August 24, 2018

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: Seema Verma
CMS–1720–NC
P.O. Box 8013
Baltimore, MD 21244–8013

Re: Request for Information Regarding the Physician Self-Referral Law (CMS-1720-NC)

Dear Ms. Verma:

The Healthcare Quality Coalition writes in response to the Centers for Medicare and Medicaid Services Request for Information Regarding the Physician Self-Referral Law. We appreciate your leadership and commitment to seeking administrative solutions for the regulatory barriers provided by the Physician Self-Referral Law. This is an important policy issue impacting the delivery of healthcare services by our providers and hospitals. We believe CMS has an opportunity to reform the regulatory landscape authorized under the Physician Self-Referral law that often stands in the way of designing innovative models of care. The Physician Self-Referral Law, commonly known as the *Stark Law*, needs reform to recognize and support team-based, value-based care. We also strongly encourage CMS to issue a request for information regarding the Anti-Kickback Statute and the civil monetary penalty laws, which often intersect with the Stark Law impacting healthcare providers' and hospitals' ability to design comprehensive care models.

The Healthcare Quality Coalition (HQC) comprises of clinicians, hospitals, associations, and cooperatives dedicated to value-based care. In short, we believe healthcare providers should be held accountable for the quality and value provided to their patients and communities. The HQC is committed to supporting value-based initiatives in a way that encourages fair reimbursement to providers delivering high value care to the patients they serve. While we strongly support new, innovate models to care, existing regulatory and statutory barriers often impede progress towards improved quality and reduced cost of care. It is imperative the Administration continue to focus on reducing regulatory barriers to value-based care, and we urge continued action on this policy front.

To that end, we offer CMS the following policy principles and comments on the Physician Self-Referral Law:

Policy Principles to Removing Stark Law Barriers to Coordinated Care

- The existing Stark Law is complex and often confusing to implement and interpret
- The Stark Law is a barrier to value-based care arrangements and population health programming, and limits the seamless implementation of alternative payment models
- Waivers and exceptions granted in the regulations are often overly complex, too short in duration, or only pertain to very specific activities
- The **HQC recommends** the Department of Health and Human Services simplify the existing regulations and provide broader exceptions for value-based models and community health activities aimed at improving health and lowering cost while ensuring safeguards for patient choice.

Background

The physician Self-Referral Law was created to prohibit a physician from referring patients for certain designated health services to an entity with which they may have a financial relationship. The Stark Law and its implementing regulations provide exceptions in certain specified situations and arrangements; however, meeting and interpreting the criteria for the exceptions is often complex and challenging. Exceptions are often very narrow and specific, compounding complexity about designing a model to fit the exception. As Medicare and the private sector move toward payment arrangements that focus on value and quality-based outcomes, as opposed to fee-for-service, the Stark Law has proved to be an impediment in advancing toward this goal.

The basic tenets of the Stark Law need to be re-visited and evaluated to: 1) determine the applicability to team-based care delivery; and 2) ensure beneficiary protections and choice of healthcare provider. Stark Law reforms should be simplified to recognize that alternative payment models, rather than fee-for-service arrangements, are quickly becoming the primary source of care delivery.

In addition to alleviating regulatory and administrative tasks and the Stark Law's applicability to Medicare specific alternative payment models we support advancing broader reform opportunities. The Stark Law's applicability to compensation arrangements is anchored in a fee-for-service environment where physicians were predominately self-employed, hospitals were separate entities, and both billed for services on a piecemeal basis. With limited and narrowly defined exceptions, the Stark Law prohibits physicians from referring patients to any provider if the physician has any financial relationship, such as an ownership interest or a compensation arrangement, with the provider. Transactions must be conducted within "fair market values" and "commercially reasonable" standards that are vague or interpreted too narrowly.

Alternative Payment Models

- **Alternative payment models should be broadly defined where the basis of the model (payment or performance metrics) integrates measures of cost and/or quality. The**

underlying incentive should recognize value-based care, rather than volumes and fee-for-service arrangements.

- **Stark Law exceptions should be applied to all alternative payment models in a consistent manner.**

Alternative payment models aim to divorce the systemic fee-for-service reimbursement system from volume-laden financial incentives. The foundational elements of the Stark Law aim to prevent and mitigate financial relationships and arrangements that would exploit a fee-for-service system. As care delivery has transitioned more towards non-fee-for-service models, the existing Stark Law has become less relevant as a mechanism to protect against financial abuse. Incentives are being designed to reduce unnecessary medical care service utilization through the form of shared savings, capitation, global services, and bundled payments.

While CMS has authorized various Stark Law exceptions for alternative payment models, it should recognize broader definitions of alternative payment and care delivery models outside of the current scope. For example, exceptions to Stark Law are often narrow and defined to specific activities and models, such as those approved by the Centers for Medicare and Medicaid Innovation (CMMI). In fact, members of the HQC have used the waivers for Accountable Care Organizations and other models to achieve cost savings. However, many care redesign models are implemented outside of the purview of CMMI and CMS that do not qualify for a Stark Law exception.

For example, waivers used for certain models developed by the CMMI are done on a case-by-case basis and oftentimes program applicants do not have up-front guidance regarding which requirements will or will not apply. In addition, some waivers provide only limited protections, are only applicable to Medicare payments, or do not include certain downstream entities. Furthermore, every model and every model's waivers are different. This continues to create complications, especially for those stakeholders who are seeking to make broad healthcare improvements that cut across different sectors and integrate different levels of care.

