalistic relationships, and improve patient outcomes.**

Cybersecurity

As healthcare has become increasingly digital, concerns regarding cybersecurity have arisen. Hospitals and practices have found themselves vulnerable to cyberattacks, threatening patient health information

and holding hostage electronic health records (EHRs) and other essential systems. Given the interest by all to increase interoperability in healthcare, this problem is only likely to grow and spread. It is unlikely to be contained easily to one hospital or one practice. As the connections between systems, hospitals, practices, pharmacies and other providers grow, the ability of hackers to take advantage of one provider's vulnerability to access an entire network will similarly grow. No doubt, this is at its core an issue of patient safety and privacy, not one of remuneration or referral capture. To that end, it is the responsibility of the government, including the OIG, to take necessary actions to limit such vulnerabilities and to encourage providers to coordinate cybersecurity activities. **The College urges the OIG to consider the creation of a safe harbor that would address this significant patient safety and privacy concern. As it develops this critical safe harbor, the OIG should consider all aspects of cybersecurity, such as hardware, software, system assessments and testing, training and ongoing maintenance.**

Conclusion

The ACC appreciates the opportunity to provide these comments as the OIG reconsiders the AKS and beneficiary inducements CMP in the concept of care coordination and alternative payment modes and would welcome an occasion to provide further input as needed. The College looks forward to working with the OIG on this and other important issues. Please direct any questions or concerns to Lisa P. Goldstein, Senior Regulatory Policy Counsel, at (202) 375-6527 or lgoldstein@acc.org.

Sincerely,

C. Michael Valentine, MD, FACC
President