Submitted Electronically

August 21, 2018

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

RE: *Request for Information: Centers for Medicare & Medicaid Services, Physician Self-Referral Law*

Dear Ms. Verma:

The Florida Hospital Association (FHA), on behalf of its more than 200 member hospitals and health systems, welcomes the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) Request for Information (RFI) on the physician self-referral law ("Stark law"). The focus of our recommendations will be related to accelerating the transformation to a system of value-based care and removing regulatory obstacles to coordinated care. These recommendations are reflective of the problems with the Stark law related to compensation arrangements that our members encounter every day. We would like to make it clear, however, that we neither recommend nor support modifying the regulations implementing the Stark law's ownership ban. The ban is a carefully crafted policy that is working as Congress intended.

As health care needs and experiences have grown increasingly complex over the past decade, our members are working to deliver more value-based care to patients, and to meet the demands of patients, other providers, the government, and other payers for accountability and affordability. However, the tools available to them are limited – their development of innovative payment arrangements has been greatly stymied by the Stark law. Our members have expressed the desire to work both within and outside of their single organization with a variety of partners to deliver comprehensive, coordinated care to patients. We are hopeful that CMS's modifications to the Stark law will enable them to do so by allowing the development and implementation of innovative programs that align providers through financial incentives, among other tools in order to improve patient outcomes and the patient experience while increasing efficiency.

ACCELERATE THE TRANSFORMATION TO A SYSTEM OF VALUE-BASED CARE

The design of the compensation prohibitions and the strict liability standard of the Stark law are very problematic. Any violation is subject to the same penalty – return of any amount paid by the Medicare and Medicaid programs for services provided to a beneficiary based on a physician's self-referral – without regard to whether the services were, in fact, medically necessary or the nature of the infraction was highly technical, such as failing to sign a form.

An essential component for the success of value-based arrangements is aligned incentives – specifically, financial incentives to promote more coordinated care and improve the patient care

experience. In their efforts to implement value-based payment arrangements that reward their physicians for delivering high-quality, cost-effective care with better outcomes, the Stark law is one of the main impediments our members face. A true value-based payment arrangement can only be accomplished through teamwork among hospitals, physicians and other health care providers across sites of care. The Stark law compensation prohibitions are at odds with the creation of such payment arrangements in that the Stark law provisions drive providers in the opposite direction, keeping them siloed. The Stark law makes it nearly impossible for providers to design flexible payment terms that could help their organizations reach these goals through the delivery of coordinated care. In order for innovative payment arrangements involving new relationships with physicians to succeed, our members need the ability to make significant investments in care coordination without running afoul of the Stark law. Current Stark exceptions do not cover many of the innovations hospitals seek to implement and the waivers of Stark for certain programs or projects are too limited to enable them to make broad-scale changes.

The FHA, therefore, recommends that CMS create a new innovative payment exception for value-based payment arrangements. We believe this proposed innovative payment exception is essential to the ability to improve patient care. The creation of this exception would present our members with a new opportunity to implement incentives that drive physician decision-making toward high-value care for each and every patient they see. We recommend that an innovative payment exception protect value-based incentive programs that promote: (1) accountability for the quality, cost and overall care of patients; (2) care management and coordination; and/or (3) investment in infrastructure and redesigned care processes for high-quality and efficient care delivery. The proposed exception should protect any remuneration that is provided and received pursuant to a clinical integration arrangement involving providers or suppliers of services and physicians or a physician practice. The exception also should protect incentive payments, shared savings based on actual cost savings, and infrastructure payments or in-kind assistance reasonably related to and used in the implementation of the clinical integration arrangement, and should be subject to objective, measurable, and transparent performance standards.

REMOVE REGULATORY OBSTACLES TO CARE COORDINATION

The FHA greatly appreciates CMS's recognition of the need to remove regulatory obstacles to care coordination. We recommend the agency do so by providing clear, unambiguous definitions of critical requirements. Both the FHA and our members are often uncertain about what is acceptable under several Stark requirements; that uncertainty decreases the ability to innovate and undercuts care transformation. By offering guidance and clarity around the requirements with which our members need to comply in order to receive payment, CMS will enable them to invest in integrated care and innovative payment arrangements in a manner that is compliant with the Stark law.

Compensation that does not take into account the volume or value of referrals. The volume/value element of the Stark law has created immense confusion, thereby chilling the drive of hospitals and health systems to create innovative payment arrangements. To combat this chilling effect, we recommend CMS clarify that, for a fixed payment, the amount of compensation does not vary or take into account the volume or value of referrals if the amount is

initially determined by a methodology that does not take into account referrals and is not subsequently adjusted during the term of the agreement based on referrals.

