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August 24, 2018

The Honorable Seema Verma, MPH Administrator Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services Baltimore, MD 21244

Dear Administrator Verma:

On behalf of the Healthcare Information and Management Systems Society (<u>HIMSS</u>), we are pleased to provide written comments to the <u>Request for Information Regarding the Physician Self-Referral Law</u> (CMS-1720-NC). HIMSS appreciates the opportunity to leverage our expertise in offering feedback on how the Centers for Medicare & Medicaid Services (CMS) can help to address potential obstacles to care coordination unintentionally caused by the physician self-referral law.

As a mission driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research, and analytics to advise global leaders, stakeholders, and influencers on best practices in health information and technology. Through our innovation companies, HIMSS delivers key insights, education, and engaging events to healthcare providers, governments and market suppliers, ensuring they have the right information at the point of decision.

As an association, HIMSS encompasses more than 73,000 individual members and 655 corporate members. We partner with hundreds of providers, academic institutions, and health services organizations on strategic initiatives that leverage innovative information and technology. Together, we work to improve health, access, as well as the quality and cost-effectiveness of healthcare. Headquartered in Chicago, Illinois, HIMSS serves the global health information and technology communities with focused operations across North America, Europe, United Kingdom, the Middle East, and Asia Pacific.

As the American healthcare system evolves through implementation of new technologies as well as new payment models, a need has arisen to look at existing laws and regulations to ensure that opportunities are offered to support such growth. HIMSS appreciates the work that CMS is undertaking with this Request for Information (RFI) to review implementation and interpretation of the physician self-referral law, also known as the "Stark Law," which, when enacted almost 30 years ago, addressed a concern that healthcare decision-making and referral patterns could be unduly influenced by profit motives when operating in a predominantly fee-for-service system. The health information and technology community has a history of working with CMS to utilize

the Physician Self-Referral waiver process to advance information technology. In 2006, CMS granted waivers to the health IT community to foster collaboration between hospitals and provider organizations for the purchase of items and services in the form of software or training services. Originally expected to sunset in 2013, CMS extended the waiver through December 31, 2021.

For our public comment, we offer the following thoughts and recommendations on how CMS may want to proceed in its review:

• The Physician Self-Referral Law Places Burdens on Providers and Inhibits Care Coordination

With the push progressing toward greater value-based care delivery, the role that alternative payment models (APMs) play in this shift is critical, which is why APMs require a flexible regulatory framework to succeed. HIMSS believes that APMs would be better served if CMS allowed more physician self-referral law waivers for APMs, similar to the waivers offered in many of the innovation models currently being piloted by CMS. For example, the Medicare Shared Savings Program (MSSP) incentivizes providers to improve quality and reduce cost, as well as resource utilization, which are efforts that require coordination in ways that would likely not occur in a typical fee-for-service relationship.

HIMSS asks that CMS vigorously use its waiver authority to allow APMs to function in a manner that allows for access to as well as the provision of the best available patient care and prioritizes the needs of patients. This waiver authority should be designed without a focus on the potential financial implications of any referrals for providers, and be aligned across all CMS programs, including in the testing of new and innovative payment and service delivery models.

This step will help increase the likelihood of success of these new payment structures, and contribute to CMS' efforts to reduce clinician burden. HIMSS recommends that CMS focus its referral process regulations on delivering the best possible care to patients by allowing referrals to providers that make the best use of health information and technology tools, thereby capitalizing on technology to accelerate advanced utilization management practices. By minimizing the hurdles in initiating a referral request to another clinician, CMS will greatly contribute to any administrative burden reduction.

With our community's growing reliance on APMs, the sharing of patient information is essential. Unfortunately, the physician self-referral law also places significant regulatory and reporting burdens on providers, and it impedes the free flow of information across providers. To share information, it is often necessary to implement, use and maintain costly tools that not all providers can readily afford, including access to multiple interoperability exchanges, networks, and approaches to share data across the care continuum.

