HIMSS Electronic Health Record Association

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

July 21, 2014

Representative Fred Upton
Chair, Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Representative Diana DeGette
Ranking Member, Subcommittee on Oversight and Investigation
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

RE: 21st Century Cures: Leveraging Technology to Accelerate the #Path2Cures

Dear Chairman Upton and Representative DeGette:

On behalf of the nearly 40 member companies of the Electronic Health Record Association (EHRA), we are pleased to respond to your white paper, "A Path to 21st Century Cures," to provide our perspectives on how technology can be harnessed to advance our nation's healthcare system to be more available and effective for more Americans. EHRA members employ industry experts in the field of health information technology (HIT) with a broad scope of expertise, including physicians, nurses, pharmacists, technologists, and policy experts. These individuals not only represent the EHR software industry, but also interact with and reflect the breadth of the entire health community. This broad perspective reflects the central role that EHRs can play in any healthcare delivery organization as the foundational technology that brings together all the information gathered during a patient's encounter – from demographics to test results, allergies, medications, nursing notes, and digital images – for every clinician with whom the patient interacts, regardless of location.

HIT, particularly through the accelerated adoption of EHRs as supported by the nation's investment in the EHR Incentive program, is a powerful tool that can support the transition of our health system toward a value-based model focused on optimal health outcomes, encouraging innovative technologies to optimize care delivery, making it more efficient, effective, and affordable. Digitized health information enables the connection of patients and providers in different physical

locations, empowers patients to become and remain active participants in their care, and provides ongoing patient-focused communication and support.

Hospital EHR adoption has grown from 72% reporting use of certified electronic health record technology (CEHRT) in 2011 to 94% in 2013[1]. Physician adoption of EHRs, perhaps more significant given financial and technical challenges in that sector, is growing rapidly as well, with 78% of physicians having adopted EHRs as of 2013 according to the National Center for Health Statistics, up from 57% in 2011[2]. Clearly, successful and meaningful adoption of EHRs is high and growing, and the EHR Incentive Program has played an important role in that growth. Given that Stage 1 of the Incentive Program was focused on accelerating EHR adoption, with the stated intention that Stages 2 and 3 would focus on improved quality and outcomes and increased interoperability, we can be optimistic that the US healthcare system will achieve real return on its investment in HIT and provide value to Americans as both taxpayers and healthcare consumers.

As detailed below, the provider requirements and EHR capabilities associated with Stage 2 will enable considerably enhanced interoperability, reinforcing accelerating private sector trends. We have urged that Stage 3 build on this platform, with a primary focus on interoperability.

This growth in HIT adoption and associated digitization, including new ecosystems of connected HIT, will drive important innovations, including personalized medicine, population health management, data analytics, and advanced payment models. The "merit-based" incentive payment system that was proposed earlier this year in the bicameral, bipartisan Sustainable Growth Rate (SGR) repeal legislation provides an excellent example of important reforms that will depend on HIT. Given the critical role that EHRs will play in enabling healthcare organizations to participate in these programs, we urge Congress and the federal government to engage with EHR developers and the broader HIT community to help prepare for and ensure the best use of technology.

Our member companies and clients are doing important work to advance these types of innovations. For example, a variety of pilot programs are showing that EHRs are a critical tool in enabling new value-based payment models, which are founded on evidence- and data-based care management analytics, population health management, and measurement of quality and efficiency. We also note that EHRs can be used to provide near real-time feedback to physicians on the outcomes of their services, months sooner than is feasible with the current reporting systems.

Based on our experiences with the EHR Incentive Program and other federal and state programs, the EHRA has been consistent in its recommendations that regulatory oversight should focus on standards to support broad-based interoperability and alignment of federal quality reporting programs. It is important to note that good progress is being made with regard to interoperability. For example, Stage 2 of the Incentive Program and requirements for 2014 certified EHR technology increase standardization of data transport and exchange with prescribed terminology and data sets.

Regulatory oversight, regardless of its focus, must be informed by stakeholders who have the experience to ensure that requirements are well-designed and practical. New or revised regulations must also be predictable. Our companies and our collective customers – the majority of hospitals and

[1] ONC Data Brief No. 16, May 2014, Adoption of Electronic Health Record Systems among U.S. Non-federal Acute Care Hospitals: 2008-2013, Dustin Charles, MPH; Meghan Gabriel, PhD; Michael F. Furukawa, PhD.

