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August 17, 2018

Seema Verma
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma,

On behalf of the 34 member companies of the Electronic Health Record Association (EHRA), we are pleased to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the request for information on how to address any undue regulatory impact and burden of the Physician Self-Referral Law, also known as the "Stark Law." We appreciate this opportunity to provide input on CMS' efforts to reduce clinician burden and improve care coordination.

EHRA members serve the vast majority of healthcare organizations that use electronic health records (EHRs) and other health information and technology (IT) to deliver high quality, efficient care to their patients. Established in 2004, EHRA operates on the premise that the rapid, widespread adoption of health IT has and will continue to help improve the quality of patient care as well as the productivity and sustainability of the healthcare system. Our core objectives focus on collaborative efforts to accelerate health IT adoption, enhance usability of EHRs, advance interoperability, and improve healthcare outcomes through the use of these important technologies.

We echo the concerns noted in the HHS Cybersecurity Task Force Report that under the current Stark 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 strong cybersecurity policies and software in place are vulnerable due to connections with less-secure providers. Therefore, the task force asked Congress to amend the Stark Law and Anti-Kickback Statute to allow healthcare organizations to help physicians implement cybersecurity software, much as they have with electronic health records.

We request an exception to the Stark Law to allow for the subsidizing of cybersecurity needs such as cybersecurity software, cybersecurity hardware, cybersecurity training, tools for threat information sharing, and hardware. We also recognize that having the right tools is not enough and that updates to the Stark 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.

Additionally, to encourage adoption of interoperable EHR technology for all types of providers that participate in Medicare, we recommend that two key provisions be made as exceptions under the physician self-referral law:

1. Any risk-bearing entity under an alternative payment model (APM) that qualifies as an Advanced APM under the Medicare Quality Payment Program (QPP) should be eligible to be a donor of EHR items and services under the exceptions to the physician self-referral law and the anti-kickback statute. We believe CMS and OIG have this authority already, without need for further statutory authorization.
2. Any provider participant in an APM that qualifies as an Advanced APM under the QPP should be eligible to receive donations under the exceptions of either the self-referral law or the anti-kickback statute. We believe CMS has the authority to consider including recipients such as post-acute care providers, skilled nursing facilities, long term care hospitals, intermediate rehabilitation facilities and home health agencies in the definition of "recipient" under the anti-kickback statute exception.

We believe the definition of eligibility of which EHR items and services can be donated could align with the donation provisions and qualifications that are already established under the physician self-referral law and anti-kickback statute exceptions.

Finally, we recommend the exceptions be updated to include language on information blocking both by donors and their health IT suppliers of the donated health IT, as defined by Section 4004 of the 21st Century Cures Act.

EHRA members look forward to continuing to work with you and to continuing the discussion on these important issues. Please contact Sarah Willis-Garcia, EHRA Program Manager, at swillis@ehra.org or 312.915.9518 with questions or for more information.

Sincerely,

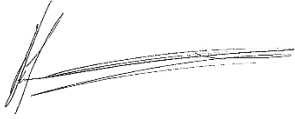


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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.