HIMSS recommends that the physician self-referral regulations be changed so as to no longer prohibit any data sharing scenario that aggregates, normalizes, or secures patient data in connection with the coordination of care for a patient. As such, we ask CMS to use its authority to ensure its policies and programs facilitate greater information flow for the benefit of patients, and in support of CMS' MyHealthEData and Blue Button 2.0 initiatives.

Overall, healthcare providers are very concerned about making sure that their patients have access to the best possible care. HIMSS members state that, due to the physician self-referral regulation provisions—and its focus on where a patient is referred rather than what is the most appropriate level of care for that patient at that time—patients are often referred to a lower level setting of care because of complexities around potential financial relationships between providers. Such a scenario is not in the best interest of the patient, and should be addressed as part of future changes to the physician self-referral regulation.

HIMSS suggests that when this concern arises, providers would be empowered to be transparent with their patients with the freedom to offer multiple options. Allow providers to explain the benefits and drawbacks of each appropriate care setting, including being transparent and providing information about any potential financial arrangements that accompanies the referral. In this patient consultation scenario, we suggest providers use data from CMS quality rating programs (i.e. Hospital Compare, Physician Compare, etc.) to highlight the quality of care the patient can expect in different care settings.

Given the goal of APMs is to enhance care quality, reduce cost, and encourage coordination, the concern of improperly motivated referrals underlying the physician self-referral regulation is reduced, if not eliminated, in the above scenario. It is important to note that the physician self-referral regulation was implemented at a time when the health system was functioning fully in a fee-for-service environment, which meant providing a high volume of services was needed to generate more fees regardless of value. Since many APMs operate under a per member, per month or other fixed fee that is not influenced by the volume of services performed, the inherent premise of restrictions on physician self-referral does not necessarily apply to APMs because APMs incentivize providers to be more thoughtful about the services rendered and do not reward the volume of care delivered.

As care delivery has evolved from fee-for-service to a value-based care model, we encourage CMS to undertake an expansive evolution of the physician self-referral regulation to support further development of APMs and broader healthcare transformation efforts.

• The Physician Self-Referral Law Inhibits Provider Access to Cybersecurity Services

HIMSS echoes the concerns noted in the June 2017 HHS Cybersecurity Task Force Report that, under the current physician self-referral law, vulnerabilities exist due to the legal prohibition on larger healthcare organizations helping smaller organizations and physician practices to purchase cybersecurity software, training, hardware, and operational services.

Because cybersecurity is so dependent on all the players in the networked industry, even organizations that put robust cybersecurity policies and software in place remain vulnerable due to connections with less-secure providers. Therefore, the task force asked Congress to amend the physician self-referral law and anti-kickback statute to allow healthcare organizations to help physicians implement cybersecurity software, along the lines of what they have done with electronic health records.

HIMSS requests an exception to the physician self-referral law to allow for the subsidizing of cybersecurity needs such as cybersecurity software, hardware, training, and tools for threat

information sharing, and hardware. HIMSS notes that many health care organizations have a very small cybersecurity budget (six percent or less of the IT budget) according to the <u>2018 HIMSS</u> <u>Cybersecurity Survey</u>. As a result, this exception would be very beneficial. We also recognize that having the right tools is not enough; updates to the physician self-referral law should also make exceptions for operational support such as IT assistance and other skilled services to aid smaller organizations with deployment and maintenance of these cybersecurity solutions.

HIMSS' membership represents a wide variety of stakeholders from across the healthcare sector, including our Legal Task Force, which is composed of attorneys in private practice that assist HIMSS in advising our organization on healthcare policy issues. We would be happy to convene our volunteers with CMS officials to share specific experiences and recommendations as they relate to the physician self-referral law.

We look forward to the opportunity to further discuss these issues in more depth. Please feel free to contact <u>Jeff Coughlin</u>, Senior Director of Federal & State Affairs, at 703.562.8824, or <u>Eli Fleet</u>, Director of Federal Affairs, at 703.562.8834, with questions or for more information.

Thank you for your consideration.

Sincerely,

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