The volume/value element requires that the methodology used to formulate the amount of compensation paid must not take into account referrals. The parties' state of mind in arriving at the amount of compensation is not relevant; rather, the central question is whether the methodology actually utilizes a physician's referrals in determining the amount of compensation paid to a physician or an immediate family member. This clarification is essential to the ability to align the goals of the hospital or system and of their physicians and to incentivize physicians to make value-based modifications on a patient-by-patient basis. In addition, CMS could adopt a new deeming provision that would establish that any compensation which does not fluctuate with a physician's referrals is deemed not to take into account the volume or value of a physician's referrals.

We also urge CMS to clarify and reaffirm that the volume/value requirement is not implicated where the payment is based on physicians' personally performed services, even when those services incidentally increase or decrease the delivery of designated health services (DHS) by a hospital or other DHS entity. This clarification will reduce concerns that arise when our members engage in efforts to improve quality and efficiency through greater cooperation with their physicians (such as quality bonus programs, shared savings arrangements, and provision of infrastructure or other assistance at no charge).

Fair market value (FMV). We strongly recommend that CMS restore the definition of fair market value to the original language of the statute. Doing so would rightfully de-couple FMV from the volume/value element of the Stark law, giving hospitals a chance to design incentives that may impact referrals but that do not drive overutilization nor undercut medically necessary utilization. Therefore, we recommend CMS define fair market value as the value in arms-length transactions consistent with general market value and define general market value as the price of an asset or compensation for a service that would result from bona fide bargaining between well-informed parties to the agreement. Whether or not the parties are in a position to generate business for each other is irrelevant and the agency's addition of that language to the regulation has created needless confusion.

In addition, the regulations should establish a presumption of FMV. Currently, FMV is a requirement of the exceptions and, therefore, the burden of proof for FMV is on the provider. Currently, all transactions are presumed <u>not to be</u> FMV unless the provider can prove otherwise. This has resulted in *qui tam* relators being able to survive motions to dismiss based on groundless allegations of compensation in excess of FMV. This presumption also reflects an outdated view that all hospital-physician relationships should be viewed with suspicion.

Commercial reasonableness. Despite guidance over the years on the definition of commercial reasonableness, there is still confusion on what is needed to satisfy that prong of various Stark law exceptions. We urge CMS to clarify that commercial reasonableness is a question of whether the items or services being purchased are useful in the purchaser's business and purchased on terms and conditions typical of similar arrangements between similarly situated parties. As described above, asking whether the amount of the purchase is reasonable is the subject of fair

market value determinations, not commercial reasonableness. This change will enable hospitals and health systems to clinically integrate with physicians for improved care coordination even when the purchase of a physician practice, for example, results in a net loss to the system.

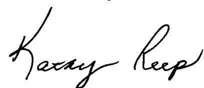
Referral. Because care coordination requires some degree of care management, hospitals need the ability to work together across their entire organizational system, and even outside of it, to ensure patients get the right care at the right time. However, some physician efforts to do so are considered “referrals” under the current Stark law, even if the referral presents no risk for increased payment to the organization. Therefore, we urge CMS to clarify that a referral only implicates the Stark law when it results in an additional or increased payment from CMS to the DHS entity.

In addition to implementing fixes to the Stark law that will enable and protect value-based payment arrangements and expand the ability to provide coordinated care, we request that you also provide relief from certain technicalities of the Stark law that inhibit hospitals’ ability to focus on patient care. Specifically, we recommend that you address needlessly confusing and burdensome documentation requirements that expose providers to potentially catastrophic payment denials without protecting against problematic arrangements. To do so, we urge you to provide an alternative method of compliance with documentation requirements that focuses on whether, based on a review of any documentation commonly relied upon by reasonably prudent persons in the conduct of their affairs, the parties reached an agreement as to the terms of an arrangement to which they intended to be bound. Use of this method would eliminate the need for a signature requirement, while preserving the substantive intent of the exception – that an agreement exists to terms upon which the parties have agreed. Further, this objective standard avoids the potentially numerous inconsistent standards that would result from reliance on state law.

Finally, we urge you to de-couple Stark and the anti-kickback statute (AKS) by eliminating from regulatory exceptions to the Stark law the requirement that financial arrangements must not violate the federal AKS. This requirement is unnecessary and will be an impediment to comprehensive, coordinated care by, for example, placing an unreasonable burden of proof on entities seeking payment with no offsetting benefit or protection to the Medicare program.

Again, the FHA appreciates the opportunity to provide these recommendations related to the current physician self-referral law and suggested changes to further innovative payment arrangements focused on advancing affordable value-based care to the patients in Florida and across the country. If there are questions on these comments, please do not hesitate to contact me at kathyr@fha.org.

Sincerely,



Kathy Reep
Vice President/Financial Services