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August 23, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare Program; Request for Information Regarding the Physician Self-Referral Law [CMS-1720-NC]

Dear Administrator Verma:

The American College of Cardiology (ACC) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) regarding its request for information on the physician self-referral (Stark) law as published in the *Federal Register* on June 25, 2018. The ACC is a 52,000-member medical society that is the professional home for the entire cardiovascular care team. The College's mission is to transform cardiovascular care and improve heart health. The ACC leads in health policy formation, standards and guidelines. The College operates national registries to measure and improve care, provides professional medical education, promotes cardiovascular research and bestows credentials on cardiovascular specialists who meet stringent qualifications.

General Comments

Clinicians, particularly cardiovascular care team members, are primarily motivated by one goal: providing high quality patient care and delivering the best outcomes possible to those patients. To provide this level of care, clinicians must be allowed to concentrate on patients and their 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 upon the provision of that care.

The Stark law, as it is commonly known, has become a significant administrative burden on clinicians, impeding their ability to focus on patient care. After major rulemakings in 1992, 1995, 1998, 2004 and 2007, along with smaller revisions and clarifications in other years, it is now clear that this complex and burdensome law cannot be fixed with minor adjustments. Instead, the law, and enabling regulations, have imposed significant hurdles to innovation in care delivery models, innovation that Congress, CMS, clinicians and the American public have recognized as essential to improving care quality and increasing patient engagement. **The ACC urges CMS and Congress to undertake a thorough "top to bottom" review of the law and its purposes.** Such a fresh look, with the benefit of almost 30 years of experience, may suggest that the law is no longer necessary or appropriate given dramatic changes to Medicare payment systems, including the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and in the healthcare delivery system at large, since the law's enactment in 1989. It is important to examine the law holistically and consider broad changes to the law, as adding new exceptions or amending existing exceptions creates confusion.

Alternative Payment Models and the Stark Law

Section III. N. 9 of the 2016 proposed Physician Fee Schedule raised questions regarding the relationship between the regulatory restrictions imposed by the Stark law and other federal fraud and abuse provisions and the government's experimentation with, and advocacy for, alternative payment models. At that time, as now, CMS invited commenters to respond to a list of questions concerning possible revisions to existing exceptions, development of new ones, or differential application of existing exceptions depending on the payment model. No changes were proposed or finalized, based on those comments.

The ACC recommends that CMS focus on the larger picture, the real and stated desire of all stakeholders to change the system used by Medicare to compensate clinicians. The question remains whether or not leaving the Stark law in place will allow the healthcare system to achieve the new goal of moving from a system that pays for volume to one that pays for value as laid out by Congress in MACRA. In other words, will the Stark law allow for the financial alignment of hospitals, healthcare systems or practices with employed or affiliated clinicians for the purposes of driving higher quality, higher value care? The answer at present is murky at best. Rather than providing bright lines to facilitate compliance as originally intended, it has become a regulatory nightmare, which, when combined with the False Claims Act, now poses enormous risks for those it regulates. Quoting from Judge Wynn in the 4th Circuit, it has become "a booby trap rigged with strict liability and potentially ruinous exposure." (Concurring Opinion of Judge Wynn in *Drakeford v. Tuomey*, U. S. Court of Appeals for the 4th Circuit, July 2015). Physicians have been hesitant to pursue traditional solutions, much less push the boundaries of the regulations to create new arrangements, and it is clear that post-MACRA, the situation remains unchanged.

Recent experience with limited waiver of Stark and other regulatory restraints to promote accountable care organizations (ACOs) as part of health reform is telling. If the law must be waived to achieve the essential purposes of health care reform, is it not time to question whether the law must be substantially changed, if not eliminated entirely to accomplish the very goals for which Congress has recently indicated overwhelming support? Cardiovascular care team members report that even with the ACO waivers in place, compliance certainty is still elusive, and clinical and organizational relationships in ACOs are driven more by fear of running afoul of the Stark law than by what might advance reform most successfully. This reality increases costs to the system and prevents the development of innovative payment models that might assist in achieving the overarching goal of improving patient outcomes at decreased cost.

The College believes that CMS and Congress must thoroughly examine the Stark law to determine whether it remains relevant in today's evolving health care system, and whether the benefits justify the regulatory burden it has come to represent. If, upon the conclusion of that review, it is apparent that the Stark law is impeding progress towards achieving higher quality and more cost-effective care, the ACC calls upon Congress and the Administration to take any and all steps necessary to remedy the situation. It is essential that all hurdles to providing patients with the best care possible be removed.

Principles

The ACC has adopted a series of principles to guide discussions regarding potential revisions to the Stark law. Specifically:

- Changes must improve access to/quality of care, especially for vulnerable patient populations.
- Revisions must simplify the law to reduce the exorbitant legal fees and administrative burdens imposed on clinicians.
- As we transition to paying for quality vs. quantity, changes must allow clinicians to be compensated appropriately for the work they do and the quality of care they provide.
- Modifications must allow and encourage collaboration among clinicians, as well as collaboration between clinicians and hospitals, across private practices and multiple health systems, to provide coordinated care in an appropriate manner.
- Modifications to the law should reflect an emphasis on quality measurement, the use of outcome-based clinical data registries such as the National Cardiovascular Data Registry, and the importance of collaborative, team-based care models and other innovative payment structures that underscore best practices.
- Changes must allow for the evolution of clinical practice and future flexibility in the structure of the Medicare program.
- Revisions must allow clinicians the ability to offer their patients both the best care and access to care, particularly for clinical and diagnostic testing in an appropriate setting of the patient's choice.
- Revisions must distinguish between willful and inadvertent violations of the law.

Medicare Care Coordination Improvement Act of 2017

While the College encourages CMS to holistically review the Stark law, we recognize that may not be feasible and encourage the Agency to consider changes similar to those 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 and succeed in alternative payment models. Congress explicitly recognized the Stark Law as a barrier to care coordination when it authorized the HHS Secretary to waive the self-referral and anti-kickback prohibitions for ACOs. **The College believes that physician-led alternative payment models, similarly focused on care coordination, should be afforded similar opportunities to explore innovative methods for doing so and urges the Agency to take the necessary steps to allow them to do so.**

Conclusion

The ACC appreciates the opportunity to provide these comments on potential changes to the Stark law and welcomes the opportunity to provide additional input. The College looks forward to working with CMS 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