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December 31, 2019

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

Re: CMS-1720-P, Medicare Program: Modernizing and Clarifying the Physician Self-Referral Regulations

Submitted electronically via http://www.regulations.gov

Dear Administrator Verma:

The American Association of Clinical Urologists (AACU) respectfully submits these comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed exceptions to the physician self-referral law for certain value-based compensation arrangements between or among physicians, providers and suppliers, published in the *Federal Register* on October 17, 2019 *(Vol. 84, pages 55766-55847).*

Founded in 1968 by urologists concerned by the government's increasing role in the practice of medicine, the AACU is a professional organization representing the interests of more than 4,000 member urologists, and urologic societies engaged as advocacy affiliates across the United States. We are dedicated to developing and advancing heath policy education as it affects urologic practice in order to preserve and promote the professional autonomy of our members and support the highest quality of care for patients.

The AACU strongly supports efforts to modernize the physician self-referral law, also known as "Stark law", particularly in light of the continued shift from fee-based to value-based care. We have expressed this need in comments submitted to CMS in response to prior Requests for Information, including CMS-1720-NC ("Physician Self-Referral Law") and CMS-6082-NC ("Reducing Administrative Burden To Put Patients Over Paperwork").

In its current form, Stark law poses a significant risk to implementing advanced payment models and other value-based and/or innovative financial arrangements. The existing exceptions to the Stark Law for value-based arrangements are extremely technical and require providers to navigate the law for their case-specific contexts.

The complexity and ambiguity under Stark have made it extremely difficult for even the most attentive and diligent providers, who may even have robust compliance programs in place, to comply with Stark. As a result, providers must invest significant

resources to remain in compliance in the form of legal consultation, additional staff, and increased time on administrative matters.

The potential liability associated with an alleged Stark violation creates an enormous barrier to a provider's ability to defend against a claim, even when a provider has valid defenses. Moreover, because Stark has a strict liability provision that holds providers liable for unintentional noncompliance, even minor technical violations, such as missing signatures or out-of-date paperwork, can trigger the onerous penalties specified under the law, including civil monetary penalties and potential exclusion from federal health care programs.

The AACU welcomes the agency's efforts to reverse some of the negative effects the Stark law has had on innovation and the transition to a value-based health care system. The proposed rule will provide additional space for the types of alternative arrangements among physicians that can enhance care coordination, improve quality and reduce costs. Additional reforms that streamline regulatory compliance with Stark will reduce administrative burdens on providers and mitigate paperwork errors.

Overall, we believe the proposed rule will accomplish the following key objectives, which we have previously identified as priorities for Stark law reform:

(1) Creation of new value-based exceptions that foster cooperation between physicians to bring about high-quality, cost effective care with better outcomes

(2) Greater clarification and improved definitions of compensation regulations – "commercial reasonableness", the "volume or value standard", and "fair market value"

(3) Simplification of documentation requirements and the distinction between substantive violations and technical violations

Exceptions for Value-Based Arrangements

The proposed rule creates new exceptions to the Stark Law for value-based arrangements based on the types of remuneration protected (e.g. financial, in-kind), the level of financial risk assumed by the parties to the arrangement (e.g. full, downside), and the types of safeguards in place to prevent abuse.

The AACU supports the joint proposal with the Office of Inspector General (OIG) to create three distinct exceptions (under Stark) and safe harbors (under the Anti-Kickback Statute) when a value-based arrangement 1) assumes full financial risk from a payor, 2) assumes meaningful downside risk, or 3) does not assume any financial risk, but incorporates certain care coordination and care management practices.

These waivers reflect the need for more pathways for providers to participate value-based care models. Urologists apply their expertise to the diagnosis and management of a wide variety of medical conditions, and thus are integral in any care coordination efforts. In fact, many urologists already coordinate care for their patients with pathologists, radiologists, oncologists and other healthcare providers. Increasing integration between these specialties will improve patient care and the patient care experience overall.

Further, it is important that the exceptions include arrangements beyond those that assume full or substantial downside risk, as well as both monetary and non-monetary remuneration. Even one-sided models, when directly connected to care coordination and care management, deliver significant value to the healthcare system and improve patients' quality of care.

We caution, however, that efforts to implement reforms geared toward accelerating the pace of transition to value-based care, should not advantage large practices over small and independent practices. To that end, CMS should support policies that minimize the costs of transition to value-based care models. It

should also monitor the implementation of these rules in relation to their impact on long-term trends of provider consolidation.

Finally, given the various waivers included in the proposed rule for value-based arrangements, CMS is advised to provide clear guidelines and training to help providers determine their eligibility for a waiver under Stark and the process for obtaining such clearance for their practice. CMS should also strive for simplicity in the final rules, and as such, should work with OIG to correlate the terminology and requirements that apply to Stark law exceptions and AKS safe harbors.

Updated Definitions of Compensation Regulations

The AACU strongly supports the proposed changes to terminology and concepts inherent in the physician self-referral law, namely "commercially reasonable", "fair market value", and compensation that "takes into account the volume or value" of Medicare referrals. These conditions are mostly the product of an outdated, volume-based, fee-for-service environment. At a minimum, clear and straightforward statutory standards should be established by clarifying definitions for these key terms and removing the ambiguity that creates barriers to innovation and coordinated, value-based care.

CMS notes that an arrangement should be considered "commercially reasonable" if it makes sense as a means to accomplish the parties' goals – from the perspective of the parties involved in the arrangement. The determination of commercial reasonableness should not depend on valuation or require profitability. The new definition recognizes that compensation arrangements that do not result in profit for one or more of the parties may nonetheless be commercially reasonable.

