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November 9, 2017

United States Senate
Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray,

On behalf of the more than 30 members of the Electronic Health Record Association (EHRA), we are pleased to offer our input in relation to the Committee’s October 31, 2017, hearing on “Implementation of the 21st Century Cures Act: Achieving the Promise of Health Information Technology.”

EHRA members serve the vast majority of hospitals and ambulatory care organizations that use electronic health records (EHRs) and other health information technology to deliver high quality, efficient care to their patients. The Association 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.

The health information technology impacts of the 21st Century Cures Act are focused on improving patient care through interoperable exchange of data. EHRA agrees that interoperability is essential to enable data to follow the patient, to assist providers in the coordination of care, provide the data to the patient, and to contribute data to public health, registries, and research to enable a learning health system. We are supportive of efforts to promote implementation of interoperable and functional health information technology to advance clinical care and assist both patients and providers in decision-making.

We do have concerns around the pending rulemaking that will define “information blocking” per section 3022 of Cures. As you know, the 21st Century Cures Act has detailed provisions on and enforcement provisions for information blocking, including penalties of up to \$1 million per violation for health IT developers, networks, and health information exchanges (HIEs), creating significant exposure for physicians, technology providers, and HIEs. This regulation, which will provide a definition of “reasonable and necessary” safe harbors related to information-blocking, is currently being promulgated by the Office of the Inspector General at the Department of Health and Human Services (HHS). As you’re also aware, a companion regulation will also apply Cures “information blocking” provisions into the current product certification process.

We emphasize that EHRA, our member companies, and non-member companies that have adopted the [EHR Developer Code of Conduct](#) strongly oppose information blocking. This position is clearly stated in the Code: “Given our strong support for interoperability, adherents to the Code do not engage in data blocking.”

Fundamentally, determinations of information blocking, with or without enforcement actions, would be serious and should be reserved for conduct that objectively contradicts the final definitions of “reasonable and necessary.” In defining “reasonable and necessary,” and in case-specific assessments of potential information blocking, policy and enforcement efforts must consider the need for advancement of important interests, including:

- Furthering the availability of electronic health information as needed for authorized and important purposes
- Protecting and promoting patient safety
- Maintaining the privacy and security of electronic health information
- Protecting the legitimate economic interests and incentives of providers, developers, and other market participants to innovate and compete in ways that ultimately enhance technology, healthcare delivery, and consumer health and welfare, consistent with public policy goals

Examples of activities that may be perceived as information blocking, but we believe are reasonable and necessary to support healthcare operations and business activities and should be recognized as such in the forthcoming regulation include:

- Privacy protections
- Data security
- System performance
- Use of non-standard applications
- Network participation
- Fees
- Other agreements and terms of use that enable, expand, and enhance information sharing

We have provided detailed input on these issues to HHS. In addition, we have urged HHS to defer enforcement of the information-blocking provision of Cures until six months after this rulemaking is complete. The intervening period after final rules are published will enable healthcare providers, networks, exchanges, and health IT developers the essential time necessary to make any needed changes to comply with final rules while ensuring that privacy, security, and patient safety are not compromised. We also request that this deferral be made public to ensure that providers, developers, and others do not embark on wasteful and costly compliance efforts that could delay innovation and investment in meeting patient and provider needs.

It is essential that the regulatory implementation of these and other HIT-related elements proceed in an expeditious and transparent manner, and avoid approaches that impose significant uncertainty and excessive and wasteful compliance costs for providers, developers, and HIEs.

Thank you for this opportunity to provide input to you and your Committee colleagues. EHRA would be pleased to discuss this matter further with Committee staff; the collective expertise of our membership makes EHRA uniquely positioned to provide insights to policymakers to help ensure that health IT

regulations such as the 21st Century Cures Act add the greatest value, have the intended effects, are minimally burdensome, and remain responsive to market demands.

Please contact Sarah Willis-Garcia, EHRA Program Manager, at swillis@himss.org if we may be of assistance.

Sincerely,



Sasha TerMaat
Chair, EHR Association
Epic

HIMSS EHR Association Executive Committee



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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.