AMERICAN
COLLEGE of
CARDIOLOGY

Heart House
2400 N Street, NW
Washington, DC 20037-1153
USA

202-375-6000
800-253-4636
Fax: 202-375-7000
www.ACC.org

December 23, 2019

The Honorable Joanne M. Chiedi
Acting Inspector General
Office of the Inspector General
Department of Health and Human Services
Cohen Building, Room 5521
330 Independence Ave., SW
Washington, DC 20201

RE: Proposed Revisions to Safe Harbors under the Anti-Kickback Statute and to CMP Rules Governing Beneficiary Inducements [OIG-0936-AA10-P]

Dear Acting Inspector General Chiedi:

The American College of Cardiology is pleased to submit these comments in connection with the proposed rule published by your Office ("the OIG") on October 17, 2019 at 84 Fed. Reg. 55694 *et seq.* ("the OIG Proposal"). This rulemaking includes proposed (1) new safe harbors to facilitate coordinated care and value-based payment arrangements, (2) revisions to certain existing safe harbors, and (3) changes to the rules governing patient inducements under the Civil Money Penalties law. Many aspects of the OIG Proposal will affect the College's diverse membership, and we urge your careful consideration of our comments as well as those of other stakeholders.

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.

The College has long been engaged in the public policy debate surrounding the move from Medicare payment based on the volume of services provided to a more value-based payment approach. This approach involves innovations to payment methodologies that incentivize collaboration among physicians,

hospitals, and other providers, and reward the provider community for the delivery of high quality, cost-effective, and outcomes-oriented patient-centered care. The debate over value-based payments has also focused attention on the degree to which existing regulatory frameworks, including that under the physician self-referral (or "Stark" law), the Anti-Kickback Statute and related "safe harbors," and restrictions on patient inducements, impede payment reforms and impose administrative and cost burdens on providers that have little to do with patient care.

In evaluating regulatory reform to encourage value-based payment arrangements, the College believes the framework should reflect the following core principles:

- Facilitate and promote care coordination, not impede it;
- Accommodate a wide variety of physician practice types and a wide range of physician collaborations with other clinicians and healthcare providers;
- Simplify wherever possible, so as to reduce administrative burdens;
- Coordinate Stark law exceptions with safe harbors under the Anti-Kickback Statute to avoid situations where a physician complies with an exception under one law only to be exposed to potentially "dire" enforcement risks under the other;
- Provide increased regulatory certainty for the regulated community; and
- Be site-neutral so that cardiologists have the same opportunities for regulatory protection regardless of their practice setting.

The College has applied these general principles in evaluating the OIG Proposal.

GENERAL COMMENTS

In addition to the more detailed section-by-section comments set forth below, the College submits for your consideration these general comments. First, ACC applauds your effort to provide new protections that will facilitate care coordination and other value-based initiatives. The new safe harbors for value-based arrangements with either full financial risk or substantial downside risk appear largely appropriate, although we note that they will likely apply only to a small fraction of currently existing value-based arrangements.

Second, ACC supports the concept of an expanded personal services safe harbor for outcomes-based payments, but as explained below, to be effective it must be coordinated with the Stark exception for value-based arrangements.

Third, the College does not support the proposed new safe harbor for care coordination arrangements without financial risk. By limiting protection to "in kind" remuneration, it would exclude a wide variety of activities that are not abusive and should be encouraged.

Fourth, while the College appreciates the efforts OIG and CMS have made to align their regulatory approaches to value-based care, those efforts are thus far only partially successful. We urge both

offices to move further towards a consistent regulatory framework. Without consistency, there will be no regulatory certainty for the clinician community.

SPECIFIC COMMENTS

Section 1001.952 (d)(1) (Personal Services and Management Contracts)

The College strongly supports the OIG's proposal to eliminate the requirements for specifying the exact schedule of part time service arrangements and the aggregate compensation to be paid over the term of the agreement. These requirements have prevented nearly all physician personal service arrangements from qualifying for safe harbor protection.

Section 1001.952 (d)(2) and (3) (Outcomes-Based Payments)

The College strongly opposes many of the specifics of the OIG's proposed framework for protecting outcomes-based payments, due to its inconsistency with the proposed Stark law exception for remuneration paid under a value-based arrangement (proposed 42 CFR §411.357(aa)(3)). The College is at a loss to understand why the OIG has not proposed a safe harbor that directly correlates with CMS' proposed value-based payments exception. Without one, physicians will find themselves in the position of evaluating a value-based payment proposal for compliance with the many criteria of the Stark exception only to discover that the proposal will expose them to dire risk under the AKS.

For example, the OIG has, despite some confusion in the preamble (see page 55745), again failed to provide clear safe harbor protection for so-called "gainsharing" arrangements. By focusing only on payor costs (proposed (3)(ii)(B)) and expressly excluding payments that relate "solely to the achievement of internal cost savings for the principal," (proposed (3)(iii)(B)), the OIG Proposal ignores two important realities. First, that cost savings generated within providers, particularly hospitals, are valuable in their own right, and often require clinician participation which is enhanced when that participation is incentivized. Second, that savings on the provider side generally result in payor savings even if the effect is not immediate. The OIG's proposal is clearly at odds with, and narrower than, what CMS has proposed for Stark purposes, and will leave the regulated community still reliant on the expensive and time-consuming advisory opinion process.