The proposed definition of "the volume or value of referrals" clarifies terms that have long created confusion among providers and enforcement agencies. CMS is advised to create further clarification that personal productivity compensation is protected in all settings. Given past legal challenges to this concept, final regulatory guidance should clearly state that compensation for personal productivity is permissible under the personal services, fair market value compensation, and indirect compensation arrangements exceptions.

Another positive definition change clarifies that the fair market value requirement should be separate and distinct from the "volume and value" of referrals and other business-generated standards. Compliance with Stark should not hinge on whether compensation arrangements take into account or anticipate referrals.

Providing Flexibility for Non-Abusive Business Practices

The AACU supports the revision to the fair market value exception that allows for arrangements under which a physician receives limited remuneration (up to $3,500 per calendar year) for items or services actually provided by the physician. This exception will help address provider concerns regarding technical non-compliance related to non-abusive practices.

The proposed rules list a variety of criteria which must be met for this exception to be authorized, such as the remuneration must further a legitimate business purpose for both parties, must not exceed the fair market value for the items or services, and not be related in any way to the volume or value of referrals or other business generated by the physician. The AACU believes these are reasonable minimum requirements that provide safeguards from abuse and therefore does not support limiting the applicability of the exception to items and services that are personally furnished by the physician. A condition specifying that these arrangements do not violate the AKS or other Federal or state law or regulation on billing and claim submission is also unnecessary.

CMS set a remuneration limit of $3,500 per year under this exception to accommodate non-abusive compensation arrangements and offer more flexibility. The AACU encourages the agency to consider raising the annual aggregate limit to better reflect the typical range of commercially reasonable arrangements for the provision of items and services that a physician might provide to an entity on an infrequent or short-term basis. While the remuneration limit, together with other safeguards in this exception, will help prevent any possibility of program or patient abuse, the low threshold may result in the continuation of technical violations that are non-abusive, but which nonetheless require reporting.

Finally, this exception should not require prior documentation detailing the formula used for calculating remuneration, as long as the arrangement complies with the proposed safeguards.

Simplification of Documentation Requirements

The AACU has long advocated for minimizing and simplifying the documentation requirements associated with Stark law compliance. We therefore support the proposal that creates a 90-day grace period for providers to finalize and sign documentation detailing their compensation arrangements, as long as the arrangement meets all the requirements of an applicable exception. This revision will help ensure that physicians have the opportunity to avoid penalties due to unintentional, technical violations that can be quickly remedied without risk to patients or the Medicare program.

We urge CMS to finalize this proposed change and to also consider clarifying that electronic signatures and documents are permitted as acceptable forms of documentation for formalizing compensation arrangements.

Conversely, we oppose a proposal to require physicians to provide a notice (or have a policy regarding such notices) that alerts patients that their out-of-pocket costs may differ depending on their insurance coverage and where the services are delivered. If finalized, this requirement would only confuse patients and create unnecessary paperwork for providers. The AACU supports congressional action on price transparency and welcomes the opportunity to work collaboratively with other stakeholders on ways to better inform patients about their estimated out-of-pocket costs prior to receiving medical treatment.

Electronic Health Records (EHR) and Cyber-Security Exceptions

One update to the Stark law that the AACU has communicated to CMS about in the past is making permanent the existing safe harbors for EHR software and technologies, and broadening the definition of "electronic health record" beyond clinical diagnosis and treatment to include such things as information sharing and cyber-security.

In the proposed rule, CMS includes a series of "modest" changes to the EHR exception that create greater consistency across the Stark and AKS statutes. The revisions would remove the sunset date for the donation of interoperable EHR software, clarifies that certain cyber-security technology is included as part of an EHR arrangement, updates provisions regarding interoperability and data lock-in, modifies the 15 percent physician contribution requirement, and permits certain donations of replacement technology.

The AACU supports elimination of the EHR exception's sunset date as donations of EHR technologies are necessary in order for providers to continue to be able to absorb the often-prohibitive costs associated with these technologies. As EHR software continues to evolve and improve, it will bring about greater efficiencies and enhanced patient care and outcomes. Making the exception permanent will provide participants in value-based arrangements with more predictability, facilitate the goals of

meaningful use, and pave the road for patient self-management tools that include patient demographics, medical history, clinical orders and laboratory results.

CMS also proposes to eliminate the 15-percent contribution requirement in this exception for all recipients. The AACU also supports this update as the requirement has proven to be burdensome to some providers, particularly those in smaller practices who have more difficulty meeting the 15-percent cost sharing requirement for participation. Removal of the 15-percent contribution will alleviate one of the barriers to adoption of EHR and also minimize the administrative burden of tracking and calculating the contribution. At a minimum, the requirement should be removed for small and rural practices and for updates to previously donated EHR technology.

In addition, CMS clarifies in the proposed rules that certain cyber-security software and services that "protect" electronic health records are protected under this exception. Given the rise in cyber-security attacks, and electronic health care information particularly vulnerable, this exception is essential to safeguarding and ensuring patient privacy. Maintaining the cyber-security of EHR can be costly and burdensome especially for small and independent practices. This new exception will allow more practices to be protected, ensuring the safety of patient data while allowing for advancement of interoperability, which is also a key driver of high quality care.

Conclusion

The AACU appreciates the opportunity to provide comments on the proposed changes to the physician self-referral law. In general, we believe these reforms will support urologists' ability to deliver high-quality care to their patients. We encourage CMS to finalize the proposed updates in CMS-1720-P as quickly as possible in order to reduce regulatory burden, simplify and streamline compliance obligations, and facilitate the transition to innovative, value-based care models.

If you have any questions regarding this letter or would like to discuss any of our comments, please contact Yehuda Sugarman, Federal Affairs Manager, at Yehuda.Sugarman@naylor.com or 800-369-6220, ext. 1900.

Sincerely,

Scott B. Sellinger, M.D., F.A.C.S.
AACU President