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December 23, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1720-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations [CMS-1720-P]

Dear Administrator Verma:

The American College of Cardiology (ACC) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule to reduce the regulatory burden of the physician self-referral law, also referred to as the Stark Law. The College commends CMS for recognizing the need to modernize these regulations as part of the Regulatory Sprint to Coordinated Care. The physician-self referral law, as well as the anti-kickback statute under the Office of the Inspector General (OIG), must be modernized to truly achieve value-based care.

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.

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 ACC supports the proposals in this rule that encourage collaborative care arrangements through the three new exceptions for physicians engaged in value-based care arrangements and the clarification of terms used to protect compensation arrangements between physicians and providers of designated health services (DHS).

However, the College remains concerned that even with the proposed changes and preamble language, the Stark law, Anti-Kickback Statute, and accompanying regulations remain highly complex and compliance will continue to be based on the eye of the beholder. CMS must ensure that this complexity does not stand in the way of meaningful change. The ability of physicians to innovate and collaborate on new care arrangements in the best interest of the patient should not be hindered due to confusing regulations that may lead many to continue taking what may be overly cautious approaches.

A. Facilitating the Transition to Value-Based Care and Fostering Care Coordination

The ACC supports CMS' proposals to define three new exceptions from the physician self-referral law to protect the compensation paid to physicians in value-based care arrangements. The College is pleased that these proposed exceptions are designed to recognize a range of value-based care delivery activities and are not narrowly construed to recognize participation in Medicare payment models only. As value-based care models continue to evolve, the College reminds CMS that future revisions may be necessary and eventual elimination of the physician-self referral law by Congress may be appropriate.

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.

Before commenting on each of the three exceptions in turn, the College would like to note its appreciation that CMS appears to intend for so-called "gainsharing" arrangements to be at least eligible for protection under each of the three (see preamble discussion at page 55780). **The College recommends that CMS make this positive development even clearer by adding "appropriately reducing provider costs," and not just payor costs, to paragraph (3) in the definition of "Value-based purpose" in proposed Section 411.351.**

The ability to align incentives through value-based gainsharing arrangements between physicians and providers of DHS will further promote coordination among the members of a patient's care team. The College is pleased to see that CMS recognizes this; however, we would like to make the Agency aware that the OIG, in its proposed rule, still fails to provide clear safe harbor protection for so-called "gainsharing" arrangements to align with CMS' proposed value-based payments exceptions. 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. **As CMS and the OIG finalize both proposed rules, the ACC requests that CMS work with the OIG to develop and align safe-harbors for remuneration paid under a value-based arrangement with the proposed value-based arrangement exceptions under Stark.**

Given the ACC's interest in ensuring that physicians and DHS providers take advantage of the three proposed value-based arrangement exceptions, the College provides the following comments on each of the categories.

1. Value-Based Enterprise at Full Financial Risk; Proposed §411.357(aa)(1)

This proposed exception protects remuneration among physicians and other participants in a "value-based enterprise" (VBE) where the VBE has assumed full prospective financial risk, payments are made to physicians under a "value-based arrangement," for "value-based activities" to achieve "value-based purposes," for patients in a target population, and not conditioned on the referral of patients not in the target population. The College supports this exception. However, we remind CMS that many entities are not assuming full financial risk for their patient populations. While this exception is the most straightforward, it may not facilitate sweeping change until more physicians and entities are able to enter into full risk-sharing arrangements.

2. Value-Based Arrangements with Meaningful Downside Financial Risk to the Physician; Proposed §411.357(aa)(2)

This proposed exception is similar to the one above except risk is measured at the physician level, not at the entity. Under the exception, CMS defines "meaningful" risk as either 25 percent of the value of the payment for physician's services under the value-based arrangement is subject to return for failure to achieve the value-based purposes of the VBE; or the physician is at prospective risk for all or a defined set of patient care items and services for the target population for a defined time period.

While the College supports this exception, we encourage CMS to revisit its definition of meaningful downside financial risk and lower the 25 percent threshold. Under the current landscape, it remains difficult for many individual clinicians, especially specialists, to meet the 25 percent downside risk threshold. Until 2018, physicians had to meet or exceed a threshold of 25 percent of their Medicare Part B payments or 20 percent of their patients attributed to a two-sided risk based Advanced Alternative Payment model to be considered a qualifying participant (QP) under the Quality Payment Program (QPP) established under MACRA. In 2019, this threshold was increased to 50 percent of payments or 35 percent of patients, as required by statute. The ACC has

long advocated that the threshold of risk at the clinician level should be lowered below 25 percent of payments under the QPP and recommends that CMS do the same under this proposed rule.

3. Other Value-Based Arrangements

Of the three proposed value-based exceptions, this category provides the most opportunity for physicians and DHS providers. **The ACC is pleased that CMS has proposed this category as many physicians are currently engaged in initiatives to advance the quality of patient care even if they are not yet ready or able to assume financial risk.**

The ACC also appreciates that as proposed the value-based arrangements exception will permit the use of "virtual groups" for purposes of measuring the achievement of value-based purposes. Team-based care is critical to the transition to value-based payment, and as proposed the value-based payments exception does not restrict groups from consisting not only of those physicians in a group practice under the same Taxpayer Identification Number (TIN), but also virtual groups that span across the inpatient and outpatient settings.