Further, the College believes that the safe harbor for outcomes-based payments is so complex and ambiguous that it will place physicians at considerable risk. The safe harbor contains nine criteria, many of which contain numerous sub-criteria, and these criteria and sub-criteria require the participants to make judgments upon which reasonable people may disagree. Taking one example, consider how a participating physician will have certainty that the outcomes-based payment is "commercially reasonable" or consistent with fair market value. Unlike office leases or physician salaries, outcomes-based payments are emerging innovations without a lengthy track record of valuation or standardized appraisal techniques, and often without ready "comparables" in a particular geographic area.

As another example, how does a participating physician decide whether he or she believes the payer has established policies to "promptly" address and correct "material performance failures" or "material deficiencies" in quality of care "resulting from" the outcomes-based payment arrangement? In most instances, due to an imbalance of information, the participant will have to rely on the payer to make this judgment, and simply decide whether he or she can afford not to participate in the

arrangement. It will be exceedingly difficult for physicians to have confidence that their decisions will not be second-guessed in a whistleblower strike suit.

The ACC supports the movement to outcomes-based payments based on performance on evidence-based measures such as those offered under the Quality Payment Program and the National Cardiovascular Data Registry (NCDR). In the move to value-based models, physicians already must navigate myriad program requirements and focus on establishing new clinical and operational workflow infrastructure. The College is concerned that the complexity of this safe harbor may add additional administrative burden. **The ACC urges the OIG to simplify or eliminate the criteria described above that introduce new uncertainty and to work with CMS to align with CMS' proposed value-based payments exception under the Stark rule.**

Section 1001.952 (y) (Electronic Health Records Items and Services)

The College strongly supports the OIG's proposals to include cybersecurity items and services within the scope of the EHR safe harbor, and we encourage the OIG to remove the cost sharing component of this safe harbor. The College believes the cost sharing component has made compliance with the safe harbor unnecessarily complex and has become an impediment to adoption of EHR technology.

Section 1001.952 (bb) (Local Transportation)

The ACC supports the OIG's proposal to extend the mileage limitation on local transportation from 50 miles to 75 miles if the patient resides in a rural area. The College encourages the OIG to adopt a similar mileage expansion for local transportation in areas that are within an urban area, as defined in the existing safe harbor. Many metropolitan areas extend beyond 25 miles, and some innovative healthcare providers in those communities have developed evidenced-based clinical quality intervention strategies for high-risk patients that are dependent upon free patient transportation to be successful.

For example, a patient may undergo a procedure in a system's center of excellence in a distant town or city, while receiving follow-up care and engaging in services such as cardiac rehabilitation closer to their home. Providing patients with ridesharing and transportation over a greater distance is a low-cost, high-value way to ensure access to care. Expanding the safe harbor's mileage limit from 25 miles to at least 50 if not 75 miles in urban areas would further these important innovative care models.

Section 1001.952 (hh) (Patient Engagement Tools and Support)

The College supports the proposed new safe harbor for the provision of patient engagement tools and support by physicians participating in a value-based enterprise. This would protect physicians under both the AKS and CMP laws that might otherwise apply. ACC believes the proposal could be improved either by increasing the annual limit above $500 or providing some flexibility that recognizes that this too is an emerging field with significant variation in costs based on differing technologies, frequency of patient use (e.g. daily vs. weekly or monthly), and potential benefits to different classes of patients.

The College also encourages OIG to make this safe harbor available beyond the context of value-based enterprises as defined for purposes of the OIG Proposal. Patient engagement tools and other

support can have the same benefit to patients and ultimate payor costs in a variety of other payment models. As long as similar protections are built into the delivery of the tools or support, barriers to their delivery should be removed across the board.

Section 1001.952(jj) (Cybersecurity Technology and Related Services)

The College strongly supports this proposal and applauds the OIG for making the terms of this safe harbor consistent with those of the proposed cybersecurity technology and related services exception under the Stark rule. The ability of physicians to efficiently and securely share patient records and information with all members of a patient's care team is crucial to care coordination.

CONCLUSION

While the ACC supports CMS' and the OIG's focus on the transition to value in these proposed rules, both rules do little to provide genuine regulatory relief. If both rules are adopted as proposed, cardiologists will still face a complicated and burdensome regulatory landscape filled with dangerous pitfalls, leaving them constantly reliant on lawyers, consultants and other compliance professionals whose services are expensive, time-consuming and largely disconnected from the clinician's fundamental mission to provide quality patient-centered care in a cost-effective manner.

Thus, the College urges, as it has before, the OIG and CMS to engage with the Congress and clinicians in a genuine effort to roll back the monstrously complex set of laws and regulations originally designed for a world of fee-for-service payments that is rapidly disappearing.

The ACC appreciates the opportunity to comment on the OIG proposal. Please contact Christine Perez, Director of Payer and Care Delivery Policy at cperez@acc.org or (202) 375-6630 should you have any questions or require additional information.

Sincerely,

Richard J. Kovacs, MD, FACC
President

CC: Robert Saner, Esq.
Mark Fitzgerald, Esq.
Powers, Pyles, Sutter & Verville, P.C.