WISCONSIN HOSPITAL ASSOCIATION, INC.

August 24, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

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

Dear Ms. Verma:

On behalf of the Wisconsin Hospital 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"). We are very pleased that CMS has made efforts to reduce the regulatory burden a priority in this administration and stand willing to work with you on ideas to get government regulations out of the way in order to allow hospitals to improve care in our communities.

Wisconsin hospitals have a stellar reputation for providing value-based care. Wisconsin was listed number one in quality by the federal Agency for Healthcare Research and Quality in 2017, and has finished in the top 5 states in the country every year but one in the last decade. Yet, though we consistently have been among the top in quality rankings nationally, data on Medicare reimbursements suggest Wisconsin providers are paid lower Medicare rates than many states with lower quality scores. In fact, in 2014, Wisconsin was among the lowest spending states per Medicare beneficiary, according to the Kaiser Family Foundation. Clearly, if Medicare wants to incentivize higher quality performance, it should be paying more for better quality outcomes, not less. Alternative payment models (APMs) are one avenue that provide more payments based on value, yet the Stark Law can sometimes interfere with these APMs.

As you know, the Stark Law, named after its lead author, former California Congressman Pete Stark, is now more than 25 years old. When it was envisioned, Congress was trying to ensure physicians refer patients for services and tests only based on whether they are necessary, by making sure physicians do not receive financial incentives for such referrals. While well intended, over the years, new codes and well-intentioned exceptions have made the law increasingly complex to follow.

While many hospitals have desired to create contracts with physicians designed to reward them for providing high-quality patient care, they must be careful that such contracts

follow Stark to the letter of the law, rather than simply the spirit of it. They now must dedicate an inordinate amount of attorney and compliance staff time to reviewing such payment arrangements before they are made, leading some to abandon such arrangements altogether due to the perceived risk being higher than the potential reward.

In order to ease this burden on hospitals, we recommend CMS do everything possible within its statutory limitations to make the law less complex and more user-friendly. We recognize this is a complex law and that careful consideration must be given to the balance of trying to streamline such a maze of regulations while still being able to provide the detail needed to understand what is and is not a violation. We suggest CMS focus on four key areas to make it a law that is easier to comply with and that does not deter providers from pursuing value-based payment reforms:

1. Clearer exceptions for value-based payments.
2. Clearer key definitions.
3. Prioritize intentional, rather than unintentional violations.
4. Harmonize Stark Law regulations with those under the Anti-Kickback Statute

**Clearer Exceptions**

As previously mentioned, many providers who participate in value-based payment arrangements do so as recognized by an exception within the existing law. While these exceptions are useful, it can be confusing to understand whether a newly proposed arrangement will neatly fit within a previously established exception. Additionally, some current exceptions may be too narrow, or too short in duration. We therefore urge CMS to work to make it easier to understand exceptions, either by streamlining existing exceptions with a broader basis, or by creating a wholly new exception that is specifically focused on innovative value-based payment arrangements.

This type of exception should prioritize accountability for quality, cost, and patient outcomes while allowing for care coordination and care management. The exception should recognize everyone who collaborates to create the value-based arrangement so that no entity is penalized for good-faith efforts to improve quality or reward value over volume. Incentive payments, shared savings based on cost savings, and infrastructure payments should all be allowable exceptions so long as they are accounted for in a measurable and transparent manner.

**Clearer Definitions**

The RFI requests feedback on a number of definitions. WHA strongly encourages CMS to simplify regulatory definitions to be more consistent with the original intent of the statute. In particular, the terms *fair market value* and *commercial reasonableness* can be difficult to fully understand when attempting to comply with the Stark Law. We recommend CMS streamline these definitions in their regulations so that healthcare providers have clear

expectations on how to evaluate their agreements and whether they are Stark Law compliant.

We also urge CMS to evaluate referrals based on the impact they have on the beneficiaries they serve. In other words, there may be numerous positive reasons for referrals under value-based and innovative alternative payment arrangements. Care coordination and care management require that healthcare providers be allowed to work together within and outside of their organizations in order to prioritize the right care in the right setting at the right time for patients. The Stark Law needs to do a better job of allowing for such referrals so long as they are not misutilization or overutilization of services done to generate additional revenue based on volume.

**Intentional Versus Technical Violations**

We understand that the Stark Law is a strict liability statute, and as a result, CMS is bound by the statute to not consider the intent to violate the statute when investigating violations. We support Congressional attention to this area of the statute and believe CMS should work with stakeholders to develop statutory changes that could be supported by a wide bipartisan majority of Congress. At present, the threat of unintentional violations is a major risk that many organizations are not willing to take. If we are going to see a wider movement toward value-based alternative payment methodologies, embraced by both large integrated and small independent health systems, then this area of the statute must be reformed.

In the meantime, CMS should do what is within its authority to prioritize intentional versus unintentional, technical violations. Transparency in relationships as well as the potential benefit of referrals and their impact on patients should be encouraged so that providers acting in good faith with good intentions are not unduly penalized.

**Harmonizing Stark Law with the Anti-Kickback Statute**

One theme that is consistent throughout this effort is how confusing and maze-like the self-referral regulations have become overtime. The Stark Law also intersects with the Anti-Kickback Statute and healthcare providers must hire attorneys to undergo extensive reviews of both statutes and their regulations in order to determine if a financial arrangement would violate any terms of either law.

While this is a burdensome exercise on its face, it becomes even more complex when realizing that different federal agencies are responsible for different statutes. This means that one may need to interact with bureaucrats from CMS, the Department of Justice (DOJ), and the Office of the Inspector General (OIG) when questions come up. This is another area where Congress should consider streamlining and providing authority to one agency if possible. In the meantime, CMS should work with DOJ and OIG to determine areas where the agencies could better coordinate efforts.

**Conclusion**

The Wisconsin Hospital Association again thanks CMS for issuing this request for information. We sincerely appreciate the efforts CMS had undergone to listen to healthcare providers to hear what unnecessary obstacles continue to be barriers to more widespread adoption of value-based healthcare. We suggest CMS review its existing regulations to clarify exceptions to the Stark Law, simplify definitions so that they are easier to understand, prioritize intentional violations so that good actors are not unduly penalized, and harmonize Stark Law regulations with those of intersecting agencies and statutes. In all actions, CMS should view these regulations through the lens of how they might better benefit patients.

WHA appreciates the opportunity to provide CMS with our comments.

Sincerely,

Eric Borgerding
President & CEO