July 31, 2018

Honorable Peter Roskam
Chair, Committee on Ways & Means, Subcommittee on Health
U.S. House of Representatives
2246 Rayburn House Office Building
Washington, DC 20515

Honorable Sander Levin
Ranking Member, Committee on Ways & Means, Subcommittee on Health
U.S. House of Representatives
1236 Longworth House Office Building
Washington, DC 20515

Re: Hearing on *Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program*

Dear Mr. Roskam, Mr. Levin, and members of the Committee on Ways and Means, Subcommittee on Health:

On behalf of the Healthcare Quality Coalition, we thank the subcommittee for holding a hearing on July 18 entitled *Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program*. This is an important policy issue impacting the delivery of healthcare services. We believe Congress has an opportunity to reform an antiquated 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 the subcommittee to convene a hearing on the Anti-Kickback Statute, which often intersects the Stark Law impacting healthcare providers and hospitals ability to design comprehensive care models.

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. It is imperative Congress 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 the subcommittee the following policy principles and comments on the Physician Self-Referral Law:

Removing 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** Congress simplify the existing laws 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.

The Stark Law was created to prohibit a physician from referring patients for certain designated health services to an entity with which the physician may have a financial relationship. Regulations allow for exceptions to Stark Law in certain specified situations and arrangements; however, meeting 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.

Members of the Ways and Means committee have introduced and advanced legislation, including the Stark Administrative Simplification Act to ease the impact of the Stark Law's strict liability provisions. This past February, language was included in the Bi-partisan Budget Act of 2018 to modernize the application of the Stark Law on errors for signature omission errors, lease arrangements, and other administrative activities. But 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.

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 statutorily simplified to recognize that alternative payment models, rather than fee-for-service arrangements, are quickly becoming the primary source of care delivery.

The HQC appreciates the subcommittee 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 the committee 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 committee 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

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