33 W. Monroe, Suite 1700
Chicago, IL 60603
Phone: 312-915-9582
Fax: 312-915-9511
E-mail:
himssEHRA@himss.org

June 5, 2013

Ms. Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health & Human Services
Washington, DC 20201

Dear Ms. Tavenner:

The Electronic Health Record Association (EHR Association) is pleased to respond to the request for comments solicited by the Centers for Medicare & Medicaid Services (CMS) Health & Human Services (HHS) Office of Inspector General (OIG) regarding the "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements" ("proposed rule").

Established in 2004, the EHR Association is comprised of more than 40 companies that supply the vast majority of operational EHRs to physicians' practices and hospitals across the United States. The 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.

We appreciate CMS' engagement of the public on this important topic and transparency into the agency's considerations with regards to health IT and its impact on the healthcare ecosystem. We share a common goal of creating an interoperable, digitized healthcare system in support of better, lower cost, more accessible healthcare.

To that end, we provide the following comments regarding the (1) deeming provision, (2) electronic prescribing provision, and (3) sunset provision, as well as feedback on additional topics the agency considers in the proposed rule.

Deeming Provision
The EHR Association agrees with the proposed modification at § 411.357(w)(2) to reflect that Office of the National Coordinator for Health IT (ONC) is responsible for "recognizing" certifying bodies, as referenced in this provision.

Additionally, we agree with CMS' proposal to deem software as covered technology "if, on the date it is provided to the recipient, it has been certified to any edition of the electronic health record certification criteria that is identified in the then applicable definition of Certified EHR Technology in 45 CFR part 170". We believe that both modifications would create greater harmonization across regulations and agencies, which the Association encourages in this proposed rule and in general.

Electronic Prescribing Provision
The Association agrees that appropriate drivers are in place to promote the continued adoption of electronic prescribing functionality by health professionals. As such, we likewise agree with CMS' proposal to propose to delete the electronic prescribing condition at §411.357(w)(11).

Sunset Provision
CMS stated "that the need for donations of electronic health records technology should diminish substantially over time as the use of such technology becomes a standard and expected part of medical practice" in its prior rulemaking, "Exceptions to federal physician self-referral law ," published on August 8, 2006 (71 FR 45140) at 42 CFR 411.357(w).

The EHR Association agrees that this conclusion was understandable at that time of relatively low EHR adoption. We have learned that adoption of an EHR by a health professional involves functionality and technology components that change substantially over time with technological advances, regulatory requirements, and in response to the evolving needs of the healthcare delivery system. As a result, health professionals who have already adopted EHRs have needed and will continue to need modified EHR functionality and new technologies to keep pace with regulatory, billing, patient engagement, and other requirements towards the overall improvement of healthcare delivery.

Due to the constantly evolving nature of health IT to support better, lower cost, more accessible care, the Association believes that healthcare organizations should continue to have the ability, consistent with the proposed CMS and OIG regulations, to provide financial support to health professionals in their adoption and use of technology. Therefore, rather than extend the sunset provision to either December 31, 2016 or December 31, 2021, we encourage CMS to remove the sunset provision from these regulations, while providing for a review by the two agencies during 2021.

In line with this suggestion, we encourage CMS and OIG to revisit the definition of which technologies may be deemed covered as health IT and requirements evolve, and believe that CMS and OIG should continue to analyze the impact of the donations on the relationships between protected donors and health professionals.

Should CMS determine that a sunset provision is appropriate, we agree that establishing a sunset date of December 31, 2021, in line with the end of the Medicaid EHR Incentive Program, is appropriate. That sunset date would help health professionals successfully achieve meaningful use of health IT within the context of the program; provide more time to ensure the wide-spread adoption of interoperable health IT within and beyond the program, particularly for specialists whose specific technology needs are still being refined; and provide a consistent approach for health professionals to rely on in an otherwise fast-changing regulatory landscape.

Protected Donors
Although the EHR Association appreciates CMS' desire to limit the scope of permissible donors as a means for preventing activities that may lead to "referral lock-in," we do not believe the list of protected donors should be further limited. In particular, we are concerned that limiting the set of protected donors could have an impact on specialists, whose adoption rates are still relatively low and who most likely stand to benefit from donations from the full range of protected donors.

Data Lock-In and Exchange
The EHR Association appreciates the two goals articulated by CMS regarding data lock-in and exchange. As an association, we do not believe that data or referrals should be locked in by technology, and support in our policy and development efforts the exchange of health information. We have been a strong proponent for the development of interoperability standards and believe that making meaningful use certification a part of the deeming provision will ensure a baseline interoperability capability of EHRs.

Ultimately, however, achievement of free and ubiquitous exchange of health information will not occur primarily as a result of technology characteristics, and regulations that attempt to limit ways in which technology is implemented will likely create unintended consequences. Rather than new provisions as suggested, we encourage CMS to continue foster business cases for providers to exchange health information. For example, payment models that incorporate care coordination activities will be critical to the promotion of exchange activities on the foundation of standards achieved through meaningful use.

Covered Technology
At present, retaining the current definition of covered technology is appropriate. However, we emphasize that, as the landscape of health IT changes with the needs of providers and patients, CMS should revisit what is meant by covered technology. In doing so, we urge CMS to carefully consider the comments from other responders to this rule, and in any event, make a recommendation no later than 2016.

Conclusion
On behalf of the EHR Association, we appreciate the opportunity to provide feedback and hope to serve as a positive resource in moving our nation forward in the transformation of healthcare delivery. To that end, we offer our ongoing support and perspective as you consider these issues.

Sincerely,

Michele McGlynn
Chair, EHR Association
Siemens

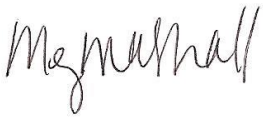
Leigh Burchell
Vice Chair, EHR Association
Allscripts

HIMSS EHR Association Executive Committee

Jason Colquitt
Greenway Medical Technologies

Lauren Fifield
Practice Fusion, Inc.

Charlie Jarvis
NextGen Healthcare



Meg Marshall
Cerner Corporation

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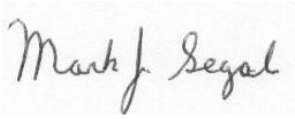
McKesson Corporation



Mark Segal
GE Healthcare IT

About HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 40 companies that supply the vast majority of operational 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 the Healthcare Information and Management Systems Society (HIMSS). Membership in the Association is open to HIMSS corporate members with legally formed companies designing, developing and marketing their own commercially available EHRs with installations in the US. For more information, visit http://www.himssehra.org.