Under this category, CMS proposes that the value-based arrangement be documented and that the performance or quality standards against which the recipient of remuneration will be measured, if any, are objective and measurable. **The ACC supports the use of quality and performance standards, especially as CMS does not limit standards to those measures currently used by the Agency in its QPP programs.** As proposed, the rule allows for the use of internal performance metrics as well as clinical quality measures such as those used in the National Cardiovascular Data Registry (NCDR).

In the proposed rule, CMS seeks comment on whether any performance or quality standards against which the recipient of remuneration will be measured should be required to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery. While the ACC supports the intent of "driving meaningful improvements," the College urges caution when CMS states that measures "should not simply reflect the status quo." Ideally, a high-performing entity will excel at its quality measures and maximize efficiencies; the status quo should lend itself to a high-value care environment. An entity may want to continue utilizing quality metrics and standards that some consider to be "topped out" to ensure that performance does not drop. Performance and quality standards should be required to drive optimal care processes and outcomes; improvement should be considered where there is opportunity to improve.

The College also encourages CMS to guard against mandating a "meaningful improvements" requirement without specifying clear and objectively verifiable standards in the regulation. Ambiguous requirements that are dependent upon interpreting CMS commentary not contained in the rule will only perpetuate the existing problems that have resulted in the self-referral rule acting as a barrier to innovative coordinated care programs.

Finally, under the proposed rule, entities are required to utilize performance and quality metrics to assess whether their arrangement results in higher value. If it is determined that the intended activities are not achieving the value-based purpose of the arrangement, the exception is no longer valid. Many value-based activities begin as pilot programs that take time to develop, implement, and test. **CMS should ensure that any rules governing the withdrawal of an exception for not**

meeting the value-based purpose include a grace or transition period that allow an entity to redesign its activity or implement a new activity while maintaining the exception. Immediately dropping the exception could lead to disruption or even hesitation to take advantage of the exception in the first place.

B. Clarifying Fundamental Terms Important to Multiple Stark Exceptions

The ACC supports steps taken by CMS to incorporate greater certainty in the terms related to compensation arrangements between physicians and DHS providers. However, even with the proposed clarifications discussed below, the Stark law rules remain open to subjective interpretation. Many of the proposed changes in this rule, while positive, have the potential to introduce greater uncertainty. As long as this lack of certainty remains, the regulatory burden of the Stark law has not been eliminated. After CMS finalizes this proposed rule, the Agency should continue to issue clarifying public guidance to ensure that physicians and entities take advantage of the new exceptions to support engagement in value-based activity.

1. "Takes into account" Rule

Several exceptions require that compensation relationships be structured in a manner that do not take into account the volume or value of referrals or other business generated between parties. Varying interpretations of "take[s] into account" have led to confusion around the application of Stark law exceptions. In response to RFI comments, CMS proposes a new bright-line rule stating that a compensation arrangement takes into account neither volume nor value unless:

- The formula used to calculate the physician's compensation includes the physician's referrals to the entity as a variable, resulting in an increase in the physician's compensation that positively correlates with the number or value of the physician's referrals to the entity or negatively correlates if the compensation flows from the physician to the entity (i.e., the physician pays less to the entity as referrals to the entity increase); or
- There is a predetermined direct correlation between the physician's prior referrals or other business generated and the prospective compensation to the physician.

The ACC supports the above clarification provided with respect to the "takes into account volume or value" rule and encourages the Agency to seek additional ways to build certainty around other key terms used to define Stark law exceptions.

2. Group Practice Compensation Test

The College supports clarification of §411.352(i) to permit the distribution of profits within a group practice that are directly attributable to a physician's participation in a value-based enterprise. CMS states that such profits would be considered not to directly take into account the volume or value of the physician's referrals.

Physician involvement is at the core of any value-based care delivery initiative. Allowing a group to share the profits of its participation in an arrangement with the physicians in that group is a step toward aligning incentives to encourage care coordination. CMS should consider additional leeway that would allow a group to share its value-based payment profits not only with physicians under that group, but also with physicians in other groups (under a different TIN) who may also be responsible for the care of the same patient population.

Conclusion

The ACC's concerns with this proposed rule could best be addressed by eliminating the Stark law completely. CMS must realize that finalizing this rule must not be considered the completion of Stark law reform. The world of fee-for-service payment is rapidly disappearing; these regulations must stay ahead of these changes in order to support clinicians in this transition to value. Ongoing efforts should include assessing the care landscape to determine if new exceptions are needed or if the current exceptions need to be redefined; adoption of unambiguous regulatory criteria that are not dependent on being conversant with multiple pages of Federal Register commentary to understand the boundaries of the law without the fear of triggering a whistleblower suit; and continued efforts to support physicians in the movement to value-based care through the development of clinician-led payment models.

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

Sincerely,

Richard J. Kovacs, MD, FACC
President

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