Alternative payment models are often limited to those approved by the CMMI. If a hospital and physicians/physician groups partner on reducing hospital readmissions, a Stark Law exception may not apply. Even though the care model aims to reduce utilization and reduce healthcare costs, the model would need to meet the parameters of Stark Law and is often prohibited since readmissions often implicates the "volume of referrals" requirements of the law. Models can also be closely related to existing CMS programs, such as Hospital Readmissions Reduction, Hospital Value-based Purchasing, and the Physician Quality Payment program. These should be recognized within the framework of alternative payment models and be subject to allowable exceptions.

We specifically urge a broad interpretation of alternative payment models as many innovative reforms are still in development. Rather than stifle ongoing efforts to design new care arrangements, a new value-based exception should be sufficiently flexible to accommodate changes that are beyond the

current models being used today. CMS should consistently and broadly define alternative payment models, and apply exceptions in a standardized manner.

Terminology

- **We ask that CMS provide clarity on three key terms – fair market value, volume and value of referrals, and commercial reasonableness – that are commonly used in Stark Law exceptions.**
- **In re-defining terminology as it applies to Stark Law, it should be oriented around beneficiary protection. Financial terminology aims squarely at business relationships, but in care delivery that is growing in capitation and risk-based arrangements, the application of Stark terms should be focused on ensuring beneficiary protections.**
- **Terminology should be in plain language with accompanying "frequently asked questions" for guidance.**
- **Technical modifications can reduce administrative burdens and protect patients. HHS should focus resources on violations that directly harm beneficiaries as opposed to mere technical violations, such as signature omissions.**

The HQC believes the overall approach to complying with the Stark Law and its implementing regulations should be re-visited. Rather than focusing on terminology aimed at transactions and services occurring between healthcare providers, CMS should flip the perspective to impact on patient care and beneficiaries.

In addition, we would welcome CMS to consider a greater focus on harm to beneficiaries as opposed to these vague terms that only look at the financial components of an arrangement. CMS could better use its advisory opinion process to give certainty to situations that pose little to no risk of abuse. This could include more appropriate guidance on how to address mere technical violations, like signature requirements, keeping documentation etc., that are inadvertent actions and do not directly impact the quality of care.

Stark Law terminology is primarily anchored in the context of the service provided and referral. However, we believe re-visiting the terminology oriented on potential impact to beneficiaries would be a better approach. Healthcare providers would need to adhere to guidance that ensures beneficiaries are protected, including choice of care providers, while complying with Stark Law. We recommend CMS re-focus the overall definitions and terminology toward beneficiary protection.

Technical modifications can also help ensure beneficiary protection and reduced administrative burden. Focusing on fraud, waste and abuse would be better served than on violations regarding signature omissions and excessive documentation. We realize the balance that must be achieved between compliance and oversight, but minor technical violations can impede efforts towards enforcing misuse and abuse.

Revisions and/or Additions to Stark Law Exceptions

- **The HQC supports broadened exceptions to the Stark law to recognize and support innovative care delivery models and community health activities.**
- **Exceptions should recognize the underlying goals of cost reduction and improved quality as the foundation—not restrictions based on fee-for-service arrangements.**

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. Existing waivers do not protect all APMs or only provide temporary relief, which undercuts a provider's ability to adopt permanent changes across all patient populations. **Therefore, the HQC recommends that CMS create a new innovative payment exception for value-based payment arrangements and community health activities**. The creation of this exception would provide an opportunity to implement incentives that advance models and population health efforts. 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/physician practices. 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.

Similarly we would support a new exception that allows community health activities that may be outside of a formal value-based arrangement. Often hospitals and other providers would like to offer one time or more limited assistance to local entities that need funding to provide important community benefits. For example, entities have wanted to support counseling services acknowledging the severe lack of access to mental health providers. Such support may not be done in a formal alternative payment model but still could be held accountable to CMS via protections that show no harm to beneficiaries or significant revenue to other entities.

Roles of Transparency & Ways to Mitigate Abuse

Maintaining integrity and compliance with the Self-Referral Statute is imperative. The HQC believes other methods can be utilized to meet the statutory requirements of the law while ensuring Medicare beneficiaries are protected. Transparency in care delivery model designs and care options can help meet the intent of Stark Law while ensuring beneficiary choice, awareness, and education. Disclosure of relationships and potential benefit of referral versus actions required of the patient should be openly encouraged and discussed. Focusing on the interactions of care with the patient—rather than

documentation and administrative tasks on ensuring the model meets the specific definitions of financial relationships can help mitigate the barriers faced by providers and hospitals.

Conclusion

The HQC appreciates CMS undertaking efforts to examine Stark Law policy issues. We strongly support reforming regulatory and administrative barriers inhibiting value-based care design and delivery, and believe the long-term viability of the Medicare program lies in crafting reimbursement policies that reflect robust value-based policy. We ask CMS to also examine ways to reform the Anti-Kickback Statute in tandem with the Physician Self-Referral Law and look forward to being an active partner with the agency on seeking solutions to removing regulatory barriers to value-based care delivery.

Please feel free to contact us with any questions.

Sincerely,

The Healthcare Quality Coalition

The Healthcare Quality Coalition (HQC) is comprised of clinicians, hospitals, associations, and cooperatives dedicated to value-based care. In short, we believe healthcare providers should be held accountable for the quality and value provided to their patients and communities. The HQC is committed to supporting value-based initiatives in a way that encourages fair reimbursement to providers delivering high value care to the patients they serve. www.qualitycoalition.net