EHRA
HIMSS ELECTRONIC HEALTH RECORD ASSOCIATION

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October 7, 2024

The Honorable Diana DeGette
United States House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Larry Bucshon, M.D.
United States House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

Re: Request for Information on 21st Century Cures Act and Cures 2.0

Dear Representative DeGette and Representative Bucshon,

On behalf of the 29 member companies of the HIMSS Electronic Health Record (EHR) Association, we appreciate the opportunity to submit comments in response to your Request for Information regarding the 21st Century Cures Act and the ongoing initiatives under Cures 2.0. We appreciate your willingness to accept our feedback after the requested deadline.

As a trade organization of health IT developers dedicated to advancing interoperability, health information technology, and effective patient care, we feel strongly about the need for continued progress in these areas. We are committed to working with Congress and other stakeholders to ensure that the policies developed under the original 21st Century Cures legislation and any future finalized Cures bill that comes to fruition help create an environment that fosters innovation while addressing the real-world challenges faced by the healthcare and IT industries.

Though the original Cures 2.0 legislation covers numerous topics—ranging from FDA operations and public health to telehealth and research—the EHR Association's primary focus remains on the implications of health IT and interoperability. Of particular interest to our members are provisions related to telehealth expansion, a national strategy for pandemic preparedness, and the designation of a standards maintenance organization for electronic prescribing (eRx) and electronic prior authorization (ePA).

We would like to highlight several key areas from the original 21st Century Cures Act that remain unaddressed and should be considered additions to the next revision of Cures 2.0—which we understand will be referred to as Cures 2.1—legislative language:

1. Expansion of Requirements to Non-Certified Health IT Developers

While the information blocking provisions in the original Cures Act were a significant step forward, they remain incomplete for a variety of reasons, as outlined below.

One limitation in the scope of the compliance efforts related to the information blocking provisions is the focus solely on developers of certified health IT. Under the current definitions, if a health IT developer meets the definition by offering certified health IT in the market, all other products and services being offered by that developer come under the provisions of the information blocking regulations. Conversely, developers that do not offer any certified health IT products do not have direct compliance considerations regarding information blocking regulations. While there may be compliance considerations for these non-certified developers through contractual obligations with their clients, the differentiation still creates an uneven environment in terms of obligations to maximize data exchange and information sharing.

That said, the framework for information blocking as outlined originally is not restricted to only certified products. Healthcare providers and developers of certified health IT, as well as Health Information Exchanges and Health Information Networks, must consider compliance across all health IT systems that contain EHI; this includes many non-certified health IT products. This creates a challenge in evaluating an enforcement environment in which vendors of non-certified technologies could be held accountable on some level with the concepts of information blocking without straying from the voluntary status of product certification. We do not believe it would be appropriate for those developers to be required to begin adhering to ASTP's certification requirements, but there is room for evaluating how they can be more effectively encouraged to ensure they are exchanging EHI under the requirements of the information blocking provisions, similar to other actors. A structure could be created with robust industry input in which facts and circumstances unique to these non-certified developers, including the limited resources of many of them, are considered in determining if there is a practice of information blocking.

The Assistant Secretary for Technology and Policy and the Office of the National Coordinator for Health IT (ASTP) does not currently have authority over non-certified health IT developers, and that presents a challenge in scoping these suggested requirements in such a way as to find an effective balance. However, we believe expanding the definition of health IT developers to include non-certified entities would enhance the overall impact of the legislation. Doing so would ensure that all developers are held to the same standards for information sharing, thus promoting greater alignment across the industry and benefiting patients, regardless of whether they see a provider using certified or non-certified health IT. We encourage consideration of this challenge in the Cures 2.1 bill language.

2. Incentives / Disincentives for Healthcare Providers Not Previously Targeted

As noted in the previous section, the definition of health care providers is very broad, but only a select few within that definition have had any disincentives outlined by 'appropriate agencies.' Through rulemaking from the Department of Health and Human Services (HHS), along with ASTP and the Centers for Medicare and Medicaid Services (CMS), it has been made clear that these agencies consider themselves limited to creating disincentives via only a narrow list of pre-existing CMS programs under which the exchange of EHI is a key factor.

