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Representative Diana DeGette
United States Congress
2111 Rayburn House Office Building
Washington, DC 20515

Representative Fred Upton
United States Congress
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives Degette and Upton,

On behalf of the 33 members of the Electronic Health Record (EHR) Association, we are pleased to share our comments regarding *Cures 2.0 Call to Action*.

EHR Association members serve the vast majority of hospitals and ambulatory care organizations that use electronic health records (EHRs) and other health information technology to deliver transformative, innovative care to their patients. We focus on collaborative efforts to accelerate health IT adoption, advance interoperability, and improve the quality and efficiency of care through the use of these important technologies.

EHR Association members share your vision of a digitally enabled learning health system that can bring life-saving treatment quickly to those in need. We offer our recommendations based on the experience of our members and the healthcare delivery organizations they serve. Our experience with 2016's 21st Century Cures Act (Cures) and the resulting regulations (at this time still in the rulemaking process) has uncovered both opportunities and pitfalls, and we appreciate this opportunity to provide guidance.

In a digitally connected health landscape, data must flow freely.
Data that flows "without special effort" is data that is well-defined and adheres to a standardized format. Cures specified that all data must be shared among all

participants in the digital ecosystem, but the lack of well-defined standards, that everyone can support, as a minimum or floor for "all" data has led to confusion and uncertainty as healthcare delivery organizations scramble to demonstrate compliance to un-measurable criteria while not being able to share data consistently. As Congress considers the new frontiers of data exchange to enable the digital health ecosystem, we urge you to focus on standardized exchange of defined data sets building on the evolving U.S. Core Data for Interoperability (USCDI) set.

Unambiguous standards and definitions make compliance straightforward and ensure patients and providers can access data "without special effort." The number of data classes and elements for which standards are available is constantly expanding and currently focuses on USCDI. Congress could aid acceleration of standardized data sets by instructing ONC to convene bodies to create new standards, as necessary, and to address stakeholders that don't yet sufficiently adopt consistent standards even where they exist, such as labs, pharmacies, and state and specialized public health registries.

EHR Association members note that it is important to refrain from undermining the strong progress that has already taken place in information exchange across the healthcare ecosystem. For example, it would be unnecessary to impose any certain implementation of LOINC standards on lab companies to the point of having to replace all interfaces that have been built today; rather, requiring addition and preservation of LOINC encoding across all laboratory interfaces should be sufficient. We emphasize that in looking forward and framing new work that will take place, a stronger standards approach beyond certified products would be beneficial and welcomed by the EHR Association.

A digital health ecosystem includes many players beyond the providers.
Traditionally, health information exchange legislation and regulation has focused on certified electronic health record technology (CEHRT), which in the pre-Cures world was often the primary repository of health-related documentation. However, as we contemplate the ecosystem enabled by Cures 2.0, Congress must consider data holders beyond providers such as research databases, personal health accounts, public health databases, payers, and others.

While it is sensible to build on existing investments in data exchange where appropriate, we encourage Congress to tie future appropriations for interoperability investments to the use of standards by all players, not just certified EHR technology for providers.

A digital ecosystem will thrive when intellectual property protections are assured.
Cures 2.0 strives to create a modernized health system where digital technologies such as artificial intelligence (AI) and machine learning can deliver insight directly to the point of care, enabling faster diagnoses and treatment of patients.

As developers ourselves, EHR Association members have invested decades of work and billions of dollars in researching, developing, testing, and improving our solutions to benefit patients. Therefore, it is imperative, both for established players and new market entrants, that this investment is respected and that new innovations or modernization of previous technologies can be priced at fair market value, lest innovation slows down. In its interpretation of Cures, HHS went beyond its Congressional mandate, opening the door to unrestricted screen-scraping, compulsory licensing of proprietary technology, and even pricing capped at cost recovery in some instances—which only incentivizes less efficient development.

With Cures 2.0, we encourage the creation of an environment that rewards innovation and new market entrants and explicitly protects intellectual property under various forms of intellectual property legal protections, proprietary information, and market-based pricing.

A patient's digital health experience should transcend physical boundaries, not be limited by them.
Previous efforts to digitize the learning health environment have been hindered when states were given wide latitude to interpret Congressional direction. For example, variances in state policy on the privacy rights of adolescents have led to a fragmented system for caregivers when their family members are seen at multiple sites, resulting in hesitancy or inability to share critical data without special effort.

A similar fragmentation emerged in the nation's response to the opioid crisis–a digital network of prescription drug monitoring programs (PDMPs) that could reveal diversion or misuse. PDMPs have been powerful tools in giving providers and policymakers the data to help combat the opioid crisis, but patchwork policies across the states introduced confusion and delay as prescribers struggled to interpret their own responsibilities, especially in regions close to state lines.

The EHR Association advises Congress to clearly define policy at the federal level, and where that is infeasible, incent policy and standards alignment to a federal reference standard among states.

When contemplating the digital health experience of the future, first remove barriers to existing digital technologies.
Telemedicine, or the ability for a professional to deliver care at a distance, was envisioned nearly a century ago, and technology to support digital home monitoring, asynchronous questionnaire-based eVisits, and synchronous video visits has long been available. However, CMS has been slow to recognize the importance of telemedicine for reaching rural and working patients who struggle to be physically present: reimbursement is fractional, non-existent, or gated by challenging prerequisites. There has been progress but not quickly enough for the good of patients.

Before considering reimbursement for emerging technologies such as digital therapeutics, remove existing barriers to telehealth, as described in the CONNECT for Health Act of 2019, which was endorsed by the EHR Association and more than 120 other organizations.

The digital health ecosystem cannot come at the price of privacy.
While the digital health landscape relies on the free and open flow of information, health data is powerful and valuable. Opening this landscape to new players, including those with a vested interest in such data, risks exposing citizens to indiscriminate and careless intentions of the highest bidder to access such data if there is not sufficient oversight over its responsible use respecting patient privacy by giving patients the right to informed consent.

We share your enthusiasm for the promise of technology to address and cure some of the most pressing problems facing Americans today. We look forward to continuing to work with you as you move forward on Cures 2.0.

Sincerely,

Cherie Holmes-Henry
Chair, EHR Association
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About the HIMSS 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.