[2] Hsiao C-J, Hing E., Use and characteristics of electronic health record systems among office-based physician practices: United States, 2001–2013. NCHS data brief, no 143. Hyattsville, MD: National Center for Health Statistics, 2014.

ambulatory practices using EHRs in the US – make significant investments based on good faith in the government's guidance and regulatory timelines. For example, the HIT industry and provider organizations spent significant time and money to prepare for the October 2014 switch to ICD-10. Although this work is the foundation of ICD-10 compliance whenever it is required, this change came unexpectedly at a time when many organizations had resource deployment plans in place to meet the initial date, creating disruption and uncertainty. Moving forward, it is essential that policies and requirements be designed and implemented in ways that enable initial plans to proceed on schedule, without the need for costly and disruptive changes in direction or timing.

To ensure that technology developers are able to respond to customers' requests and pursue market-driven innovation, any HIT regulation must not be overly prescriptive. EHRA has encouraged CMS and the Office of the National Coordinator for Health IT (ONC) to take a very focused and prioritized approach to Stage 3 of the Incentive Program based on what we have learned from Stages 1 and 2. This approach will free vendors to meet priorities identified by our customers and reduce the extent to which government requirements supersede customer requested development, impose costs and uncertainty, slow certification and implementation, and hinder usability. It will also enable ONC and CMS to achieve their policy goals, with excellence in implementation, within the limitations of their leaner budgets for managing the EHR Incentive Program and related initiatives.

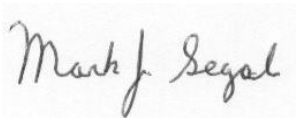
In general, we believe that new and emerging technologies that enable value-based payments and accountable care should advance in an innovative manner, outside of the EHR Incentive Program (i.e., meaningful use and certification). Some of these new approaches will be part of traditional EHRs and others will not. For example, EHRs provide not only basic reporting on the required measures, but can also enhance the patient experience and reduce costs with integrated care plans, documented interventions, task management, and outcomes measurement/reporting. With specific focus on accountable care organizations (ACOs), EHRs can be leveraged to promote proactive identification and management of high risk patients, align patients with care teams, help care teams coordinate across delivery sites, coordinate care for multiple problems, support real-time decision-making and population surveillance with evidence-based guidelines, and engage and educate patients to encourage self-care, prescription drug adherence, and lifestyle improvement. These capabilities should not be forced into a regulatory EHR construct. We believe that the market will, in fact, produce the right functionality.

The EHRA has encouraged the use of pilot programs to ensure that proposed regulations are adequately tested before they are codified and rolled out on a broad scale. We encourage thoughtful policies that are based on collaboration with HIT developers to test feasibility and practicality of these requirements as well as impact on physician productivity before they are finalized.

Finally, patient safety is, of course, an important consideration in HIT deployment and oversight. We've long held that patient safety is of paramount importance, with shared responsibility among all participants in the healthcare community – physicians, nurses, hospitals, clinics and other clinicians providing care to the patients; software developers and those who implement HIT; and health information exchange (HIE) organizations. EHRA supports the approach proposed in the Food and Drug Administration Safety Innovation Act (FDASIA) draft report, which categorizes HIT based on the level and nature of risk, then applies appropriate oversight mechanisms to ensure that only HIT that represents the greatest risk to patient safety should be regulated as "medical devices" by the FDA. We note that this three-level approach, including limits on FDA regulation of HIT, is reflected in the SOFTWARE bill being considered by your Committee. We encourage Congress to recognize that HIT can be a factor in improving patient safety, and should be considered appropriately for any proposed oversight to ensure that its role in the delivery of care services is well understood before pursuing burdensome regulation.

Representing a key stakeholder group, we look forward to participating in future activities that drive innovative approaches to address the opportunities described in your white paper. We encourage you to leverage our collective, extensive experience in developing and deploying EHRs and other HIT in thousands of healthcare organizations.

Sincerely,

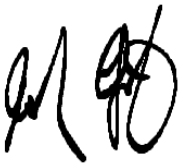


Mark Segal, PhD
Chair, EHR Association
GE Healthcare IT

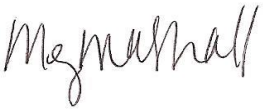
Sarah Corley, MD
Vice Chair, EHR Association
NextGen Healthcare

HIMSS EHR Association Executive Committee

Leigh Burchell
Allscripts



Joseph Geretz
SRSsoft



Meg Marshall, JD
Cerner Corporation

Ginny Meadows, RN
McKesson Corporation

Hatem (Tim) Abou-Sayed, MD
Modernizing Medicine

Sasha TerMaat
Epic

About HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 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 HIMSS. For more information, visit www.ehrassociation.org.