

August 23, 2018

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:

On behalf of North Carolina Healthcare Association, thank you for the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) Request for Information (RFI) on the physician self-referral law ("Stark law").

As health care needs and experiences have grown increasingly complex over the past decade, our organization is 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 us are limited—our development of innovative payment arrangements has been greatly stymied by the Stark law. We are eager to work both within and outside of our organization with a variety of partners to deliver comprehensive, coordinated care to our patients. We are hopeful that CMS's modifications to the Stark law will enable us to do so by allowing us to develop and implement innovative programs that align providers through financial incentives, among other tools. **We are confident that, with changes to the Stark law that support the adoption of value-based payment arrangements while removing obstacles to care coordination, we can improve patient outcomes and the patient experience while increasing efficiency.**

Our recommendations, enumerated below, include: (1) accelerating the transformation to a system of value-based care, and (2) removing regulatory obstacles to coordinated care. These recommendations are reflective of the problems with the Stark law related to compensation arrangements that we encounter every day. We refer you to comments from the American Hospital Association (AHA) for an all-inclusive response to your RFI and wish to express our support for those recommendations. **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.**

ACCELERATE THE TRANSFORMATION TO A SYSTEM OF VALUE-BASED CARE

In our efforts to implement value-based payment arrangements that reward our physicians for delivering high-quality, cost-effective care with better outcomes, the Stark law is one of the main impediments we face. Specifically, the Stark law makes it nearly impossible for us to design flexible payment terms that could help our organization reach these goals through the delivery of coordinated care. In order for innovative payment arrangements involving new relationships with physicians to succeed, we 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 we seek to implement and the waivers of Stark for certain programs or projects are too limited to enable us to make broad-scale changes.

We, therefore, recommend that CMS create a new innovative payment exception for value-based payment arrangements. The creation of this exception would present us 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.

We believe this proposed innovative payment exception is essential to our ability to improve patient care. Specifically, [**Consider inserting example of payment arrangement you have not been able to implement because it's not clear whether it would be permitted, or one you've implemented under a waiver that would be good for any similar beneficiary's care, and how the proposed exception would allow you to implement it. It would also be beneficial to highlight any special obstacles that disadvantage hospitals, such as those in rural areas**].

REMOVE REGULATORY OBSTACLES TO CARE COORDINATION

Our organization 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. We are often uncertain about what is acceptable under several Stark requirements; that uncertainty decreases our ability to innovate and undercuts care transformation. By offering guidance and clarity around the requirements with which we need to comply in order to receive payment, CMS will enable us 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 in our field, 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 our ability to align the goals of our organization and of our physicians and to incentivize physicians to make value-based modifications on a patient-by-patient basis.

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 we engage in efforts to improve quality and efficiency through greater cooperation with our physicians (such as quality bonus programs, shared savings arrangements, and provision of infrastructure or other assistance at no charge).

Fair market value. **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 our organization a chance to design incentives that may impact referrals but that do not drive overutilization nor undercut medically necessary utilization. **To that end, 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).

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 us to clinically integrate with physicians for improved care coordination even when the purchase of a physician practice, for example, is a net loss to our system.

Referral. Because care coordination requires some degree of care management, we need the ability to work together across our organization, and even outside of it, to ensure patients get the right care at the right time. However, some of our physicians' efforts to do so are considered "referrals" under the current Stark law, even if the referral presents no risk for increased payment to our 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 our ability to provide coordinated care, we request that you also provide relief from certain technicalities of the Stark law that inhibit our ability to focus on patient care. Specifically, we recommend that you address needlessly confusing and burdensome documentation requirements that expose us 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 there is a legally binding agreement between the parties. **This method should provide that an agreement enforceable under applicable state law will be sufficient to satisfy the requirement in any Stark exception that an arrangement be set out in writing and signed by the parties.**

Finally, in order to give effect to any modifications you make to the Stark law, **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, we thank you for your focus on improving value for patients and providers and for your consideration of our comments and comments from the AHA.

Sincerely,



Stephen J. Lawler
President
North Carolina Healthcare Association