This presents an immediate issue that has led to only a select few provider types being subject to disincentives, and the impact is that a significant portion of stakeholders who directly affect the exchange of health data are not further incented to accelerate their standards-based exchange practices. More specifically, only those few healthcare provider types who have already had incentives

to adopt, implement, and/or use certified health IT, or any health IT (such as through participation in CMS programs that measure interoperability), are affected by the recently finalized information blocking disincentive structure.

Included in the groups therefore not currently being motivated by information blocking disincentives are several other critical stakeholder groups, such as labs, imaging centers, and pharmacies. These groups have proven themselves less likely to adopt standards-based exchange practices, still sticking in many cases to proprietary approaches to interfaces, for example, and adding unnecessary costs to the healthcare system. HHS needs additional authority – not just within CMS or the newly-renamed ASTP – to consider a broader opportunity for disincentives.

Further, it must be noted that the current health IT model leaves out many healthcare providers from participating in the same robust exchange environment as other provider types, particularly those in behavioral health, long-term care, and post-acute care settings. They have historically not been incentivized to adopt interoperable health IT systems, and they often face significant financial and technical challenges in upgrading their IT infrastructure. This puts them at a disadvantage when it comes to meeting the interoperability requirements of the Cures Act, as well as generally elevating their information exchange capabilities. We strongly encourage the consideration of targeted incentive programs for these provider types to accelerate progress in interoperability across all areas of care, as well as consideration to provide additional authority to CMS, or other appropriate agencies, to develop programs focused on the adoption, implementation, and use of health IT, certified or not.

3. Clarification on Information Blocking and Private Rights of Action

We urge Congress to specify in clear language that the information blocking provisions of the Cures Act should not be used to establish legal private rights of action specific to information blocking. To this point, there have been two cases of which we are aware in which the statutory and regulatory framework for information blocking compliance was utilized as part of a private right of action relating to tortious interference.

We believe it is clear in the 21st Century Cures language that it was not the intent of Congress to create an additional private right of action related to information blocking or additional work for the State and Federal Court system. Instead, statutory language from the 21st Century Cures Act granted sole authority to investigate and enforce information blocking complaints to the Office of the Inspector General under HHS (OIG). Conversely, allowing private rights of action would likely lead to inconsistent interpretations of the law between OIG and the various courts (Municipal, State, and Circuit), creating confusion in the industry and ultimately slowing innovations in interoperability by making actors more hesitant to commit to certain activities.

Therefore, because some have created an opportunity to try to apply information blocking as a lever in private disputes between business entities, we believe a firm clarification is critical to avoid unintended consequences, such as an increase in litigation, which could disproportionately burden health IT developers and healthcare providers alike. Enforcement should remain in the hands of government agencies, such as the OIG, who have a substantial knowledge base to build upon and are therefore better positioned to oversee compliance and address violations in a way that ensures fairness and consistency.

4. Information Blocking Advisory Opinion Authority

Both the ASTP and OIG have made strides in outlining the regulations for information blocking; however, the health IT development industry and provider organizations lack clarity on many practices that may or may not be considered information blocking. Due to these agencies' lack of authority to issue advisory opinions, stakeholders are often left to interpret the regulations without clear guidance, leading to inconsistency. We strongly recommend that Congress grant ASTP and/or the OIG the authority to issue advisory opinions on fact-specific scenarios, providing the healthcare community with much-needed clarity on compliance.

We encourage Congress and the authors of Cures 2.1 to consider the recommendations outlined above. We believe these enhancements will help ensure that the advances made under the 21st Century Cures Act continue to benefit the entire healthcare ecosystem.

The EHR Association welcomes the opportunity to further discuss these points and provide any additional insight or clarification that may be helpful. The Association's leadership can be reached to schedule a conversation by contacting Kasey Nicholoff at knicholoff@ehra.org.

Thank you once again for the opportunity to provide our input.

Sincerely,

Stephanie Jamison
Chair, EHR Association
Greenway Health

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